Agreement State;

3. Not export products containing radium-226 except in accordance with 10 CFR Part 110;

4. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under this Chapter, or equivalent regulations of the NRC or an Agreement State, or as otherwise approved by the NRC or an Agreement State; and

5. Respond to written requests from the Division to provide information relating to the general license within ~~thirty~~ 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Division, by an appropriate method listed in 10 CFR 30.6(a), a written justification for the request.

(d) The general license in subparagraph (a) of this paragraph does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.11~~ 0400-20-10-.11 Filing of Application for Specific Licenses.

(1) Application for specific licenses shall be filed in duplicate on a form prescribed by the Division.

(2) The Division 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 Division to determine whether the application should be granted or denied or whether a license should be modified or revoked.

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

(4) An application for a license may include a request for a license authorizing one or more activities.

(5) In his application, the applicant may incorporate by reference information contained in previous applications, statements or reports filed with the Division provided such references are specific.

(6) Applications and documents submitted to the Division may be made available for public inspection except that the Division may withhold any document or part thereof from public inspection if disclosure of its contents involves proprietary information.

(7) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source shall either:

(a) Identify the source or device by manufacturer and model number as registered with the NRC under 10 CFR 32.210 or with an Agreement State or for a source or a device containing radium-226 or accelerator-produced radioactive material with an Agreement State under provisions comparable to 10 CFR 32.210; or

(b) Contain the information identified in 10 CFR 32.210(c).

(c) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the NRC under 10 CFR

32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:

1. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

2. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(8) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Chapter ~~1200-02-07~~ 0400-20-07 or equivalent Agreement State requirements shall include:

(a) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(b) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in ~~Rule 1200-02-10-.13~~ part (10)(a)2 of Rule 0400-20-10-.13;

(c) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in ~~Rule 1200-02-10-.13~~ part (10)(b)2 of Rule 0400-20-10-.13; and

(d) Information identified in ~~Rule 1200-02-10-.13~~ part (10)(a)3 of Rule 0400-20-10-.13 on the PET drugs to be noncommercially transferred to members of its consortium.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.12~~ 0400-20-10-.12 General Requirements for the Issuance of Specific Licenses.

A license application will be approved if the Division determines that:

(1) The applicant has properly trained a sufficient number of personnel to use the material in question for the purpose required in accordance with these regulations in such a manner as to protect the public health and safety or property;

(2) The applicant's proposed equipment, facilities and procedures are in good repair and working order and designed to protect the public health and safety or property;

(3) The applicant satisfies all applicable requirements of these regulations;

(4) The applicant or an existing licensee in any of the classes specified in subparagraph (a) of this paragraph and not otherwise specifically exempted by subparagraph (m) of this paragraph has provided financial assurance as herein specified. (See paragraph (6) of this Rule for definitions of terms used in this paragraph.)

(a) Classes for financial assurance:

1. Major processors

2. Waste handlers

3. Ore refineries

4. Former USAEC or USNRC licensed facilities

5. Other persons with or applicants for a specific license as determined by the Commissioner.

(b) The financial assurance shall be filed with and maintained by the Director, Division of Radiological Health (hereafter referred to as Director), in a dollar amount determined by the Commissioner as necessary to provide for the protection of public health and safety in the event of abandonment, insolvency or other inability of the licensee to perform to the satisfaction of the Commissioner. The Commissioner shall consider the following in making his determination of the financial assurance requirements for each individual applicant or licensee:

1. The probable extent of contamination through the use or possession of radioactive material at the facility or site and the probable cost of removal of such contamination to a level in conformance with prevailing national standards or guidelines. This consideration shall encompass all probable contaminating event associated with the licensee's methods or modes of operation;

2. The amount of possible off-site property damage caused by operation of the facility or site;

3. The cost of removal and disposal of sources of radiation, which are or would be generated, stored, processed or otherwise present at the licensed facility or site; and

4. The costs involved in reclaiming the property on which the facility or site is located. For purposes of this part, "reclaiming" shall mean return of the property to a condition or state such that the property no longer presents a public health or safety hazard or threat to the environment.

(c) Each applicant or licensee of each facility to which it is applicable must file and maintain with the Director financial assurance for reclaiming the facility in accordance with the requirements of this subparagraph.

1. The applicant or licensee must choose from the financial assurance mechanisms as specified in subparagraph (d) of this paragraph. (NOTE: See also subparagraphs (e), (f) and (g) of this paragraph.)

2. The applicant or licensee must file and maintain financial assurance in an amount at least equal to the current reclaiming cost estimate.

(i) Whenever the reclaiming cost estimate increases to an amount greater than the amount of financial assurance currently filed with the Director, the licensee must, within 60 days after the increase, file additional financial assurance at least equal to this increase.

(ii) Whenever the current reclaiming cost estimate decreases, and upon the written request of the licensee, the Commissioner shall, provided the decrease is validated, reduce the amount of financial assurance required for the facility to the amount of the current reclaiming cost estimate. Upon such occurrence, the Director shall, as appropriate considering the financial assurance mechanism(s) on file, either cause to be released to the licensee cash or collateral equal to this reduction or allow the licensee to substitute for the mechanism(s) on file a new mechanism(s) in the reduced amount.

3. An applicant for a license must file the financial assurance instruments(s) before the license can be issued.

4. The financial assurance must be maintained by the applicant or licensee until the Commissioner releases the licensee from the requirements of this subparagraph, as specified in this part, or until the Commissioner orders forfeiture of the financial assurance as provided in part 5 of this subparagraph.

5. The Commissioner may order that any financial assurance filed by a licensee pursuant to this subparagraph be forfeited to the State if the Commissioner determines that the licensee has failed to perform reclaiming in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other license requirements when required to do so. Any such forfeiture action shall follow the procedures provided in subparagraph (h) of this paragraph.

(d) Mechanisms of financial assurance.

1. Surety Bond

An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by obtaining and filing a surety bond which conforms to the requirements of this part.

(i) The surety company issuing the bond must be licensed to do business as a surety in Tennessee.

(ii) The wording of the surety bond must be identical to the wording specified in part (j)1 of this paragraph.

(iii) The bond must guarantee that:

(I) Funds will be available to perform reclaiming in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other requirements of the license for the facility whenever required to do so.

(II) The licensee will provide alternate financial assurance as specified in this paragraph and obtain the Director's written approval of the assurance provided within 90 days of receipt by both the licensee and the Director of a notice of cancellation of the bond from the surety.

(iv) Under the terms of the bond, the surety will become liable on the bond obligation when the licensee fails to perform as guaranteed by the bond. Following a determination by the Commissioner that the licensee has failed to so perform, under the terms of the bond the surety will perform reclamation to the satisfaction of the State as guaranteed by the bond or will forfeit the amount of the penal sum, as provided in part (c)5 of this paragraph.

(v) The penal sum of the bond must be in an amount at least adequate to provide the necessary financial assurance.

(vi) Under the terms of the bond, the surety may cancel the bond by sending notice of cancellation by certified mail to the licensee and to the Director. Cancellation may not occur, however, during the 180 days beginning on the date of receipt of

the notice of cancellation by both the licensee and the Director, as evidenced by the return receipts.

(vii) The surety will not be liable for deficiencies in the performance of reclaiming after the Commissioner releases the licensee from the financial assurance requirements as provided in part (c)4 of this paragraph.

2. Personal Bond Supported by a Letter of Credit

An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of an irrevocable standby letter of credit. He must guarantee funds to perform reclaiming in accordance with acceptable practice for protection of health and safety and other requirements of the license for the facility. The irrevocable standby letter of credit supporting this guarantee must conform to the following requirements:

(i) The institution issuing the letter of credit must be an entity which has the authority to issue letter of credit and whose letter-of-credit operations are regulated and examined by a Federal or State agency.

(ii) The wording of the letter of credit must be identical to the wording specified in part (j)2 of this paragraph.

(iii) The letter of credit must be accompanied by a letter from the licensee referring to the letter of credit by number, issuing institution and date and providing the following information: The radioactive material license number, name and address of the facility and the amount of funds assured for reclaiming of the facility by the letter of credit. (NOTE: This letter from the licensee may also contain his personal performance guarantee.)

(iv) The letter of credit must be irrevocable and issued for a period of at least ~~one~~ 1 year. The letter of credit must provide that the expiration date will be automatically extended for a period of at least ~~one~~ 1 year unless, at least 180 days before the current expiration date, the issuing institution notifies both the licensee and the Director by certified mail of a decision not to extend the expiration date. Under the terms of the letter of credit, the 180 days will begin on the date when both the licensee and the Director have received the notice, as evidenced by the return receipts.

(v) The letter of credit must be issued in an amount at least adequate to provide the necessary financial assurance.

(vi) The Commissioner may draw on the letter of credit upon forfeiture as provided in part (c)5 of this paragraph. The Commissioner will also draw on the letter of credit if the licensee does not establish alternate financial assurance as specified in this paragraph and obtain written approval of such alternate assurance from the Director within 90 days after receipt by both the licensee and the Director of a notice from the issuing institution that it has decided not to extend the letter of credit beyond the current expiration date. The Director may delay the drawing if the issuing institution grants an extension of the term of the credit. During the last 30 days of any such extension the Commissioner will draw on the letter of credit if the licensee has failed to provided alternate financial assurance as specified in this paragraph and obtain written approval of such assurance from the Director.

3. Personal Bond Supported by Insurance

An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of an insurance policy. He must guarantee funds sufficient to perform reclaiming in a manner deemed acceptable by the Commissioner for protection of health and safety and other requirements of the license for the facility. The insurance policy supporting this guarantee must conform to the following requirements:

(i) The insurer must be licensed to transact the business of insurance or eligible to provide insurance as an excess or surplus lines insurer in the State of Tennessee.

(ii) The insurance policy must be accompanied by a certificate of insurance whose wording is identical to the wording specified in part (j)3 of this paragraph.

(iii) The insurance policy must be for a face amount at least adequate to provide the necessary financial assurance. The term "face amount" means the total amount the insurer is obligated to pay under the policy. Actual payments by the insurer will not change the face amount, although the insurer's future liability will be lowered by the amount of the payments.

(iv) The insurance policy must guarantee that funds will be available for reclaiming the facility whenever reclaiming is necessary.

(v) Upon forfeiture of financial assurance as provided in part (c)5 of this paragraph, the Commissioner will direct the insurer to pay the full face amount to the State.

(vi) The licensee must maintain the policy in full force and effect until the Commissioner releases the financial assurance mechanism as provided in this paragraph. Failure to pay the premium, without substitution of alternate financial assurance as specified in this paragraph, will constitute a significant violation of these regulations, warranting such remedy as the Commissioner deems necessary. Such violation will be deemed to begin upon receipt by the Director of a notice of future cancellation, termination or failure to renew due to nonpayment of the premium, rather than upon the date of expiration.

(vii) The policy must provide that the insurer may not cancel, terminate or fail to renew the policy except for failure to pay the premium. The automatic renewal of the policy must, at a minimum, provide the insured with the option of renewal at the face amount of the expiring policy. If there is a failure to pay the premium, the insurer may elect to cancel, terminate or fail to renew the policy by sending notice by certified mail to the licensee and the Director. Cancellation, termination or failure to renew may not occur, however, during the 180 days beginning with the date of receipt of the notice by both the Director and the licensee, as evidenced by the return receipts. Cancellation, termination or failure to renew may not occur and the policy will remain in full force and effect in the event that on or before the date of expiration:

(I) The Commissioner deems the facility abandoned;

(II) The license is terminated or revoked or renewal is denied;

(III) Closure is ordered by the Commissioner or a court of competent jurisdiction;

(IV) The licensee is named as debtor in a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code; or

(V) The premium due is paid.

(viii) Commencing on the date that liability to make payments pursuant to the policy accrues, the insurer will thereafter annually increase the face amount of the policy. Such increase must be equivalent to the face amount of the policy, less any payments made, multiplied by an amount equivalent to 85 percent of the most recent investment rate or of the equivalent coupon-issue yield announced by the U.S. Treasury for 26-week Treasury securities.

4. Personal Bond Supported by Securities

An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by filing his personal performance guarantee accompanied by collateral in the form of securities. He must guarantee sufficient funds to perform reclaiming in accordance with acceptable practices for protection of health and safety and other requirements of the license for the facility. The securities supporting this guarantee must be fully registered as to principal and interest in such manner as to identify the State and the Division as holder of such collateral and to also identify that person filing such collateral. These securities must have a current market value at least adequate to provide the necessary financial assurance and must be included among the following types:

(i) Negotiable certificates of deposit assigned irrevocably to the State.

(I) Such certificates of deposit must be automatically renewable and must be assigned to the State in writing and recorded as such in the records of the financial institution issuing such certificate.

(II) Such certificates of deposit must also include a statement signed by an officer of the issuing financial institution which waives all rights of lien which the institution has or might have against the certificate.

(ii) Negotiable United States Treasury securities assigned irrevocably to the State.

(iii) Negotiable general obligation municipal or corporate bonds which have at least an "A" rating by Moody's and/or Standard & Poor's rating services and which are assigned irrevocably to the State.

5. Personal Bond Supported by Cash

An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by filing his personal performance guarantee accompanied by cash in an amount at least adequate to provide the necessary financial assurance.

6. Financial Test and Corporate Guarantee.

(i) An applicant or licensee may satisfy the requirements of subparagraph (c) of this paragraph by demonstrating that he passes a financial test as specified in this part. To pass this test the licensee must meet the criteria of either item (I) or (II) of this subpart as follows:

(I) The applicant or licensee 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;

II. Net working capital and tangible net worth each at least ~~six~~ 6 times the current reclaiming cost estimate;

III. Tangible net worth of at least $10 million; and

IV. Assets in the United States amounting to at least 90 percent of this total assets or at least ~~six~~ 6 times the current reclaiming cost estimate.

(II) The applicant or licensee must have:

I. A current rating for his most recent bond issuance of AAA, AA, A or BBB as issued by Standard & Poor's, or Aaa, Aa, A or Baa as issued by Moody's;

II. Tangible net worth at least ~~six~~ 6 times the current reclaiming cost estimate;

III. Tangible net worth of at least $10 million; and

IV. Assets located in the United States amounting to at least 90 percent of his total assets or at least ~~six~~ 6 times the current reclaiming cost estimate.

(ii) The phrase "current reclaiming cost estimates" as used in subpart (i) of this part refers to the cost estimates required to be shown in paragraphs 1 through 4 of the letter from the applicant's or licensee's chief financial officer.

(iii) To demonstrate that he meets this test, the applicant or licensee must submit the following items to the Director:

(I) A letter signed by the applicant's or licensee's chief financial officer and worded as specified in part (j)4 of this paragraph;

(II) A copy of the independent certified public accountant's report on examination of the applicant's or licensee's financial statements for the latest completed fiscal year; and

(III) A special report from the applicant's or licensee's independent certified public accountant to the applicant or licensee stating that:

I. He has compared the data which the letter from the chief financial officer specifies as having been derived from the independently audited, year-end financial statements for the latest fiscal year with the amounts in such financial statements; and

II. In connection with that procedure, no matters came to his attention which caused him to believe that the specified data should be adjusted.

