From: Paul Lohaus
To: udl.internet3("tcf0303@hub.doh.wa.gov")
Subject: Engineering Review -Reply

Terry,

This is in response to your e-mail attached below. I am currently acting for Paul and was given proxy on his e-mail. Please note that we are working on your request. We have forwarded your request to the NMSS, Division of Industrial and Medical Nuclear Safety, SS&D Branch for assistance in responding to your request. Please note that we plan to do an electronic search of our regulations to provide you with c.ting .n "engineering." However, this will take us a little time to complete. We will keep you posted regarding our status.

Cardelia Maupin Acting for Paul Lohaus

>>> Frazee, Terry <tcf0303@hub.doh.wa.gov> 09/24/97 08:37pm >>>
A question has been raised as to whether we are "practicing engineering" in our review and approva' of equipment and facilities under the radioactive materials licensing process. In this state the practice of engineering must be done or at least approved by a licensed Professional Engineer. It is our contention that (with the exceptions noted below) we perform or practice "health physics" and "review" the engineering work of others. We assert that only "creative" engineering work requires the PE's approval and that is accomplished by the licensee or applicant when needed.

The exception would be the NRC requirements for specific engineering input on the design and construction of covers for uranium mill impoundments and LLW sites and perhaps for the evaluation of SS&Ds. We can meet these requirements through the use of outside consultants. We do not believe NRC requires us to have engineering expertise on staff.

Our questions to you:

1. Under what Title, chapter and section of CFR is "engineering" review required of an Agreement State?
2. If a SS&D licensee uses a licensed PE (whether in-house or an outside consultant paid by the licensee), is a second independent PE review by the state required?
3. Please cite all references to engineering in Title 10 that apply to source, by-product and SNM.
4. Do you agree with or wish to modify our statement concerning the "practice of engineering" versus the role of health physics as stated above?

We urgently need the 10 CFR citations for a letter to the state Board of Engineers. Please respond as soon as you can. Detail can follow. Thank you.

****
This message from: Terry Frazee

Quick ways to reach me:
Voice = 360-753-3461

- All initial and concurrence reviews[3] are performed by persons having adequate training. (iii)

- All registrations clearly summarize the product evaluation and provide license reviewers with adequate information to license possession and use of the product. (iv)

- Deficiency letters clearly state regulatory positions and are used at the proper time. (v)

- An independent technical review of the application and proposed certificate of registration is performed by a second individual and supports the finding that the product is acceptable for licensing purposes. (It is important to keep in mind that the independent technical reviewer must concur with the initial review.) (vi)

- Applicable guidance documents are followed, unless approval to use alternate procedures is obtained from management. (vii)

- Completed registration certificates, and the status of obsolete registration certificates, are clear and are promptly transmitted to interested parties. (viii)

- Reviewers ensure that registrants have developed and implemented adequate quality assurance and control programs. (ix)

- There is a means for enforcing commitments made by registrants in their applications and referenced in the registration certificates by the program. No potentially significant health and safety issues can be linked to a specific product evaluation that was improperly conducted. (x)

Satisfactory With Recommendations for Improvement (b)

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[3] A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, prototype testing, etc.) but the concurrence review is not to the same level of detail as the initial review (i.e., it is not necessary to review every page of the applicant's submittal). The concurrence review must be focused upon ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices.

and appendix F to 20.1001-20.2401.

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

(1) In Section 20.2104, NRC Form 4 is approved under control number 3150-0005.

(2) In Sections 20.2106 and 20.2206, NRC Form 5 is approved under control number 3150-0006.

[57 FR 57878, Dec. 8, 1992]

Subpart B -- Radiation Protection Programs

Source: 56 FR 23396, May 21, 1991. unless otherwise noted.

Section 20.1101 Radiation protection programs. -HDS

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See Section 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Subpart C -- Occupational Dose Limits

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

Section 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under Section 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of --

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin, and to the extremities, which are:

(i) An eye dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin or to any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that

In addition to the requirements in Section 20.1601, the licensee shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

Subpart H -- Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Source: 56 FR 23400, May 21, 1991, unless otherwise noted. H+S

Section 20.1701 Use of process or other engineering controls.

The licensee shall use, to the extent practicable, process or other engineering controls (e.g., containment or ventilation) to control the concentrations of radioactive material in air.

Section 20.1702 Use of other controls. - H+S

When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(a) Control of access;
(b) Limitation of exposure times;
(c) Use of respiratory protection equipment or
(d) Other controls.

Section 20.1703 Use of individual respiratory protection equipment.

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to Section 20.1702 --

(1) The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).

(2) If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

(3) The licensee shall implement and maintain a respiratory protection program that includes --

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes;

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(3) The licensee shall implement and maintain a respiratory protection program that includes --

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes;

(iii) Testing of respirators for operability immediately prior to each use;

(iv) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately

prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(v) Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment.

(4) The licensee shall issue a written policy statement on respirator usage covering --

(i) The use of process or other engineering controls, instead of respirators;

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The periods of respirator use and relief from respirator use.

(5) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(6) The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.

(b) In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to Section 20.1702, provided that the following conditions, in addition to those in Section 20.1703(a), are satisfied:

(1) The licensee selects respiratory protection equipment that provides a protection factor (see appendix A to Sections 20.1001 - 20.2401) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in appendix B to Sections 20.1001 - 20.2401, table 1, column 3. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in Section 20.1702 of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used.

(2) The licensee shall obtain authorization from the Commission before assigning respiratory protection factors in excess of those specified in appendix A to Sections 20.1001 - 20.2401. The Commission may authorize a licensee to use higher protection factors on receipt of an application that --

(i) Describes the situation for which a need exists for higher protection factors, and

(ii) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(c) The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

(d) The licensee shall notify, in writing, the Regional Administrator of the appropriate NRC Regional Office listed in appendix D to Sections 20.1001 - 20.2401 at least 30 days before the date that respiratory protection equipment is first used under the provisions of either Section 20.1703 (a) or (b).

[56 FR 23400, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992]

Section 20.1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to those in Sections 20.1702, 20.1703, and appendix A to Sections 20.1001 - 20.2401 to --

(a) Ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and

(b) Limit the extent to which a licensee may use respiratory protection

equipment instead of process or other engineering controls.

Subpart I -- Storage and Control of Licensed Material

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

Section 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Section 20.1802 Control of material not in storage.

The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Subpart J -- Precautionary Procedures

assure:

(i) Control of procurement and use of byproduct material;

(ii) Completion of safety evaluations of proposed uses of byproduct material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) Review, approval, and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with paragraph (b)(2)(ii) of this section prior to use of the byproduct material.

Section 33.15 Requirements for the issuance of a Type C specific license of broad scope.

An application for a Type C specific license of broad scope will be approved if:

(a) The applicant satisfies the general requirements specified in Section 30.33 of this chapter; and

(b) The applicant submits a statement that byproduct material will be used only by, or under the direct supervision of, individuals who have received:

(1) A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(2) At least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used; and

(c) The applicant has established administrative controls and provisions relating to procurement of byproduct material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

Section 33.16 Application for other specific licenses.

An application filed pursuant to Part 30 of this chapter for a specific license other than one of broad scope will be considered by the Commission as an application for a specific license of broad scope under this part if the requirements of the applicable sections of this part are satisfied.

Section 33.17 Conditions of specific licenses of broad scope.

experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by Section 36.23, the radiation monitors required by Section 36.29, the method of detecting leaking sources required by Section 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the --

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by Section 36.61.

Section 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by Section 170.31. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site

surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

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enforceable date.

Operation means that a uranium or thorium mill tailings pile or impoundment is being used for the continued placement of byproduct material or is in standby status for such placement. A pile or impoundment is in operation from the day that byproduct material is first placed in the pile or impoundment until the day final closure begins.

Point of compliance is the site specific location in the uppermost aquifer where the ground-water protection standard must be met.

Reclamation plan, for the purposes of Criterion 6A, means the plan detailing activities to accomplish reclamation of the tailings or waste disposal area in accordance with the technical criteria of this appendix. The reclamation plan must include a schedule for reclamation milestones that are key to the completion of the final radon barrier including as appropriate, but not limited to, wind blown tailings retrieval and placement on the pile, interim stabilization (including dewatering or the removal of freestanding liquids and recontouring), and final radon barrier construction. (Reclamation of tailings must also be addressed in the closure plan; the detailed reclamation plan may be incorporated into the closure plan.)

Surface impoundment means a natural topographic depression, man-made excavation, or diked area, which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well.

Uppermost aquifer means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

I. Technical Criteria

Criterion 1 -- The general goal or broad objective in siting and design decisions is permanent isolation of tailings and associated contaminants by minimizing disturbance and dispersion by natural forces, and to do so without ongoing maintenance. For practical reasons, specific siting decisions and design standards must involve finite times (e.g., the longevity design standard in Criterion 6). The following site features which will contribute to such a goal or objective must be considered in selecting among alternative tailings disposal sites or judging the adequacy of existing tailings sites:

Remoteness from populated areas;

Hydrologic and other natural conditions as they contribute to continued immobilization and isolation of contaminants from ground-water sources; and

Potential for minimizing erosion, disturbance, and dispersion by

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natural forces over the long term.

The site selection process must be an optimization to the maximum extent reasonably achievable in terms of these features.

In the selection of disposal sites, primary emphasis must be given to isolation of tailings or wastes, a matter having long-term impacts, as opposed to consideration only of short-term convenience or benefits, such as minimization of transportation or land acquisition costs. While isolation of tailings will be a function of both site and engineering design, overriding consideration must be given to siting features given the long-term nature of the tailings hazards.

Tailings should be disposed of in a manner that no active maintenance is required to preserve conditions of the site.

Criterion 2 -- To avoid proliferation of small waste disposal sites and thereby reduce perpetual surveillance obligations, byproduct material from in situ extraction operations, such as residues from solution evaporation or contaminated control processes, and wastes from small remote above ground extraction operations must be disposed of at existing large mill tailings disposal sites; unless, considering the nature of the wastes, such as their volume and specific activity, and the costs and environmental impacts of transporting the wastes to a large disposal site, such offsite disposal is demonstrated to be impracticable or the advantages of onsite burial clearly outweigh the benefits of reducing the perpetual surveillance obligations.

Criterion 3 -- The "prime option" for disposal of tailings is placement below grade, either in mines or specially excavated pits (that is, where the need for any specially constructed retention structure is eliminated). The evaluation of alternative sites and disposal methods performed by mill operators in support of their proposed tailings disposal program (provided in applicants' environmental reports) must reflect serious consideration of this disposal mode. In some instances, below grade disposal may not be the most environmentally sound approach, such as might be the case if a ground-water formation is relatively close to the surface or not very well isolated by overlying soils and rock. Also, geologic and topographic conditions might make full below grade burial impracticable: For example, bedrock may be sufficiently near the surface that blasting would be required to excavate a disposal pit at excessive cost, and more suitable alternative sites are not available. Where full below grade burial is not practicable, the size of retention structures, and size and steepness of slopes associated exposed embankments must be minimized by excavation to the maximum extent reasonably achievable or appropriate given the geologic and hydrologic conditions at a site. In these

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impoundments because this will help in controlling particulate and radon emissions during operation. To control dusting from diffuse sources, such as tailings and ore pads where automatic controls do not apply, operators shall develop written operating procedures specifying the methods of control which will be utilized.

Milling operations producing or involving thorium byproduct material must be conducted in such a manner as to provide reasonable assurance that the annual dose equivalent does not exceed 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public as a result of exposures to the planned discharge of radioactive materials, radon-220 and its daughters excepted, to the general environment.

Uranium and thorium byproduct materials must be managed so as to conform to the applicable provisions of Title 40 of the Code of Federal Regulations, Part 440, ''Ore Mining and Dressing Point Source Category: Effluent Limitations Guidelines and New Source Performance Standards, Subpart C, Uranium, Radium, and Vanadium Ores Subcategory,'' as codified on January 1, 1983.

Criterion 8A -- Daily inspections of tailings or waste retention systems must be conducted by a qualified engineer or scientist and documented. The licensee shall retain the documentation for each daily inspection as a record for three years after the documentation is made. The appropriate NRC regional office as indicated in Appendix D to 10 CFR Part 20 of this chapter, or the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, must be immediately notified of any failure in a tailings or waste retention system that results in a release of tailings or waste into unrestricted areas, or of any unusual conditions (conditions not contemplated in the design of the retention system) that is not corrected could indicate the potential or lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

II. Financial Criteria

Criterion 9 -- Financial surety arrangements must be established by each mill operator prior to the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the mill and site and for the reclamation of any tailings or waste disposal areas. The amount of funds to be ensured by such surety arrangements must be based on Commission-approved cost estimates in a Commission-approved plan for (1) decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and (2) the reclamation of tailings and/or waste areas

in accordance with technical criteria delineated in Section I of this Appendix. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and evaluates alternatives for mitigating these impacts. The surety must also cover the payment of the charge for long-term surveillance and control required by Criterion 10. In establishing specific surety arrangements, the licensee's cost estimates must take into account total costs that would be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the Commission may accept financial sureties that have been consolidated with financial or surety arrangements established to meet requirements of other Federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance and control, provided such arrangements are considered adequate to satisfy these requirements and that the portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge is clearly identified and committed for use in accomplishing these activities. The licensees's surety mechanism will be reviewed annually by the Commission to assure, that sufficient funds would be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability must be

retained until final compliance with the reclamation plan is determined.

This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance would be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) yet which must be automatically renewed unless the surety notifies the beneficiary (the Commission or the State regulatory agency) and the

than 100 years following transfer of control of the disposal site to the owner.

Subpart E -- Financial Assurances

Section 61.61 Applicant qualifications and assurances.

Each applicant shall show that it either possesses the necessary funds or has reasonable assurance of obtaining the necessary funds, or by a combination of the two, to cover the estimated costs of conducting all licensed activities over the planned operating life of the project, including costs of construction and disposal.

Section 61.62 Funding for disposal site closure and stabilization.

(a) The applicant shall provide assurance that sufficient funds will be available to carry out disposal site closure and stabilization, including: (1) Decontamination or dismantlement of land disposal facility structures; and (2) closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance, and monitoring are required. These assurances shall be based on Commission-approved cost estimates reflecting the Commission-approved plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total capital costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

(b) In order to avoid unnecessary duplication and expense, the Commission will accept financial sureties that have been consolidated with earmarked fi-

nancial or surety arrangements established to meet requirements of other Federal or State agencies and/or local governing bodies for such decontamination, closure and stabilization. The Commission will accept this arrangement only if they are considered adequate to satisfy these requirements and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

(c) The licensee's surety mechanism will be annually reviewed by the Commission to assure that sufficient funds are available for completion of the closure plan, assuming that the work has to be performed by an independent contractor.

(d) The amount of surety liability should change in accordance with the predicted cost of future closure and stabilization. Factors affecting closure and stabilization cost estimates include: inflation; increases in the amount of disturbed land; changes in engineering plans; closure and stabilization that has already been accomplished and any other conditions affecting costs. This will yield a surety that is at least sufficient at all times to cover the costs of closure of the

NUREG-1556
Vol. 3

Consolidated Guidance About Materials Licenses

Applications for Sealed Source and Device Evaluation and Registration

Draft Report for Comment

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

J. Lubinski, S. Baggett, D. Broaddus, M. Burgess, E. Compton,
K. Randall, T. Rich, B. Smith

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3. The National Technical Information Service, Springfield, VA 22161–0002

Although the listing that follows represents the majority of documents cited in NRC publications, it is not intended to be exhaustive.

Referenced documents available for inspection and copying for a fee from the NRC Public Document Room include NRC correspondence and internal NRC memoranda; NRC bulletins, circulars, information notices, inspection and investigation notices; licensee event reports; vendor reports and correspondence; Commission papers; and applicant and licensee documents and correspondence.

The following documents in the NUREG series are available for purchase from the Government Printing Office: formal NRC staff and contractor reports, NRC-sponsored conference proceedings, international agreement reports, grantee reports, and NRC booklets and brochures. Also available are regulatory guides, NRC regulations in the *Code of Federal Regulations*, and *Nuclear Regulatory Commission Issuances*.

Documents available from the National Technical Information Service include NUREG-series reports and technical reports prepared by other Federal agencies and reports prepared by the Atomic Energy Commission, forerunner agency to the Nuclear Regulatory Commission.

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions. *Federal Register* notices, Federal and State legislation, and congressional reports can usually be obtained from these libraries.

Documents such as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings are available for purchase from the organization sponsoring the publication cited.

Single copies of NRC draft reports are available free, to the extent of supply, upon written request to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852–2738, for use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from the American National Standards Institute, 1430 Broadway, New York, NY 10018–3308.

NUREG-1556
Vol. 3

Consolidated Guidance About Materials Licenses

Applications for Sealed Source and Device Evaluation and Registration

Draft Report for Comment

Manuscript Completed: September 1997
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COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Please specify the report number, draft NUREG-1556, Vol. 3, in your comments, and send them by the due date published in the Federal Register notice to:

Chief, Rules Review and Directives Branch
Office of Administration
Mail Stop T6-D59
Washington, DC 20555-0001

Abstract

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (***NRC***) is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539, "Methodology and Findings of the ***NRC***'s Materials Licensing Process Redesign," and draft NUREG-1541, "Process and Design for Consolidating and Updating Materials Licensing Guidance." Draft NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated September 1997, is designed to provide applicants for requests for a sealed source or device safety evaluations, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

This document combines the guidance previously found in NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and the Office of Nuclear Material Safety and Safeguards Policy and Guidance Directives 84-22, "What Source and Device Designs Require an Evaluation," and 84-5, "Source and Device Evaluation Technical Assistance Request."

Note that this document is strictly for public comment and NOT for use in preparation or review of applications for sealed source and device evaluations until it is published in final form.

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FOREWORD

The ***NRC*** is using Business Process Redesign techniques to redesign its materials licensing process. This effort is described in NUREG-1539. A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. Below is a listing of volumes currently included in the NUREG-1556 series:

Vol. No.	Volume Title	Status
1	Program-Specific Guidance About Portable Gauge Licenses	Final Report
2	Program-Specific Guidance About Radiography Licenses	Draft for Comment
3	Applications for Sealed Source and Device Evaluation and Registration	Draft for Comment

Draft NUREG-1556, Vol. 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," dated September 1997, provides applicants requesting a sealed source or device safety evaluation, and reviewers of such requests, with the information and materials necessary to make determinations that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

A team composed of ***NRC*** headquarters staff prepared draft NUREG-1556, Vol. 3, drawing on its collective experience in radiation safety in general and as specifically applied to sealed source and devices designs, and the experience gained through development and publication of NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," that was published in 1996.

Draft NUREG-1556, Vol. 3, represents a step in the transition from the current paper-based process to the new electronic process. This document is available electronically by visiting the ***NRC***'s Home Page (***http://www.nrc.gov***) and choosing Nuclear Materials, then Business Process Redesign Project, then Library, and then draft NUREG-1556, Vol. 3. Text shown in bold italics indicates information that will be linked electronically allowing the user, by simply "pointing and clicking," to see the actual text of regulations, acronyms and abbreviations, and other referenced documents.

This draft guide is being distributed for comment and is NOT for use in preparation or review of applications for sealed source and device evaluations until it is published in final form. Please submit comments within 60 days of its publication. Comments received during the comment

period on this draft guide will be considered in developing the final guide. After the final guide is published, applicants may use the document in preparation of applications for sealed source and device evaluations and the *NRC* staff will use it in its review of requests for sealed source and device evaluations.

Address comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays. Comments may also be submitted through the Internet by addressing electronic mail to dlm1@nrc.gov.

Draft NUREG-1556, Vol. 3, is not a substitute for *NRC* regulations, and compliance is not required. The approaches and methods described in this draft report are provided for information and comment only.

Donald A. Cool, Director
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Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

ACKNOWLEDGMENTS

The writing team thanks the individuals listed below for assisting in the development and review of the draft report. All participants provided valuable insights, observations, and recommendations.

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ABBREVIATIONS

ALARA	As Low As is Reasonably Achievable
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DCD	Document Control Desk
FDA	United States Food and Drug Administration
GPO	Government Printing Office
IMNS	Division of Industrial and Medical Nuclear Safety
ISO	International Organization of Standardization
MOU	Memorandum of Understanding
NARM	Naturally occurring or Accelerator-produced Radioactive Material
NRC	United States Nuclear Regulatory Commission
OC	Office of the Controller
OGC	Office of the General Counsel
OSP	Office of State Programs
QA	Quality Assurance
QC	Quality Control

1 PURPOSE OF DRAFT REPORT

This draft NUREG provides assistance to applicants on submitting requests to the ***NRC*** for radiation safety evaluation and registration of sealed sources and devices containing byproduct material. In addition, it is designed to provide the reviewer of such requests for sealed source and device safety evaluations with guidance, information, and materials necessary to make a determination that the product is acceptable for licensing purposes. It provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Radiation safety programs for the use of byproduct material as a sealed source or device are structured on the presumption that the byproduct material will not breach its containment and contaminate the environment, or unnecessarily expose individuals to radiation. This presumption depends largely upon the adequacy of the containment properties of the sealed sources or devices in withstanding the stresses imposed by the environment in which they are possessed and used.