(iv) After the initial submission of items specified in subpart (iii) of this part, the licensee must send updated information to the Director within 90 days after the

close of each succeeding fiscal year. This information must consist of all three items specified in subpart (iii) of this part.

(v) If the licensee no longer meets the requirements of subpart (i) of this part, he must send notice to the Director of intent to establish alternate financial assurance as specified in this paragraph. 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 licensee no longer meets the requirements. The licensee must provide the alternate financial assurance within 120 days after the end of such fiscal year.

(vi) The Director may, based on a reasonable belief that the licensee may no longer meet the requirements of subpart (i) of this part, require reports of financial condition at any time from the licensee in addition to those specified in subpart (iii) of this part. If the Director finds, on the basis of such reports or other information, that the licensee no longer meets the requirements of subpart (i) of this part, the licensee must provide alternate financial assurance as specified in this paragraph within 30 days after notification of such a finding.

(vii) The Director may disallow use of this test on the basis of qualifications in the opinion expressed by the independent certified public accountant in his report on examination of the applicant's or licensee's financial statements. An adverse opinion or a disclaimer of opinion will be cause for disallowance. The Director will evaluate other qualifications on an individual basis. The applicant or licensee must provide alternate financial assurance as specified in this paragraph within 30 days after notification of the disallowance.

(viii) An applicant or licensee may meet the requirements of subparagraph (c) of this paragraph by obtaining a written guarantee, hereafter referred to as "corporate guarantee." The guarantor must be the parent corporation of the licensee. The guarantor must meet the requirements for applicants or licensees in subparts (i) through (vii) of this part and must comply with the terms of the corporate guarantee. The wording of the corporate guarantee must be identical to the wording specified in part (j)5 of this paragraph. The corporate guarantee must accompany the items sent to the Director as specified in subpart (iii) of this part. The terms of the corporate guarantee must provide that:

(I) If the licensee fails to perform reclaiming of a facility covered by a corporate guarantee for reclaiming in accordance with acceptable practices to protect health and safety and other license requirements whenever required to do so, the guarantor will do so or forfeit to the State monies in an amount equal to the current reclaiming cost estimate for the facility, as provided in part (c)5 of this paragraph.

(II) The corporate guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and to the Director. Cancellation may not occur, however, during the 180 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Director as evidenced by the return receipts.

(III) If the licensee fails to provide alternate financial assurance as specified in this paragraph and obtain the written approval of such alternate assurance from the Director within 90 days after receipt by both the licensee and the Director of a notice of cancellation of the corporate guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(e) Use of Multiple Financial Mechanisms

In meeting the requirements of subparagraph (c) of this paragraph, an applicant or licensee may utilize more than one financial assurance mechanism per facility. These mechanisms are limited to personal bonds supported by letters of credit, insurance, securities or cash. The mechanisms must be as specified in subparagraph (d) of this paragraph, except that it is the combination of mechanisms, rather than the single mechanism, which must provide financial assurance for the necessary amount.

(f) Use of a Financial Mechanism for Multiple Facilities

An applicant or licensee may use a financial assurance mechanism specified in subparagraph (d) of this paragraph to meet the requirements of subparagraph (c) of this paragraph for more than one facility he owns or operates in Tennessee. If so, the mechanism submitted to the Director must include a list showing, for each facility, the license number, name, address and amount of funds for reclaiming care assured by the mechanism. The amount of funds available through the mechanism must be no less than the sum of funds that would be available if a separate mechanism had been filed and maintained for each facility.

(g) Substituting Alternate Financial Assurance

In meeting the requirements of subparagraph (c) of this paragraph, a licensee may substitute alternate financial assurance meeting the requirements of this paragraph for the financial assurance already filed with the Director for the facility. However, the existing financial assurance shall not be released by the Commissioner until the substitute financial assurance has been received and approved by him.

(h) Procedures for Forfeiture of Financial Assurance.

1. Upon the determination of abandonment, insolvency or other inability of the licensee to perform to the satisfaction of the Commissioner, a notice of non-compliance shall be served upon the licensee. Such notice shall be hand-delivered or forwarded by certified mail. The notice of non-compliance shall specify in what respects the licensee has failed to perform as required.

2. If the Commissioner determines that the licensee has failed to perform as specified in the notice of non-compliance, or as specified in any subsequent compliance agreement which may have been reached by the licensee and the Commissioner, the Director shall cause a notice of show cause meeting to be served upon the licensee. Such notice shall be signed by the Director and either hand-delivered or forwarded by certified mail to the licensee. The notice of show cause meeting shall establish the date, time and location of a meeting scheduled to provide the licensee with the opportunity to show cause why the Director should not pursue forfeiture of the financial assurance filed to guarantee such performance.

3. If no mutual compliance agreement is reached at the show cause meeting, or, upon the Commissioner's determination that the licensee has failed to perform as specified in such agreement that was reached, the Director shall request the Commissioner to order forfeiture of the financial assurance filed to guarantee such performance.

4. The Commissioner shall order forfeiture of the financial assurance upon his validation of the Director's determinations and upon his determination that the procedures of this subparagraph have been followed. The Commissioner may, however, at his discretion, provide opportunity for the licensee to be heard before himself before issuing such order. Upon issuance a copy of the order shall be hand-delivered or forwarded by certified mail

to the licensee. Any such order issued by the Commissioner shall become effective 30 days after the receipt by the licensee.

5. If necessary, upon the effective date of the order of forfeiture, the Commissioner shall give notice to the State Attorney General who shall collect the forfeiture.

6. All funds from forfeited financial assurances shall be deposited in the State's radiation reclamation trust fund account for use by the Commissioner as set forth in ~~Section 68-23-405 of the Act~~ T.C.A § 68-202-405.

(i) Incapacity of Applicants or Licensees, Guarantors, or Financial Institutions.

1. An applicant or licensee must notify the Director by certified mail of the commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming the applicant or licensee as debtor, within ~~ten~~ 10 days after commencement of the proceeding. A guarantor of a corporate guarantee as specified in part (d)6 of this paragraph must make such a notification if he is named as debtor, as required under the terms of the corporate guarantee.

2. An applicant or licensee who fulfills the requirements of this paragraph by obtaining a surety bond, letter of credit or insurance policy will be deemed to be without the required financial assurance in the event of bankruptcy of the issuing institution or a suspension or revocation of the authority of the institution issuing the surety bond, letter of credit or insurance policy to issue such instruments. The applicant or licensee must establish other financial assurance within 30 days after such an event.

(j) Wording of the Instruments.

1. A surety bond guaranteeing funds for reclaiming as specified in part (d)1 of this paragraph, must be worded as follows except that the instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

SURETY BOND

Date bond executed: _____
Effective date: _____
Principal: (legal name and business address of applicant or licensee)
Type of organization: (insert "individual," "joint venture," "partnership" or "corporation")
State of incorporation: _____
Surety(ies): (Name(s) and business address(es))
License number, name, address and reclaiming cost for each facility guaranteed by this bond (list amounts separately):
$_____
Total penal sum of bond: $_____
Surety's bond number: _____

KNOW ALL PERSONS BY THESE PRESENTS, that we, the Principal and Surety(ies) hereto are firmly bound to the Tennessee Department of Environment and Conservation (hereinafter called Department), in the above penal sum for the payment of which we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally; provided that, where the Surety(ies) are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sum "jointly and severally" only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself, jointly and severally with the Principal, for the payment of such sum only as is set forth opposite the name of such Surety, but if no limit of liability is indicated, the limit of liability shall be the full amount of the penal sum.

WHEREAS said Principal is required, under the Tennessee Radiological Health Service Act, as amended, to have a license in order to receive, possess, store and use radioactive material at the facility identified above, and

WHEREAS said Principal is required to provide financial assurance for reclaiming as a condition of the license;

NOW, THEREFORE, the conditions of this obligation are such that if the Principal shall faithfully perform reclaiming, whenever required to do so, of each facility for which this bond guarantees funds for reclaiming, to the satisfaction of the Commissioner, Tennessee Department of Environment and Conservation in accordance with acceptable practices for protection of health and safety pursuant to all applicable laws, statutes, rules and regulations, as such laws, statutes, rules and regulations may be amended,

OR, if the Principal shall provide alternate financial assurance as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12, and obtain the written approval of such assurance from the Director, Division of Radiological Health (hereinafter called Director), within 90 days after the date notice of cancellation is received by both the Principal and the Director from the Surety(ies), then this obligation shall be null and void, otherwise it is to remain in full force and effect.

The Surety(ies) shall become liable on this bond obligation only when the Principal has failed to fulfill the conditions described above.

Upon notification by the Director that the Principal has been found in violation of the reclaiming requirements of the Division, for a facility for which this bond guarantees funds for performance of reclaiming, the Surety(ies) shall forfeit the reclaiming cost amount guaranteed for the facility to the Department as directed by the Director.

Upon notification by the Director that the Principal has filed to provide alternate financial assurance as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12, and obtain written approval of such assurance from the Director during the 30 days following receipt by both the Principal and the Director of a notice of cancellation of the bond, the Surety(ies) shall forfeit funds in the amount guaranteed for the facility(ies) to the Department as directed by the Director.

The Surety(ies) hereby waive(s) notification of amendments to licenses, applicable laws, statutes, rules and regulations and agree(s) that no such amendment shall in any way alleviate its (their) obligation on this bond.

The liability of the Surety(ies) shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penal sum of the bond, but in no event shall the obligation of the Surety(ies) hereunder exceed the amount of said penal sum.

The Surety(ies) may cancel the bond by sending notice of cancellation by certified mail to the Principal and to the Director, provided, however, that cancellation shall not occur during the 180 days beginning on the date of receipt of the notice of cancellation by both the Principal and the Director, as evidenced by the return receipts.

The Principal may terminate this bond by sending written notice to the Surety(ies), provided, however, that no such notice shall become effective until the Surety(ies) receive(s) written authorization for termination of the bond by the Director.

IN WITNESS WHEREOF, the Principal and Surety(ies) have executed this SURETY BOND and have affixed their seals on the date set forth above.

The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety(ies) and that the wording of this surety bond is identical to the wording specified in ~~1200-02-10-.12~~ part (4)(j)1 of Rule 0400-20-10-.12 as such regulation was constituted on the date this bond was executed.

PRINCIPAL

(Signature(s))
(Name(s))
(Title(s))
(Corporate seal)
CORPORATE SURETY(IES)
(Name and address)
State of incorporation: _____
Liability limit: $_____
(Signature(s))
(Name(s) and title(s))
Corporate seal:
(For every co-surety, provide signature(s), corporate seal and other information in the same manner as for Surety above.)
Bond premium: $_____

2. A letter of credit, as specified in part (d)2 of this paragraph, must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

IRREVOCABLE STANDBY LETTER OF CREDIT

Director
Division of Radiological Health
Tennessee Department of Environment and Conservation

Dear Sir or Madam:

We hereby establish our Irrevocable Standby Letter of Credit No. _____ in your favor, at the request and for the account of (applicant's or licensee's name and address) up to the aggregate amount of (in words) U.S. dollars $ _____, available upon presentation of:

1) your sight draft, bearing reference to this letter of credit No. _____, and

2) your signed statement reading as follows: "I certify that the amount of the draft is payable pursuant to regulations issued under authority of the Tennessee Radiological Health Service Act, as amended."

This letter of credit is effective as of (date) and shall expire on (date at least ~~one~~ 1 year later), but such expiration date shall be automatically extended for a period of (at least ~~one~~ 1 year) on (date) and on each successive expiration date, unless, at least 180 days before the current expiration date, we notify both you and (applicant's or licensee's name) by certified mail that we have decided not to extend this letter of credit beyond the current expiration date. In the event you are so notified, any unused portion of the credit shall be

available upon presentation of your sight draft for 180 days after the date of receipt by both you and (licensee's name), as shown on the signed return receipts.

Whenever this letter of credit is drawn on under and in compliance with the terms of this credit, we shall duly honor such draft upon presentation to us, and we shall forfeit the amount of the draft to the State of Tennessee in accordance with your instructions.

> We certify that the wording of this letter of credit is identical to the wording specified in ~~1200-02-10-.12~~ part (4)(j)2 of Rule 0400-20-10-.12 as such regulation was constituted on the date shown immediately below.

(Signature(s) and title(s) of official(s) of issuing institution) (Date)

This credit is subject to (insert "the most recent edition of the Uniform Customs and Practice for Documentary Credits, published by the International Chamber of Commerce," or "the Uniform Commercial Code").

3. A Certificate of Insurance, as specified in part (d)3 of this paragraph must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

CERTIFICATE OF INSURANCE FOR RECLAIMING

Name and Address of Insurer
(herein called the "Insurer"): _____

Name and Address of Insured
(herein called the "Insured"): _____

Facilities Covered: (List for each facility: The license number, name, address and the amount of insurance for reclaiming (these amounts for all facilities covered must total the face amount shown below))

Face Amount: $ _____

Policy Number: _____

Effective Date: _____

The Insurer hereby certifies that it has issued to the Insured the policy of insurance identified above to provide financial assurance for reclaiming the facilities identified above. The Insurer further warrants that such policy conforms in all respects with the requirements of ~~1200-02-10-.12~~ part (4)(j)3 of Rule 0400-20-10-.12, as applicable and as such regulations were constituted on the date shown immediately below. It is agreed that any provision of the policy inconsistent with such regulation is hereby amended to eliminate such inconsistency.

Whenever requested by the Director, Division of Radiological Health, Tennessee Department of Environment and Conservation, the Insurer agrees to furnish to the Director, Division of Radiological Health a duplicate original of the policy listed above, including all endorsements thereon.

I hereby certify that the wording of this certificate is identical to the wording specified in ~~1200-02-10-.12~~ part (4)(j)3 of Rule 0400-20-10-.12 as such regulation was constituted on the date shown immediately below.

(Authorized signature for Insurer)

(Name of person signing)

(Title of person signing)

Signature of witness or notary: _____

(Date)

4. A letter from the chief financial officer, as specified in part (d)6 of this paragraph must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

LETTER FROM CHIEF FINANCIAL OFFICER

(Address to Director, Division of Radiological Health)

I am the chief financial officer of (name and address of firm). This letter is in support of this firm's use of the financial test to demonstrate financial assurance, as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12.

(Fill out the following four paragraphs regarding facilities and associated cost estimates. If your firm has no facilities that belong in a particular paragraph, write "None" in the space indicated. For each facility, include its license number, name, address and current reclaiming cost estimates.)

1. This firm is the licensee at the following facility for which financial assurance for reclaiming is demonstrated through the financial test specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12. The current reclaiming cost estimate covered by the test is: $ _____.

2. This firm guarantees, through the corporate guarantee specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12, the reclaiming of the following facility owned or operated by a subsidiary of this firm. The current cost estimates for reclaiming so guaranteed is: $ _____.

3. In other states, this firm, as licensee or guarantor, is demonstrating financial assurance for reclaiming of the following facilities through the use of a test equivalent or substantially equivalent to the financial test specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12. The current reclaiming cost estimates covered by such a test are shown for each facility: $ _____.