The regulations provided in Title 10 of the Code of Federal Regulations (***CFR***), Section ***30.32(g)*** require an applicant for a license to use a sealed source or device to identify the sealed source or device as registered with ***NRC*** in accordance with ***10 CFR 32.210*** or to provide the information contained in ***10 CFR 32.210***. ***10 CFR 32.210*** provides for the registration of a product and provides a means for having a single safety evaluation of the product performed. This process allows applicants and license reviewers to reference the evaluation when licensing the product for use or distribution without having to perform a complete evaluation of the product for each licensing action.

The ***NRC*** maintains a registry of radiation safety information on sealed sources and devices containing byproduct material. Agreement States also provide information on their radiation safety evaluations to the ***NRC*** for the registry. Both the ***NRC*** and the Agreement States use the information in the registry. Thus a vendor needs to provide detailed information about its sealed source or device only to a single agency, and the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the device throughout the United States.

Any information collection activities mentioned in this document are contained as requirements in 10 ***CFR*** Parts 19, 20, 21, 30, 31, 32, 34, 35, 36, 39, 40, 70, and 71, which provide the regulatory basis for this document. The information collection requirements in these parts have been cleared under Office of Management and Budget Clearance Nos. 3150-0044, 3150-0014, 3150-0035, 3150-0017, 3150-0016, 3150-0001, 3150-0007, 3150-0010, 3150-0158, 3150-0130, 3150-0024, 3150-0009, and 3150-0008, respectively.

2 AGREEMENT STATES

Certain states, called Agreement States (see Figure 2.1), have entered into agreements with the ***NRC*** that give them the authority for certain activities, including performing safety evaluations and registration of byproduct, source, or special nuclear materials used, possessed, or distributed by persons within their borders. A current list of Agreement States (including names, addresses, and telephone numbers of responsible officials) may be obtained upon request from the ***NRC***'s Office of State Programs (***OSP***). Any applicant, other than a Federal agency or distributor of a product to persons exempt from licensing, that is located in an Agreement State and wishes to apply for safety evaluation and registration of a sealed source or device needs to contact the responsible officials in that State for guidance on preparing an application; file these applications with State officials, not with the ***NRC***. Table 2.1 provides a quick way to check on which agency has regulatory authority.

> Three Agreement States, **Iowa**, **North Dakota**, and **Utah**, have voluntarily relinquished their authority to perform sealed source and device safety evaluations. Therefore, applicants and registration certificate holders located in these States are regulated by the ***NRC*** in the same manner, with respect to sealed source and device registration, as those not located in an Agreement State.

When an Agreement State issues a registration certificate, a copy of the registration certificate is forwarded to the Division of Industrial and Medical Nuclear Safety (***IMNS***) by the State. ***IMNS*** performs an administrative review of each certificate that includes looking for gross errors or omissions and ensures the inclusion of all necessary information on the first page of the certificate. The certificate is incorporated into the national registry and copies are distributed to the ***NRC*** regions, all Agreement States, and appropriate Federal and international agencies. If any administrative problems or errors are identified with an Agreement State registration certificate, they are resolved directly with the Agreement State.

Agreement State regulations may vary from ***NRC*** regulations. As such, sealed sources or devices registered by an Agreement State may not have met the regulations required of an ***NRC*** licensee. In addition, the ***NRC*** may identify significant safety concerns about a sealed source or device that has been evaluated by an Agreement State. In these cases, ***IMNS*** will continue to incorporate the registration certificate into the national registry. However, a cover letter indicating why the sealed source or device is not approved for use by ***NRC*** licensees is attached to the registration certificate. ***IMNS*** will raise the safety issues with the State that issued the registration certificate and with the vendor through ***OSP***. In addition, the ***NRC*** will attempt to obtain a listing of any ***NRC*** licensees that may have acquired the device and will take

appropriate action. Corrective actions to resolve the registration issues, if any, will be the responsibility of the Agreement State.[1]

The above process is necessary to: (1) ensure that ***NRC*** license reviewers are aware of particular ***NRC*** concerns with the registration certificate and (2) provide other Agreement States with the information necessary to determine whether a license to use the sealed source or device should be approved. If the registration certificates and cover letters are not included, an ***NRC*** or Agreement State license reviewer may receive a copy of the registration certificate directly from the registration certificate holder or an Agreement State and may inadvertently assume that products listed in the registration certificate are acceptable for licensing.

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[1] This policy is described in the memorandum to Office of the General Counsel (OGC) dated September 30, 1993, and OGC's response dated December 23, 1993 (Appendix A).

Table 2.1 Who Evaluates Sealed Sources and Devices?

APPLICANT AND ITS LOCATION	REGULATORY AGENCY
Distributor of products to persons exempt from licensing regardless of location	*NRC*
Federal agency regardless of location	*NRC*
Non-Federal entity in non-Agreement State, US territory or possession	*NRC*
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site NOT subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally-controlled site subject to exclusive Federal jurisdiction	*NRC*

Figure 2.1 - U.S. Map - Location of *NRC* Offices and Agreement States

3 MANAGEMENT RESPONSIBILITY

The ***NRC*** recognizes that effective applicant/registration certificate holder management is vital to achieving safety and complying with regulatory requirements. The ***NRC*** also believes that consistent compliance with its regulations provides reasonable assurance that regulated activities will be conducted accordingly. Based on results of routine and special inspections of licensed activities, the ***NRC*** has determined that ineffective management is frequently the underlying cause of compliance problems. Management refers to a senior-level manager who has responsibility for overseeing regulated activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments and responsibility for the following:

- Completeness and accuracy of records and all information provided to the ***NRC*** (***10 CFR 30.9***);
- Knowledge about the contents of the application;
- Applying for a registration certificate amendment if the information provided in the application or contained in the certificate is modified or changed. Registration certificate holders must comply with the information in the registration certificate until the certificate is amended; and,
- Committing adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to ensure that the registration certificate holder meets its regulatory requirements. The registration certificate holder is required to manufacture or distribute the product in accordance with: (1) the statements and representations contained in the application for safety review and registration; (2) the provisions of the registration certificate; and, (3) ***NRC*** regulations.

Applicants and registration certificate holders may be subject to enforcement actions due to noncompliance with regulatory requirements. For information on the ***NRC*** enforcement program, see "General Statement of Policy and Procedures for ***NRC*** Enforcement Actions," (***NUREG-1600***), which is available from the ***NRC*** upon request. NUREG-1600 is also available on the Internet. Visit NRC's Home Page (**http://www.nrc.gov**), choose "Nuclear Materials," then "Enforcement Program," "Enforcement Guidance Documents," and then "Enforcement Policy."

4 APPLICABLE REGULATIONS

It is the applicant's or registration certificate holder's responsibility to have up-to-date copies of applicable regulations, read them, and abide by each applicable regulation.

The following Parts of 10 ***CFR*** Chapter I contain regulations applicable to sealed source and device evaluations:

- 10 ***CFR*** Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders"
- 10 ***CFR*** Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigation"
- 10 ***CFR*** Part 20, "Standards for Protection against Radiation"
- 10 ***CFR*** Part 21, "Reporting of Defects and Noncompliance"
- 10 ***CFR*** Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 10 ***CFR*** Part 31, "General Domestic Licenses for Byproduct Material"
- 10 ***CFR*** Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"
- 10 ***CFR*** Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"
- 10 ***CFR*** Part 35, "Medical Use of Byproduct Material"
- 10 ***CFR*** Part 36, "Licenses and Radiation Safety Requirements for Irradiators"
- 10 ***CFR*** Part 39, "Licenses and Radiation Safety Requirements for Well Logging"
- 10 ***CFR*** Part 40, "Domestic Licensing of Source Material"
- 10 ***CFR*** Part 70, "Domestic Licensing of Special Nuclear Material"
- 10 ***CFR*** Part 71, "Packaging and Transportation of Radioactive Material"
- 10 ***CFR*** Part 170, "Fees for Facilities, Materials, Import and Export Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended"
- 10 ***CFR*** Part 171, "Annual Fees for Reactor Operating Licenses, and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by ***NRC***"

To request copies of the above documents, call the Government Printing Office (***GPO***) order desk in Washington, DC at (202) 512-1800. Order the two-volume bound version of Title 10, ***CFR***, Parts 0-50 and 51-199 from the ***GPO***, Superintendent of Documents, Post Office Box 371954, Pittsburgh, Pennsylvania 15250-7954. Single copies of the above documents may be requested from the ***NRC***'s Regional or Field Offices (see Figure 2.1 for addresses and telephone numbers).

The regulations embodied in ***10 CFR 30.32(g)*** and ***32.210*** codify the current and long-standing practice whereby vendors of sealed sources of radioactive material and devices containing sealed

sources submit radiation safety information necessary to perform an independent, technical safety evaluation, and to obtain registration of radiation safety information on certain sealed sources and devices. The practice has been used by the United States Atomic Energy Agency/*NRC* since the 1950's and by the Agreement States starting in 1962.

The specific provisions in ***10 CFR 30.32(g)*** require a license applicant to either make reference to a registered sealed source or device or provide the information necessary to perform a safety evaluation of the sealed source or device. ***Section 32.210*** outlines the *NRC* safety evaluation and registration criteria and clarifies the regulatory responsibility of registration certificate holders of products for which the *NRC* evaluates and registers radiation safety information.

Current regulations only require that products used under a specific license issued in accordance with 10 CFR Part 30 be registered with the Commission. However, if registration of a product design is deemed necessary by NRC, the applicant needs to provide the information contained in ***10 CFR 32.210*** and the application will be evaluated in the same manner as all registration applications.

The products listed in Sections 4.1 through 4.5 are used by persons exempt from licensing requirements or used in accordance with a general license and *NRC* has determined that registration of the product design is necessary. However, in addition to the general registration criteria in ***10 CFR 32.210***, the regulations require that the products meet certain specific requirements. These specific requirements are listed in the appropriate section (Sections 4.1 through 4.5) and need to be addressed during the product evaluation.

Some specific-licensed products are required, by regulation, to meet certain specific requirements in addition to the general registration criteria provided in ***10 CFR 32.210***. The specific requirements for these products are listed in Sections 4.6 through 4.9 and need to be addressed during the product evaluation.

4.1 Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147 for Use by Persons Exempt from Licensing Requirements

Under ***10 CFR 30.19***, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to ***10 CFR 32.22***. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 *CFR* Regulations
Design	*30.19(a) & (c), 32.22(a)*
Maximum Radiation Levels	*32.22(a)(2)(vi)*
Maximum Dose Commitments	*32.22(a)(2)(xiii)&(xiv)*
Labeling	*32.25(b)*[2]

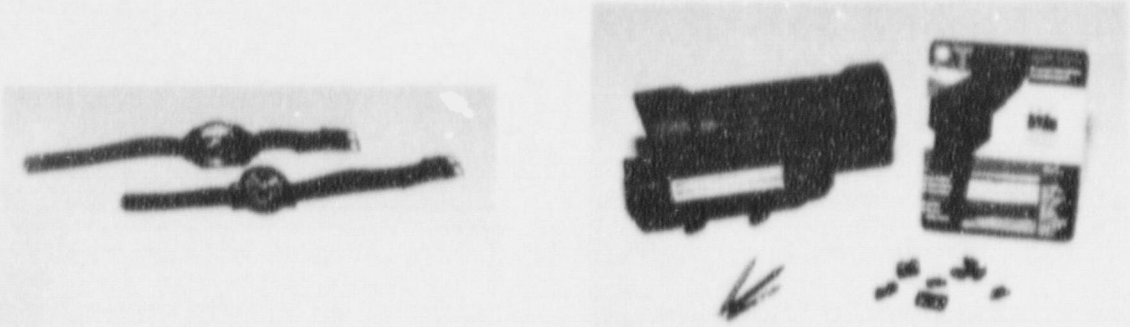

Figure 4.1 - Watches and Aiming Sights - Watches and aiming sights are products distributed to persons exempt from licensing under 10 CFR 30.19.

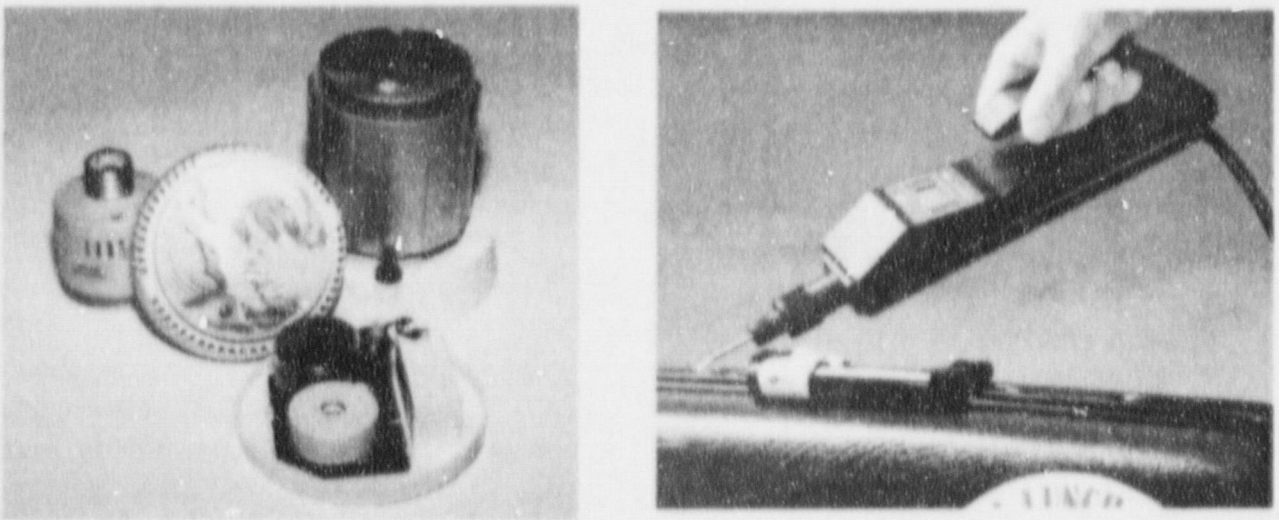

Figure 4.2 - Smoke and Chemical Agent Detectors - Smoke and chemical agent detectors are products distributed to persons exempt from licensing under 10 CFR 30.20.

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[2] The regulation requires identification of the person licensed under ***10 CFR 32.22***. Identification can be the full name of the licensee, their registered trademark, or their ***NRC*** exempt distribution license number.

4.2 Gas and Aerosol Detectors Containing Byproduct Material for Use by Persons Exempt from Licensing Requirements

Under *10 CFR 30.20*, persons are exempted from licensing requirements if the products are initially transferred in accordance with a license issued pursuant to *10 CFR 32.26*. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 *CFR* Regulations
Design	*30.20(a), 32.26*[3]
Maximum Radiation Levels	*32.26(b)(6)*
Maximum Dose Commitments	*32.26(b)(13)&(14)*
Labeling	*32.29(b)*[4]

4.3 Devices Used under the General License in *10 CFR 31.5*

Under *10 CFR 31.5*, persons may use certain devices in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to *10 CFR 32.51*. The devices used under the general license include devices designed for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 *CFR* Regulations
Design	*31.5(a), 32.51(a)(2)(I)*
Maximum Dose Commitments	*32.51(a)(2)(ii)&(iii)*
Labeling	*32.51(a)(3)*
Leak Testing	*32.51(b)*
Testing and Servicing	*32.51(b) & (c)*

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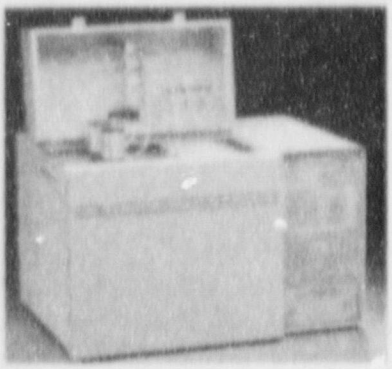
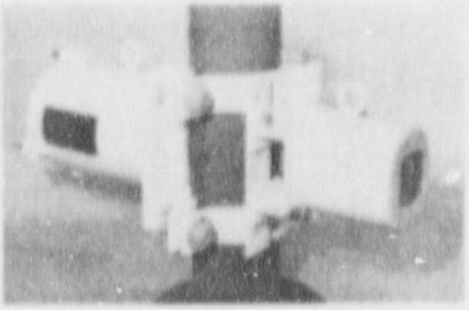
[3] This regulation is applicable to devices designed to protect life or property from fires and airborne hazards. It has been determined that gas and aerosol detectors designed to detect explosives or chemical agents may be licensed for distribution in accordance with this regulation.

[4] The regulation requires identification of the person licensed under *10 CFR 32.26*. Identification can be the full name of the licensee, their registered trademark, or their *NRC* exempt distribution license number.





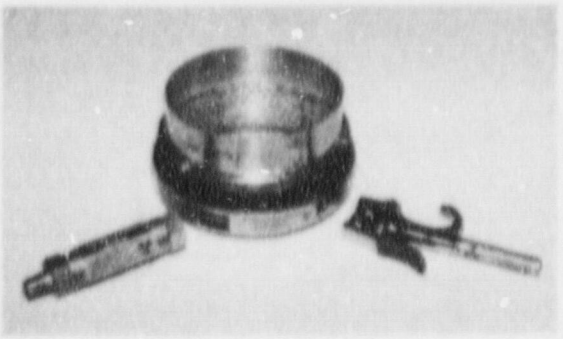


Figure 4.3 - 10 CFR 31.5 General License - Gas chromatographs, density gauges, and static elimination devices are products used under 10 CFR 31.5 general license.

4.4 Luminous Safety Devices Used in Aircraft under *10 CFR 31.7*

Under ***10 CFR 31.7***, persons may use luminous safety devices containing tritium or promethium-147 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to ***10 CFR 32.53***. Therefore, the requirements for product evaluation are imposed on the person licensed to manufacture or initially transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation, are listed below:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Design	***32.53(c)&(d)***
Prototype Testing	***32.53(d)(4), 32.101***
Labeling	***32.54***
Quality Control	***32.55, 32.110***

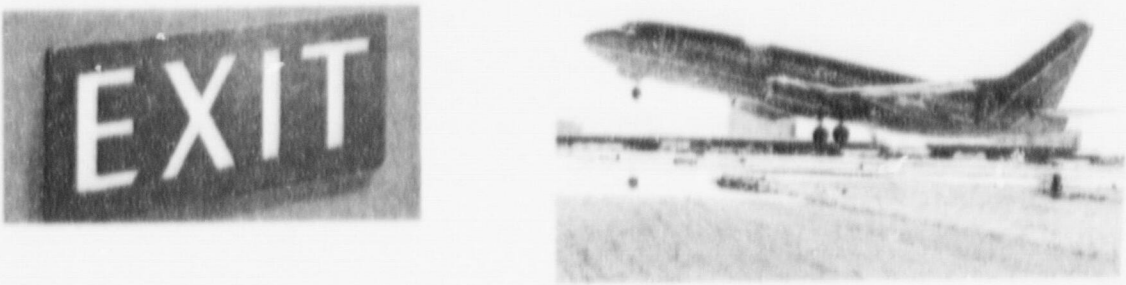


Figure 4.4 - 10 CFR 31.7 General License - Safety devices, such as exit signs, containing tritium or promethium-147 and used in aircraft may be used under 10 CFR 31.7 general license.