4. This firm is the licensee of the following facilities receiving, possessing, using or storing radioactive material for which financial assurance for reclaiming is not demonstrated either to the Division, another State, or the U.S. Nuclear Regulatory Commission through the financial test or any other financial assurance mechanisms specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12 or equivalent or substantially equivalent mechanisms. The current reclaiming cost estimates not covered by such financial assurance are shown for each facility: $ _____.

This firm (insert "is required" or "is not required") to file a Form 10K with the Securities and Exchange Commission (SEC) for the latest fiscal year.

The fiscal year of this firm ends on (month, day). The figures for the following items marked with an asterisk are derived from this firm's independently audited, year-end financial statement for the latest completed fiscal year, ending (date).

(Fill in Alternative I if the criteria of item (d)6(i)(I) of this paragraph are used. Fill in Alternative II is if the criteria of item (d)6(i)(II) of this paragraph are used).

ALTERNATIVE I

1.	Sum of current reclaiming cost estimates (total of all cost estimates shown in the four paragraphs above)	$ _____
*2.	Total liabilities (if any portion of the reclaiming cost estimate is included in total liabilities, you may deduct the amount of that portion from this line and add that amount to lines 3 and 4)	$ _____
*3.	Tangible net worth	$ _____
*4.	Net worth	$ _____
*5	Current assets	$ _____
*6	Current liabilities	$ _____
*7	Net working capital (line 5 minus line 6)	$ _____
*8.	The sum of net income plus depreciation, depletion, and amortization	$ _____
*9.	Total assets in U.S. (required only if less than 90% of firm's assets are located in the U.S.)	$ _____

		YES	NO
10.	Is line 3 at least $10 million?	_____	_____
11.	Is line 3 at least 6 times line 1?	_____	_____
12.	Is line 7 at least 6 times line 1?	_____	_____
*13.	Are at least 90% of firm's assets located in the U.S.? If not, complete line 14	_____	_____
14.	Is line 9 at least 6 times line 1?	_____	_____
15.	Is line 2 divided by line 4 less than 2.0?	_____	_____
16.	Is line 8 divided by line 2 greater than 0.1?	_____	_____
17.	Is line 5 divided by line 6 greater than 1.5?	_____	_____

ALTERNATIVE II

1.	Sum of current reclaiming cost estimates (total of all cost estimates shown in the four paragraphs above)	$ _____	
2.	Current bond rating of most recent issuance of this firm and name of rating service	_____	
3.	Date of issuance of bond	_____	
4.	Date of maturity of bond	_____	
*5.	Tangible net worth	$ _____	
*6	Total assets in U.S. (required only if less than 90% of firm's assets are located in the U.S.)	$ _____	
		YES	NO
7.	Is line 5 at least $10 million?	_____	_____
8.	Is line 5 at least 6 times line 1?	_____	_____
9.	Are at least 90% of firm's assets located in the U.S.? If not, complete line 10.	_____	_____
10.	Is line 6 at least 6 times line 1?	_____	_____

I hereby certify that the wording of this letter is identical to the wording specified in ~~1200-02-10-.12~~ part (4)(j)4 of Rule 0400-20-10-.12 as such regulations were in effect on the date shown immediately below.

(Signature)
(Name)
(Title)
(Date)

5. A corporate guarantee, as specified in part (d)6 of this paragraph, must be worded as follows except that instructions in parentheses are to be replaced with the relevant information and the parentheses deleted:

CORPORATE GUARANTEE FOR RECLAIMING

Guarantee made this (date) by (name of guaranteeing entity), a business corporation organized under the laws of the State of (insert name of State), herein referred to as guarantor, to the Tennessee Department of Environment and Conservation (Department), obligee, on behalf of our subsidiary (applicant or licensee) of (business address).

Recitals

1. Guarantor meets or exceeds the financial test criteria and agrees to comply with the reporting requirements for guarantors as specified in ~~1200-02-10-.12~~ part (4)(d)6 of Rule 0400-20-10-.12.

2. (Applicant or licensee) owns or operates and is licensed by the Department to receive, possess, store and use radioactive material at the facility covered by this guarantee: (List for the facility: license number, name and address).

3. For value received from (licensee), guarantor guarantees to the Department that in the event that (licensee) fails to perform reclaiming of the above facility in a manner deemed acceptable by the Commissioner to assure health and safety from radiation hazards and other license requirements, the guarantor shall do so or forfeit to the State of Tennessee, as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12 monies in an amount equal to the current reclaiming cost estimates as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12.

4. Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 30 days, by certified mail, notice to the Director of the Department's Division of Radiological Health (Division Director) and to (licensee) that he intends to provide alternate financial assurance as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12, in the name of (licensee). Within 90 days after the end of such fiscal year, the guarantor shall establish such financial assurance unless (licensee) has done so.

5. The guarantor agrees to notify the Division Director, by certified mail, of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming guarantor as debtor, within ~~ten~~ 10 days after commencement of this proceeding.

6. Guarantor agrees that within 30 days after being notified by the Division Director of a determination that guarantor no longer meets the financial test criteria or that he is disallowed from continuing as a guarantor for reclaiming he shall establish alternate financial assurance as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12 in the name of (licensee) unless (licensee) has done so.

7. Guarantor agrees to remain bound under this guarantee notwithstanding any or all of the following: amendment or modification of the license, the extension or reduction of the time of performance of reclaiming or any other modification or alteration of an obligation of the licensee pursuant to these regulations.

8. Guarantor agrees to remain bound under this guarantee for so long as (licensee) must comply with the applicable financial assurance requirements of ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12 for the above-listed facility, except that guarantor may cancel this guarantee by sending notice by certified mail to the Division Director and to (licensee), such cancellation to become effective no earlier than 180 days after receipt of such notice by both the Department and (licensee), as evidenced by the return receipts.

9. Guarantor agrees that if (licensee) fails to provide alternate financial assurance as specified in ~~1200-02-10-.12~~ paragraph (4) of Rule 0400-20-10-.12, and obtain written approval of such assurance from the Division Director within 30 days after a notice of cancellation by the guarantor is received by the Division Director from guarantor, guarantor shall provide such alternate financial assurance in the name of (licensee).

10. Guarantor expressly waives notice of acceptance of this guarantee by the Department or by (licensee). Guarantor also expressly waives notice of amendments or modification of the facility license.

I hereby certify that the wording of this guarantee is identical to the wording specified in ~~1200-02-10-.12~~ part (4)(j)5 of Rule 0400-20-10-.12 as such regulations were in effect on the date first above written.

Effective Date: _____

(Name of guarantor)

(Authorized signature for guarantor)

(Name of person signing)

(Title of person signing)

Signature of witness or notary: _____

(k) Persons licensed at the time these financial assurance regulations become effective and upon notice by the Department must, within a period of ~~ninety~~ 90 days following such notice, provide the required financial assurance.

(l) The Department may reevaluate, at any time, the adequacy of existing financial assurance and may require their adjustment by either increasing or decreasing the amount of financial assurance required so that adequate funds will be available.

(m) Except that the following persons are exempt from the requirements of this paragraph:

1. State and local government agencies.

2. Educational institutions accredited by the Southern Association of Colleges and Schools.

3. Licensees of the State Licensing Board for the Healing Arts and those medical facilities possessing or utilizing radioactive materials for medical purposes when supervised by such licensees.

4. Veterinarians possessing or utilizing radioactive materials in their veterinary practice.

5. Persons possessing or utilizing radioactive materials for "in vitro" medical purposes.

6. Persons possessing or utilizing only generally licensed quantities of radioactive materials.

(n) Each person licensed under 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 ~~1200-02-10-.16~~ Rule 0400-20-10-.16, a licensee 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 Division considers important to decommissioning consists of:

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);

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:

   (i) All areas designated and formerly designated restricted areas as defined in paragraph (62) of Rule ~~1200-02-05-.32~~ 0400-20-05-.32;

   (ii) All areas outside of restricted areas that require documentation under part ~~(4)(n)~~1 of ~~Rule 1200-02-10-.12~~ this subparagraph;

   (iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under Rule ~~1200-02-05-.137~~ 0400-20-05-.137; and

   (iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in Rule ~~1200-02-10-.36~~ 0400-20-10-.36, or apply for approval for disposal under Rule ~~1200-02-05-.121~~ 0400-20-05-.121.

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.

(5) The applicant or an existing licensee, for whom financial assurance is required and where it is intended that the licensed facility will eventually cease to operate while containing, storing or possessing radioactive sources on the premises and will require continuing and perpetual care or surveillance over the facility to protect public health, safety or welfare, shall deposit sums to a Perpetual Care Trust Fund maintained by the Commissioner in the name of the State.

   (a) The Commissioner shall consider the following in making his determination of the Perpetual Care Trust Fund deposits for each individual applicant or licensee.

      1. The nature of the licensed radioactive material; including its radiotoxicity, half-life, chemical and physical form and containment;

      2. Size and type of facility to be decommissioned; and

      3. The anticipated cost to the State of perpetual care and surveillance.

   (b) The Department may reevaluate at any time the adequacy of a licensee's contributions to the existing Perpetual Care Trust Fund and may adjust by increasing or decreasing the rate of contribution or the specified amount required of a licensee so that the fund may be adequate in amount to meet perpetual care requirements of that licensee.

(6) Definitions of terms used in paragraph (4) of this rule.

   (a) "Current reclaiming cost estimate" means the most recent of the estimates prepared in accordance with parts ~~(4)~~(c)1, 2, and 3 ~~of paragraph (4)~~ of this rule.

   (b) "Director" means the Director of the Division of Radiological Health of the Department of Environment and Conservation.

(c) "Parent corporation" means a corporation which directly owns at least 50 percent of the voting stock of the corporation which is the facility owner or operator; the latter corporation is deemed a "subsidiary" of the parent corporation.

(d) The following terms are used in the specifications for the financial tests for financial assurance for reclaiming. The definitions are intended to assist in the understanding of these regulations and are not intended to limit the meanings of terms in a way that conflicts with generally accepted accounting practices.

1. "Assets" means all existing and all probable future economic benefits obtained or controlled by a particular entity.

2. "Current assets" means cash or other assets or resources commonly identified as those which are reasonably expected to be realized in cash or sold or consumed during the normal operating cycle of the business.

3. "Current liabilities" means obligations whose liquidation is reasonably expected to require the use of existing resources properly classifiable as current assets or the creation of other current liabilities.

4. "Independently audited" refers to an audit performed by an independent certified public accountant in accordance with generally accepted auditing standards.

5. "Liabilities" means probable future sacrifices of economic benefits arising from present obligations to transfer assets or provide services to other entities in the future as a result of past transactions or events.

6. "Net working capital" means current assets minus current liabilities.

7. "Net worth" means total assets minus total liabilities and is equivalent to owner's equity.

8. "Tangible net worth" means the tangible assets that remain after deducting liabilities; such assets would not include intangibles such as goodwill and rights to patents of royalties.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.13~~ 0400-20-10-.13 Special Requirements for Issuance of Specific Licenses.

(1) Reserved

(2) Reserved

(3) Reserved

(4) Multiple quantities of types of radioactive material for use in research and development. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license for multiple quantities or types of radioactive material for use in research and development will be issued only if:

(a) The applicant has established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and approve, in advance of purchase of radioisotopes, proposals for use; and

(b) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems.

(5) Manufacture, distribution or initial distribution of devices to persons generally licensed under ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license to distribute certain devices of the types enumerated in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 to persons generally licensed under ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State will be issued only if:

(a) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide assurance that:

1. The device can be safely operated by persons not having training in radiological protection;

2. Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and no person will receive in ~~one~~ 1 year a dose in excess of ~~ten~~ 10 percent ~~(10%)~~ of the limits specified in ~~1200-02-05-.50~~ Rule 0400-20-05-.50; and

3. Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Table RHS 7-1:

TABLE RHS 7-1
TABLE OF ORGAN DOSES

Part of Body	rem	mSv/ Sv
Whole body; head and trunk; active blood forming organs; gonads; or lens of eye	15	150 mSv
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200	2 Sv
Other organs	50	500 mSv

(b) Each device bears a durable, legible clearly visible label or labels approved by the Division that contain(s) in a clearly identified and separate statement:

1. Instructions and precautions for safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

2. The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of the radioactive material by isotope, quantity of radioactivity and date of determination of the quantity; and

3. The information called for in one of the following statements in the same or similar form:

(i) The receipt, possession, use, and transfer of this device, Model _____,[9] Serial No. _____,[9] are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

_____
(Name of manufacturer or distributor)

(ii) The receipt, possession, use and transfer of this device Model _____,[9] Serial No. _____,[9] are subject to a general license or the equivalent and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

_____
(Name of manufacturer or distributor)

(c) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "CAUTION - RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in ~~1200-02-05-.110~~ Rule 0400-20-05-.110 and the name of the manufacturer or initial distributor.

(d) Each device meeting the criteria of ~~1200-02-10-.10~~ Rule 0400-20-10-.10 bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "CAUTION – RADIOACTIVE MATERIAL," and, if practicable, the radiation symbol described in ~~1200-02-05-.110~~ Rule 0400-20-05-.110.

(e) In the event the applicant desires that the device be tested at intervals longer than ~~six~~ 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material, or for both, he shall include in his application information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material or failure of the on-off mechanism indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Division will consider information that includes, but is not limited to:

1. Primary containment (source capsule);

2. Protection of primary containment;

3. Method of sealing containment;

4. Containment construction materials;

[9] If specified elsewhere in labeling affixed to the device, the model, serial number and manufacturer or distributor may be omitted from this label.

5. Form of contained radioactive material;

6. Maximum temperature withstood during prototype tests;

7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and

10. Operating experience with identical devices or similarly designed and constructed devices;

(f) In the event the applicant desires that the general licensee under ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities and the basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, will not cause that individual to receive in one year a dose in excess of ~~ten~~ 10 percent ~~(10%)~~ of the limits specified in ~~1200-02-05-.50~~ Rule 0400-20-05-.50;

(g) Before radioactive material may be transferred in a device for use under a general license, each person licensed under ~~1200-02-10-.13(5)~~ this paragraph shall furnish the following information to each person to whom he directly or through an intermediate person transfers radioactive material in a device. In the case of a transfer through an intermediate person, the information shall be provided to the intended user and to the intermediate person prior to initial transfer to the intermediate person.

For use under the general license contained in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10	For use under equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State
1. A Copy of the general license contained in ~~1200-20-10-.10~~ paragraph (2) of Rule 0400-20-10-.10.	A copy of the general license contained in the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations equivalent to ~~1200-02-10-.10~~ paragraph (2) Rule 0400-20-10-.10. Alternatively, he may furnish a copy of the general license contained in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10. If a copy of the general license in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, Agreement State or Licensing State under requirements substantially the same as those in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10;

If parts ~~1200-02-10-.10~~ (2)(c)2 through 4 or ~~1200-02-10-.10(2)(c)~~ 13 of Rule 0400-20-10-.10 do not apply to the particular device, those parts may be omitted;	If ~~paragraphs (c)(2) through (4) or (c)(13)~~ parts (2)(c)2 through 4 or 13 of Rule 0400-20-10-.10, or sections of the Agreement State or Licensing State regulations equivalent to these ~~paragraphs~~ parts, do not apply to the particular device, these ~~paragraphs~~ parts may be omitted.
2. A copy of ~~1200-02-10-.26~~ Rules 0400-20-10-.26, ~~1200-02-05-.140~~ 0400-20-05-.140 and ~~1200-02-05-.141~~ 0400-20-05-.141.	A copy of 10 CFR §§31.2, 30.51, 20.2201, and 20.2202 or the Agreement State or Licensing State regulations equivalent to these NRC regulations.

3. A list of services that may only be performed by a specific licensee;

4. Information on acceptable disposal options including estimated costs of disposal;

5. A statement that regulatory agencies may issue citations and civil penalties for improper disposal; and

6. The name or title, address, and phone number of the person at the appropriate regulatory agency from whom additional information may be obtained.

(h) An alternative approach to informing customers may be proposed by the licensee for approval by the Division.

(i) Each device that is transferred ~~one 1 year~~ after ~~the effective date of this rule~~ on May 26, 2008 or later shall meet the labeling requirements in subparagraphs ~~1200-02-10-.13(5)~~ (b), (c) and (d) of this paragraph.

(j) Each person licensed under ~~1200-02-10-.13(5)~~ this paragraph to distribute devices to generally licensed persons shall:

1. Report to the Division, at its offices located at the address in Rule ~~1200-02-04-.07~~ 0400-20-04-.07, all transfers of such devices to persons for use under the general license in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10.

2. Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

3. Report to the responsible Agreement or Licensing State agency all transfers of devices manufactured and distributed pursuant to ~~1200-02-10-.13(5)~~ this paragraph for use under a general license in that state's regulations equivalent to ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10.

4. Reports required by parts ~~(5)(j)~~ 1, 2, and 3 of this subparagraph shall identify:

   (i) Each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

   (ii) The name, title and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number and serial number of the device transferred; and

(v) The quantity and type of radioactive material contained in the device.

5. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

6. For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

7. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report shall identify the general licensee, the device, and the changes to information on the device label.

8. The report shall cover each calendar quarter, shall be filed within 30 days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

9. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

10. If no transfers have been made to or from persons generally licensed under ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 during the reporting period, the report shall so indicate.

11. Keep records showing the name, address of use, and responsible individual for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in ~~1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. The records shall show the date of each transfer, the model number, serial number and the isotope and quantity of radioactivity in each device transferred, the identity of any intermediate person(s), and compliance with the report requirements of this subparagraph. The records required by this part ~~(5)(j)11~~ shall be maintained for a period of ~~three~~ 3 years from the date of the recorded event.

(6) The use of sealed sources in industrial radiography.

In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license for use of sealed sources in industrial radiography will be issued only if:

(a) The applicant will have a program for training radiographers and radiographer's assistants and submits to the Division for approval a schedule or description of such program which specifies the:

1. Initial training:

(i) This initial training will consist of a complete training program as outlined in ~~1200-02-08-.07~~ Rule 0400-20-08-.07; or

(ii) Résumés of prior training and experience of individuals that show fulfillment of the requirements of ~~1200-02-08-.07~~ subparagraphs (7)(a) and (b) of Rule 0400-20-08-.07 and the program for the initial training of such individuals in the licensee's or registrant's specific industrial radiography program as outlined in ~~1200-02-08-.07~~ subparagraphs (7)(c), (d) and (e) of Rule 0400-20-08-.07;

2. Periodic training;

3. On-the-job training;

4. Means to be used by the applicant to determine the radiographer's knowledge and understanding of and ability to comply with Division regulations and licensing requirements and the operating and emergency procedures of the applicant; and

5. Means to be used by the applicant to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(b) The applicant has established and submits to the Division for approval written operating and emergency procedures as described in ~~1200-02-08-.05~~ paragraph (2) of Rule 0400-20-08-.05;

(c) The applicant will have an internal inspection system to assure that Division regulations, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed ~~three~~ 3 months and the retention of records of such inspections for inspection by the Division.

(d) The applicant submits to the Division a description of his overall organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(e) The applicant who desires to conduct his own leak tests must establish procedures to be followed in testing sealed sources for possible leakage and contamination and submit to the Division for approval a description of such procedures including:

1. Instrumentation to be used;

2. Method of performing tests, e.g., points on equipment to be smeared and method of taking smear; and

3. Pertinent experience of the person who will perform the test.

(7) Multiple quantities or types of radioactive material for use in processing.

In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license for multiple quantities or types of radioactive material for use in processing for distribution to other authorized persons will be issued only if[10]:

(a) The applicant's staff has experience in the use of radioisotopes for processing and distribution; and

[10] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, DC 20555.

(b) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems.

(8) Introduction of radioactive material into products in exempt concentrations.

In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under ~~1200-02-10-.04~~ subparagraph (1)(a) of Rule 0400-20-10-.04 will be issued only if:

(a) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(b) The applicant provides assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule RHS 8-4, that reconcentration of the radioactive material in concentrations exceeding those in Schedule RHS 8-4 is not likely, that lower concentrations cannot be used, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. Each person licensed under this paragraph ~~(8)~~, shall file an annual report with the Division which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period, name and address of the person who owns or possesses the product or material into which radioactive material has been introduced at the time of introduction, the type and quantity of radioactive material introduced into each product or material, and the initial concentrations of radioactive material in the product or material at the tie of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this paragraph ~~(8)~~ during the reporting period, the report shall so indicate. The report shall be submitted within 30 days after the end of each calendar year.

(9) Radioactive material in luminous safety devices for use in aircraft.

In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license to manufacture, assemble, repair, or distribute to persons generally licensed under ~~1200-02-10-.10~~ paragraph (3) of Rule 0400-20-10-.10 luminous safety devices containing radioactive materials for use in aircraft will be issued only if the requirements of Sections 32.53, 32.54, 32.55, 32.56 and 32.101 of 10 CFR Part 32 or their equivalent are met.

(10) Manufacture, preparation or transfer for commercial distribution of radiopharmaceuticals containing radioactive material for medical use.

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons authorized pursuant to Chapter ~~1200-02-07~~ 0400-20-07 will be approved if:

1. The applicant satisfies the general requirements specified in Rule ~~1200-02-10-.12~~ 0400-20-10-.12;

2. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture,

preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by the Tennessee Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

3. The applicant submits information on the radionuclide; chemical and physical form; packaging including maximum activity per vial, syringe, generator or other container of the radioactive drug; and shielding provided by the packaging of the radioactive material for safe handling and storage of radiopharmaceuticals by medical use licensees; and

4. The applicant satisfies the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than ~~one hundred~~ 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by subpart (a)2(iii) of this paragraph:

1. May prepare radiopharmaceuticals for medical use, as defined in Rule ~~1200-02-07-.05~~ 0400-20-07-.05, provided that the radiopharmaceuticals are prepared by either an authorized nuclear pharmacist, as specified in parts 2 and 4 of this subparagraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule ~~1200-02-07-.19~~ 0400-20-07-.19.

2. May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in ~~Rule 1200-02-07-.05(4)~~ Rule 0400-20-07-.05,

(ii) This individual meets the requirements specified in ~~Rule 1200-02-07-.25~~ paragraph (2) of Rule 0400-20-07-.25 and Rule ~~1200-02-07-.27~~ 0400-20-07-.27, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with part 4 of this subparagraph.

3. The actions authorized in parts 1 and 2 of this subparagraph are permitted in spite of more restrictive language in license conditions.

4. May designate a pharmacist (as defined in Rule ~~1200-02-07-.05(24)~~ 0400-20-07-.05) as an authorized nuclear pharmacist if:

   (i) The individual was a nuclear pharmacist at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

5. Shall provide to the Division a copy of each individual's:

   (i) Certification by a specialty board whose certification process has been recognized by the Division, U.S. Nuclear Regulatory Commission or an Agreement State as specified in ~~Rule 1200-02-07-.25~~ paragraph (1) of Rule 0400-20-07-.25 with the written attestation signed by a preceptor as required by ~~Rule 1200-02-07-.25~~ subparagraph (2)(b) of Rule 0400-20-07-.25; or

   (ii) The Division, U.S. Nuclear Regulatory Commission or other Agreement State license; or

   (iii) NRC master materials licensee permit; or

   (iv) The permit issued by a licensee or NRC master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorization nuclear pharmacist; or

   (v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

   (vi) A copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, the individual to work as an authorized nuclear pharmacist under subparts 2(i) and (ii) of this subparagraph.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha–, beta–, or photon–emitting radioactive drugs before transfer for commercial distribution. In addition, the licensee shall:

   1. Perform tests before initial use, periodically and following repair, on each instrument for accuracy, linearity and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

   2. Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this rule relieves the licensee from complying with applicable FDA, other Federal and State requirements governing radioactive drugs.

(11) Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, a specific license to manufacture and distribute generators or reagent kits containing radioactive

material for preparation of radiopharmaceuticals by persons licensed pursuant to ~~1200-02-07~~ Chapter 0400-20-07 will be issued only if[11]:

(a) The requested site for manufacture and/or distribution of generators or reagent kits is located within this State;

(b) The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the United States Food and Drug Administration (FDA), a biologic product license issued by FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) accepted by FDA; or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(c) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity and date of assay;

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Division pursuant to ~~1200-02-07~~ Chapter 0400-20-07 of these regulations, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

(f) The labels, leaflets or brochures required by subparagraphs (d) and (e) of this paragraph are in addition to the labeling required by the FDA and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(12) Manufacture and distribution of sources or devices containing radioactive material for medical uses. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under ~~1200-02-07~~ Chapter 0400-20-07 of these regulations for use as a calibration, transmission, or reference source or for the uses listed in ~~1200-02-07-.51~~ Rules 0400-20-07-.51, ~~1200-02-07-.61~~ 0400-20-07-.61, ~~1200-02-07-.63~~ 0400-20-07-.63, and ~~1200-02-07-.81~~ 0400-20-07-.81 will be approved if:

(a) The applicant satisfies the general requirements in ~~1200-02-10-.12 of these regulations~~ Rule 0400-20-10-.12.

---

[11] Although the Department does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have reagent kits approved by the Department for use by persons licensed pursuant to ~~1200-02-07~~ Chapter 0400-20-07 may submit the pertinent information specified in this paragraph ~~(10)~~.

(b) The applicant submits information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

1. The radioactive material contained, its chemical and physical form and amount;

2. Details of design and construction of the source or device;

3. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered;

4. For devices containing radioactive material, the radiation profile of a prototype device;

5. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

6. Procedures and standards for calibrating sources and devices;

7. Legend and methods for labeling sources and devices as to their radioactive content; and

8. Instructions for handling and storing the source or device for radiation safety; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Division has approved distribution of the (name of the source or device) to persons licensed to use radioactive material identified in ~~1200-02-07-.31~~ Rules 0400-20-07-.31, ~~1200-02-07-.51~~ 0400-20-07-.51, ~~1200-02-07-.61~~ 0400-20-07-.61, and ~~1200-02-07-.63~~ 0400-20-07-.63 as appropriate, and to persons who hold an equivalent license issued by the U.S. NRC or an Agreement State.

(d) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than ~~six~~ 6 months, the applicant shall include in his application information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for test of leakage of radioactive material, the Division will consider information that includes, but is not limited to:

1. Primary containment (source capsule);

2. Protection of primary containment;

3. Method of sealing containment;

4. Containment construction materials;

5. Form of contained radioactive material;

6. Maximum temperature withstood during prototype tests;

7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and

10. Operating experience with identical sources or devices or similarly designed and constructed devices;

(13) Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

In addition to the requirements set forth in Rule ~~1200-02-10-.12~~ 0400-20-10-.12, a specific license to manufacture or distribute radioactive material for use under the general license of ~~Rule 1200-02-10-.10~~ paragraph (7) of Rule 0400-20-10-.10 will be issued only if:

(a) The radioactive material is to be prepared for distribution in prepackaged units of:

1. Iodine-125 in units not exceeding 10 microcuries each.

2. Iodine-131 in units not exceeding 10 microcuries each.

3. Carbon-14 in units not exceeding 10 microcuries each.

4. Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

5. Iron-59 in units not exceeding 20 microcuries each.

6. Cobalt-57 in units not exceeding 10 microcuries each.

7. Selenium-75 in units not exceeding 10 microcuries each.

8. Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(b) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-131, iodine-125, cobalt-57, selenium-75, or carbon-14; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

2. Displaying the radiation caution symbol described in Rule ~~1200-02-05-.110~~ 0400-20-05-.110 and the words, "Caution, Radioactive Material" and "Not for Internal or External Use in Humans or Animals."

(c) The following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for "in vitro" clinical or laboratory tests not involving internal or external administration of the material, or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

(d) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule ~~1200-02-05-.120~~ 0400-20-05-.120.

(14) Distribution of radioactive material in exempt quantities[12].

(a) An application for a specific license to distribute NARM to persons exempt from these regulations pursuant to ~~1200-02-10-.04~~ paragraph (3) of Rule 0400-20-10-.04 will be approved if:

1. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

2. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

3. The applicant submits copies of prototype labels and brochures and the Division approves such labels and brochures.

(b) The license issued under ~~1200-02-10-.13(14)~~ subparagraph (a) of this paragraph is subject to the following conditions:

1. No more than ~~ten~~ 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

2. Each exempt quantity shall be separately and individually packaged. No more that 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to ~~1200-02-10-.04~~ paragraph (3) of Rule 0400-20-10-.04. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

3. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(i) Identifies the radionuclide and the quantity of radioactivity; and

(ii) Bears the words "Radioactive Material."

4. In addition to the labeling information required by ~~1200-02-10-.13(14)(b)~~ part 3 of this subparagraph, the label affixed to the immediate container, or an accompanying brochure, shall:

(i) State that the contents are exempt from Licensing State requirements;

---

[12] See footnote 2 of this Chapter.

(ii) Bear the words "Radioactive Material - Not for Human Use -Incorporation into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined"; and

(iii) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(c) Each person licensed under ~~1200-02-10-.13(14)~~ this paragraph shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under ~~1200-02-10-.04~~ paragraph (3) of Rule 0400-20-10-.04 or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Division. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to ~~1200-02-10-.13(14)~~ this paragraph during the reporting period, the report shall so indicate.

(15) Incorporation of naturally occurring and accelerator-produced radioactive material into gas and aerosol detectors.

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under ~~Rule 1200-02-10-.04~~ part (2)(a)9 of Rule 0400-20-10-.04 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

(16) Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under ~~1200-02-10-.10~~ paragraph (4) of Rule 0400-20-10-.10.

(a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under ~~Rule 1200-02-10-.10~~ paragraph (4) of Rule 0400-20-10-.10 will be approved if:

1. The applicant satisfies the general requirement of Rule ~~1200-02-10-.12~~ 0400-20-10-.12; and

2. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of americium 241, plutonium or radium-226 in the source;

(ii) Details of construction and design;

(iii) Details of the method of incorporation and binding of the americium-241, plutonium or radium-226 in the source;

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, to demonstrate that the americium-241, plutonium or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(v) Details of quality control procedures to be followed in manufacture of the source;

(vi) Description of labeling to be affixed to the source or the storage container for the source; and

(vii) Any additional information, including experimental studies and tests, required by the Division to facilitate a determination of the safety of the source.