4.5 Ice Detection Devices Containing Strontium-90

Under ***10 CFR 31.10***, persons may use ice detection devices containing strontium-90 in accordance with a general license provided the devices were manufactured or initially transferred in accordance with a license issued pursuant to ***10 CFR 32.61***. Therefore, the requirements for product evaluation are imposed on the person licensed to transfer the product. Specific requirements, imposed on the product design, that must be addressed during the product evaluation are listed below:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Design	*32.61(c)&(e)*
Labeling	*32.61(d)*
Prototype Testing	*32.61(e)(4), 32.103*
Quality Control	*32.61(e)(5), 32.62, 32.110*

4.6 Radiography Equipment

Persons specific licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 ***CFR*** Part 34. The vendor or custom user of the equipment may demonstrate that the equipment meets these requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of radiography equipment, the items listed below must be addressed:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Design	***34.20(a), 34.22***
Leak Testing	***34.27***
Labeling	***34.20***
Prototype Testing	***34.20***
Maximum Radiation Levels	***34.20, 34.21***

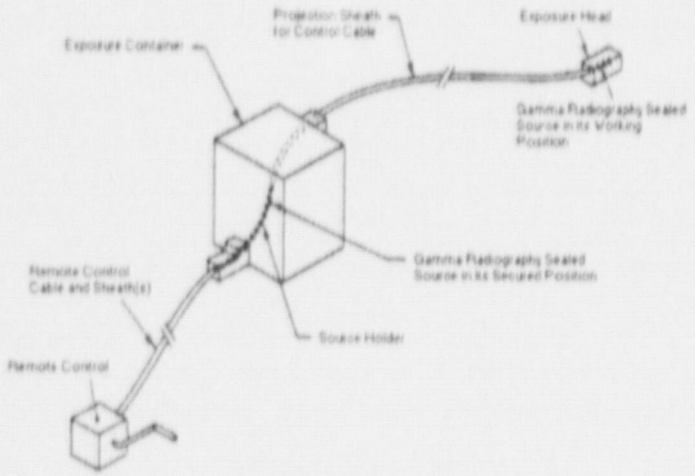


Figure 4.5 - Radiography Equipment - Radiography equipment, such as the equipment shown above, must meet the requirements of 10 CFR Part 34.

4.7 Well-Logging Equipment

Persons specifically licensed to perform well-logging operations are only authorized to use equipment that meets the requirements of 10 ***CFR*** Part 39, Subpart C. One such requirement is that the licensed material be as insoluble and nondispersible as practicable. The vendor or custom user of the equipment may demonstrate that the equipment meets the requirements as part of the evaluation and registration of the equipment. Therefore, during an evaluation of well-logging equipment, the items listed below must be addressed:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Labeling	***39.31(a)***
Leak Testing	***39.35***
Design	***39.41(a)(1) & (2)***
Prototype Testing	***39.41(a)(3)***

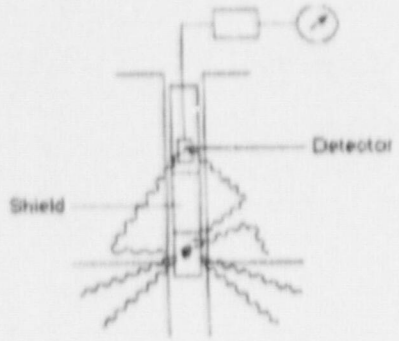
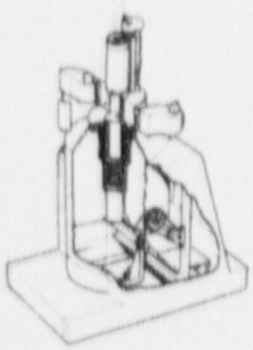


Figure 4.6 - Well-Logging Operations - Sealed sources used in well logging operations must meet the requirements of 10 CFR Part 39.

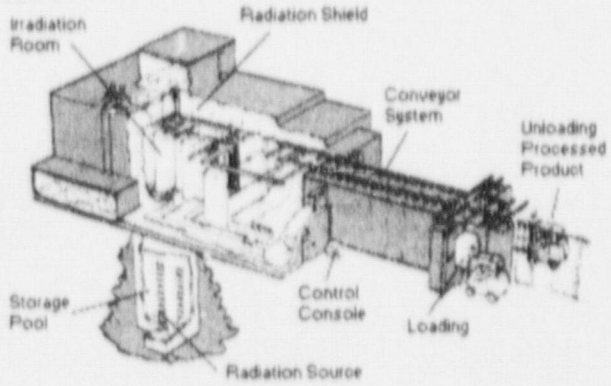
4.8 Irradiators

Persons specifically licensed to use sealed sources in irradiators are only authorized to use sealed sources that meet the requirements of ***10 CFR 36.21***. One such requirement is that the licensed material be as insoluble and nondispersible as practicable if used in a wet-source-storage or wet-source change irradiator. The vendor or custom user of the sealed sources may demonstrate that the sealed sources meet the requirements as part of the evaluation and registration of the sealed source. Therefore, during an evaluation of irradiator sources, the items listed below must be addressed:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Design	***36.21(a)(2), (3), & (4)***
Leak Testing	***36.59***
Prototype Testing	***36.21(a)(5)***



(a)



(b)

Figure 4.7 - Irradiators - NRC evaluates both (a) category I (self-shielded) irradiators and, (b) sealed sources used in category IV (panoramic, wet source storage) irradiators.

4.9 Sealed Sources and Devices for Medical Use

In accordance with ***10 CFR 35.49***, only sealed sources and devices that are manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to ***10 CFR 32.74*** may be used for medical uses. The vendor of the sealed sources may demonstrate that the sealed source meets the requirements as part of the evaluation and registration of the sealed source or device. Therefore, during an evaluation of medical sealed sources or devices, the items listed below must be addressed:

Area to be Addressed	Applicable 10 ***CFR*** Regulations
Labeling	***32.74(a)(2)(viii) & (a)(3)***
Leak Testing	***32.74(b)***

One exception to the above requirement is teletherapy sources. Specifically, teletherapy sources do not need to meet the requirements of ***10 CFR 32.74***. However, ***10 CFR 35.49(b)*** indicates that they do need to be manufactured and distributed in accordance with a license issued pursuant to ***10 CFR Part 30***.

5 GENERAL POLICIES AND PROCEDURES

5.1 Sealed Source and Device Designs That Do Not Require Evaluation by *IMNS*

10 CFR 30.32(g) applies to all sealed sources and devices used by ***NRC*** specific licensees and requires evaluation of the product by ***NRC***. However, the possession and use of certain products does not require the evaluation and registration of the product by ***IMNS***. Specifically, evaluation and licensing of the following products should be handled as indicated below by the license reviewer:

5.1.1 Calibration and Reference Standards

Calibration and reference sources may be licensed without evaluation review by ***IMNS*** if the sources do not exceed the following:

- For beta and/or gamma emitting material - 3.7 MBq (100 microcuries) or ten times the quantity specified in ***Section 30.71, Schedule B, 10 CFR 30***, whichever is greater.

- For alpha emitting material - 0.37 MBq (10 microcuries).

The above values were chosen because they represent minimal hazard to public health and safety. To license these sources, license reviewers need to identify the isotope in Item 6 of the license, use the statement "calibration or reference sources" in Item 7, and state the maximum quantity for each source in Item 8. Both possession and distribution to specific licensees may be authorized.

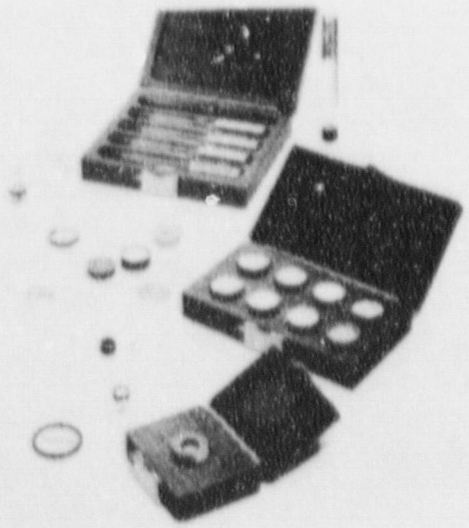


Figure 5.1 - Calibration and Reference Sources - Calibration and reference sources may not need evaluation and registration by IMNS.

5.1.2 Products Used in Research and Development or by Broad Scope Licensees

Sealed sources or devices containing sealed sources that are intended only for use under research and development or broad scope licenses need not be evaluated by ***IMNS*** if the licensing reviewer has made a determination that:

- for unregistered sources, or registered sealed sources not possessed and used in accordance with the registration, - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

- for registered sealed sources contained in unregistered devices - the licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form.

If a research and development or broad scope licensee wishes to transfer a sealed source or device to another specific licensee, then the recipient must meet the criteria listed above or the sealed source or device must be registered in accordance with ***10 CFR 32.210*** prior to transfer.

License reviewers should utilize the following standard license condition for those recipients of the registered sealed source contained in unregistered devices:

> "The licensee shall use only sealed sources for which a sealed source registration certificate has been issued by the U. S. Nuclear Regulatory Commission pursuant to ***10 CFR 32.210(e)*** or an Agreement State. Possession and use of the sealed sources used must adhere to the conditions and limitations of the registration certificate."

5.1.3 Custom Sealed Sources or Devices

Sealed sources or devices containing sealed sources built to the unique specifications of a given user (custom) need not be sent to ***IMNS*** for evaluation if: (a) they contain less than 7.4 GBq (200 millicuries) of radioactive material or less than 740 GBq (20 curies) of tritium, and (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in unsealed form. Thus, the applicant would not have to rely on the intrinsic safety of the sealed source or device to demonstrate compliance with ***10 CFR 30.33***. Custom sealed source and devices which contain an activity greater than that listed above must be submitted to ***IMNS*** for evaluation and registration.

To license these custom sealed sources and/or devices, license reviewers need to identify the isotope in Item 6 of the license, use the statement "custom source" (for unregistered sources) or "sealed source" (for registered sealed sources) including a unique identifier (e.g., drawing or model number), if possible, in Item 7, and state the maximum quantity of radionuclide per

source or device in Item 8. In Item 9 (authorized use) license reviewers need to describe, as clearly as possible, the actual use of the custom source or device. Examples: "For use in a Model A analyzer custom built for the licensee by ABC Company in Notown" or "Custom source for use in XYZ Model 100 gauge."

The authorization to use sources or devices described above, that have not been evaluated and registered by ***IMNS***, apply to only to the custom user of the product.

5.2 Custom Users

A user of a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant is considered a custom user. Custom users are specifically identified on the first page of registration certificates. The request for the safety evaluation and registration of the product may be made by the custom user or vendor. Regardless of the applicant, the custom user is required to meet all commitments made in the application and registration certificate. Typically, no more than two different ***NRC*** or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

5.3 As Low As Is Reasonably Achievable

The Commission's requirements to establish programs, procedures, and engineering controls for achieving doses that are as-low-as-is-reasonably-achievable (***ALARA***) are included in ***10 CFR 20.1101***. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," explains the ***NRC***'s position on this subject. Although these requirements apply to possession and use of radioactive material, applicants should consider the ***ALARA*** philosophy when designing and constructing sealed sources or devices to avoid unnecessary exposures during installation, maintenance, repair, and use of the sealed source or device. Regulatory Guide 8.10 may be useful to applicants for establishing and following an ***ALARA*** philosophy during the design of a sealed source or device.

5.4 Naturally Occurring or Accelerator-Produced Radioactive Material

Agreement and Non-Agreement States issue registration certificates for sealed sources or devices containing Naturally occurring or Accelerator-produced Radioactive Material (***NARM***). Copies of these registration certificates are provided to ***IMNS*** by the States. ***IMNS*** does not perform a review of these certificates, but does incorporate these certificates into the national registry. Copies are forwarded to the ***NRC*** regions, all Agreement States, and appropriate Federal and international agencies as a service to the States. This practice replaces the United States Food and Drug Administration (***FDA***) "Radioactive Materials Reference Manual." Questions concerning ***NARM*** certificates should be directed to ***OSP***, the State, or ***FDA***.

As a general rule, the ***NRC*** does not accept applications for radiation safety evaluation and registration of sealed sources or devices that contain ***NARM***. Exceptions to this general rule include sealed sources or devices that contain material that can be reactor or accelerator produced (e.g., cadmium-109), or sealed sources or devices that contain ***NARM*** commingled with byproduct material, in either the same or separate encapsulations (e.g., moisture density gauges containing radium-226 and cesium-137).

5.5 Foreign Vendors

Foreign vendors present a unique situation for the ***NRC*** in that the ***NRC*** has no jurisdiction over foreign entities. The ***NRC*** has historically followed the regulation of 10 ***CFR*** Part 110 since a foreign vendor is required to establish an address in the United States to which the ***NRC*** can correspond and serve papers as necessary to accomplish its mission. In addition, the ***NRC*** inspects the United States distributor of the product and may occasionally audit foreign vendors to determine if the products distributed are in accordance with the statements made in support of the registration certificates.

Figure 5.2 - Map of the World - Foreign vendors are required to establish an address in the United States to which the ***NRC*** can correspond and serve papers as necessary to accomplish its mission.

5.6 Use of International or Foreign Standards

In some cases, an applicant may wish to test a product in accordance with an international or foreign standard. In order for the ***NRC*** to find this acceptable, the applicant must first demonstrate and the reviewer confirm that the standard meets or exceeds any specific regulatory requirements (e.g., compliance with American National Standards Institute (***ANSI***) N432-1980 for radiography equipment). The applicant and reviewer must each review the requirements and acceptance criteria of the standard based on the normal and likely accident conditions associated with use, handling, storage, and transport of the product to determine if the standard is acceptable. The foreign or international standard may be compared with an

applicable United States standard in determining the acceptance of the standard. This may include professional judgement on the parts of the applicant and reviewer.

5.7 *FDA-NRC* Memorandum of Understanding

The ***FDA*** and the ***NRC*** signed a Memorandum of Understanding (***MOU***)[5] to coordinate existing ***FDA*** and ***NRC*** regulatory programs for medical devices, drugs, and biological products that make use of byproduct, source, or special nuclear materials. The principal statute under which the ***FDA*** regulates devices is the Federal Food and Drug and Cosmetic Act, as amended by the Safe Medical Devices Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992.

Under the ***MOU***, the agencies agree to promptly inform each other whenever they receive a report or otherwise become aware of any potential public health problems involving products of mutual regulatory concern. Further, the agencies will share information to the extent practicable. For ***IMNS***, this includes information used by the ***NRC*** for product evaluations and approvals, and any incidents involving product failures. The ***FDA*** must be notified in writing when the ***NRC*** begins an evaluation of a medical product, whether it is for a new product or for an amendment to an existing product. The notification should include the company, product model number, and the scope of the request. ***NRC*** policy precludes the approval of a medical sealed source or device unless the applicant has submitted a pre-marketing approval (510k) issued by ***FDA***. If the pre-marketing approval is not submitted with the application, the applicant will be instructed to contact the ***FDA*** and obtain the appropriate approval.

Applicants needing information on ***FDA*** requirements may contact:

Food and Drug Administration
Office of Compliance
HFZ-300
2098 Gaither Road
Rockville, MD 20850
(301) 594-4692

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[5] The MOU was published in the Federal Register (***58 FR 47300***) on September 8, 1993.

5.8 Computer Software

NRC safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators. Software applications that deal with process controls are not part of the product evaluation. The reviewer will determine that if such systems fail (e.g., a power failure), the sealed source or shielding would return to, or remain in, the fully shielded position. Medical applications involving computer software and patient planning systems are, in general, within ***FDA*** jurisdiction and ***FDA*** is responsible for any necessary review of the software.

Figure 5.3 - Computer Software - Safety evaluations concentrate only on those systems that control fundamental safety processes such as checking an interlock, source or shielding position, and the functionality of position indicators.

Applicants should note that some computer systems and software programs, including embedded microprocessors, currently in use, and some systems and programs being distributed, may experience problems as a result of the turn of the new century. Applicants should evaluate the effects of the problems on the normal operation and the operation of the safety features of their equipment.

5.9 Registration Certificate Revocation

If it is determined that a sealed source or device evaluated by the ***NRC*** may pose an undue hazard when used in accordance with the conditions of the registration certificate and corrective actions cannot be implemented or agreed upon between the registration certificate holder and the ***NRC***, the ***NRC*** may modify or remove the registration certificate from the national registry and may issue orders modifying licenses to all persons licensed by the ***NRC*** to use the sealed source or device. ***IMNS*** will also notify ***OSP*** so that the Agreement States are made aware of the ***NRC*** actions concerning the sealed source or device.

5.10 Incidents

Incidents involving products evaluated and registered by the ***NRC*** are assessed to determine whether the integrity or adequacy of the product was compromised. The assessment involves a re-evaluation of the product to determine its integrity and adequacy, taking into account the causes of the incident. If it is determined that a generic product fault exists, the registration certificate holder will be notified and appropriate actions, affecting both products currently in

use and newly manufactured products, will be taken. In addition, the ***NRC*** will re-evaluate similar products to ensure they are not susceptible to the same type of faults.

Usually, incidents caused by abnormal or unauthorized use of the product would be considered licensing issues and would not require a re-evaluation of the product.

Some information concerning incidents involving products evaluated by the ***NRC*** is kept on file by ***IMNS*** for use in performing future evaluations of the products involved and products similar to those involved. However, the Office of Analysis and Evaluation of Operational Data is the ***NRC*** Office responsible for compiling, tracking, and analyzing incidents and reports.

5.11 Proprietary Information

Registration certificates and information contained in the background files for the registration certificates, such as applications, may be made available to the public. Persons may request access to this information in accordance with ***10 CFR 9.23***.

Proprietary information (i.e., information not to be disclosed to the public) should not be included in an application unless it is the only means to adequately describe the radiation safety properties of the product. If an application contains information marked as "proprietary," "confidential," "restricted," or "is the express property of Company X," the reviewer needs to determine whether the information is necessary to perform the safety evaluation. If the information is not necessary, it should be returned to the applicant.

If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request, in accordance with ***10 CFR 2.790***, for withholding the information. The reviewer needs to evaluate the applicant's request for withholding against the requirements in ***10 CFR 2.790*** (Appendix B includes a checklist for requests for withholding information from public disclosure). If the request is denied, in whole or in part, the reviewer needs to give the applicant the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer needs to notify the applicant in writing that the request for withholding has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with Management Directive 12.6, "***NRC*** Sensitive Unclassified Information Security Program" and the applicant should be notified in writing that the ***NRC*** plans to honor the request. However, the notification needs to inform the applicant that the ***NRC*** may have cause to review the determination in the future, for example, if the scope of a Freedom of Information Act request includes the information. In all review situations, if the ***NRC*** needs additional information from the applicant or makes a determination adverse to the initial determination, the applicant will be notified in advance of any public disclosure.

5.12 Transportation

This document does not cover detailed requirements for the transportation of devices and sealed sources. The ***NRC***'s transportation requirements are contained in 10 ***CFR*** Part 71, "Packaging and Transportation of Radioactive Material." 10 ***CFR*** Part 71 establishes (1) requirements for quality assurance, packaging, preparation for shipment, and transportation of licensed material and (2) procedures and standards for ***NRC*** approval of packaging and shipping procedures for fissile material and for a quantity of licensed material in excess of a "Type A quantity" (i.e., exceeding A_1 or A_2 as defined in ***10 CFR 71.4***).

Although an application for radiation safety evaluation of a sealed source or device as discussed in this document is not expected to include a detailed description of packaging and transportation procedures to demonstrate compliance with 10 ***CFR*** Part 71, the applicant is expected to be familiar with the way those requirements apply to the sealed source or device and the action needed to ensure that transportation of the device is performed in accordance with applicable requirements.

Any vendor who has questions about the requirements for transportation may contact the appropriate ***NRC*** region or ***NRC***'s Transportation Safety and Inspection Branch, Spent Fuel Project Office, at (301) 415-8502 to obtain assistance.

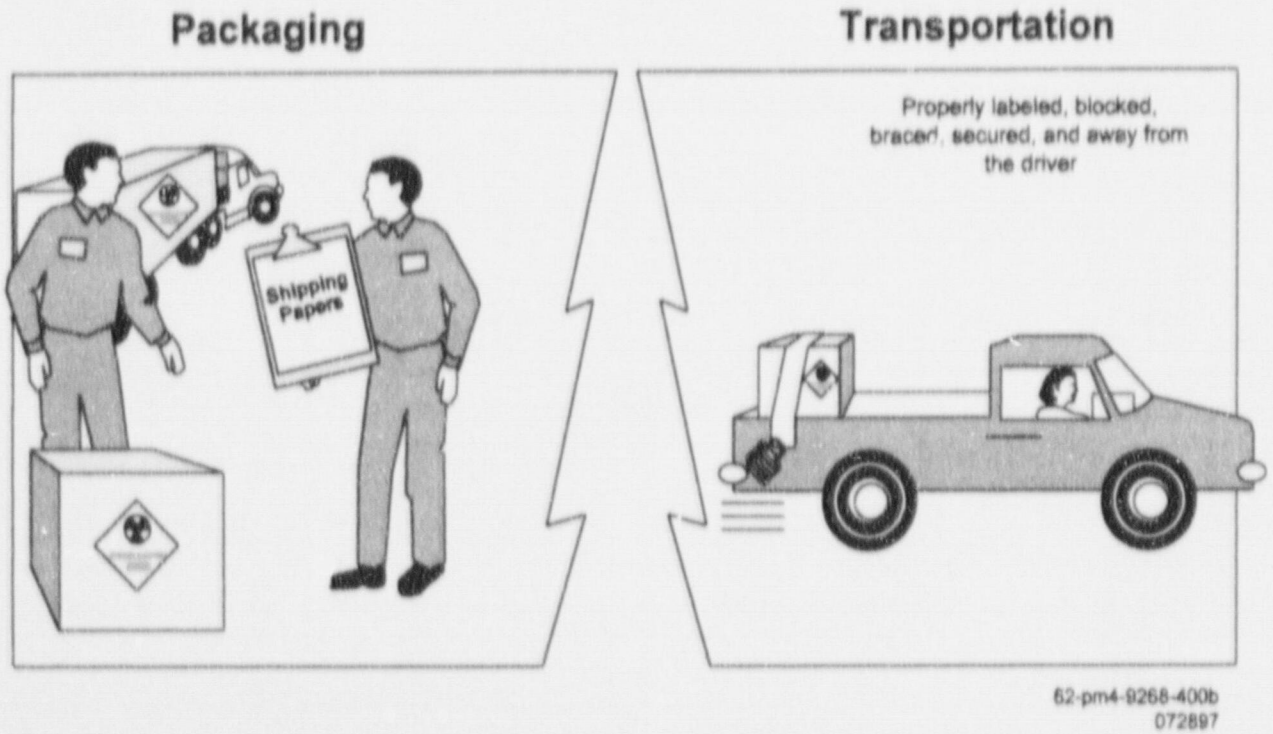

Figure 5.4 - Packaging and Transportation - Registration certificate holders must meet all NRC and DOT requirements for packaging and transporting sealed sources and devices.

Although ***IMNS*** does not evaluate packaging or transportation requirements during sealed source or device evaluations, ***IMNS*** does evaluate the effects the packaging or transportation has on normal use and operation of the product as part of the evaluation. Specifically, ***IMNS*** evaluates the effects of normal conditions experienced during transport (e.g., extreme temperatures, vibration) on the sealed source or device. Applicants should consider these effects during the design of the products and packaging for transport.

6 HOW TO FILE

No special form is required for applications for sealed source or device evaluations. However, to facilitate the review process, applicants for a sealed source or device evaluation are encouraged to do the following:

General/Format:

- Be sure to review the applicable regulations and use the most recent guidance, including this document, in preparing an application.
- Submit all documents, including all drawings if practicable, printed, on standard 8-1/2 inch x 11 inch paper. If submission of larger documents is necessary, they should be folded to 8-1/2 inch x 11 inch.
- All pages in an application should be numbered consecutively. If revisions are necessary after an application has been submitted, revised or replacement pages should be submitted and should show the date of revision or revision number. Supplemental pages submitted for insertion should be indicated alphanumerically (e.g., 12a, 12b, etc.).
- Submit an original, signed application and one additional copy. Retain a copy of the your registration application for future reference.
- Applicants may include a copy of their submittal on 3.5 inch disk in WordPerfect format.

Content:

- Complete the "Summary Data" section of Appendix C, "Application and Review Checklist."
- Attach the balance of the application to the "Summary Data" information. The order of the information in the application should correspond to the appropriate sub-section in Section 10.
- Complete the "Checklist" included in Appendix C as a guide to determine whether all necessary information has been provided.
- The application should also include a drawing(s), no larger than about 4 inch x 6 inch, that may be included in the registration certificate, and that provide an overall representation of the product and its safety features.
- When drawings, operating manuals, descriptive sales literature, or similar documents are submitted as part of an application, they should be identified clearly as being part of the application. This might be done by marking the materials individually and listing them

on a cover sheet for the application or listing them as enclosures to the letter that transmits the application.

- Avoid submitting proprietary information unless it is absolutely necessary.

- The application should include a clear, concise presentation of the information necessary for the evaluation, avoiding ambiguous and conflicting statements and wordy descriptions that do not contribute to a technical review.

- Terms included in the application should be used as they are defined in ***NRC*** regulations and national consensus standards, as applicable. All abbreviations and acronyms should be defined.

Engineering Drawings:

- All drawings should have a drawing number, revision number, company name, title, scale, and date. References to parts or other drawings should be clearly indicated.

- If drawings have been reduced or enlarged, this should be clearly indicated.

- All drawings should include one or several isometric projection diagrams showing components pertinent to radiation safety such as shielding material, shielding thickness, on-off mechanism, on-off indicator, label location, assembly methods, source mounting and security, and dimensions, tolerances, and materials of construction.

- Engineering drawings, must be in English. To facilitate preparing an application on a product manufactured outside the United States, the applicant may elect to write or otherwise affix the English translation directly on an engineering drawing.

It may be advantageous to submit a product (without radioactive material) or a part of a product with an application. For example, a vendor of radiography equipment may elect to submit a "pigtail" connector (used to join the source assembly to the drive cable) as a means of clarifying the related engineering drawings and operating instructions. Large pieces of equipment should not be submitted because of handling and storage limitations at the ***NRC*** offices.

All license applications will be available for review by the general public in the ***NRC***'s public document room. If it is necessary to submit proprietary information, follow the procedure in ***10 CFR 2.790***. See Section 5.10 of this NUREG for additional details.

Applications may be scanned or put through an optical character reader to convert them to electronic format. To assist with the conversion of the application to electronic media, applicants are requested to follow these suggestions:

- Submit printed or typewritten, not handwritten, text on smooth, crisp paper that will feed easily into the scanner.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

7 WHERE TO FILE

Applicants located in states or territories subject to ***NRC*** jurisdiction wishing to register a sealed source or device may file an application with the ***NRC*** by submitting the application to:

United States Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Washington, DC 20555-0001

Please note that the above address is different from that of the appropriate ***NRC*** region to which persons would apply for authority to possess and use radioactive material under a manufacturing and distribution license.

The above address cannot accept mail requiring the receiver's signature (e.g., express mail). Mail requiring the receiver's signature should be sent to:

United States Nuclear Regulatory Commission
Sealed Source Safety Section
Division of Industrial and Medical Nuclear Safety
Two White Flint North
11545 Rockville Pike
North Bethesda, MD 50852

Applicants in locations subject to Agreement State jurisdiction wishing to apply for safety evaluation and registration of a sealed source or device should file the application with the appropriate Agreement State agency, not the ***NRC***. See Section 2 for additional information concerning filing applications with Agreement States.

8 REGISTRATION FEES

Each application for which a fee is specified, including applications for new registration certificates and registration certificate amendments, must be accompanied by the appropriate fee. Refer to ***10 CFR 170.31*** to determine the amount of the fee. For applicants for sealed source and device evaluations, the appropriate fee categories are 9A, 9B, 9C, and 9D. The registration certificate or amendment will not be issued until full payment of the fee has been received.[6] Once the technical review process has begun, no fees will be refunded; application fees will be charged regardless of the ***NRC***'s disposition of an application or the withdrawal of an application.

Most ***NRC*** registration certificate holders are also subject to annual fees; refer to ***10 CFR 171.16***. Consult ***10 CFR 171.11*** for additional information on exemptions from annual fees and ***10 CFR 171.16(c)*** on reduced annual fees for registration certificate holders that may qualify as "small entities."

Direct all questions about ***NRC***'s fees to the Office of the Controller (***OC***) at the ***NRC*** headquarters in Rockville, Maryland, (301) 415-7554. You may also call ***NRC***'s toll free number (800) 368-5642 and then ask for extension 415-7554.

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[6] This guidance is in accordance with a memorandum from Ronald Scroggins, Office of the Controller, to all Regional Administrators dated March 17, 1994 (Appendix D).

9 DOCUMENT FLOW

9.1 Application Receipt and Assignment to a Reviewer

Requests for safety evaluations of sealed sources or devices usually are submitted by the applicant directly to ***IMNS***. However, applications may be submitted to other ***NRC*** sections or Offices (e.g., as part of a licensing action) and forwarded to IMNS as a technical assistance request. For example, the ***NRC*** regions and other sections within ***IMNS*** may receive requests as part of a license request, or ***OC*** may receive a request to make a registration certificate inactive. The processing of the application is the same in all cases.

NRC staff submitting technical assistance requests for sealed source and device evaluations to IMNS should use ***NRC Form 567***, "Request for a Sealed Source Device Evaluation." The requester needs to follow the instruction block at the top of the form for specific detail on how and what to submit.

When ***IMNS*** receives an application, an acceptance review is performed to determine whether there is sufficient information to initiate a review. If there is sufficient information to initiate a review, the applicant is sent a letter acknowledging receipt of the application; if not, the entire package is returned to the applicant for resubmission of a complete application.

Applications are logged into the sealed source and device action tracking system where they await assignment to a reviewer. Each action is assigned a unique tracking number. Assignment to a reviewer is determined on a first-in basis. An application may be assigned a higher priority based on the dire need for the product to protect public health and safety, the product providing a currently unavailable benefit to society, or commercial hardship that is likely to be experienced by the applicant if the evaluation process is delayed. Requests for higher priority should include adequate justification.

While an application is awaiting assignment to a reviewer, a copy of the cover letter to the application and the ***NRC Form 567*** is sent to the ***OC*** for verification that the appropriate application fees have been received. ***OC*** will return ***NRC Form 567*** to ***IMNS*** indicating whether the appropriate fees have been collected. ***IMNS*** may start an evaluation of a sealed source or device before fees are collected, however, a final approval of the product will not be issued until the application fees are paid in full.

9.2 Reviewer's Responsibilities

The reviewer is responsible for performing the technical evaluation of the product, ensuring the product meets all applicable standards and regulations, corresponding with the applicant to obtain additional information, if necessary, generating the registration certificate, and ensuring the application is reviewed and signed by two persons having signature authority. In addition,

the reviewer needs to identify any complex policy issues and bring them to management's attention.

In some cases, the adequacy of an element of the product design may not be readily evident. As a result, it may be necessary for the reviewer to exercise professional judgment regarding the adequacy and safety of the product design. Such judgment should be discussed with the applicant and included in a note from the reviewer to the registration file. A copy of the note to the registration file should be provided to the applicant.

Once the evaluation and registration are complete, the registration certificate, including cover letter to the applicant and technical assistance request response, if applicable, and all information used in support of the evaluation, are forwarded to the registration assistant for distribution and filing.

See Section 2 concerning the ***NRC*** review of Agreement State registration certificates.

9.3 Distribution of Completed Certificates

The registration assistant processes distribution of all registration certificates issued by the ***NRC*** and the Agreement States.

After the registration certificate is completed and the package is forwarded to the registration assistant, all correspondence between the ***NRC*** and the applicant is sent to the Document Control Desk (***DCD***). Copies of Agreement State certificates also are forwarded to ***DCD***. ***DCD*** ensures that the information is included in Nuclear Documents System and the Public Document Room.

The registration assistant distributes copies of all registration certificates to the ***NRC*** regions, all Agreement States, other Federal agencies, and international agencies. The ***NRC*** file center ensures that original ***NRC*** registration certificates are maintained in the registration folders and that a master set of copies of the certificates are maintained and easily accessible to ***IMNS***.

9.4 Inclusion in the Sealed Source and Device Computerized Registration System

Once issued, the registration certificate is added to the sealed source and device computerized registration system. The information included on the first page of the registration certificate is included in the system and certificate information can be located by searching on any item that is included in the first page of the certificate (see Section 12.2).

10 CONTENTS OF THE APPLICATION AND THE REVIEW PROCESS

Applicants requesting safety evaluations and persons who evaluate the adequacy of products must address the following items to verify sufficient information is submitted and determine whether the design of the product is adequate for its proposed uses.

Applicants are encouraged to follow the instructions in Section 6 and use Appendix C as a guideline when submitting applications. Applicants should complete the "Summary Data" section of the appendix and use the "Checklist" to ensure that they have addressed all items listed in this section. The balance of the application should be attached to the copy of the appendix. Reviewers should use the checklist to verify the applicant has addressed all items listed in this section.

It should be noted that certain regulations include specific requirements applicable to evaluation and registration of products. Section 4 lists these regulations and each regulation also is listed at the end of the applicable topic of this section. The regulatory requirements take precedence over the general guidance provided in this section. Applicants must ensure, and reviewers verify, that all regulatory requirements are met.

> The checklist is not considered an all inclusive review document. It is designed to highlight important aspects of the application. Further detail and review of specific areas of the applications may be necessary.

10.1 Summary Information

Manufacturer and Distributor

Applications must include the complete names and addresses of both the manufacturer and distributor of the product. The same person may be both the manufacturer and distributor. However, if different, the distributor should be the person applying for the evaluation. The distributor will be responsible for meeting the requirements associated with the registration, whether the information is supplied by the distributor or by the manufacturer on behalf of the distributor.

Custom User

Applications must indicate whether the product is intended for use by a custom user. The customer user needs to be identified by name and complete address. See Section 5.2 for additional information concerning custom users.

A product specifically designed and constructed to the order of a single licensee may be considered a custom product. Since there is a single user of the product, the ***NRC*** can appropriately consider specific departures from accepted standards from the point of view of compensating qualifications or conditions of use for the particular licensee. Usually, these departures occur in the areas of prototype testing and quality control (***QC***) procedures.

Other Companies Involved

The application must include the name, complete mailing address, and function of all other companies involved in the manufacture and distribution of the product.

Model Number, Sealed Source or Device Type, and Principal Use Code

The application must clearly state the model number designation for the product. This model number will be listed on the registration certificate for the product and may be listed on licenses of persons applying to use the product. The model number is used by the ***NRC*** and Agreement States to uniquely identify the product.

An applicant may request to have a model listed as a series. In order to have the model listed as a series, there should be similarities in the design and construction of the products. Applicants should provide detailed engineering drawings of each basic source or device series containing overall dimensions, maximum and minimum dimensions, tolerances, materials of construction, and differences between models in the series.

The application needs to identify the sealed source or device type as used by the industry (e.g., level gauge, radiography device, self-shielded irradiator, teletherapy unit, etc.) and the principal use code that most accurately describes the product. A listing of principal use codes is included in Appendix E. This information assists applicants and reviewers in determining the applicable regulations, codes, and standards that affect registration of the product.

The application also needs to identify whether the device is intended to be used under a specific license, general license, either a specific or general license, or by persons exempt from licensing requirements. If applicable, the applicant and reviewer need to determine which general license or exemption applies for possession and use of the product. Information needed to make this determination must be provided by the applicant. This is discussed further under Section 10.2, which discusses the conditions of use of the product.

Radionuclides Used in the Product

The applicant must identify all radionuclides that will be used in the product and include the maximum requested activity for each, including loading tolerance. The application must also include the form of the byproduct material, including contaminates or impurities, if applicable. It is not necessary for applicants to provide information on contaminates or impurities that

have little effect on the radiation levels from the sealed source or on how the sealed source will react under extreme environmental conditions.

For evaluations of devices, the applicant must identify whether the associated sealed source is currently registered. If so, the model number designation and the manufacturer or distributor of the sealed source, as listed on the registration certificate for the sealed source, must be identified.

If the sealed source is not currently registered, the sealed source must be registered separately or as part of the device. In either case, the applicant must submit sufficient information to register the sealed source and the reviewer must perform a complete evaluation of the sealed source. If the sealed source is registered as part of the device, the registration certificate for the device should note that the sealed source is not registered separately, is registered as part of the device, and is only approved for use in the device.

Leak Test Frequency

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products are required to be leak tested at intervals not to exceed 6 months. Leak test procedures must be capable of detecting the presence of 185 Bq (0.005 microcurie) of removable contamination.

Products containing only krypton-85, hydrogen-3 (tritium), radioactive gas, isotopes with half-lives of 30 days or less, beta- or gamma-emitting material of no more than 3.7 MBq (100 microcuries), or alpha-emitting material of no more than 370 kBq (10 microcuries) are exempt from periodic leak testing requirements. However, prior to initial distribution of the product, a leak test should be performed.

Devices may be approved with leak test intervals greater than 6 months if sufficient information is submitted to justify such a request. Current policy requires, for specific- or general-licensed products, the applicant to supply the information listed in ***10 CFR 32.51(b)*** or ***32.74(b)(1)*** for evaluation if a longer leak test interval is requested.

The following regulations should be referenced for additional information concerning leak testing:

Regulations	**Applicability**
10 CFR 32.51(b)	Devices used under the ***10 CFR 31.5*** general license.
10 CFR 34.27	Sources and devices designed for use in radiography operations.
10 CFR 39.35	Sources used in well logging operations.
10 CFR 36.59	Irradiator operations.
10 CFR 32.74(b)	Sources or devices for medical use.

Certification and Signature of a Management Representative

Individuals acting in a private capacity are required to date and sign the application. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application. **Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant.** As discussed previously in Section 3 "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the regulatory requirements. **The *NRC* will return all unsigned applications for proper signature**.

- It is a criminal offense to make a willful false statement or representation on applications or correspondence (18 U.S.C. 1001).
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

10.2 Conditions of Use

The applicant must identify, and the reviewer evaluate, the intended use and users of the product and which standards, policies, and regulations are applicable. Applicable standards or regulations may specify prototype testing, labeling, design, maximum external radiation levels, maximum dose commitments, ***QC*** and quality assurance (***QA***), or leak testing requirements.

The intended use of the product should include descriptions of the types of users, the locations of use, the occasions when persons will be near the device and the frequency of these occasions, and the possibility that the device may be used as a component in other products.

The applicant and reviewer must also evaluate the likely environments to which the product will be subjected during normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during use, handling, storage, and transportation (extremes experienced during accident conditions during transportation need not be considered). The applicant and reviewer need to evaluate whether the product will be subject to extreme conditions of corrosion, vibration, impact, puncture, compressive loads, explosion, flooding, poor air quality, excessive high or low temperatures, change in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

The applicant should provide the estimated working life of the product. The reviewer should evaluate the product's estimated working life to determine whether it is justified based on the information submitted. Inclusion of the working life of the product is important since registration certificates do not have expiration dates. Therefore, the working life provides an indication of when servicing or re-evaluation of a product integrity may be necessary.

10.3 Construction of the Product

Applicants need to describe construction aspects of the product including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. This should include a brief written description and summary of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets.

The brief written description and summary of the construction aspects should include the overall operation of the product, identification of primary components and safety features, type of installation including method of attachment to its mounting if installed in a fixed location and means of relocation if portable, the primary construction materials used for the product's structure and integrity and for its safety features, accessibility of the radiation beam during use, the means of providing containment, security, and shielding of the radiation source including shutters or other movable shielding, location and operation of on/off or shielded/exposed indicators, and identification of other design features that protect the product from abuse or tampering. In addition, the identification of the components of the product and safety features should include a description of each's purpose, function, and operation. An overall drawing of the product identifying primary components and safety features and indicating overall dimensions is useful as a complement to the written description of the product and for providing an understanding of the operation of the product.

Detailed design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the product's safety and integrity. This should include complete annotated engineering design and/or construction drawings of all safety critical components, specification sheets, materials lists, and/or detailed written descriptions. In particular, mounting and integrity of the radioactive material or sealed source in the product must be described in detail. Drawings of safety critical parts and components should be fully dimensioned with tolerances, include identification of the safety critical parts, indicate the materials of construction or refer to a materials specification sheet or list, indicate fabrication and assembly methods, and include a drawing number and revision date or number. Parts critical to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source. In addition, drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the product should be provided. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

All special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source need to be adequately described. In addition, accessibility of the radiation beam during use, including the size of

10.3 Construction of the Product

Applicants need to describe construction aspects of the product including components of the product, materials of construction, dimensions, assembly methods, source containment and shielding, and operation of the product and its safety features. This should include a brief written description and summary of the construction aspects as well as specific, detailed descriptive data such as engineering drawings and product specification sheets.

The brief written description and summary of the construction aspects should include the overall operation of the product, identification of primary components and safety features, type of installation including method of attachment to its mounting if installed in a fixed location and means of relocation if portable, the primary construction materials used for the product's structure and integrity and for its safety features, accessibility of the radiation beam during use, the means of providing containment, security, and shielding of the radiation source including shutters or other movable shielding, location and operation of on/off or shielded/exposed indicators, and identification of other design features that protect the product from abuse or tampering. In addition, the identification of the components of the product and safety features should include a description of each's purpose, function, and operation. An overall drawing of the product identifying primary components and safety features and indicating overall dimensions is useful as a complement to the written description of the product and for providing an understanding of the operation of the product.

Detailed design and construction data should be sufficient to allow the reviewer to fully understand the construction and operation of the product and its components and safety features and to evaluate the product's safety and integrity. This should include complete annotated engineering design and/or construction drawings of all safety critical components, specification sheets, materials lists, and/or detailed written descriptions. In particular, mounting and integrity of the radioactive material or sealed source in the product must be described in detail. Drawings of safety critical parts and components should be fully dimensioned with tolerances, include identification of the safety critical parts, indicate the materials of construction or refer to a materials specification sheet or list, indicate fabrication and assembly methods, and include a drawing number and revision date or number. Parts critical to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source. In addition, drawings and descriptions of non-safety critical components and parts that contribute to safety and/or integrity of the product should be provided. These drawings should include sufficient descriptive information to determine how the components contribute to the safety and/or integrity of the product, how the component is integrated with other components of the product, and determine if the non-safety critical components could degrade the effectiveness or usefulness of safety critical components.