3. Each source will contain no more than 185 kBq (5 μCi) of americium-241, plutonium or radium-226.

4. The Division determines, with respect to any type of source containing more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, that:

(i) The method of incorporation and binding of the americium-241, plutonium or radium-226 in the source is such that the americium-241, plutonium or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by subparagraph (b) of this paragraph.

(b) Schedule C- prototype tests for calibration or reference sources containing americium-241, plutonium or radium-226.

An applicant for a license pursuant to subparagraph (a) of this paragraph shall conduct prototype tests for any type of source which is designed to contain more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, in the order listed, on each of five prototypes of such source, which contains more than 185 Bq (0.005 μCi) of americium-241, plutonium or radium-226, as follows:

1. Initial measurement.

The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

2. Dry wipe test.

The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe.

3. Wet wipe test.

The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried or by direct measurement of the radioactivity on the source following the wet wipe.

4. Water soak test.

The source shall be immersed in water at room temperature for a period of ~~twenty-four~~ 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after it has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

5. Dry wipe test.

On completion of the preceding test in part 4 of this subparagraph, the dry wipe test described in part 2 of this subparagraph shall be repeated.

6. Observations.

Removal of more than 185 Bq (0.005 μCi) of radioactivity in any test prescribed by this subparagraph shall be cause for rejection of the source design. Results of prototype tests submitted to the Division shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(c) Labeling of devices.

Each person licensed under subparagraph (a) of this paragraph shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model __, Serial No. __,
are subject to a general license and the regulations of the NRC or an
Agreement State. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL--
THIS SOURCE CONTAINS AMERICIUM-241 [PLUTONIUM OR RADIUM-226].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

(d) Leak testing of each source. Each person licensed under subparagraph (a) of this paragraph shall perform a dry wipe test upon each source containing more than 3.7 kBq (0.1 μCi) of americium-241, plutonium or radium 226 prior to transferring the source to a general licensee under ~~Rule 1200-02-10-.10~~ paragraph (4) of Rule 0400-20-10-.10. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 185 Bq (0.005 μCi) of americium-241, plutonium, or radium-226. If any such test discloses more than 185 Bq (0.005 μCi) of radioactive material, the source shall be deemed to be leaking or losing americium-241, plutonium or radium-226 and shall not be transferred to a general licensee under ~~Rule 1200-02-10-.10~~ paragraph (4) of Rule 0400-20-10-.10 or equivalent regulations of the NRC or an Agreement State.

(17) Emergency preparedness.

(a) Emergency preparedness for possession of radioactive material other than uranium and plutonium.

1. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, all specific licenses issued, or for which an initial application or an application to amend is submitted, to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Table RHS 7-2 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 subpart ~~(a)~~1(i) of this subparagraph:

(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 in Table RHS 7-2 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 Table RHS 7-2;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in Table RHS 7-2; or

(vii) Other factors appropriate for the specific facility.

Table RHS 7-2
Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

Radioactive material [1]	Release fraction	Quantity (curies)	Radioactive material [1]	Release fraction	Quantity (curies)
			Europium-154	0.01	400
Actinium-228	0.001	4,000	Europium-155	0.01	3,000
Americium-241	0.001	2	Germanium-68	0.01	2,000
Americium-242	0.001	2	Gadolinium-153	0.01	5,000
Americium-243	0.001	2	Gold-198	0.01	30,000
Antimony-124	0.01	4,000	Hafnium-172	0.01	400
Antimony-126	0.01	6,000	Hafnium-181	0.01	7,000
Barium-133	0.01	10,000	Holmium-166m	0.01	100
Barium-140	0.01	30,000	Hydrogen-3	0.5	20,000
Bismuth-207	0.01	5,000	Iodine-125	0.5	10
Bismuth-210	0.01	600	Iodine-131	0.5	10
Cadmium-109	0.01	1,000	Indium-114m	0.01	1,000
Cadmium-113	0.01	80	Iridium-192	0.001	40,000
Calcium-45	0.01	20,000	Iron-55	0.01	40,000
Californium-252	0.001	9 (20 mg)	Iron-59	0.01	7,000
Carbon-14	0.01	50,000	Krypton-85	1.0	6,000,000
Cerium-141	0.01	10,000	Lead-210	0.01	8
Cerium-144	0.01	300	Manganese-56	0.01	60,000
Cesium-134	0.01	2,000	Mercury-203	0.01	10,000
Cesium-137	0.01	3,000	Molybdenum-99	0.01	30,000
Chlorine-36	0.5	100	Neptunium-237	0.001	2
Chromium-51	0.01	300,000	Nickel-63	0.01	20,000
Cobalt-60	0.001	5,000	Niobium-94	0.01	300
Copper-64	0.01	200,000	Phosphorus-32	0.5	100
Curium-242	0.001	60	Phosphorus-33	0.5	1,000
Curium-243	0.001	3	Polonium-210	0.01	10
Curium-244	0.001	4	Potassium-42	0.01	9,000
Curium-245	0.001	2	Promethium-145	0.01	4,000
Europium-152	0.01	500	Promethium-147	0.01	4,000

Radium-226	0.001	100	Titanium-44	0.01	100
Ruthenium-106	0.01	200	Vanadium-48	0.01	7,000
Samarium-151	0.01	4,000	Xenon-133	1.0	900,000
Scandium-46	0.01	3,000	Yttrium-91	0.01	2,000
Selenium-75	0.01	10,000	Zinc-65	0.01	5,000
Silver-110m	0.01	1,000	Zirconium-93	0.01	400
Sodium-22	0.01	9,000	Zirconium-95	0.01	5,000
Sodium-24	0.01	10,000	Any other beta-gamma emitter	0.01	10,000
Strontium-89	0.01	3,000	Mixed fission products	0.01	1,000
Strontium-90	0.01	90	Mixed corrosion products	0.01	10,000
Sulfur-35	0.5	900	Contaminated equipment beta-gamma	0.001	10,000
Technetium-99	0.01	10,000	Irradiated material, any form other than		
Technetium-99m	0.01	400,000	solid noncombustible	0.01	1,000
Tellurium-127m	0.01	5,000	Irradiated material, solid noncombustible	0.001	10,000
Tellurium-129m	0.01	5,000	Mixed radioactive waste, beta-gamma	0.01	1,000
Terbium-160	0.01	4,000	Packaged mixed waste, beta-gamma[2]	0.001	10,000
Thulium-170	0.01	4,000	Any other alpha emitter	0.001	2
Tin-113	0.01	10,000	Contaminated equipment, alpha	0.0001	20
Tin-123	0.01	3,000	Packaged waste, alpha[2]	0.0001	20
Tin-126	0.01	1,000	Combinations of radioactive materials listed above [1]		

[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 Table RHS 7-2 exceeds one.

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

(b) Emergency preparedness for possession of uranium hexafluoride.

1. In addition to the requirements set forth in ~~1200-02-10-.12~~ Rule 0400-20-10-.12, all specific licenses to possess uranium hexafluoride in excess of 50 kilograms in a single container or 1000 kilograms total must contain either:

   (i) An evaluation showing that the maximum intake of uranium by a member of the public due to a release would not exceed 2 milligrams; or

   (ii) An emergency plan for responding to the radiological hazards of an accidental release of source material and to any associated chemical hazards directly incident thereto.

2. One or more of the following factors may be used to support an evaluation submitted under subpart ~~(b)~~1(i) of this subparagraph:

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

   (ii) Facility design or engineered safety features in the facility would reduce the amount of the release; or

   (iii) Other factors appropriate for the specific facility.

(c) Emergency preparedness for possession of plutonium.

1. In addition to the requirements set forth in ~~1200-02-02-.12~~ Rule 0400-20-10-.12, all specific licenses to possess plutonium in excess of 2 curies in unsealed form or on foils or plated sources must contain either:

   (i) An evaluation showing that the maximum dose to a member of the public offsite due to a release of plutonium would not exceed 1 rem effective dose equivalent, or

(ii) An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto.

2. One or more of the following factors may be used to support an evaluation submitted under subpart ~~(c)~~1(i) of this subparagraph:

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

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

(iii) In the case of fires or explosions, the release fraction would be lower than 0.001 due to the chemical or physical form of the material;

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

(v) The facility design or engineered safety features in the facility would cause the release fraction to be lower than 0.001;

(vi) Operating restrictions or procedures would prevent a release large enough to cause a member of the public offsite to receive a dose exceeding 1 rem effective dose equivalent; or

(vii) Other factors appropriate for the specific facility.

(d) An emergency plan for responding to a release of radioactive material submitted under subpart (a)1(ii), (b)1(ii) or (c)1(ii) of this paragraph must include the following information:

1. Facility description.

A brief description of the licensee's facility and area near the site.

2. Types of accidents.

An identification of each type of accident for which protective actions may be needed.

3. Classification of accidents.

A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents.

Identification of the means of detecting each type of radioactive materials accident in a timely manner.

5. 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.

6. Assessment of releases.

A brief description of the methods and equipment to assess releases of radioactive material.

7. 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 Division of Radiological Health; also responsibilities for developing, maintaining and updating the plan.

8. 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 Division of Radiological Health immediately after notification of the offsite response organizations and not later that ~~one~~ 1 hour after the licensee declares an emergency. [13]

9. 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 Division of Radiological Health.

10. Training.

A brief description of the frequency, performance objectives and plan 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.

11. Safe shutdown.

A brief description of the means of restoring the facility to a safe condition after an accident.

12. 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

[13] These reporting requirements do not supersede or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 (42 U.S.C. Chapter 116) or other state or federal reporting requirements.

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.

13. 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, Public Law 99-499 (42 U.S.C. Chapter 116), if applicable to the applicant's activities at the proposed place of the use of the source material.

(e) 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 the Division of Radiological Health. The licensee shall provide any comments received within the 60 days to the Division of Radiological Health with the emergency plan.

(f) Licensees required to submit emergency plans by this paragraph shall follow the emergency plan approved by the Division of Radiological Health. The licensee may change the plan without Division of Radiological Health approval if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Division of Radiological Health and to affected offsite response organizations within ~~six~~ 6 months after the change is made. Proposed changes that decrease the effectiveness of the approved emergency plan may not be implemented without application to and prior approval by the Division of Radiological Health.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.14~~ 0400-20-10-.14 Reserved.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.15~~ 0400-20-10-.15 Issuance of Specific Licenses.

(1) Upon a determination that an applicant meets the requirements of ~~the Act~~ T.C.A §§ 68-202-201 et seq. and the ~~regulations~~ rules of the Division will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The Division may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this Chapter as it deems appropriate or necessary in order to:

(a) Protect the public health and safety or property;

(b) Require such reports and the keeping of such records, and to provide for such inspection of activities under the license as may be necessary to evaluate activities conducted under the license; and

(c) Prevent loss or theft of material subject to this Chapter.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.16~~ 0400-20-10-.16 Specific Terms and Conditions of Licenses.

(1) Each license issued pursuant to this Chapter shall be subject to all provisions of ~~the Act~~ T.C.A. §§ 68-202-201 et seq., now or hereafter in effect, and to all rules, regulations, and orders of the Division.

(2) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of ~~the Act~~ T.C.A. §§ 68-202-201 et seq.

(3) Each person licensed by the Division pursuant to this Chapter shall confine has use and possession of the material licensed to the locations and purposes authorized in the license.

(4) Each licensee authorized under ~~Rule 1200-02-10-.13~~ paragraph (5) of Rule 0400-20-10-.13 to distribute certain devices to generally licensed persons shall:

(a) Report to the Division within ~~thirty~~ 30 days after the end of each calendar quarter all transfers of such devices to persons generally licensed under ~~Rule 1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10 or, if no transfers have been made during the reporting period, the report shall so indicate. For all transfers the report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Division and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device; and

(b) Furnish to each general licensee in this State to whom he transfers such device a copy of the general license contained in ~~Rule 1200-02-10-.10~~ paragraph (2) of Rule 0400-20-10-.10.

(5) Each specific licensee shall notify the Division in writing when the licensee decides to permanently discontinue all activities involving radioactive materials authorized under the license.

(6) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule ~~1200-02-07-.41~~ 0400-20-07-.41. The licensee shall record the results of each test and retain each record for ~~three~~ 3 years after the record is made.

(7) Each specific licensee and each general licensee meeting the criteria of ~~Rule 1200-02-10-.10~~ part (2)(c)14 of Rule 0400-20-10-.10 shall:

(a) Provide the Division written notification, at the address in Rule ~~1200-02-04-.07~~ 0400-20-04-.07, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code (U.S.C.):

1. By or against the licensee;

2. By or against 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

3. By or against an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee;

(b) Include in the notification required in subparagraph (a) of this paragraph the bankruptcy court in which the petition for bankruptcy was filed; and

(c) Include in the notification required in subparagraph (a) of this paragraph the date of the filing of the petition.

(8) When temporary job-sites are authorized on a specific license, radioactive material may be used at temporary job-sites, in areas not under exclusive federal jurisdiction, throughout the State of Tennessee.

(9) Each portable gauge licensee shall use a minimum of ~~two~~ 2 independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(10) (a) Authorization under ~~Rule 1200-02-10-.11~~ paragraph (8) of Rule 0400-20-10-.11 to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and Agreement State requirements governing radioactive drugs.

(b) Each licensee authorized under ~~Rule 1200-02-10-.11~~ paragraph (8) of Rule 0400-20-10-.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in ~~Rule 1200-02-10-.13~~ part (10)(a)4 of Rule 0400-20-10-.13 for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in ~~Rule 1200-02-10-.13~~ subparagraph (10)(c) of Rule 0400-20-10-.13.

(c) A licensee that is a pharmacy authorized under ~~Rule 1200-02-10-.11~~ paragraph (8) of Rule 0400-20-10-.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

1. An authorized nuclear pharmacist that meets the requirements in ~~Rule 1200-02-10-.13~~ part (10)(b)2 of Rule 0400-20-10-.13, or

2. An individual under the supervision of an authorized nuclear pharmacist as specified in Rule ~~1200-02-07-.19~~ 0400-20-07-.19.

(d) A pharmacy, authorized under ~~Rule 1200-02-10-.11~~ paragraph (8) of Rule 0400-20-10-.11 to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of ~~Rule 1200-02-10-.13~~ part (10)(b)5 of Rule 0400-20-10-.13.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.17~~ 0400-20-10-.17 Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

(1) Expiration of specific licenses.

Except as provided in ~~1200-02-10-.17~~ paragraph (2) of this rule, each specific license shall expire at the end of the day, in the month and year stated therein.

(2) Termination of specific licenses:

(a) Specific licenses shall continue in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Division notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

1. Limit actions involving radioactive material to those related to decommissioning; and

2. Continue to control entry to restricted areas until they are suitable for release in accordance with Division requirements.