All special design features that protect the product from abuse, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source need to be adequately described. In addition, accessibility of the radiation beam during use, including the size of

openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use need to be addressed.

The reviewer must evaluate how the product is constructed and evaluate its integrity. The reviewer should be able to determine the construction of the product from the drawings and written description provided with the application. During the evaluation of product integrity, the reviewer needs to ensure the following:

- The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.

- If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).

- The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation or expected conditions of use.

- The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

- The fixed shielding will not move nor easily become dislodged from the device.

- The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.

- All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source.

- The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition, if applicable.

- The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red should be used for the open condition where exposure could occur and green should be used for the closed condition where the source is "safe" in the shielded position.

- Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).

- If pneumatic or hydraulic systems are used, there are appropriate filtration, relief valves, and operating pressures.

- The operation is designed to be fail-safe, that is, loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.

- If applicable, tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing.

- If applicable, the device is hermetically sealed from foreign materials or moisture.

- Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, if applicable. In addition, void spacing should allow for any thermal expansion of the materials.

Integrity of the product does not necessarily mean the product will perform its intended uses after being subjected to an accident or unlikely use conditions. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Appendix F includes a listing of references that may be useful in determining the adequacy and integrity of the product design.

The following regulations should be referenced for additional information concerning product designs:

Regulations	**Applicability**
10 CFR 30.19(a)&(c) ***10 CFR 32.22(a)***	Devices used under the ***10 CFR 30.19*** exemption.

Regulations	Applicability
10 CFR 30.20(a), 10 CFR 32.26	Devices used under the ***10 CFR 30.20*** exemption.
10 CFR 31.5(a), 10 CFR 32.51(a)(2)	Devices used under the ***10 CFR 31.5*** general license.
10 CFR 32.53(c)&(d)	Devices used under the ***10 CFR 31.7*** general license.
10 CFR 32.61(c)&(e)	Devices used under the ***10 CFR 31.10*** general license.
10 CFR 34.20 & 34.22	Sources and devices designed for use in radiography operations.
10 CFR 39.41(a)(1)&(2)	Sources used in well logging operations.
10 CFR [illegible]1)(2)(3)&(4)	Sources used in irradiator operations.

10.4 Labeling

Applicants must provide a description of the labeling of the product, including information contained on the label, materials of construction of the label, and how and where the label is attached. The labeling should be sufficiently durable to remain legible for the useful life of the product and, for devices, should be in a readily visible location. It is recommended that applicants provide samples or copies of the labels as part of the application.

The reviewer must verify that the application includes sufficient information concerning the labeling of the product. In addition to applicable regulatory requirements, applicants and reviewers should follow the guidelines outlined below for labeling of products:

- For Devices: Model Number, Serial Number, Isotope, Activity, Distributor's Name, Date of Assay, Trefoil Symbol, and the words "CAUTION - RADIOACTIVE MATERIAL."[7] If applicable, the label should include a statement that it contains depleted uranium as shielding and include the total weight of the uranium. The label should also include limiting conditions of use or other information necessary for safe use of the product, such as servicing instructions, if applicable.

- For Sealed Sources: Should contain the same information as included on a device. However, because of its size, all of the information may not fit. Therefore, it should contain as much of the information as possible with inclusion based on the importance of the information. The applicant should provide a justification for which information will be included. Final approval of the information is left to the discretion of the

[7] The word danger may be used in lieu of the word caution.

reviewer. Below is a listing, in no particular order, of the information, with a description of why the information may be important:

- Trefoil Symbol and/or the Words "CAUTION - RADIOACTIVE MATERIAL" - This information is important if a source is found by a member of the public since it alerts the person finding the source that it contains radioactive material. The trefoil system is fairly well recognized. Therefore, for small sources where all the information may not fit, it is probably more important than the words "CAUTION - RADIOACTIVE MATERIAL."

- Serial Number - The serial number can usually be traced back to determine the original activity, isotope, date of assay, and the last known user of the source. The current activity can be calculated, given this information. However, to trace back to this information, either the vendor or the last person possessing the source must be known and be in business. The serial number may be important for sources that would be stored in large quantities. This would assist the licensee in maintaining accountability of each source.

- Distributor's Name or Logo - This may be important in trying to locate additional information concerning the source. However, if the serial number is not known or the distributor is no longer in business, this information may not be of much value.

- Model Number - The ***NRC*** includes the sealed source model numbers in its sealed source and device computerized registration system. Therefore, the ***NRC*** could identify the distributor, possible isotopes, and maximum allowable activities, given the model number.

- Isotope, Activity, Date of Assay - This information could assist trained personnel in responding to an incident involving the source. However, this information could be obtained from other information included on the source, as indicated above, or by analysis and from surveying radiation levels around the source.

The reviewer must evaluate whether the labeling is durable, will remain on the product, and will remain legible under normal use conditions through the working life of the product.

The preferred method of labeling sealed sources is engraving or laser etching the information. For devices, the preferred method is a metal label, with the information engraved or etched into the label, and the label attached to the device with screws or rivets. Other materials and methods may be acceptable depending on the likely environments in which the product will be used.

Labels must be placed so that they are easily visible to the users of a device and will remain attached to the part of the device that contains the radioactive material, that is, they are not attached to the detector housing or to a barrier or guard. The applicant may elect to have additional labels on the detector housing or on barriers or guards.

The reviewer needs to verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations. For example, devices distributed to specific licensees must not include statements concerning use of the device under a general license.

The following regulations should be reviewed for additional information concerning product labeling:

Regulations	Applicability
10 CFR 32.25(b)	Devices used under the ***10 CFR 30.19*** exemption.
10 CFR 32.29(b)	Devices used under the ***10 CFR 30.20*** exemption.
10 CFR 32.51(a)(3)	Devices used under the ***10 CFR 31.5*** general license.
10 CFR 32.54	Devices used under the ***10 CFR 31.7*** general license.
10 CFR 32.61(d)	Devices used under the ***10 CFR 31.10*** general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.
10 CFR 39.31(a)	Sources used in well logging operations.
10 CFR 32.74(a)(2)(viii) & (a)(3)	Sources and devices for medical use.

10.5 Prototype Testing

An applicant must provide information that verifies that the product design will maintain its integrity when subjected to conditions of normal use and likely accident conditions. Normal use and likely accident conditions should include those experienced during installation, use, handling, maintenance, storage, and transportation (only normal conditions during transportation need to be considered). Applicants need to determine an appropriate method to demonstrate the product's ability to maintain its integrity when subjected to conditions of normal use and likely accident conditions. This may include:

(1) Testing a prototype of the product. A prototype product must be a complete representation of the final product that includes all safety features, shielding, safety markings (if appropriate), and any accessory features or mounting that may have a detrimental effect to the safety and integrity of the product when subjected to normal or likely accident conditions. Prototypes must be constructed from the same materials

and to the same dimensions and tolerances as the final product, but may be a scale representation of the final product. Any variations of the prototype product from the final product must be analyzed for the effect to the test results the change would be expected to cause (see engineering analysis below).

(2) Performing an engineering analysis. An engineering analysis consists of a detailed, systematic analysis of the design and materials of construction of the product and the processes used in the manufacturing of the product to determine the product's ability to maintain its integrity when subjected to normal and likely accident conditions. The analysis may consist of calculations, modeling, sample testing, and evaluation. In addition, when evaluating products for which an industry standard is applicable, an engineering analysis may be used to demonstrate that the item would successfully pass the standard tests, if it were subjected to the tests. The conclusions of an engineering analysis should be fully justified with supporting documentation describing the analysis and including calculations or other applicable reference material.

(3) Operational history of the product. Operational history includes identical devices (excluding accessory equipment that has no effect on the safety or integrity of the product) used in equivalent or more severe conditions of normal use. This typically includes products used in the United States as a custom product or in another country. Operational history should include the environmental and operating conditions, numbers of cycles per year, the results of any known accident conditions, the results and root causes of any known product failures, and the years of use of the product. Operational history must be sufficient to demonstrate that the product would be expected to operate safely and maintain its integrity during the product's intended normal conditions of use. In addition, if operational history is sufficiently comprehensive, it may also be used to demonstrate product integrity for likely accident conditions. However, a product's operational history would not be sufficient to demonstrate its ability to operate safely or maintain its integrity if it has never been subjected to the extremes of expected normal use or likely accident conditions.

(4) Comparison to a similar or equivalent model previously reviewed and registered. Information concerning a similar or equivalent product may be used to demonstrate safety or integrity of the requested product, if the design of the similar or equivalent product and its intended normal and likely accident conditions of use are identical or similar to the requested product or can be related (through engineering analysis) to the requested product's conditions of use. In addition, prototype testing of the similar product may also be submitted if it can be related to the requested product. The comparison should contain the information on the similar or equivalent product including prototype testing, applicable engineering analyses, or operational history and a detailed discussion and analysis of how this information relates to the requested product. In addition, the comparison must demonstrate that the requested product's ability to operate safely and maintain its integrity is equivalent to or more robust than

the previously-approved product, or that the differences between the products are such that the integrity and safety would not be affected.

Regardless of which approach the applicant chooses to pursue, the reviewer must evaluate whether the applicant has adequately demonstrated that the product will maintain its integrity during normal use and likely accident conditions, and whether the information adequately addresses all concerns about the source or device's integrity when used in a way the applicant has defined as the normal conditions of use.

If the product is registered for use by a custom user, prototype testing may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Therefore, it may not be feasible to manufacture and test a prototype product which may not be able to be used after testing. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

Sources

Typically, for sealed sources, the ***NRC*** will only accept actual testing of a prototype unit to demonstrate integrity. This is because the sealed source is the primary containment of the radioactive material. The sealed sources should normally be tested in accordance with ***ANSI*** N542, "Sealed Radioactive Sources, Classification," or International Organization of Standardization (***ISO***) 2919, "Sealed Radioactive Sources, Classification." When reviewing the testing, the reviewer must evaluate the test methods, procedures, and conditions of the tests and acceptance criteria used by the applicant against the standard. Any variations must be evaluated.

In addition to testing in accordance with an ***ANSI*** or ***ISO*** standard, the applicant may need to perform additional testing to verify that the source will withstand the conditions of use. For example, long sources may need to be subjected to a bend test and applicants may need to verify a source design will withstand corrosive environments.

Depending on the wall thickness of a source, engraving or etching the labeling information may have a detrimental effect on the source integrity. For thin walled sources, the prototype source should include all engraved or etched labeling information prior to testing.

Devices

When evaluating a device, the reviewer must verify that the sealed source incorporated in the device has achieved the appropriate ***ANSI*** N542 or ***ISO*** 2919 classification for its intended use and be authorized for the activity to be loaded. The registration certificate for the sealed source should include its classification.

Devices should be tested in accordance with applicable industry and consensus standards. A listing of applicable standards is included in Appendix G[8]. If there is no applicable standard for a product, the applicant and reviewer, using professional judgement, need to ensure that the testing performed sufficiently simulates the conditions that may be expected during use, handling, storage, and transport of the product. The applicant and reviewer may obtain useful general guidance from a standard for a comparable source or device.

In addition to the testing recommended in the standards, the applicant and reviewer need to consider other potential use and accident conditions that may affect a particular device's integrity. Devices should be tested to demonstrate they will maintain their containment integrity and that the necessary safety features remain operable after being subjected to any conditions they are likely to experience.

The testing does not need to verify that a device will operate and perform its intended function after being subjected to accident condition testing. However, the product should still ensure the byproduct material is not dispersed, the source capsule remains within the protective source housing, and the shielding integrity is not compromised. Typically, an increase in radiation of greater than 20% constitutes a compromise of the shielding integrity.

Occasionally, an applicant may indicate that a product has been tested in accordance with a standard that has limited applicability in demonstrating that the product will perform adequately, from a radiological standpoint, during normal use and likely accident conditions. Some examples of such standards are Type 7A package testing, special form testing for sealed sources, and testing to Underwriters Laboratory standards. The reviewer should ensure that the applicant does not rely on this testing alone to demonstrate device integrity.

The following regulations should be referenced for additional information concerning prototype testing:

Regulations	**Applicability**
10 CFR 32.53(d)(4), 10 CFR 32.101	Devices used under the ***10 CFR 31.7*** general license.
10 CFR 32.61(e)(4), 10 CFR 32.103	Devices used under the ***10 CFR 31.10*** general license.
10 CFR 34.20	Source and devices designed for use in radiography operations.

[8] For copies of standards, contact the Health Physics Society, 1313 Dolley Madison Blvd, Suite 402, McLean, VA 22101.

10 CFR 39.41(a)(3)	Sources used in well logging operations.
10 CFR 36.21(a)(5)	Sources used in irradiator operations.

10.6 Radiation Profiles

The applicant should provide the maximum radiation levels around the product when it contains the maximum allowable quantity of each nuclide, or combination of nuclides. The applicant should include the maximum radiation levels on the surface of the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and levels in the radiation beam (if the beam is accessible). If applicable, radiation levels should include when the device is in the open and closed conditions and when material is present in the measuring area. Doses during transient conditions and during other conditions of use, such as during calibration, may also need to be reported. The reviewer must verify that the applicant has provided the maximum radiation levels.

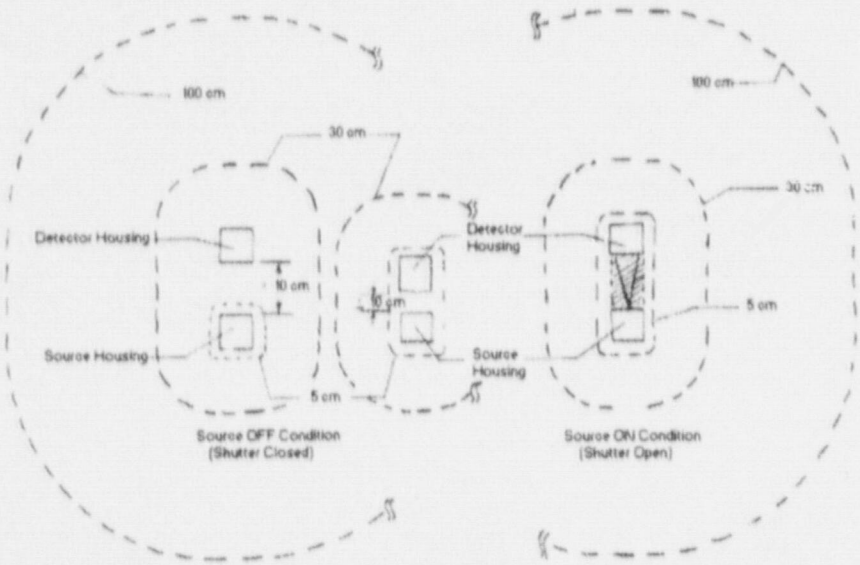


Figure 10.1 - Radiation Profiles - ANSI-538 suggest radiation profiles be provided as indicated above.

Measured radiation levels are preferable, but calculated levels also are acceptable. If the measured radiation levels are submitted, the reviewer needs to verify that the conditions under which the measurements were taken and the equipment used -- including type, window thickness, and sensitivity -- are acceptable for the nuclide and quantity included in the product. If calculated levels are submitted, the reviewer needs to verify the calculations were performed in accordance with acceptable methods or standards.

If the applicant is taking credit for external shielding or barriers or guards that restrict access to higher radiation areas, the radiation levels at, and at distances from, each barrier or guard need to be reported.

The reviewer needs to verify that radiation levels are reasonable. The levels for gamma emitters should be consistent with the inverse-square law and levels for non-gamma emitters should not. The reviewer also needs to assess whether levels that initially appear unreasonable, such as higher levels farther from the product, are possible because of scatter.

Even though 50 μSv/hr (5 mrem/hr) at 30.5 cm (12 in.) is an industry goal that has been used for many years, in general, there are no maximum external radiation level limitations for sealed sources and specifically licensed devices. Ultimately, it is the responsibility of the user to ensure the product is used in accordance with 10 ***CFR*** Part 20, (e.g., the specific licensee is responsible for ensuring that persons do not receive doses in excess of the occupational limits or limits for members of the public and that occupational exposures are ***ALARA***).

If a device is intended for use on a patient, the dose to the patient for a typical application should be provided. This will serve as a reference point in approving and licensing the product.

The following regulations should be referenced for additional information concerning radiation profiles and maximum dose commitments:

Regulations	**Applicability**
10 CFR 32.22(a)(2)(vi), (xiii), and (xiv)	Devices used under the ***10 CFR 30.19*** exemption.
10 CFR 32.26(b)(6), (13), and (14)	Devices used under the ***10 CFR 30.20*** exemption.
10 CFR 32.51(a)(2)(ii) &(iii)	Devices used under the ***10 CFR 31.5*** general license.
10 CFR 34.20 & 34.21(a)	Source and devices designed for use in radiography operations.

10.7 Quality Control and Quality Assurance

The applicant must provide details of the ***QC*** program that will be implemented to ensure that the product is manufactured and distributed in accordance with the representations made in the application, and the statements contained in the registration certificate for the product. At a minimum, the ***QC*** program needs to ensure that: (1) the materials of construction and the final assembly meet the design specifications; (2) the final product is leak tested; (3) a final radiation profile is performed; (4) a test that verifies the product operates as intended,

including all safety functions, is performed; and, (5) a visual and mechanical inspection of components that are considered critical to safety or are expected to be susceptible to failure under extreme or unusual conditions must be performed. Some of these inspections may be performed on a sample basis. The reviewer must verify that the applicant has provided adequate information concerning the ***QC*** program.

Current practice allows acceptance of the submission of a ***QA*** program in lieu of a ***QC*** program. The ***QA*** program provides control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices. This puts more emphasis on the overall management structure and on the program that covers construction of the device from the time of initial design through refurbishment. Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," provides applicants with information necessary to establish and implement a ***QA*** program that encompasses all of the ***QA*** and ***QC*** requirements necessary for the manufacture and distribution of sealed sources and devices. The guide contains sample documentation and a checklist for assessing completeness and implementation of the program. ***QA*** programs submitted by applicants are evaluated against Regulatory Guide 6.9. It should be noted that Regulatory Guide 6.9 discusses acceptance of programs meeting the requirements of other established ***QA*** standards.

If the product is registered for use by a custom user, submission of a complete ***QC*** program may not be required. This is typical in a situation where only a limited number of units will be manufactured, usually one or two. Since the purpose of a ***QC*** program is to ensure all devices are manufactured to the same specifications, development and submission of a complete program may not be feasible. Since only one licensee is using the product, additional administrative controls can be implemented by the licensee.

The following regulations should be referenced for additional information concerning quality assurance and control:

Regulations	**Applicability**
10 CFR 32.55 & 32.110	Devices used under the ***10 CFR 31.7*** general license.
10 CFR 32.61(e)(5), 32.62, & 32.110	Devices used under the ***10 CFR 31.10*** general license.

10.8 Installation, Servicing, and Instructions to Users

The applicant should provide any special procedures that need to be followed when the product is installed at the user's facility. These include verifying the integrity of the mounting, the installation of interlocks, guards or barriers, and determining whether the

installation needs to be performed by a specific licensee. General licensees may be permitted to perform installation depending on the design of the product.

In addition, the applicant needs to indicate whether other services necessary to support safe use of the products need to be performed by a specific licensee or may be performed by a general licensee. These include calibration, relocation, leak test, routine maintenance, radiation surveys, necessary training for users, changing of sources, and final disposal of the byproduct material. The applicant needs to indicate whether the applicant, or the manufacturer or distributor, will provide the necessary services or identify an entity that will provide such services. If the applicant cannot identify an entity that will provide the necessary services, the registration certificate should include this in a reviewer note. However, if the device is to be possessed and used by a general licensee, and the applicant cannot identify an entity that will provide services that cannot be performed by the general-licensed users, the device should not be registered. Reviewers should recognize that vendors or service companies may discontinue providing services. The ***NRC*** is typically notified when a vendor decides to no longer provide services.