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

1. The licensee has properly disposed of radioactive material;

2. The licensee has made reasonable effort to eliminate residual radioactive contamination, if present;

3. The premises are suitable for release in accordance with Division requirements. The licensee may demonstrate suitability for release by:

(i) Performance of the radiation survey described in ~~1200-02-10-.17~~ part (3)(d)2 of this rule, or

(ii) Submission of other information that the Division determines is acceptable;

4. The licensee has complied with any requests for information from the Division; and

5. The licensee has submitted a written request for license termination to the Division.

(3) Decommissioning of sites or separate buildings or outdoor areas:

(a) Each specific licensee shall notify the Division in writing, at the address in ~~1200-02-04-.07~~ Rule 0400-20-04-.07, within 60 days of any of the following occurrences:

1. The license has expired pursuant to ~~1200-02-10-.17~~ paragraph (2) of this rule;

2. The licensee has decided to permanently cease principal activities, as defined in this rule:

(i) At the entire site, or

(ii) In any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Division requirements;

3. No principal activities under the license have been conducted for 24 months; or

4. No principal activities have been conducted for 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Division requirements.

(b) Each specific licensee:

1. If not required by ~~1200-02-10-.17(3)~~ subparagraph (g) of this paragraph to submit a decommissioning plan, shall begin decommissioning its site or any separate building or outdoor area that contains residual radioactivity within 60 days of any occurrence listed in ~~1200-02-10-.17(3)~~ subparagraph (a) of this paragraph.

2. If required by ~~1200-02-10-.17(3)~~ subparagraph (g) of this paragraph to submit a decommissioning plan, shall:

(i) Submit a decommissioning plan within 12 months of notification of any occurrence listed in ~~1200-02-10-.17(3)~~ subparagraph (a) of this paragraph, and

(ii) Begin decommissioning upon Division approval of that plan.

(c) Coincident with the notification required by ~~1200-02-10-.17(3)~~ subparagraph (a) of this paragraph, the specific licensee shall maintain in effect all financial assurances that were established, pursuant to ~~1200-02-10-.12~~ paragraph (3) of Rule 0400-20-10-.12 in conjunction with a license issuance or renewal, or that are required by this rule.

1. The Division will determine if the licensee shall increase, or may decrease, the amount of the financial assurance to cover the detailed cost estimate for decommissioning established pursuant to ~~1200-02-10-.17(3)~~ part (i)5 of this paragraph.

2. The licensee may with Division approval reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site.

(d) As the final steps in decommissioning, specific licensees shall:

1. Certify the disposition of all licensed material, including accumulated wastes; and

2. Demonstrate that the premises are suitable for release in accordance with Division requirements.

(i) The licensee shall:

(I) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, or

(II) Submit other information that the Division determines is acceptable.

(ii) The licensee shall, as appropriate:

(I) Report levels of gamma radiation in units of microroentgens (millisieverts) per hour at 1 meter from surfaces, and

(II) Report levels of radioactivity, including alpha and beta, in units of

I. Disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters — removable and fixed — for surfaces,

II. Microcuries (megabecquerels) per milliliter for water, and

III. Picocuries (becquerels) per gram for solids such as soils or concrete, and

(III) Specify the survey instrument(s) used and certify that each instrument was properly calibrated and tested at the time of the survey.

3. Records required by paragraphs (4) and (6) of Rule ~~1200-02-10-.26~~ 0400-20-10-.26 have been received.

(e) Except as provided in ~~1200-02-10-.17(3)~~ part (k)3 of this paragraph, specific licensees shall complete decommissioning of the site or separate building or outdoor area so that the site, building or outdoor area is suitable for release in accordance with Division requirements as soon as practicable but no later than 24 months following the initiation of decommissioning.

(f) Except as provided in ~~1200-02-10-.17(3)~~ part (k)3 of this paragraph, when decommissioning involves the entire site, the specific licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(g) A specific licensee shall submit a decommissioning plan if:

1. Required to do so by license condition; or

2. The Division determines that 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 Division and that these procedures could increase potential health and safety impacts to workers or to the public. Some examples are procedures:

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

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

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

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

(h) Specific licensees shall not carry out procedures with potential health and safety impacts before Division approval of the decommissioning plan.

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

1. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

2. A description of planned decommissioning activities;

3. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

4. A description of the planned final radiation survey;

5. A detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for financial assurance, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

6. 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 ~~1200-02-10-.17(3)~~ part (k)3 of this paragraph.

(j) The Division will approve the proposed decommissioning plan if the information in the plan demonstrates that the licensee:

1. Will complete decommissioning as soon as practicable; and

2. Will adequately protect the health and safety of workers and the public.

(k) Requests for extensions:

1. A licensee may request a delay in initiating decommissioning.

(i) The Division may grant this delay, if the Division determines that this delay is not detrimental to the public health and safety and is otherwise in the public interest.

(ii) The request for a delay shall be submitted no later than 30 days before notification pursuant to ~~1200-02-10-.17(3)~~ subparagraph (a) of this paragraph.

(iii) The schedule for decommissioning set forth in ~~1200-02-10-.17(3)~~ subparagraph (b) of this paragraph shall not start until the Division has made a determination on the request.

2. A licensee may request an alternative schedule for the submittal of a decommissioning plan. The Division may approve the alternative schedule, if the Division 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.

3. A licensee may request an alternative schedule for the completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate. The Division may approve the alternative schedule for completion of decommissioning, if the Division determines that it is warranted by consideration of the following:

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

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

(iii) Whether allowing short-lived radionuclides to decay will achieve a significant volume reduction in wastes requiring disposal;

(iv) Whether allowing short-lived radionuclides to decay will achieve a significant reduction in radiation exposure to workers;

(v) Other site-specific factors that the Division may determine are beyond the control of the licensee.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.18~~ 0400-20-10-.18 Renewal of License.

(1) Applications for renewal of specific licenses shall be filed in accordance with ~~1200-02-10-.11~~ Rule 0400-20-10-.11.

(2) In any case in which a licensee, not less than ~~thirty~~ 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the Division.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.19~~ 0400-20-10-.19 Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with ~~1200-02-10-.11~~ Rule 0400-20-10-.11 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.20~~ 0400-20-10-.20 Division Action on Application to Renew or Amend.

In considering an application by a licensee to renew or amend his license, the Division will apply the criteria set forth in ~~1200-02-10-.12~~ Rules 0400-20-10-.12 and ~~1200-02-10-.13~~ 0400-20-10-.13, as applicable.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.21~~ 0400-20-10-.21 Inalienability of Licenses.

No license issued or granted under this Chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this Chapter 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 Division shall, after securing full information, find that the transfer is in accordance with the provisions of ~~the Act~~ T.C.A. §§ 68-202-201 et seq., and shall give its consent in writing.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.22~~ 0400-20-10-.22 Transfer of Material.

(1) No licensee shall transfer radioactive material except as authorized pursuant to this rule.

(2) Any licensee may transfer radioactive material:

(a) To the Division provided such transfer is accepted by the Division in writing;

(b) To the U.S. Department of Energy;

(c) To any person exempt from the regulations in this Chapter to the extent permitted under such exemption;

(d) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Division, the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State; or

(e) As otherwise authorized by the Division in writing.

(3) Before transferring sources of radiation to a specific licensee of the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with or report to the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the source of radiation, the transferor of the source of radiation shall verify that the transferee's authorization is for the receipt of the type, form, and quantity of the source of radiation to be transferred.

(4) The following methods for the verification required in ~~1200-02-10-.22~~ paragraph (3) of this rule are acceptable:

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

(b) 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 the source of radiation to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(c) For emergency shipments the transferor may accept oral certification containing all of the information specified in ~~1200-02-10-.22(4)~~ subparagraph (b) of this paragraph provided that written certification is forwarded to the transferor within ~~ten~~ 10 days following the oral communication;

(d) The transferor may obtain other information compiled by a reporting service from official records of the Division, the U.S. Nuclear Regulatory Commission or the licensing agency of any state as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

(e) When none of the methods of verification described in ~~1200-02-10-.22(4)~~ subparagraphs (a) through (d) of this paragraph 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 Division, the U.S. Nuclear Regulatory Commission, or the licensing agency of any state that the transferee is authorized to receive the source of radiation.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.23~~ 0400-20-10-.23 Modification, Revocation, and Termination of Licenses.

(1) The terms and conditions of all licenses may be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to ~~the Act~~ T.C.A. §§ 68-202-201 et seq., or by reason of rules or regulations issued by the Department.

(2) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under provisions of ~~the Act~~ T.C.A. §§ 68-202-201 et seq., or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule or regulation of the Department. This action will be taken pursuant to ~~Tennessee Code Annotated, Chapter 23~~ T.C.A. Title 68, Chapter 202.

(3) The Division may terminate a specific license upon request submitted by the licensee to the Division in writing.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.24~~ 0400-20-10-.24 Registration.

(1) The owner or person having possession of any radiation machine or accelerator, except those specifically exempted in ~~1200-02-10-.07~~ Rule 0400-20-10-.07, shall register such sources within ~~ten~~ 10 days after acquisition of such machine. The owner or possessor of any accelerator shall substitute an application for certified registration required in Chapter ~~1200-02-09~~ 0400-20-09. The application for certified registration must be received by the Department within ~~ten~~ 10 days after acquisition of the accelerator; however, an accelerator may not be energized until registered pursuant to Chapter ~~1200-02-09~~ 0400-20-09. In addition, every person who provides inspections as provided for in ~~1200-02-10-.27~~ paragraph (4) of Rule 0400-20-10-.27 and every person who assembles, installs, or services radiation machines shall register with the Division of Radiological Health, Tennessee Department of Environment and Conservation. Registration under this rule shall be on Department Form RHS 8-4, Form RHS 8-4a or Form RHS 8-4b, as appropriate, as furnished by the Department and may be obtained from the Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243-1532. A registration fee in accordance with the Classification and Fee Schedule in ~~1200-02-10-.24~~ paragraph (3) of this rule shall be due upon receipt of an invoice from the Division of Radiological Health following the submittal of the completed registration form. The check for the fee shall be made payable to "Treasurer, State of Tennessee."

(2) An annual registration fee will be due the first working day following January 1 of each year as long as the radiation machine or service is subject to registration. Each registrant shall submit the annual fee payable to, "Treasurer, State of Tennessee," in the appropriate dollar amount in accordance with the Classification and Fee Schedule in ~~Rule 1200-02-10-.24~~ paragraph (3) of this rule to the Division of Radiological Health. Payment shall be accompanied by a copy of the fee invoice properly completed. The invoice for the annual fee will be dated January 17 and will require payment by March 17 of the indicated year. At the time of the annual payment a registrant of only Class II radiation machines may request specific times or list restricted hours during normal work hours for inspections pursuant to Rule ~~1200-02-10-.27~~ 0400-20-10-.27 by personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation.

(3) Classification and fee schedule. For purposes of inspections and payment of fees the classification and fee schedule shall be as follows:

(a) Radiation Machines

CLASS I

Dental Radiation Machines:	$ 65 per tube
All diagnostic equipment used exclusively for dental diagnostic procedures.	

CLASS II

Priority Two Medical Radiation Machines:	$ 150 per tube
All medical diagnostic x-ray equipment, not in Class III, used exclusively for medical or veterinary diagnostic procedures.	

CLASS III

Priority One Medical Radiation Machines:	$ 200 per tube
All diagnostic x-ray equipment used in radiologists' offices, orthopedic surgeons' offices or hospitals exclusively for medical diagnostic procedures.	

CLASS IV

Therapy Medical Radiation Machines:	$ 300 per tube
All x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.	

CLASS V

Priority Two Industrial and Educational Radiation Machines:	$ 600 per tube
Closed-beam analytical radiation machines, gauges or industrial radiation machines used in shielded room or cabinet radiography.	

CLASS VI

Priority One Industrial and Educational Radiation Machines:	$ 900 per tube

All x-ray machines used for industrial radiography and all open-beam analytical x-ray machines and all radiation machines not specifically included in Class I, II, III, IV, V or VII.	
CLASS VII	
Accelerators: All devices defined as accelerators as per "State Regulations for Protection Against Radiation."	$ 2,000 annual fee, plus an initial fee of $ 375 per maximum nominal rated MeV for initial certified registration review (initial review fee not to exceed $ 150,000)

(b) A person providing assembly installation/servicing, except as provided by subparagraph ~~1200-20-10-.24(3)~~ (f) of this paragraph, shall pay an annual registration fee of ~~six hundred dollars~~ $ 600. — $ 600

(c) A person provided assembly/installation/servicing, except as provided by subparagraph ~~1200-02-10-.24(3)~~ (f) of this paragraph, shall pay an annual registration fee of ~~six hundred dollars~~ $ 600. — $ 600

(d) A registrant may qualify to pay a registration fee equal to ~~eighteen~~ 18 percent ~~(18%)~~ of that listed in this paragraph ~~(3)~~, subject to the following conditions:

1. All tubes subject to registration are inspected in accordance with paragraphs ~~1200-02-10-.27~~ (3), (4) and (5) of Rule 0400-20-10-.27.

   (i) For purposes of the ~~eighteen~~ 18 percent ~~(18%)~~ fee, the first inspection performed on an x-ray tube on or after ~~the effective date of these rules~~ December 6, 2011, will establish a new baseline date for that tube. Previous baseline dates will be reset to the last day of the month of performance of the previous inspections.

      (I) Each subsequent inspection of a tube shall be performed during the same month as the preceding inspection or the month immediately following resulting in "baseline periods" of from 59 days to 62 days, depending upon applicable new 2 month periods, according to the schedule set out in subparagraph (3)(a) of Rule ~~1200-02-10-.27~~ 0400-20-10-.27.

      (II) An inspection performed prior to or after the applicable new 2 month period shall establish a new baseline date for that tube.

      (III) An inspection performed after the applicable new ~~two~~ 2 month period shall not qualify the registrant for the ~~eighteen~~ 18 percent ~~(18%)~~ fee.

      (IV) An inspection performed prior to the applicable new 2 month period and meeting all other requirements found in paragraphs (3), (4) and (5) of Rule ~~1200-02-10-.27~~ 0400-20-10-.27 shall qualify the registrant for the ~~eighteen~~ 18 percent ~~(18%)~~ fee.

   (ii) Reserved.

2. Each newly acquired tube subject to registration is inspected within ~~six~~ 6 months of ownership or possession.

3. An individual who satisfies the requirements in paragraph ~~1200-02-10-.27~~ (4) of Rule 0400-20-10-.27 performs all inspections.

4. The registrant submits to the Division, at L&C Annex, 3rd Floor, 401 Church Street, Nashville, TN 37243-1532:

   (i) Copies of the appropriate State evaluation forms within 60 days after the inspection.

   (ii) Copies of applicable service reports to document correction of any deficiencies noted within 60 days after the inspection.

   (iii) A signed "X-Ray Inspection Notification and Certification of Compliance" form within 60 days of the inspection.

5. Inspections found by the Division to be unsatisfactory under this subparagraph or under paragraph ~~1200-02-10-.27~~ (4) or (5) of Rule 0400-20-10-.27 shall not qualify for the 18 percent ~~(18%)~~.

   (i) The registrant shall correct and re-submit the report(s) and documentation of an inspection found to be unsatisfactory within 30 days of the date of notification by the Division. Failure to correct and re-submit the report(s) and documentation of an unsatisfactory inspection will subject the registrant to the Division's normal enforcement actions, penalties and assessments.

   (ii) The 30-day correction period shall not establish a new baseline. It shall not:

      (I) Qualify an existing tube for reduced fee for the following calendar year, or

      (II) Qualify a newly acquired tube for reduced fee for the current calendar year.

(e) Reserved.

(f) A person providing inspection services, as permitted by paragraph ~~1200-02-10-.27~~ (4) of Rule 0400-20-10-.27, or a person providing assembly/installation/servicing, who is a staff member of the facility registered pursuant to ~~Tennessee Code Annotated, (T.C.A.) §68-202-101 et seq.~~ T.C.A. Title 68, Chapter 202 and these ~~regulations~~ rules, and who performs such inspection services or assembly/installation/servicing only for that registrant, shall not be subject to subparagraphs (b) and (c) ~~above~~ of this paragraph.

(4) Any failure to pay an invoiced amount by the date specified on the invoice, unless qualified by ~~1200-02-10-.24~~ subparagraph (3)(d) ~~above~~ of this rule, shall be deemed to constitute a violation of ~~Tennessee Code Annotated~~ T.C.A. §§ 68-203-101 et seq.

(5) Whenever there is a change in information such as address, ownership, possessor, or location of use from that declared on the last previous registration, the completion of a new Form RHS 8-4 shall be required within 10 days of the change.

(6) Each registrant, or his estate, who permanently discontinues the use of or transfers all of his radiation machines at an installation shall notify the Division in writing within ~~sixty~~ 60 days of such action. In the event of a transfer, the notification shall include the name and address of the transferee.

~~(6)~~(7) No person shall state or imply that any activity under such a registration has been approved by the Division.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.25~~ 0400-20-10-.25 Reports.

(1) Any person who sells, leases, transfers, assembles, reassembles, or lends radiation machines, except those exempted from registration by ~~1200-02-10-.07~~ Rule 0400-20-10-.07 shall report to the Division, within ~~thirty~~ 30 days after the end of each calendar quarter, the name and address of persons to whom they have transferred such items and the date of transfer. Persons routinely engaged in the sale, transfer, leasing, lending, assembling, or reassembling of x-ray equipment shall report each calendar quarter, including a report for calendar quarters in which no radiation machine transfer occurs. Such reports shall be held proprietary by the Division.

(2) Each out-of-state person who brings radiation machines into the State, except those exempted in ~~1200-02-10-.07~~ Rule 0400-20-10-.07, for any temporary use shall:

(a) Notify the Division in writing at least ~~three~~ 3 days prior to engaging in such use. Such notification shall indicate the location, period, and type of proposed use within the State. If, for a specific case, the 3-day period would impose an undue hardship, he may, upon application to the Division obtain permission to proceed sooner;

(b) Register the radiation machines with this Division on Form RHS 8-4 prior to entry into the State; and

(c) Comply with all applicable regulations of the Division including the payment of the fee for the Class, as appropriate, contained in ~~1200-02-10-.24~~ paragraph (3) of Rule 0400-20-10-.24.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.26~~ 0400-20-10-.26 Records.

(1) Each person who receives radioactive material pursuant to a license issued pursuant to these rules shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

(a) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for ~~three~~ 3 years following transfer or disposal of the material.

(b) The licensee who transferred the material shall retain each record of transfer for ~~three~~ 3 years after each transfer, unless a specific requirement in another part of these rules dictate otherwise.

(c) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Division terminates each license that authorizes disposal of the material.

(2) A licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Division terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(3) Records which must be maintained pursuant to this rule may be the original or a reproduced copy. 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. A licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) 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 Division:

(a) Records of disposal of licensed material made under ~~1200-02-05-.121~~ Rules 0400-20-05-.121 (including burials authorized before January 28, 1981), ~~1200-02-05-.122~~ 0400-20-05-.122, ~~1200-02-05-.123~~ 0400-20-05-.123, ~~1200-02-05-.124~~ 0400-20-05-.124; and

(b) Records required by ~~1200-02-05-.132~~ subparagraph (2)(d) of Rule 0400-20-05-.132.

(5) If licensed activities are transferred or assigned in accordance with ~~1200-02-10-.16~~ paragraph (2) of Rule 0400-20-10-.16, 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:

(a) Records of disposal of licensed material made under ~~1200-02-05-.121~~ Rules 0400-20-05-.121 (including burials authorized before January 28, 1981), ~~1200-02-05-.122~~ 0400-20-05-.122, ~~1200-02-05-.123~~ 0400-20-05-.123, ~~1200-02-05-.124~~ 0400-20-05-.124; and

(b) Records required by ~~1200-02-05-.132~~ subparagraph (2)(d) of Rule 0400-20-05-.132.

(6) Prior to license termination, each licensee shall forward the records required subparagraph (4)(n) of Rule ~~1200-02-10-.12~~ 0400-20-10-.12 to the Division.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.27~~ 0400-20-10-.27 Inspections.

(1) Each licensee or registrant shall afford the Division at all reasonable times opportunity to inspect sources of radiation, premises, facilities and activities subject of these regulations and records maintained pursuant to these regulations.

(a) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of the regulations, license, and Certified Registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

1. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, these regulations, or license or Certified Registration condition, or any unnecessary exposure to radiation or radioactive material under the licensee's or registrant's control. Any such notice in writing shall comply with paragraph (2) of this rule.

2. The licensee or registrant or licensee's or registrant's representative may accompany Division inspectors during other phases of an inspection.

3. The provision of ~~1200-02-10-.27(1)(a)~~ part 1 of this subparagraph shall not be interpreted as authorization to disregard instructions pursuant to ~~1200-02-04-.12~~ Rule 0400-20-04-.12.

(b) If at the time of inspection, an individual has been authorized by the workers to represent them during inspections by the Division, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

1. Different representative of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference

with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.

2. Any worker's representative shall be an employee of the licensee or registrant and should be a worker as defined in ~~1200-02-04-.04(1)(rrr)~~ Rule 0400-20-04-.04 and shall have received instructions as specified in ~~1200-02-04-.12~~ Rule 0400-20-04-.12.

3. In addition to the licensee's or registrant's representative and with the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Division inspectors during the inspection of physical working conditions.

4. The workers' representative for any area containing proprietary information shall be an individual previously authorized by the licensee or registrant to enter that area.

5. Notwithstanding the other provisions of this rule, Division inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection.

(2) Requests by Workers for Inspection.

(a) Any worker or representative of workers who believes that a violation of ~~the Act~~ T.C.A. §§ 68-202-201 et seq., these ~~regulations~~ rules, conditions of a Certified Registration, or license conditions exists or has occurred in activities subject to these regulations with regard to radiological working conditions in which the worker is engaged, may request an inspection by registering a complaint of the alleged violation with the Commissioner, Tennessee Department of Environment and Conservation; Director, Division of Radiological Health; or Division inspectors.

1. Any such complaint shall be in writing, shall set forth the specific grounds for the complaint and shall be signed by the worker or representative of workers.

2. A copy of the complaint shall be provided the licensee or registrant by the Division no later than at the time of inspection except that, upon request of the worker registering such complaint, his name and the name of individuals referred to therein shall not appear in such a copy or on any record published, released or made available by the Division except for good cause shown.

(b) If, upon receipt of such complaint, the Division determines that the complaint meets the requirements set forth in ~~1200-02-10-.27(2)~~ subparagraph (a) of this paragraph and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection will be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this paragraph need not be limited to matters referred to in the request for an inspection.

(c) If it is determined that there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified by the Division in writing.

(d) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by these regulations.

(3) Inspections of radiation machines are to be conducted:

(a) According to Class as follows:

CLASS I - once every ~~four~~ 4 years

CLASSES II and V - once every ~~two~~ 2 years

CLASSES III, IV, VI and VII – annually

(b) By personnel of the Division of Radiological Health, Tennessee Department of Environment and Conservation, or

(c) As provided in ~~1200-02-10-.27~~ paragraph (4) of this rule, and

(d) According to the same criteria and to the satisfaction of the Division and provided the appropriate Division forms are completed and submitted along with any documentation required by subparagraph ~~1200-02-10-.24(3)~~ (e) of this paragraph, and

(e) By the Division of Radiological Health on a selected number of those facilities providing an inspection report as permitted by ~~1200-02-10-.27~~ paragraph (4) of this rule.

(4) The Division will accept, as inspections for a reduced registration fee as provided for in ~~part 1200-02-10-.24~~ subparagraph (3)(d) of Rule 0400-20-10-.24, inspections by individuals other than employees of the Division:

(a) Whose inspections are satisfactory to the Division;

(b) Who are registered with the Division;

(c) Who are staff inspectors, or who have paid an annual registration fee to the Division; and

(d) Who meet one set of the following criteria:

	Formal Education or Certification	Plus	Experience
1.	Bachelor's degree in a physical science or mathematics		~~Four~~ 4 years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
2.	Bachelor's degree in a physical science or a biological science with a physical science minor and ~~one~~ 1 year of graduate work in health physics		~~Three~~ 3 years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
3.	Master's degree in health physics or radiological health		~~Two~~ 2 years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
4.	Doctor's degree in health physics or radiological health		~~One~~ 1 year of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed
5.	Certification by the American Board of		~~One~~ 1 year of applied health physics

	Health Physics or by the American Board of Radiology or be a Fellow, Canadian College of Physicists in Medicine	experience in a program with radiation safety problems similar to those in the program to be surveyed
6.	~~Two~~ 2 notarized letters of reference from persons registered to provide inspections for reduction in fees and meeting any of the above sets of criteria certifying to the individual's capabilities to perform the necessary inspections	5 years of applied health physics experience in a program with radiation safety problems similar to those in the program to be surveyed

(5) Inspections satisfactory to the Division. The following constitute a proper inspection and must occur:

(a) The inspection of an x-ray facility subject to registration under "State Regulations for Protection Against Radiation" shall identify the compliance status of the facility and each piece of equipment subject to registration with respect to requirements in Chapters ~~1200-02-04~~ 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-08, 0400-20-09 and ~~40~~ this Chapter.

(b) The qualified individual performing the inspection shall record the results of the inspection on evaluation forms provided by the Division, one form for each facility plus an appropriate form, or forms, for each piece of equipment. The evaluation forms shall describe the compliance status of the facility and equipment, as it exists at the time of the inspection. The Division will accept computer-generated forms if these contain the same questions as Division forms contain.

(c) The qualified individual shall provide signed and dated evaluation and certification of compliance forms to the registrant promptly.

(d) The registrant shall submit evaluation and certification of compliance forms to the Division as set out in ~~1200-02-10-.24~~ subparagraph (3)(d) of Rule 0400-20-10-.24.

(e) A registrant whose inspection reveals an item of non-compliance shall correct the item promptly following notification by the qualified individual. The registrant shall provide appropriate documentation of the correction to the Division as set out in ~~1200-02-10-.24~~ paragraph (3) of Rule 0400-20-10-.24.

(f) If as a result of inadvertent error or excusable neglect a tube(s) is not inspected, the Commissioner or the Commissioner's designee may grant the 18 percent ~~(18%)~~ fee for all other tubes provided they were timely inspected by a qualified individual.

(g) For a tube that is inoperable at the time of inspection, the qualified individual shall submit a form indicating the tube was inoperable. The tube shall be inspected within 60 days of its becoming functional.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.28~~ 0400-20-10-.28 Tests.

Each licensee and registrant shall perform, upon instruction from the Division, or shall permit the Division to perform, such tests as the Division may require including, but not limited to, tests of:

(1) Sources of radiation;

(2) Facilities wherein sources of radiation are used or stored;

(3) Radiation detection and monitoring instruments; and

(4) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.29~~ 0400-20-10-.29 Reciprocal Recognition of Licenses.

(1) Subject to these regulations, any individual in another state who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State, and issued by the agency having primary jurisdiction, where the licensee maintains an office for directing the licensed activities and at which radiation safety records are normally maintained, may possess or use the licensed radioactive material to conduct the activities authorized by such license within this State for a period not in excess of ~~one hundred eighty~~ 180 days in any period of ~~twelve~~ 12 consecutive months and will be considered, without obtaining a specific licensing document from this Division, a licensee of this State provided that:

(a) The out-of-state licensing document does not limit the activity authorized by such document to specified installations or locations;

(b) The out-of-state licensee notifies the Division in writing at least ~~three~~ 3 days prior to each entry into this State to engage in such activity. Such notification shall indicate the location, period, type of proposed possession, use and supervisor within this State, and shall be accompanied by a copy of the pertinent licensing document or shall indicate in the notification that such licensing document has previously been submitted to this Division. If for a specific case, the ~~three~~ 3 day period would impose an undue hardship, the Division may authorize such person to proceed sooner upon notification by telephone of intent to conduct the proposed activity provided that the licensee shall file in writing the information required in this paragraph within ~~three~~ 3 days of the telephone notification;

(c) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the provisions of this rule except by transfer to a person:

1. Specifically licensed by the Division, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive such material; or

2. Exempt from the requirements for a license for such material under ~~1200-02-10-.04~~ subparagraph (1)(a) of Rule 0400-20-10-.04;

(d) The out-of-state licensee complies with all applicable regulations of the Division and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Division; and

(e) The Division may require the out-of-state licensee to supply such other information as the Division may request.

(2) Notwithstanding the provision of paragraph (1) ~~above~~ of this rule, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State authorizing the holder to manufacture, install, or service a device described in ~~1200-02-10-.10~~ subparagraph (2)(a) of Rule 0400-20-10-.10 within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install and service such device in this State provided that:

(a) The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State; and

(b) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited."

(3) The Division may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to protect the public health and safety or property.

(4) Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site shall be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

(a) In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the NRC, and

(b) Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the NRC by either:

1. Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or

2. By applying for a specific NRC license.

(5) Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

Authority: T.C.A. §§ 68-202-101 et seq., 68-202-201 et seq., and 4-5-201 et seq.

~~1200-02-10-.30~~ 0400-20-10-.30 Packaging and Transportation of Radioactive Material.

(1) This rule establishes requirements for packaging, preparation for shipment, and transportation of radioactive material and applies to any licensee or registrant authorized by specific or general license to receive, possess, use, or transfer licensed material, if the person delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the license, or transports that material on public highways. This rule does not authorize possession of licensed material.

(2) Except as authorized in a general license or a specific license issued by the Division, or as exempted in this rule, no licensee may:

(a) Deliver licensed material to a carrier for transport; or

(b) Transport licensed material.

(3) Any physician as defined in ~~subparagraph (1)(nn) of~~ Rule ~~1200-02-04-.04~~ 0400-20-04-.04 is exempt from paragraph (4) of this rule ~~1200-02-10-.30~~ with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under this exemption must be licensed under Chapter ~~1200-02-07~~ 0400-20-07 or 10 CFR Part 35.