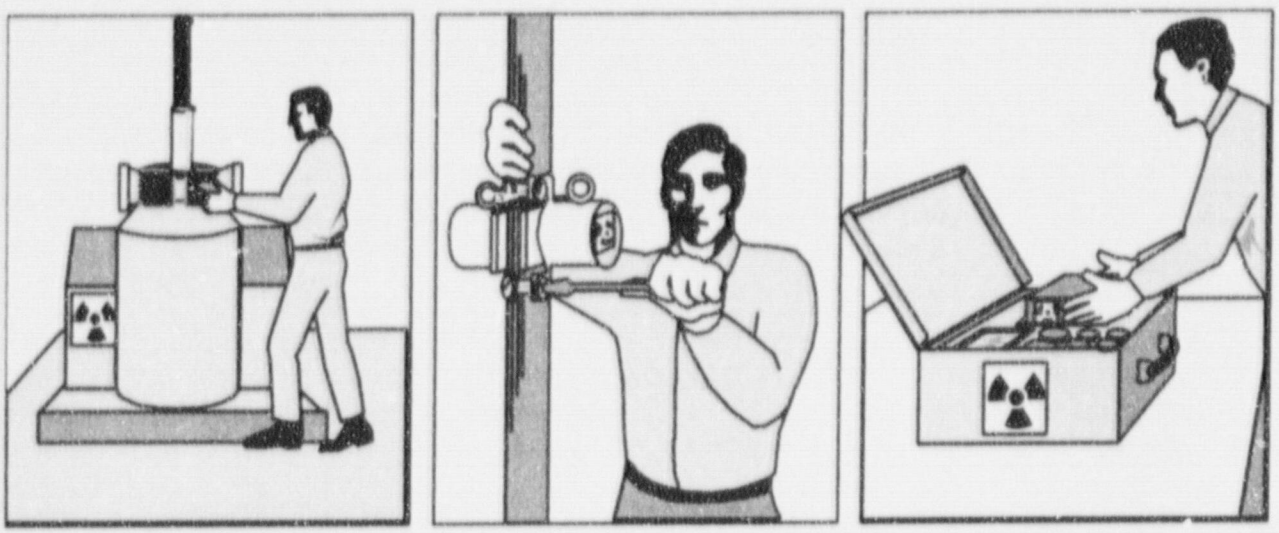
Registration certificate holders requesting to transfer a registration certificate to inactive status should identify whether they plan to continue to provide services for the registered products or whether they are aware of an entity that will provide services. See Section 13.3, "Transfers to Inactive Status"

The reviewer needs to verify that procedures for servicing the product are adequate, can be performed by the persons indicated by the applicant (e.g., by a general licensee), and do not interfere with, or compromise, the integrity of the product.

The reviewer must verify that the distributor provides the user of the product with the information necessary to safely operate and maintain the product. These include instructions for operation, maintenance, calibration, damage/failure, specific warnings, leak tests, and radiation surveys. The distributor should also provide information to the user concerning who may provide services for the product. For devices distributed to general licensees, the distributor needs to provide copies of regulations governing use and transportation of the product and a listing of regulatory authorities who license possession and use of the product.

To assist the reviewer in determining whether certain activities may be performed by general licensees, the applicant must provide an estimate of the dose to a worker for each activity to be performed.

The reviewer needs to verify that the documentation provided to users of the products does not misinterpret, misrepresent, or lead the user into violating any applicable regulations.



62-pt4-9268-401c
080597

Figure 10.2 - Installation and Servicing of Devices - Applicants must specify the qualifications needed by individuals to perform installation and servicing of devices.

The following regulations should be referenced for additional information concerning servicing:

Regulations	Applicability
10 CFR 32.51(b) & (c)	Devices used under the *10 CFR 31.5* general license.

10.9 Final Evaluation and Concurrence

Once the reviewer has evaluated all necessary information and has determined that the product is acceptable for licensing purposes, the information will be passed to a second reviewer to perform an independent technical evaluation. The second reviewer must independently arrive at the same finding as the initial reviewer. Any discrepancies between reviewers must be resolved before the registration certificate can be issued. Once both reviewers concur in the findings in the document, they will sign the certificate.

Typically, the initial reviewer will generate a draft registration certificate for evaluation by the second reviewer. The second reviewer will evaluate both the application and the draft registration certificate to ensure accuracy and completeness.

11 DEFICIENCIES IN THE APPLICATION

In the process of evaluating an application, a reviewer may determine that insufficient information has been submitted. If this is the case, the reviewer must contact the applicant to obtain the information. Depending on the type of information needed, the reviewer may obtain the information by sending a formal written request to the applicant, requesting a meeting with applicant, notifying the applicant of the need for information via telephone or electronic mail, or obtaining the information directly from the applicant during a telephone conversation or via electronic mail.

Because of the need to complete the application reviews in a timely manner, the reviewer should do the following when addressing deficiencies in applications:

11.1 Sending Deficiency Letters to Applicants

Any significant or complex deficiencies in an application for an evaluation must be set forth in a formal deficiency letter to the applicant. The letter should request that the response be provided in duplicate. The letter to the applicant should request that the applicant respond within a specified number of days from the date of the deficiency letter. The number of days is typically 30 to 60 days but depends on the complexity of the information and the level of effort needed by the applicant to respond (e.g., extra time may be needed to perform prototype testing on a product).

If a written response[9] to the deficiency letter is received within 5 working days after the date requested in the deficiency letter, the reviewer will proceed with review of the response.

If a written response to the deficiency letter is not received within 5 working days after the date requested in the deficiency letter, the reviewer should send a second letter to applicant. The second letter should notify the applicant that unless a response to the first letter is received within 30 calendar days from the date of the second letter, the reviewer will consider the application as "abandoned"[10] for failure to provide the requested information "without prejudice" to the resubmission of a complete application. Prompt action (5 working days) should be taken to "void" the application after the application has been considered as "abandoned." The application will be held in a "void file."

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[9] A written response may be either a letter or a fax from the applicant.

[10] "Abandoned" is not meant to have legal connotations. It means simply that the applicant for a new license or for an amendment to an existing license has given up its pursuit of the license or amendment. "Without prejudice" is not meant to be understood in a legal sense. This means that the applicant can resurrect its application within some reasonable time without having to pay another fee, having its application redocketed, etc. "Void" should not be thought of in its legal sense. It means here that the application is, in practical effect, nullified.

If a response to the deficiency letter is received after the application has been voided and the response is received not more than 1 year from the date of the letter, the application should be assigned a new tracking number and handled as a new application. However, no additional fee may be necessary if it is a continuation of the evaluation. Higher priority will not be assigned solely based on the fact the application is a resubmission.

11.2 Meetings with Applicants

NRC or applicants may request meetings to discuss sealed source and device applications. The meetings may be prior to submission of an application or to discuss items included in a deficiency letter. Meetings between NRC and applicants may be at an NRC office, or at the applicant's facility if it is determined that it would enhance NRC's understanding of the product.

11.3 Use of the Telephone or Electronic Mail to Obtain Additional Information

There is no prohibition on using the telephone or electronic mail for obtaining clarifying information from an applicant. These mechanisms may be used to notify an applicant of simple deficiencies, to accelerate the review process.

Use of the telephone or electronic mail for notifying an applicant of deficiencies must be limited to items that are simple and such that they can be specified simply. Simple items include a model number for a sealed source, need for a applicant commitment to perform a procedure, or clarification of a material type or a dimension.

If the deficiency is a clarification of information provided in the application, it may not be necessary to have the applicant respond in writing. This decision is left to the discretion of the reviewer. However, the applicant's response, either via telephone or electronic mail, must be documented and included as part of the application.

In all cases, the telephone conversation or electronic mail transmitting deficiencies to an applicant must be documented by the person initiating the telephone call. If the applicant does not respond within 15 calendar days, a confirmatory letter must be sent to the applicant. The confirmatory letter must clearly specify the deficiencies and be handled as a typical deficiency letter with the exception that it includes a statement that the information needs to be received within a specified time frame or the application will be voided.

11.4 Response Time Extensions

A request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. The request may be in writing or via the telephone. Typically, the reviewer responds by telephone to notify the applicant that an extension has been granted. All requests for extensions must be approved by Management and must be documented in a conversation record.

12 CONTENTS OF THE CERTIFICATE

Registration certificates are written in a standard format. This allows license reviewers and inspectors to quickly retrieve information necessary to perform a license review, perform a site inspection, or respond to incidents involving lost, damaged, and/or abandoned sealed sources or devices.

The registration certificate is a summary of the technical evaluation of the product. It contains summaries of the areas examined during the evaluation process. Appendix H includes standard formats for registration certificates for a sealed source, for a device, and for an exempt device. Further clarification of the information that is included in a registration certificate is listed below.

12.1 Header

The header includes the title of the document, the registration number, date of issuance, page numbering, and the sealed source or device type. If the certificate is amended or corrected, this is indicated in the title; the page number of each corrected page(s) needs to be listed or the header notes that the certificate is amended in its entirety. The registration number is assigned by the reviewer, in accordance with the numbering procedures in Appendix I. The issue date is the date the certificate has received both reviewer and concurrence signatures.

12.2 First Page Information

The first page of each certificate includes the name and complete address of the manufacturer and distributor, the model number of the sealed source or device, the manufacturer or distributor and model number for the sealed source incorporated in the device, isotopes, maximum allowable activity levels, leak test frequency, principal uses (including code and description), and an indication of whether the registered product is designed for custom use. If registered for custom use, the name and address of the custom user is included. This information is entered into the ***NRC*** maintained computerized registry of sealed sources and devices.

The following subsections are included in the order listed below starting on the second page of the certificate.

12.3 Description

This section provides a narrative description of the construction of the product, safety features of the product, and ON/OFF and safety indicators. The description should include the materials of construction and fabrication techniques for critical safety components of the product. These typically include source encapsulation materials, source holder materials, shutter mechanisms, welding process, and device security features, such as tamper resistant fasteners, locks, etc. Overall dimensions of the sealed source and the device are also included.

Certificates for sealed sources include the chemical and physical forms of the source material. Certificates for devices describe how the sealed source is secured within the device and how the product is protected from its intended environment (e.g., hermetically sealed, fire-proof, corrosion-resistant, etc.).

12.4 Labeling

This section describes how the labeling requirements are fulfilled. It lists the information that can be found on the label, construction of the label, and how and where the labeling is attached to the product. Any exemptions from labeling requirements or omissions of information typically included on the labels will be noted.

12.5 Diagrams

This section lists the diagrams, drawings, sketches, or pictures of the product that are included in the certificate. These are typically included as attachments to the certificate and should include overall dimensions of the product, the location of the sealed source within the device, and the safety related features of the product. A person using the certificate, such as an inspector or license reviewer, should be able to identify a device given the diagrams and the description from the certificate.

12.6 Conditions of Normal Use

This section lists the environmental conditions the product is intended to withstand. The normal intended uses of the product and any limitations that define these uses are included in this section. The working life is also included.

12.7 Prototype Testing

This section describes tests performed on prototypes of the product to demonstrate it will maintain its integrity. If the product was tested in accordance with an applicable industry or consensus standard, the corresponding classification, as defined by the standard, should be stated in this section. If the product was tested in accordance with an applicable regulation, this section specifies whether the product satisfactorily met the requirements of the regulation.

If, in lieu of prototype testing a product, an applicant submitted operational history of the product or a similar product or provided an engineering analysis that demonstrates that the product is adequately designed, this section will provide the details of the operational history or analysis and the basis for determining the design to be adequate.

12.8 External Radiation Levels

This section states the maximum radiation levels from the product when loaded with the maximum activity of each nuclide or combination of nuclides. If the manufacturer is unable to provide measured external radiation levels for the product, a conservatively calculated maximum radiation profile is listed. If applicable, the radiation profiles are listed for shutter open and closed conditions. The stated levels are the maximum radiation levels expected from the product and take into consideration factors affecting the levels, such as whether product is present in the measuring area or whether certain areas around the device are restricted from access. Any significant contaminants that would change the expected radiation levels are stated. Ideally, the radiation levels listed in this section will include the levels on contact with the product, at 5, 30, and 100 cm (2.0, 11.8, and 39.4 in.) from the product, and in the beam.

Should there be a device containing a number of isotopes and designed with a range of dimensions, a distributor may commit to ensuring that the radiation levels do not exceed a specified level. If this is the situation, the certificate needs to include the maximum allowable radiation level and include limitations concerning the installation of the device.

12.9 Quality Assurance and Control

This section includes a summary of the ***QC*** procedures that will be followed to ensure the product meets all applicable specifications. If the ***QC*** procedures meet a national or industry standard or regulation, it is specified in this section. In lieu of submitting ***QC*** procedures, an applicant may commit to following a ***QA*** program. Again, if the ***QA*** program meets a national or industry standard or regulation, it is specified in this section. If the applicant commits to following a complete ***QC*** or ***QA*** program, a short summary of the program may be included and this section should reference that details of the complete program are on file with the ***NRC***. The section also contains a statement reflecting that the ***QC*** or ***QA*** program has been assessed and deemed acceptable by the ***NRC***.

12.10 Limitations and Other Considerations of Use

This section establishes the limiting conditions imposed on the sealed source or device. These include leak testing, handling, storage, use, transfer, disposal, environmental conditions, labeling, special handling procedures and tools, and specific licensing conditions that should be addressed by the license reviewer. This section needs to clearly indicate the services that may be performed by general-licensed users of the products, state that sources or devices should not be subjected to environments that exceed their ***ANSI*** or ***ISO*** classifications, and state that if subjected to such environments, the licensee must discontinue use of the source or device until a demonstration that no affect to the source or device integrity has occurred as a result of operation outside the specified range. It also includes a limitation that states that the registration certificate and the information contained within the references shall not be changed without the written authorization of the ***NRC***.

Limitations on sealed sources and devices can be divided into two categories, the first being limitations placed on the manufacturer or distributor of the sealed source or device and the second being limitations placed on the user of the sealed source or device. Limitations of the first category are derived from regulations. In addition to regulations, the second category of limitations is also derived from conditions imposed by the manufacturer, by particular conditions of use that would reduce the radiation safety of the device, and by circumstances unique to the sealed source or device, which require that the sealed source or device receive a special limitation.

In addition, this section of the certificate may contain reviewer notes. The purpose of such notes is to identify to license reviewers areas of use of the product that cannot be controlled as part of the registration. This alerts the license reviewer to verify that the licensee implements certain administrative procedures before initial use, as part of routine use, or as part of an emergency response to an incident. For example, indicating in a reviewer note that a vendor no longer offers servicing for the product alerts the license reviewer to obtain more than a statement that services will be provided by the vendor.

12.11 Safety Analysis Summary

This section summarizes the conclusion of the evaluation performed by the reviewer and states that the product is acceptable for certain licensing conditions. Also, typically listed in this section are any additional features that the device, surroundings, environment, or accessories may contribute to the integrity or safety of the product. These may include physical constraints such as barriers, fences, or guards and actual use time in terms of radiation exposure resulting from working around the product.

12.12 References

This section incorporates by reference the documents that were submitted in support of the application. These references include applications, letters, faxes, electronic mail messages, and enclosures to such documents. The applicant is required to adhere to the information and commitments included in these references.

12.13 Issuing Agency

This section identifies the *NRC* as the regulatory agency that issued the certificate and includes the date issued and the typed names and signatures of the two persons who reviewed the certificate and all applicable documentation. All certificates include two signatures as part of the quality control measures.

12.14 Attachments

This section typically contains diagrams, drawings, sketches, or pictures of the product, as discussed previously in Section 12.5. These provide inspectors a tool by which they can easily identify the devices in the field. The attachments also may contain designations of specific models and their characteristics, such as dimensions and sealed source activities, if a series of devices are registered.

The header for the attachments is similar to that for the main body of the registration certificate. The header contains the title of the document, registration number, date of issuance, and attachment numbering. The header does not contain the sealed source or device type.

12.15 Dimensions and Use of Dual Units

The *NRC*'s Metrication Policy (*57 FR 46202*) requires that documents specific to a registration certificate holder, such as the registration certificate, include dimensions in the units employed by the registration certificate holder. In addition to including the units employed by the registration certificate holder, it is recommended that registration certificates include dual-units as specified below:

- All measurements should be stated in the units employed by the registration certificate holder, followed by the appropriate English or International System of Units conversion in parentheses.

- All measurements not provided by the applicant should be specified in English units, followed by the converted International System of Units value.

- The method of stating measurements for a specified property should be consistent throughout the document. If the measurement of the property is first stated in International System of Units, with the English conversion in parentheses, then all other measurements should be stated in International System of Units, with the English conversion in parentheses.

- If a value is being restated (i.e., the measurement is included in a table, was already stated in the same section of the document, or was included on the first page of the document (such as the maximum activity)), the restated measurement need not have the conversion following it since the conversion has already been included in the document.

13 MODIFICATIONS TO EXISTING REGISTRATION CERTIFICATES

It is the obligation of the registration certificate holder to keep the registration certificate current. If a registration certificate holder plans to make a change to the registered product that affects the commitments made in the information provided in support of the application or the conditions included in the registration certificate, the registration certificate holder must file for an amendment or correction to the registration certificate. Until the amendment request is approved and the amended certificate is issued, the registration certificate holder is obliged to comply with the information in the certificate. Registration certificate holders are encouraged to anticipate the need for certificate amendments as far in advance as possible.

An application to amend a certificate should be prepared in triplicate. The registration certificate holder should retain one copy for their records and submit the original and one additional copy to the address specified in Section 7. The application should identify the registration certificate by number and should clearly describe the changes and the effects of the changes on the safety properties of the product. References to previously submitted information should be clear and specific and should identify that information by date, document title, and page number.

An application to amend a certificate should be accompanied by the appropriate fee (Section 8) and, for medical products, the registration certificate holder needs to notify ***FDA*** about the proposed changes to the product.

The request for an amendment or correction needs to address the changes to the product and how the changes affect the original safety evaluation of the product. The reviewer needs to evaluate the changes to determine if they have any adverse effects on the safety of the product and whether the initial evaluation and the determination of adequacy are still valid. The reviewer needs to look at all aspects of the initial evaluation to determine if the change would have an effect on another aspect of the evaluation that may not be readily evident. For example, changing a part of the source holder from stainless steel to lead may improve the shielding efficiency, but may have detrimental effects on how the device will react to accident conditions. This type of detrimental effect may have been overlooked by the manufacturer.

13.1 Amendments

If the registration certificate holder requests an amendment to the certificate (i.e., it requires a safety evaluation to be performed), the certificate should be amended in its entirety. The certificate header should include, under the title, the following:

(AMENDED IN ITS ENTIRETY)

The certificate should be assigned a new issue date and the certificate should be re-issued in its entirety. When possible, the reviewer should use bold type face to highlight the changes that have been made to the certificate.

13.2 Corrections

If the change only involves corrections to the certificate (i.e, does not require a safety evaluation to be performed such as change in address or error identified in the certificate), then only the affected pages of the certificate need to be updated and issued. The reviewer should use bold type face to make the corrections. Each affected page should include, in the header, under the title, the words "CORRECTED PAGES," the number of each page affected, and the date of the correction. An example of this format is shown below:

(CORRECTED PAGES 1, 2, & 4 - JULY 5, 1776)

The issue date of the certificate should remain the same as the last issue date. It is not necessary to include the letter from the registration certificate holder in the reference section of the certificate.

If the correction requires a change to the signature page of the certificate, the certificate should be amended in its entirety. The reviewer may elect to hold off making corrections to the signature page until the registration certificate holder requests an amendment, requiring a safety evaluation, to the certificate.

13.3 Combining Registration Certificates

Registration certificate holders may request that ***NRC*** combine two or more certificates into a single certificate. However, it is ***IMNS*** policy that only products which are essentially identical in design, function, construction, and which vary only in a dimensional capacity, in the sources used or in their application, may be grouped together on a single registration certificate.

Combining registration certificates does not require a safety evaluation. However, the reviewer must determine whether the request meets ***IMNS*** policy and can administratively combine the registration certificates.

13.4 Transfers to Inactive Status

If a registration certificate holder requests that a registration certificate be transferred to inactive status[11], the registration certificate holder should provide: (1) the total number of the products sold; the number of products still in use[12]; (2) the services (including source replacement and availability) the registration certificate holder will still provide to users of the product or the identification of an entity that will provide services; (3) a commitment that the registration

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[11] NRC also will transfer a registration certificate to inactive status if it knows the registration certificate holder is out of business.

[12] The actual number of products sold and still in use may not be known by the registration certificate holder. However, the registration certificate holder should still provide a best estimate.

certificate holder will no longer commercially distribute the product; and, (4) verification that no changes were made to the product since its initial registration or last amendment. The reviewer must verify that the above information is included and that the background file for the product evaluation is complete and accurate. Because some registrations were issued many years ago, the files may not include all the information that is now required. Therefore, the reviewer should request that the registration certificate holder submit any and all additional information that would be needed to make a determination that the product is acceptable for licensing purposes. The reviewer needs to write an updated registration certificate, including the new registration number (see Appendix I for issuance of inactive registration certificate numbers) and updated information. The new certificate will contain a statement that the product will no longer be commercially distributed but may still be approved for licensing purposes. The registration certificate will replace the old registration certificate and will be used as the basis for continued licensing of the product.

13.5 Re-Activating Inactive Registration Certificates

Vendors may submit requests to re-activate inactive registration certificates. Requests to re-activate inactive registration certificates are handled in one of the two methods:

1. If the background information on file with the NRC for the inactive registration certificate is complete, up-to-date, and the vendor does not request any changes to the information, the vendor may simply submit a letter to the NRC requesting re-activation of the registration certificate. The letter must include commitments that the information on file with the NRC is complete and accurate and that the vendor commits to abide by all information on file with the NRC. The reviewer must verify the information is complete prior to assigning a new registration certificate number and re-issuing the certificate.

2. If the background information on file with the NRC for the inactive registration certificate is incomplete, not up-to-date, or the vendor requests changes to the information (e.g., changes in the design of the product or manufacturing or distribution procedures), the vendor must submit a complete application for evaluation and registration in accordance with this document. The reviewer must review and evaluate the application in the same manner as a new application.

14 IDENTIFYING AND REPORTING DEFECTS AND NONCOMPLIANCE AS REQUIRED BY 10 *CFR* PART 21

Registration certificate holders are required to adopt appropriate procedures to evaluate deviations in product designs or failures to comply with registration requirements to identify defects or failures to comply that are associated with a substantial safety hazard. A substantial safety hazard is defined in Part 21 as a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72. However, ***NRC Information Notice 91-39***: "Compliance with 10 ***CFR*** Part 21, Reporting of Defects and Noncompliance" (available from the ***NRC*** upon request) indicates that from a radiological perspective, a substantial radiation safety hazard exists if there is a potential for a moderate exposure to, or release of, licensed material. Further, it provides the following for determining moderate exposure or release of licensed material:

- Guidelines for determining moderate exposure:
  - Greater than 250 mSv (25 rem) exposure (whole body or its equivalent to other body parts) to occupationally exposed workers in a period of a year or less.
  - Greater than 5 mSv (0.5 rem) exposure (whole body or its equivalent to other body parts) to an individual in an unrestricted area in a period of a year or less.
- Guidelines for determining potential for release of licensed material:
  - Release of materials in amounts reportable under the provisions of ***10 CFR 20.2202(b)(2)***.

All defects or failures to comply that are associated with, or could lead to, a substantial safety hazard must be reported to the ***NRC*** pursuant to ***10 CFR 21.21.*** In addition, registration certificate holders are required to meet the posting requirements specified in ***10 CFR 21.6***.

Applicants are not required to submit copies of the procedures that are necessary to meet the requirements of 10 ***CFR*** Part 21. However, applicants need to be aware of the need for such procedures and the ***NRC*** will evaluate the procedures during inspections.

15 GLOSSARY

Active Registration Certificate means a registration certificate for a sealed source or device that may be authorized for initial distribution. It constitutes part of the basis for the ***NRC*** and Agreement States to issue licenses.

Active Vendor means a vendor, listed on a registration certificate, that may be authorized to initially distribute the sealed source or device listed on the registration certificate.

Agreement State means a State that has entered into an agreement with the ***NRC*** allowing the State to regulate the use of byproduct material within the State. A complete listing of the current Agreement States, including addresses and points of contacts, can be obtained from ***OSP***.

Agreement State Registration Certificate means a registration certificate, issued and maintained by an Agreement State, for a sealed source or device evaluated by the Agreement State.

Applicant means a vendor or custom user of a product that applies for a certificate of registration with the ***NRC*** or an Agreement State. The applicant is responsible for ensuring the information provided in the application is complete and accurate.

Associated Equipment is equipment that is used in conjunction with a device and directly effects the safe use of the device or ensures the device maintains its integrity (e.g., parts that move a source, control the shielding of a source, control the radiation levels around a device, come in contact with the source). Associated equipment supplied by the vendor of the device should be evaluated and registered as part of a device. If the associated equipment is supplied by another vendor, the evaluation and registration should be handled the same as a device evaluation and a separate registration certificate should be issued for the equipment.

Custom User means a licensee that uses a product that is manufactured in accordance with the unique specifications of, and for use by, a single applicant. Typically, no more than two different ***NRC*** or Agreement State licensees may be custom users of, and may register, the same product. However, a custom user may acquire and/or use more than one product.

Inactive Registration Certificate means a registration certificate for a sealed source or device that may have been authorized for distribution at one time but no longer may be authorized for initial distribution. Unless otherwise stated in the registration certificate, the sealed source or device included on an inactive registration certificate still may be authorized for use and may continue to be licensed. The vendor listed on the registration certificate may be authorized to provide service and replacement parts for the sealed source or device and may be authorized to receive the sealed source or device from a user for disposal or redistribution to a licensee. However, the design of the sealed source or device cannot be changed.

The ***NRC*** and the Agreement States may continue to issue licenses to persons to use sealed sources or devices that are included on an inactive registration certificate. This typically would occur during renewal of a license. However, the fact that the registration certificate is inactive

serves to alert the license reviewer that the user may not be able to find a firm to service the device or may not be able to find replacement parts. The license reviewer must ensure that emergency procedures, operational support, and services are still applicable.

Inactive Vendor means a vendor who no longer may be authorized to initially distribute the sealed source or device listed on a registration certificate but may be authorized to provide services for the sealed source or device.

NARM stands for Naturally occurring or Accelerator-produced Radioactive Material. This material is not subject to regulation by the ***NRC*** but is regulated by the States. ***FDA*** Center for Devices and Radiological Health assists States in their review and regulatory approval for distribution of devices containing ***NARM***.

Product means any sealed source, device, or associated equipment registered with the ***NRC*** or an Agreement State.

Registration Certificate Holder means a vendor or custom user of a product that holds a certificate of registration with the ***NRC*** or an Agreement State. The registration certificate holder is responsible for ensuring the information in the registration certificate is current and correct and for ensuring products manufactured or distributed conform with the conditions of the certificate.

Vendor means any person, licensed or unlicensed, who manufactures or distributes products.

Working Life means the time period when the product is expected to maintain its integrity. The working life should is based on the radiotoxicity, total activity, product construction, normal operating environments, likely abnormal conditions, fatigue, and wear.

APPENDIX A

MEMORANDA BETWEEN C. PAPERIELLO AND S. TREBY REGARDING LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

Appendix A: Memoranda between C. Paperiello and S. Treby Regarding Licensing of Sealed Sources and Devices Evaluated and Registered by Agreement States

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001
SEP 30 1993

MEMORANDUM FOR: Stuart A. Treby
Assistant General Counsel
for Rulemaking and Fuel Cycle
Office of the General Counsel

FROM: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: LICENSING OF SEALED SOURCES AND DEVICES EVALUATED AND REGISTERED BY AGREEMENT STATES

The purpose of this memorandum is to ensure that OGC has no legal objection to the actions we plan to take with respect to registration certificates issued by Agreement States and to request that OGC provide answers to two specific questions concerning Agreement State licensees using sealed sources or devices under reciprocity. We are providing the following background information to assist you in making your determination and answering the questions.

The Atomic Energy Commission, and now NRC, staff has evaluated sealed source and device designs from a health and safety standpoint since the mid 1950's. Although the extent of the review was shifted from a health physics point of view to an engineering based evaluation, the process has remained intact. Once the product is found to be acceptable for licensing purposes, a registration certificate is prepared and issued for the product. This practice was conducted under the general provisions of 10 CFR 30.33, which states that an application for a specific license will be approved if, among other things, "the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property."

With respect to certain equipment, applicants for specific licenses frequently describe the equipment by referring to data already filed with the NRC by the equipment manufacturer. This practice is administratively convenient to the NRC, Agreement States, manufacturers of equipment, and applicants for licenses to use the equipment because it eliminates performing redundant evaluations and simplifies paperwork. A single submission by a manufacturer is evaluated by the NRC, or an Agreement State, and the results of the evaluation are used in the NRC's or Agreement States' review of multiple applications for specific licenses as the basis for approval. This practice is provided for under the general provisions of 10 CFR 30.32(a) which states, in part, that "Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific."

In 1982 a new management control system for sealed source and device evaluations was implemented. This system established the current standard format for registration certificates, established the classification of active or inactive for vendors and products, and automated the search and retrieval

of certain information about the sealed source and device. At that time, NRC undertook the task of maintaining a national registry of all registration certificates for sealed sources and devices.

In 1985 the states requested that NRC incorporate the Radioactive Material Reference Manual(RMRM) into the national registry as a service to the States. The RMRM contains evaluation information on naturally occurring or accelerator produced radioactive material (NARM). NRC had no objection to this merger provided that a disclaimer was added to the RMRM certificates that clearly denoted that NRC has no authority to regulate NARM. Approximately 500 RMRM evaluation certificates have been entered into the national registry.

In 1987, 10 CFR 30.32(g) and 10 CFR 32.210 were added to codify the existing administrative practice for performing "pre-marketing" evaluations and registrations of radiation safety information on certain sealed sources and devices. 10 CFR 30.32(g) clarifies that an application for a specific license to use a sealed source or device reference a registration certificate issued by NRC or an Agreement State. 10 CFR 32.210 describes the NRC criteria for approving sealed source and device designs and clarifies the regulatory responsibility of manufacturers of products registered with the NRC. These rules provide some assurances that safety evaluations are performed uniformly. Although these were not made a matter of compatibility with the States, the States do recognize the advantages of participating in performing the evaluations and recognizing registrations issued by NRC or other States.

As part of maintaining the national registry of registration certificates, the NRC provides the Agreement States copies of the registration certificates they have issued and the State provide copies of the registration certificates they have issued to the NRC. Thus, when a manufacturer or distributor of products within either an Agreement State's or NRC's regulatory jurisdiction provides detailed information about its sealed source or device to its regulatory agency for registration, the registration certificate is available to the Agreement States and NRC for use in granting licensing approval to users of the source or device throughout the United States, its territories and possessions, and in Puerto Rico.

When a registration issued by an Agreement State is forwarded to OSP, OSP is responsible for performing a review of the certificate. In some cases the sealed sources or devices cannot be licensed by NRC. The same source or device may be licensed by an Agreement State due to differences between NRC and Agreement State regulations.

Based on the above discussion, we plan to do the following:

1. Continue to incorporate NARM certificates into the national registry after the Office of State Programs (OSP) has reviewed the certificate and added the disclaimer that the material covered by the certificate is not regulated by NRC.

2. Continue to incorporate registration certificates for sources and devices containing byproduct material for use only within the Agreement State into the national registry after OSP has reviewed the certificate. An example of these types of certificates are those which specify the source or device is only approved for use by a custom user.

3. Incorporate registration certificates for sources or devices which NRC believes may not provide an adequate level of safety or are prohibited for use by certain provisions of NRC regulations into the national registry with a cover letter indicating why the source or device is not approved for use by NRC licensees. NRC will then address the safety issues with the State which issued the certificate.

   We believe this action is necessary to: (1) ensure that NRC license reviewers are aware of NRC concerns with the certificate. If the certificates and cover letters are not included an NRC license reviewer may receive a copy of the certificate directly from the applicant or Agreement State and assume the registration was accepted by NRC but the registry had not been updated to include the registration; and (2) provide other Agreement States with the information necessary to determine whether a license to use the source or device should be approved.

If OGC has no legal objection to the actions listed above, we request that OGC provide answers to the following questions:

1. Can an Agreement State licensee use a sealed source or device under the general license provided in 10 CFR 150.20(a) if the NRC has determined the source or device is not acceptable for licensing purposes for either of the reasons provided in item 3 above? It would appear the use of some sources or devices would be authorized as long as the licensee's activities comply with the provisions specified in 10 CFR 150.20(b). If OGC agrees, 150.20(a) could allow Agreement State licensees to perform activities which NRC does not authorize within NRC jurisdiction. An example of this is an Agreement State licensee could perform, in NRC jurisdiction, certain mobile nuclear services which are prohibited under 10 CFR 35.29. This appears to be authorized since 10 CFR Part 35 is not listed in 150.20(b) as a condition of the general license and parts of 10 CFR Part 35 were not a matter of compatibility with the Agreement States.

2. If OGC determines that an Agreement State licensee can use a sealed source or device under the general license provided in 10 CFR 150.20(a), what actions can NRC take to prohibit the use of a source or device that NRC has determined is not acceptable for licensing purposes under the general license? Based on the case involving Wrangler Laboratories, a general licensee, and the case involving the 3M static eliminator problem it is not clear that a general license can be revoked or suspended to an individual without rulemaking.

Please address your response to this memorandum to Steven Baggett of my staff at 504-2689, mailstop OWFN 6H3.

Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

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

December 23, 1993

MEMORANDUM FOR: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle
Office of the General Counsel

SUBJECT: LICENSING OF SEALED SOURCES AND DEVICES
EVALUATED AND REGISTERED BY AGREEMENT STATES

In your memorandum dated September 30, 1993, you requested our views on two specific questions related to the approval and registration of sealed sources or devices by Agreement States, and their subsequent usage by Agreement State licensees under the reciprocity provisions of 10 CFR Part 150. For the reasons discussed below, the Agreement State licensee is not authorized to carry out activities in non-Agreement States, if NRC licensees are barred by NRC regulations from conducting such activities.

Question 1: Can an Agreement State licensee use a sealed source or device under the general license provided in 10 CFR 150.20(a) if the NRC has determined the source or device is not acceptable for licensing purposes because: (a) the NRC believes the source or device does not provide an adequate level of safety; or (b) NRC regulations prohibit the use of such source or device?

Response: From our reading of the regulations, sources licensed by an Agreement State, and prohibited by NRC regulations, are not authorized for use in a non-Agreement State. The example that you cite, certain mobile nuclear services prohibited under 10 CFR 35.29, is invalid.

The provisions of 10 CFR 150.20 are clear, "Notwithstanding any provision to the contrary in any specific license issued by an Agreement State ..., the general licenses provided in this section are subject to the provisions of ... 30.34, ..." 10 CFR 30.34, "Terms and conditions of licenses," specifically sets forth in subsection (a): "Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 35 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission." This catchall provision has the effect of

capturing the prohibitions of 10 CFR 35.29. The intent of the Commission in promulgating the reciprocity provisions in 1962 was to allow a valid Agreement State licensee the privilege to conduct licensed activities in non-Agreement States under a Federal general license, and subject to licensee compliance with NRC regulations.[1] Thus, Agreement State licensees are not authorized to conduct activities in non-Agreement States, unless such activities are also authorized by the NRC.[2]

Question 2: If OGC determines that an Agreement State licensee can use a sealed source or device under the general license provide in 10 CFR 150.20(a), what actions can NRC take to prohibit the use of a source or device that NRC has determined is not acceptable for licensing purposes under the general license?

Response: Based on our response to question 1, this situation should not arise. If an NRC licensee is barred from carrying out certain activities, an Agreement State licensee would also be barred from carrying out identical activities under an Agreement State license in the non-Agreement State.

The question remaining involves the activities of Agreement State licensees in Agreement States. If the NRC has reason to believe a safety issue exists with respect to a particular source or device, then the use of the source or device can clearly be banned in non-Agreement States via the reciprocity provisions of Part 150. With respect to activities in the Agreement States, we would believe that consultation by NRC staff with the Agreement States in question might resolve the issue; i.e., the Agreement States would agree to ban the source or device. If consultation with the Agreement States proved insufficient to resolve the issue, the NRC can take steps, pursuant to Section 274j of the Atomic Energy Act of 1954, as amended, to suspend all or part of the Agreement State

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[1] See 27 Fed. Reg. 1351, Statement of Considerations for 10 CFR Part 150 rulemaking, "Exemptions and Continued Regulatory Authority in Agreement States Under Section 274."

[2] 10 CFR Part 150 does not explicitly set forth every specific NRC regulation. However, 10 CFR 30.34 has the effect of capturing those requirements not specifically alluded to in 10 CFR 150.20(b), which should be included as terms and conditions of the specific Agreement State licenses operating in non-Agreement States. It should also be noted that this "capture" provision does not serve to bring in every omitted NRC regulation in Part 150. For example, 10 CFR 30.33 on "General Requirements for Issuance of Specific Licenses," would not be relevant. The corresponding sections of Parts 40 and 70 (Sections 40.41 and 70.32) are also referenced in 10 CFR 150.20(b) as applicable to Agreement State licensees.

program, with or without notice to the State, depending on whether an emergency situation was present.

Finally, we have no legal objection to the actions you are proposing to take with respect to the national registry. If you require further assistance on these matters, feel free to call David J. Futoma of my staff at 504-1621.

Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle
Office of the General Counsel

cc: Richard L. Bangart, OSP

APPENDIX B

CHECKLIST FOR REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC DISCLOSURE

Checklist for Requests to Withhold Information from Public Disclosure

In order to request that the ***NRC*** withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with ***10 CFR 2.790***. The applicant should submit all of the following:

- ☐ A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
- ☐ A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e., those in the brackets), leaving the non-proprietary portions intact. This copy should NOT be marked as proprietary.
- ☐ An affidavit that:
  - ☐ Is notarized.
  - ☐ Clearly identifies (such as by name or title and date) the document to be withheld.
  - ☐ Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.
  - ☐ States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
  - ☐ Provides a rational basis for holding the information in confidence.
  - ☐ Fully addresses the following issues:
    - ☐ Is the information submitted to, and received by, the ***NRC*** in confidence? Provide details.
    - ☐ To the best of applicant's knowledge, is the information currently available in public sources?
    - ☐ Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
    - ☐ Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, the ***NRC*** may send copies of this information to ***NRC*** consultants working in that area. The ***NRC*** will ensure that the consultants have signed the appropriate agreements for handling proprietary information.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, the applicant should promptly notify the ***NRC***. The applicant also should understand that the ***NRC*** may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes the information in question. In all review situations, if the ***NRC*** makes a determination adverse to the above, the applicant will be notified in advance of any public disclosure.

APPENDIX C

APPLICATION AND REVIEW CHECKLIST

SUMMARY DATA

Name and Complete Mailing Address of the Applicant:	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:**
The Applicant is (check one): ☐ Custom User ☐ Manufacturer ☐ Distributor ☐ Manufacturer and Distributor	**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:	**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:**
Model Number:	**Principal Use Code (see Appendix D):**
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):	**For Use by:** ☐ Specific Licensees Only ☐ General Licensees Only ☐ Both Specific and General Licensees ☐ Persons Exempt from Licensing
Leak-Test Frequency: ☐ Periodic Leak-Testing is Not Required ☐ 6 Months ☐ Attached is justification for a leak test frequency of greater than 6 months	**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):** **Radionuclides and Maximum Activities (including loading tolerance):**

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANYMATTER WITHIN ITS JURISDICTION.

Certifying Officer -- Typed Name and Title	
Signature:	**Date:**

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION		
1° registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 Medical - Radiography ..... 32312 Medical - γ Teletherapy ..... 53524 γ Gauges - Unprotected ..... 43333 γ Gauges - In Device ..... 43232 β Gauges, Low Energy γ Gauges, or X-ray fluorescence ..... 33222 Oil Well Logging ..... 56522 Portable Moist/Density ..... 43333 Neutron Applications ..... 43323 γ Irradiators (II, III, IV) ..... 43424 γ Irradiators (I) ..... 43323 Static Eliminators ..... 22222 Smoke Detectors 32222		
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances		
On-Off indicators (description, qty., location)		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)		
Shielding efficiency and integrity		
For medical devices: Was a 510k provided? (provide written notification to FDA)		
Well logging sources must be nondispersible and nonsoluble. (see Appendix J for a list of approved well logging sources as of November 1991)		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)		
Actions to be taken when product reaches end of its working life		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)		
How the device will be used		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing		
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis		
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)		
Conditions: including environments, setter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers		
Mounting integrity		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING					
The following activities may be performed by the persons indicated:					
Actitivity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
Installation					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship					
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					

APPENDIX D

MEMORANDUM FROM R. SCROGGINS REGARDING WORKING ON APPLICATIONS PRIOR TO RECEIPT OF FEES

Appendix D: Memorandum from R. Scroggins Regarding Working on Applications Prior to Receipt of Fees

MAR 1 7 1994

MEMORANDUM FOR: Thomas T. Martin, Administrator, RI
Stewart D. Ebneter, Administrator, RII
John B. Martin, Administrator, RIII
James L. Milhoan, Administrator, RIV
Kenneth E. Perkins, Jr., Administrator, RV

FROM: Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

SUBJECT: PROCEDURES FOR PROCESSING MATERIALS LICENSE APPLICATIONS PRIOR TO FEE VERIFICATION

In the November 1, 1993, Report of Headquarters Organizational Review, the Review Team recommended that the materials license review process should not be delayed to obtain OC fee concurrence. The EDO's January 10, 1994, memorandum to me regarding the Report, (copies to Office Directors and Regional Administrators) stated: "The EDO agrees that the verification of fees should not delay the license review process. OC is to work with the regions to establish a mutually acceptable mechanism to accomplish the regions accurate identification of license fees." As stated in my January 6, 1994, memorandum to Thomas T. Martin, Region I, copy enclosed, it is current agency policy not to delay the processing of an application pending the receipt of a fee. Accordingly, applications can be processed up to the point of issuance pending notification that the fee is paid.