(4) A licensee who, under a general or specific license, transports licensed material outside its site of authorized use or on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of this rule and with the applicable requirements of the U.S. DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(a) The licensee shall particularly note U.S. DOT regulations in the following areas:

1. Packaging: 49 CFR part 173, subparts A and B and I;

2. Marking and labeling: 49 CFR 172, subpart D, 172.400 through 172.407, and 172.436 through 172.441 of subpart E;

3. Placarding: 49 CFR part 172, subpart F, especially 172.500 through 172.519, 172.556 and appendices B and C;

4. Accident reporting: 49 CFR part 171, 171.15 and 171.16;

5. Shipping papers and emergency information: 49 CFR part 172, subparts C and G;

6. Hazardous material employee training: 49 CFR part 172, subpart H;

7. Hazardous material shipper/carrier registration: 49 CFR part 107, subpart G; and

8. Security plans: 49 CFR Part 172, Subpart I.

(b) The licensee shall also note U.S. DOT regulations pertaining to the following modes of transportation:

1. Rail: 49 CFR part 174, subparts A through D and K;

2. Air: 49 CFR part 175;

3. Vessel: 49 CFR part 176, subparts A through F and M; and

4. Public highway: 49 CFR part 177 and parts 390 through 397.

(5) If U.S. DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the U.S. DOT specified ~~above~~ in subparagraph ~~(3)(a)~~ (4)(a) of this rule to the same extent as if the shipment or transportation were subject to U.S. DOT regulations. A request for modification, waiver or exemption from those requirements, and any notification referred to in those requirements, shall be filed with, or made to, the Director of the Division of Radiological Health at the address given in Rule ~~1200-02-04-.07~~ 0400-20-04-.07.

(6) Exemptions.

(a) Exemption for low-level materials.

1. A licensee is exempt from all requirements of this rule with respect to shipment or carriage of the following low-level material:

(i) Natural material and ores containing naturally occurring radionuclides that are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in Table A-2 of Schedule 10-6 in ~~the Appendix to Chapter 1200-02-10~~ Rule 0400-20-10-.38; and

(ii) Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 of Schedule 10-6 in Rule 0400-20-10-.38, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 of Schedule 10-6 in ~~the Appendix to Chapter 1200-02-10~~ Rule 0400-20-10-.38.

2. A licensee is exempt from all requirements of this rule other than paragraphs (4), (5), and (15) of this rule ~~1200-02-10-.30(3) and (4) and (10)~~, with respect to shipment or carriage of the following packages, provided the packages contain no fissile material or the fissile material exemption standards of subparagraph (6)(b) ~~or~~ of this rule ~~1200-02-10-.30~~ or 10 CFR 71.15 are satisfied:

   (i) A package containing no more than a Type A quantity of radioactive material;

   (ii) A package in which the only radioactive material is low specific activity (LSA) material or surface contaminated objects (SCO), provided the external radiation level at 3-meters from the unshielded material or objects does not exceed 10 mSv/h (1 rem/h); or

   (iii) A package transported within locations within the United States that contains plutonium in special form with an aggregate radioactivity not to exceed 20 curies (.74 TBq).

3. A licensee is exempt from all requirements of this rule other than paragraphs (4), (5) and (15) ~~or~~ of this rule ~~1200-02-10-.30~~, with respect to shipment or carriage of low-specific-activity (LSA) material in group LSA-I, or surface contaminated objects (SCO's) in group SCO-I.

(b) Exemption from classification as fissile material.

1. Fissile material meeting the requirements of at least one of the subparts (i) through (vi) of this part are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of this rule, except as noted;

   (i) Individual package containing 2 grams or less fissile material;

   (ii) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material;

   (iii) (I) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

      I. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

      II. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material;

   (II) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material;

   (iv) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass;

(v) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2 percent by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of 2. The material must be contained in at least a DOT Type A package; and

(vi) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20 percent by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

(7) General license: U.S. NRC-approved package.

(a) A general license is hereby issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance or other approval has been issued by the U.S. Nuclear Regulatory Commission.

(b) This general license applies only to a licensee who:

1. Has a copy of the certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G and H of 10 CFR 71;

3. Submits in writing to the Director, Division of Radiological Health, at the address given in Rule ~~1200-02-04-.07~~ 0400-20-04-.07, before the licensee's first use of the package, the licensee's name and license number and the package identification number specified in the package approval; and

4. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in subpart H of 10 CFR 71.

(c) This general license applies only when the package approval authorizes use of the package under this general license.

(d) For a Type B or fissile material package, the design of which was approved by U.S. NRC before April 1, 1996, the general license is subject to the additional restrictions in paragraph (8) of this rule.

(8) Previously approved package.

(a) A Type B package previously approved by U.S. NRC but not designated as B(U) or B(M) in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license in paragraph (7) of this rule with the following additional conditions:

1. Fabrication of the packaging was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval, as defined in U.S. DOT regulations at 49 CFR 173.403; and

3. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

(b) A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the U.S. NRC but without the designation '-85' in the identification number of the U.S. NRC Certificate of Compliance, may be used under the general license in paragraph (7) of this rule with the following additional conditions:

1. Fabrication of the package was satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with 10 CFR 71.85(c);

2. A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in U.S. DOT regulations at 49 CFR 173.403; and

3. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

(9) General license: Use of foreign approved package.

(a) A general license is issued to any licensee of the Division to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by U.S. DOT as meeting the applicable requirements of 49 CFR 171.12.

(b) This general license applies only to a licensee who:

1. Has a copy of the applicable certificate, the revalidation and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2. Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of this rule. With respect to the quality assurance provisions of 10 CFR Part 71, the licensee is exempt from design, construction, and fabrication considerations; and

3. Has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in subpart H of 10 CFR 71.

(c) This general license applies only to shipments made to or from locations outside the United States.

(10) General license: Fissile material

(a) A general license is issued to any licensee of the Division or U.S. NRC to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this paragraph. The fissile material need not be contained in a package which meets the standards of 10 CFR Part 71 subparts E and F of U.S. NRC regulations; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.

(c) The general license applies only when a package's contents:

1. Contain less than a Type A quantity of fissile material; and

2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(d) The general license applies only to packages containing fissile material that are labeled with a CSI which:

1. Has been determined in accordance with subparagraph (e) of this ~~rule~~ paragraph;

2. Has a value less than or equal to 10; and

3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(e) 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } ^{235}U}{X} + \frac{\text{grams of } ^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right];$$

2. The calculated CSI must be rounded up to the first decimal place;

3. The values of X, Y, and Z used in the CSI equation must be taken from Tables RHS 7-3 or 7-4, as appropriate;

4. If Table RHS 7-4 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

5. Table RHS 7-3 values for X, Y, and Z must be used to determine the CSI if:

(i) Uranium-233 is present in the package;

(ii) The mass of plutonium exceeds 1 percent of the mass of uranium-235;

(iii) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(iv) Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table RHS 7-3. Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per subparagraph (10)(e) of Rule ~~1200-02-10-.30~~ 0400-20-10-.30

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15 percent of the moderating substance has an average hydrogen density greater than H_2O.

Table RHS 7-4 Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per subparagraph (10)(e) of Rule ~~1200-02-10-.30~~ 0400-20-10-.30

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

(11) General license: Plutonium-beryllium special form material.

(a) A general license is issued to any licensee of the Division or the U.S. NRC to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this rule. This material need not be contained in a package which meets the standards of 10 CFR Part 71 subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(b) The general license applies only to a licensee who has submitted to the Division and received Division approval for a quality assurance program that satisfies the provisions found in Subpart H of 10 CFR 71.

(c) The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(d) The general license applies only to packages labeled with a CSI which:

1. Has been determined in accordance with subparagraph (e) of this ~~rule~~ paragraph;

2. Has a value less than or equal to 100; and

3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(e) 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left[\frac{\text{Grams of } ^{239}Pu + \text{grams of } ^{241}Pu}{24} \right]; \text{ and}$$

2. The calculated CSI must be rounded up to the first decimal place.

(12) Fissile Material: Assumptions as to Unknown Properties of Fissile Material.

(a) When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

(13) Preliminary determinations.

(a) Before the first use of any packaging for the shipment of licensed material:

1. The licensee shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce the effectiveness of the packaging or impact compliance with the standards specified in 10 CFR 71.

2. Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in^2) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent ~~(50%)~~ higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure; and

3. The licensee shall conspicuously and durably mark the packaging with its model number, serial number, gross weight and a package identification number assigned by the U.S. Nuclear Regulatory Commission (U.S. NRC). Before applying the model number, the

licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. NRC.

(b) Reserved.

(14) Routine determinations.

(a) Before each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this rule and of the license. The licensee shall determine that:

1. The package is proper for the contents to be shipped;

2. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

3. Each closure device of the packaging, including any required gasket, is properly installed, secured and free of defects;

4. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid in accordance with 10 CFR 71, Subpart F;

5. Any pressure relief device is operable and set in accordance with written procedures;

6. The package has been loaded and closed in accordance with written procedures;

7. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

8. Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose, unless it satisfies the design requirements of 10 CFR 71.45;

9. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable and within the limits specified in U.S. DOT regulations in 49 CFR 173.443;

10. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

11. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

(b) Reserved.

(15) Air transport of plutonium.

(a) Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this rule or included indirectly by citation of 49 CFR Chapter I, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Schedule 10-6. Determination of A_1 and A_2 in ~~the Appendix to Chapter 1200-02-10~~ Rule 0400-20-10-.38 and in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with paragraphs (4) and (5) of this rule ~~1200-02-10-.30~~; or

4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.

(b) Nothing in subparagraph (a) of this paragraph is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

(c) For a shipment of plutonium by air that is subject to part (a) of this paragraph, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

(16) Opening instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with subparagraphs (5)(a) and (b) of Rule ~~1200-02-05-.115~~ 0400-20-05-.115.

(17) Records.

(a) Each licensee shall maintain, for a period of ~~three~~ 3 years after shipment, a record of each shipment of licensed material not exempt under paragraph (6) ~~of Rule 1200-02-10-.30~~ of this rule, showing where applicable:

1. Identification of the packaging by model number and serial number;

2. Verification that there are no significant defects in the packaging, as shipped;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package and the total quantity of each shipment;

5. For each item of irradiated fissile material:

(i) Identification by model number and serial number;

(ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

(iii) Any abnormal or unusual condition relevant to radiation safety;

6. Date of the shipment;

7. For fissile packages and for Type B packages, any special controls exercised;

8. Name and address of the transferee;

9. Address to which the shipment was made; and

10. Results of the determinations required by paragraph (14) of this rule ~~1200-02-10-.30~~ and by the conditions of the package approval.

(b) The licensee shall make available to the Division for inspection, upon reasonable notice, all records required by this rule. Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

(18) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by paragraph (13) of this rule ~~1200-02-10-.30~~; design, fabrication and assembly records; results of reviews, inspections, tests and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification and repair activities. Inspection, test and audit records shall identify the inspector or data recorder, the type of observation, the results, the acceptability and the action taken in connection with any deficiencies noted. The records shall be retained for ~~three~~ 3 years after the life of the packaging to which they apply.

(19) Inspection and tests.

In addition to the requirements in paragraph (1) of ~~1200-02-10-.27~~ Rule 0400-20-10-.27 and Rule ~~1200-02-10-.28~~ 0400-20-10-.28, the licensee shall notify the Director, Division of Radiological Health, at the address given in Rule ~~1200-02-04-.07~~ 0400-20-10-.07, at least 45 days before fabrication of a package to be used for the shipment of licensed material having a decay heat load in excess of 5 kW or with a maximum normal operating pressure in excess of 103 kPa (15 lbf/in^2) gauge.

(20) Reports.

The licensee shall report to the Director, Division of Radiological Health, within 30 days:

(a) Any instance in which there is significant reduction in the effectiveness of any approved Type B, or fissile, packaging during use;

(b) Details of any defects with safety significance in Type B, or fissile, packaging after first use, with the means employed to repair the defects and prevent their recurrence; or

(c) Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

(21) Advance notification of shipment of irradiated reactor fuel and nuclear waste.

(a) As specified in subparagraphs (b), (c) and (d) of this paragraph, each licensee shall provide advance notification to the governor of ~~of~~ a state, or the governor's designee, and to the Director, Division of Radiological Health, of the shipment of licensed material through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b) Advance notification is required under this ~~section~~ paragraph for shipments of irradiated reactor fuel in quantities less than that subject to advance notification requirements of 10 CFR 73.37(f). Advance notification is also required under this ~~section~~ paragraph for shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

1. The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;

2. The licensed material is being transported to or across the State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

3. The quantity of licensed material in a single package exceeds the least of the following:

   (i) 3000 times the A_1 value of the radionuclides as specified in Schedule 10-6 in Rule 0400-20-10-.38, Table A-1 for special form radioactive material;

   (ii) 3000 times the A_2 value of the radionuclides as specified in Schedule 10-6 in Rule 0400-20-10-.38, Table A-1 for normal form radioactive material; or

   (iii) 1000 TBq (27,000 Ci).

(c) Procedures for submitting advance notification.

1. The notification shall be made in writing to the office of each appropriate governor or governor's designee and to the Director, Division of Radiological Health.

2. A notification delivered by mail shall be postmarked at least ~~seven~~ 7 days before the beginning of the ~~seven~~ 7-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by any other means than mail shall reach the office of the governor, or of the governor's designee, and of the Director, Division of Radiological Health, at least ~~four~~ 4 days before the beginning of the ~~seven~~ 7-day period during which departure of the shipment is estimated to occur.

   (i) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306).

   (ii) The list will be published annually in the Federal Register on or about June 30 to reflect any changes in information.

   (iii) A list of the names and mailing addresses of the governors' designees is available on request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

   (iv) The licensee shall retain a copy of the notification as a record for ~~three~~ 3 years.

(d) Information to be furnished in advance notification of shipment. Each advance notification of shipment of irradiated reactor fuel or nuclear waste shall contain the following information:

1. The name, address and telephone number of the shipper, carrier and receiver of the irradiated reactor fuel or nuclear waste shipment;

2. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of U.S. DOT in 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the ~~seven~~ 7-day period during which departure of the shipment is estimated to occur;

4. The ~~seven~~ 7-day period during which arrival of the shipment at the State's boundaries is estimated to occur;

5. The destination of the shipment and the ~~seven~~ 7-day period during which arrival of the shipment is estimated to occur; and

6. A point of contact, with a telephone number, for current shipment information.

(e) Revision notice.

A licensee who finds that schedule information previously furnished to the governor, or governor's designee, and to the Director, Division of Radiological Health, in accordance with this ~~section~~ paragraph, will not be met, shall telephone a responsible individual in the office of the governor of the State, or of the governor's designee, and of the Division of Radiological Health and inform those individuals of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for ~~three~~ 3 years.

(f) Cancellation notice.

1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State, or to the governor's designee, previously notified, and to the Director, Division of Radiological Health.

2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for ~~three~~ 3 years.

(22) Quality Assurance

(a) Quality Assurance Requirements.

1. This subparagraph describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this paragraph, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The licensee, certificate holder, and applicant for a CoC are responsible for the quality assurance requirements as they apply to design, fabrication, testing, and modification of packaging. Each licensee is responsible for the quality assurance provision which applies to its use of a packaging for the shipment of licensed material subject to this paragraph.

2. Establishment of program.

Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 10 CFR 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

3. Approval of program.

Before the use of any package for the shipment of licensed material subject to this paragraph, each licensee shall obtain Division approval of its quality assurance program