If you or any member of your staff have questions regarding this policy or the procedures, or have suggestions for improving the current procedures, please contact Glenda Jackson of my staff at (301) 492-8740.

Original signed by
Ronald M. Scroggins

Ronald M. Scroggins
Deputy Chief Financial
Officer/Controller

APPENDIX E

PRINCIPAL USE CODES AND DEFINITIONS

Appendix E: Principal Use Codes and Definitions

CODE

A Industrial Radiography — The examination of the structure of materials by nondestructive methods that use sealed sources of radioactive material.

B Medical Radiography — The process of producing x-ray or gamma ray images to assist in medical diagnoses.

C Medical Teletherapy — The treatment of disease with gamma radiation from a controlled source of radiation located at a distance from the patient.

D Gamma Gauges — The use of gamma radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.

E Beta Gauges — The use of beta radiation to measure or control thickness, density, levels, interface location, radiation leakage, or chemical composition.

F Well Logging — The lowering and raising of measuring devices or tools that may contain radioactive sources into well bases or cavities for the purpose of obtaining information about the well or adjacent formation.

G Portable Moisture Density Gauges — Portable gauges that use a radioactive sealed source to determine or measure the content or density of material. Includes hand-held and dolly-transported devices with sources.

H General Neutron Source Applications — All applications, except reactor startup and well logging, that use a neutron source.

I Calibration Sources (Activity greater than 30 mCi) — Sources of a known purity and activity that are used to determine the variation in accuracy of a measuring instrument and to ascertain necessary correction factors.

J Gamma Irradiator, Category I — An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volumes undergoing irradiation is not physically possible because of the design of the irradiator.

K Gamma Irradiator, Category II — A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

L Gamma Irradiator, Category III — An irradiator in which the sealed source is contained in a storage pool (usually containing water), the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is physically restricted in its designed configuration and proper mode of use.

CODE

M Gamma Irradiator, Category IV — A controlled human access irradiator in which the sealed source is contained in a storage pool (usually containing water), is fully shielded when not in use, and is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

N Ion Generators, Chromatography — The use of an ion-generating source and a device to determine the chemical composition of material.

O Ion Generators, Static Eliminators — The use of an ion-generating source and a device to eliminate static electricity on a surface or a surrounding area.

P Ion Generators, Smoke Detectors — The use of an ion-generating source and a device to detect gases and particles created by combustion.

Q Thermal Generator — The use of a radionuclide and a device to produce heat to produce energy.

R Gas Sources — Sealed sources containing radioactive gas such as krypton-85 or hydrogen-3.

S Foil Sources — Sources that are constructed using thin metal foil. The radioactive material may be secured to the foil in a number of ways, for example, plating, laminating, or cold welding.

T Other — All uses not covered in other categories.

U X-Ray Fluorescence — Sources and devices that use radioactive material to excite the atoms of samples that in turn emit characteristic x-rays and thereby provide a means for sample analysis.

V General Medical Use — Includes diagnostic sources and devices such as bone mineral analyzers and therapeutic sources and devices such as interstitial needles, therapeutic seeds, and ophthalmic applicators.

W Self-Luminous Light Source — A source consisting of a radioactive nuclide or nuclides incorporated in solid inactive materials or sealed in a protective envelope and incorporating a phosphor to emit light.

X Medical Reference Sources — Includes flood sources, instrument check sources, spot markers.

Y Calibrators — Devices containing calibration sources that are used to determine the variation in accuracy of a measuring instrument and to determine necessary correction factors.

APPENDIX F

STANDARD REFERENCE MATERIALS

Appendix F Standard Reference Materials

Avallone, E. A., and Baumeister, T., "Marks' Standard Handbook for Mechanical Engineering, Ninth Edition," 1987

Belanger, R., Buckley, D. W., and Swenson, J. B., NUREG/CR-1156 "Environmental Assessment of Ionization Chamber Smoke Detectors Containing Am-241," November 1979

Buckley, D. W., Belanger, R., Martin, P. E., Nicholaw, K. M., and Swenson, J. B., NUREG/CR-1775 "Environmental Assessment of Consumer Products Containing Radioactive Material," October 1980

Linauskas, S. H., "Doses from Portable Gauges," (Research Report), August 1988

Schweitzer, P. A., "Handbook of Corrosion Resistant Piping," 1969

Shigley, J. E., and Mitchell, L. D., "Mechanical Engineering Design, Fourth Edition," 1983

Shreir, L. L., "Corrosion, Volume 1, Metal/Environment Reactions," 1976

Willems, N., Easley, J. T., and Rolfe, S. T., "Strength of Materials," 1981

APPENDIX G

INDUSTRY AND CONCENSUS STANDARDS

Appendix G: Industry and Concensus Standards

Brachytherapy:

ANSI N44.2-1973	"For Leak-Testing Radioactive Brachytherapy Sources"
ANSI N44.1-1973	"Integrity and Test Specifications for selected Brachytherapy Sources"

Gauges:

ISO 7205-1986(E)	"Radionuclide gauges - Gauges designed for permanent installation"
ANSI N538-1979	"Classification of Industrial Ionizing Radiation Gauging Devices"

Irradiators:

ANSI N433.1-1977	"Safe Design and Use of Self-Contained Dry Source Storage Gamma Irradiators (Category I)"
ANSI N43.10-1984	"Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)"

Light Sources:

ANSI N43.4-1975	"Classification of Radioactive Self-Luminous Light Sources"

Power Generators:

IAEA No. 33	"Guide to the Safe Design, Construction, and Use of Radioisotopic Power Generators for certain Land And Sea Applications"

Radiography:

ANSI N43.9-1991	"For Gamma Radiography - Specifications for Design and Testing of Apparatus"
ANSI N432-1980	"Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography"
ISO 3999-1977(E)	"Apparatus for Gamma Radiography - Specification"

Smoke Detectors:

Nuclear Energy Agency - 1977	"Recommendation for Ionization Chamber Smoke Detectors in Implementations of Radiation Protection Standards"

Sources (General):

ISO 2919-1980(E)	"Sealed Radiation Sources, Classification"
ANSI N542-1977	"Sealed Radiation Sources, Classification" - (Revision of ANSI N5.10-1968)
ANSI N5.10-1968	"Sealed Radiation Sources, Classification"

Teletherapy:

ANSI N449.1-1978	"Procedures for Periodic Inspection of Cobalt-60 and Cesium-137 Teletherapy Equipment"

X-Ray Fluorescence:

ANSI N43.2-1977	"Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment"
ANSI N537-1976	"Radiological Safety Standard for the Design of Radiographic and Fluoroscopic Industrial X-Ray Equipment"

Miscellaneous:

ANSI N43.3-1993	"Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV"
NCRP Report No.49	"Structural Shielding Design and evaluation for Medical use of X-Rays and Gamma Rays of Energies up to 10 MeV"

APPENDIX H

STANDARD REGISTRATION CERTIFICATE FORMATS

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-S-****-S DATE: PAGE 1 OF 5

SOURCE TYPE: *Short description of the source type*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR: *Name*
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER: *Name*
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

ISOTOPE: MAXIMUM ACTIVITY:

List Isotopes *xx millicuries (xx GBq)*
units should be such that the amount is in the 1 to 999 range

LEAK TEST FREQUENCY: *Not Required*
6 Months

PRINCIPAL USE: *(A) Industrial Radiography*
from listing in Regulatory Guide 10.11

CUSTOM SOURCE: _____ YES ____X____ NO

CUSTOM USER: *Name*
Street
City, State Zip
(delete entire subsection if not applicable)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-S-****-S DATE:

SOURCE TYPE: *Short description of the source type*

DESCRIPTION:

Provide the complete description of the source.

LABELING:

The source is engraved with the radiation symbol, isotope, activity, model number, serial number, date of assay, name of the distributor, and the words "CAUTION-RADIOACTIVE MATERIAL". The text is X" (X mm) high and is on the end/side of the source capsule.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in measuring....

The source may be used in harsh enviroments but shall not be subjected to environments that exceed its ANSI N542-1977 classification, 77C00000.

PROTOTYPE TESTING:

A prototype of the Model ABC source was constructed and subjected to the tests provided in ANSI N542-1977/ISO 2919 and achieved a classification of 77C00000.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-S-***-S DATE:

SOURCE TYPE: *Short description of the source type*

EXTERNAL RADIATION LEVELS:

The following dose rates were reported by the manufacturer for the Model ABC source containing 1.0 curie (37 GBq) of Am-241:

Table 1

		Maximum Radiation Level			
Distance		**From Window**		**From Sidewall/Back**	
(inches)	*(cm)*	*(mR/hr)*	*(μSv/hr)*	*(mR/hr)*	*(μSv/hr)*
1.97	*5*				
11.81	*30*				
39.37	*100*				

QUALITY ASSURANCE AND CONTROL:

XXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- *The source shall be distributed to persons specifically licensed by the NRC or an Agreement State.*
- *The device shall only be used by the custom user listed in this certificate, XXXXX.*
- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-S-****-S DATE:

SOURCE TYPE: *Short description of the source type*

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that these sources exhibit high dose rates, the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.*
- *The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.*
- *The source shall not be subjected to conditions that exceed its ANSI N542-1977 classification, 77C00000.*
- *This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.*

SAFETY ANALYSIS SUMMARY:

Based on review of the Model ABC sealed source, its ANSI classification, and the information and test data cited below, we (continue to) conclude that the source is acceptable for licensing purposes.

Furthermore, we (continue to) conclude that the source would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-S-****-S DATE:

SOURCE TYPE: *Short description of the source type*

REFERENCES:

The following supporting documents for the Model ABC sealed source are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-S-****-S DATE: ATTACHMENT 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 1 OF 8

DEVICE TYPE: *Short description of the device type*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR: *Name*
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER: *Name*
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

SEALED SOURCE MODEL DESIGNATION: *ACME Model 123*

ISOTOPE:	MAXIMUM ACTIVITY:
List Isotopes	*xx millicuries (xx GBq) units should be such that the amount is in the 1 to 999 range*

LEAK TEST FREQUENCY: *Not Required*
6 Months

PRINCIPAL USE: *(A) Industrial Radiography*
from listing in Regulatory Guide 10.10

CUSTOM DEVICE: _____ YES ___X___ NO

CUSTOM USER: *Name*
Street
City, State Zip
(delete entire subsection if not applicable)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-D-****-X DATE: PAGE 2 OF 8

DEVICE TYPE: *Short description of the device type*

DESCRIPTION:

Provide the complete description of the device and, if necessary, the source(s) used in the device.

LABELING:

The device is labeled in accordance with 10 CFR 20.1901. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the distributor, and the words "CAUTION-RADIOACTIVE MATERIAL".

When distributed to persons generally licensed, the device is additionally labeled in accordance with 10 CFR 32.51.

The labels are made of stainless steel or aluminum, rectangular in shape, X" x X" (X cm x X cm), and are permanently attached by rivets or screws to the device. A copy of the label is shown in attachment X.

DIAGRAM:

Reference all attachments to the document including the total number of attachments.

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for measuring....

The devices are expected to be subjected to environments typically found in laboratories occupied by humans. Since the device is portable, it may experience vibration and shock typical during normal transportation.

The device will only be used by XXXX at their XXXXX CITY, ST facility.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Short description of the device type*

CONDITIONS OF NORMAL USE (Cont.):

The devices are intended for use in industrial gauging applications. The devices are typically used in industrial process control environments for the measurement of properties of materials in a tank or vessel. The devices are designed for the following environments:

Temperature.....-40°C to 60°C (-40°F to 140°F)
Pressure.....Atmospheric
Vibration.....Ranges from zero to mild
Corrosion.....Ranges from zero to highly corrosive vapors
Fire.....NEC Division 2 hazardous area possible
Explosion .....NEC Division 2 hazardous area possible

PROTOTYPE TESTING:

A prototype of the Model XXXX was constructed and subjected to the tests listed below. No malfunction occurred nor was there any loss of shielding or containment integrity.

- *Temperature.....110°C (230°F) for a period of seven hours.*
- *Vibration.....Approximately 30 cps at an amplitude of 0.03" (0.76 mm) for 90 minutes.*
- *OFF/ON Mechanism.....Operated by a pneumatic cylinder for a total of 9320 OFF/ON cycles.*
- *Impact.....Dropped three times from a height of 4 feet.*
- *Penetration.....Dropped a 13 pound (5.9 kg), 1-1/4" (3.2 cm) diameter steel rod from a height of 40" (102 cm).*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: PAGE 4 OF 8

DEVICE TYPE: *Short description of the device type*

PROTOTYPE TESTING (Cont.):

A prototype of the device has been tested in accordance with ANSI/ISO standard .... and has achieved a classification of .... The device passed the tests in accordance with the acceptance criteria included in the standard.

The sealed sources used in the device have been tested by their manufacturers and have achieved the following ANSI (N542-1977 or ANSI N5.10-1968) classifications:

Manufacturer	*Model*	*ANSI Classification*
Amersham Corporation	*AMCL*	*77C64344*
Du Pont Merck	*NER-465*	*C33232*
Isotope Products Laboratories	*PH-55*	*C33232*

The sealed source contained in the device has achieved an ANSI N542-1977 classification of 77C00000.

The sealed source contained in the device has achieved an ANSI N5.10-1968 classification of C00000.

EXTERNAL RADIATION LEVELS:

XXXXXXXXX reports that the radiation levels from the device are not discernable from background.

XXXXXXXXX reports that the radiation levels from the device do not exceed 5 mR/hr (50 μSv/hr) at 12" (30.5 cm) from the surface of the device.

The following dose rates were reported by the manufacturer for the Model ABC transmission gauge containing a 1.0 curie (37 GBq) of Am-241 sealed source:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-D-****-X DATE:

DEVICE TYPE: *Short description of the device type*

EXTERNAL RADIATION LEVELS (Cont.):

Table 1

		Maximum Radiation Level			
Distance		**From Window**		**From Sidewall/Back**	
(inches)	*(cm)*	*(mR/hr)*	*(μSv/hr)*	*(mR/hr)*	*(μSv/hr)*
1.97	*5*				
11.81	*30*				
39.37	*100*				

The dose rates were taken with no material present in the measuring area. XXXXXXX indicates this represents the highest radiation levels of any possible configuration.

QUALITY ASSURANCE AND CONTROL:

XXXXXX maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- *Tne device shall be distributed to persons specifically licensed by the NRC or an Agreement State.*
- *The device may be distributed to specific or general licensees of NRC or an Agreement State.*
- *The device shall be distributed to persons generally licensed by the NRC or an Agreement State.*
- *The device shall only be distributed to the custom user, XXXXX.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-D-****-X DATE:

DEVICE TYPE: *Short description of the device type*

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.*
- *Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.*
- *The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.*
- *The Model XXXXXX sealed source is approved by NRC for use in the Model ABC. The source is not registered on a separate certificate.*
- *The generally licensed user is authorized to perform certain maintenance on the device (see the device operation manual). These services include...*
- *REVIEWER NOTE: Neither the distributor nor manufacturer of the device will provide servicing for the device.*
- *This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.*

SAFETY ANALYSIS SUMMARY:

The distributor has submitted sufficient information to provide reasonable assurance that:

- *The device can be safely operated by persons not having training in radiological protection.*

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-D-****-X DATE:

DEVICE TYPE: *Short description of the device type*

SAFETY ANALYSIS SUMMARY (Cont.):

- *Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.*

- *Under accident conditions associated with handling, storage, and use of the source housing, 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 the following chart:*

PART OF BODY	DOSE
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm^2 (0.15 in^2)	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

Based on review of the Model ABC, and the information and test data cited below, we (continue to) conclude that the device is acceptable for licensing purposes.

Furthermore, we (continue to) conclude that the device would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE:

DEVICE TYPE: *Short description of the device type*

REFERENCES:

The following supporting documents for the Model ABC are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-****-D-****-X DATE: ATTACHMENT 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-X DATE: ATTACHMENT 2

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE: PAGE 1 OF 2

DEVICE TYPE: *Smoke Detector/Gun Sight*

MODEL: *ABC*

MANUFACTURER/DISTRIBUTOR:

Name
Street
City, State Zip
(if manufacturer and distributor are the same, keep subheading as shown. If different, delete the word manufacturer from the subheading)

MANUFACTURER:

Name
Street
City, State Zip
(this subheading and information is not necessary if manufacturer and distributor are the same.)

SEALED SOURCE MODEL DESIGNATION: *ACME Model 123*

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	*1.0 microcurie (37 kBq)*
Hydrogen-3	*60 millicuries (2.2 GBq)*

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: *(P) Ion Generator, Smoke Detectors*
(W) Self-Luminous Light Sources

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-***-D-***-E DATE: PAGE 2 OF 2

DEVICE TYPE: *Smoke Detector/Gun Sight*

DESCRIPTION:

Provide a concise, basic description of the device and if more than one model is registered, provide the differences between models.

REFERENCES:

The following supporting documents for the Model ABC smoke detectors/gun sights are hereby incorporated by reference and are made a part of this registry document.

- *'s application dated December 25, 0000, with enclosures thereto.*
- *'s letters dated July 4, 1776, and December 25, 0000, with enclosures thereto.*
- *'s facsimiles dated July 4, 1776, and December 25, 0000.*

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____ Reviewer: _____
Name of 1st reviewer

Date: _____ Concurrence: _____
Name of 2nd reviewer

APPENDIX I

ASSIGNING REGISTRATION CERTIFICATE NUMBERS

Appendix I: Assigning Registration Certificate Numbers

Each registration certificate has a unique registration number. The registration number consist of either 10 or 11 characters as described below:

NR-XXXX-D-YYY-S

Agency Code (NR): A two-letter abbreviation of the agency issuing the certificate. All certificates issued by NRC have NR as the Agency Code.

Vendor Code (XXXX): Each vendor (manufacturer or distributor) is assigned a unique three-digit number (the number may be four-digits). The vendor code used for the registration certificate number will be the vendor code for the distributor. If the company is out of business or no longer has an active registration certificate, the vendor code will between 800 and 1000 or between 8000 and 9000. The SSSS maintains the listing of vendor codes and issues new vendor codes.

Source/Device Code (D): A one-letter code which indicates whether a registration certificate is for a sealed source (S), a device (D), or (A) associated equipment.

Unit Number (YYY): A separate series of three-digit numbers assigned to registration certificates for each vendor. These numbers are assigned in sequential order starting with 101 for active registration certificates and starting with 801 for inactive registration certificates. A new registration for an existing vendor is assigned the next available unit number. The issuance of unit numbers is typically controlled by the agency that regulates the vendor.

License Code (S): This is a one-letter code which indicates how the source or device has been registered. "S" indicates it may only be used by specific licensees, "G" indicates it may only be used by general licensees, "B" indicates it may be used by both specific and general licensees, and "E" indicates it may be used by persons exempt from licensing.

APPENDIX J

LIST OF APPROVED WELL LOGGING SOURCES

Appendix J: List of Approved Well Logging Sources

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

NOV 4 1991

TO: All Well Logging Licensees

SUBJECT: STATUS OF WELL LOGGING SOURCES

In a memorandum dated August 10, 1989, we informed Nuclear Regulatory Commission (NRC) well logging licensees of a temporary generic exemption published in the Federal Register on July 25, 1989 (54 FR 30683). The generic exemption exempted well logging licensees from the requirement to use only sealed sources that meet the prototype testing requirement specified in 10 CFR 39.41(a)(3). The exemption applied to (and allowed the continued use of) well logging sources that meet certain alternate prototype testing criteria.

The notice indicated that the exemption would remain in effect until NRC published its final findings in the Federal Register. Thus far, NRC has been unable to initiate this action due to higher priority activities; however, NRC now anticipates commencing this task in the near future.

Included in the memorandum with the Federal Register notice were three enclosures that listed various sealed source models common to well logging and identified their suitability for continued use in well logging operations. There have been a few changes to the lists since first transmitted. There are a few sources which we have determined meet the criteria specified in 10 CFR Part 39, and have added the sources to the approved list.

Enclosed are the three enclosures which have been updated on a one-time-only basis to show the apparent current status of known well logging sources. Enclosure 1 lists those source models which appear to meet Section 39.41 requirements and are approved for continued use. Enclosure 2 lists those source models whose continued use is authorized under the temporary generic exemption. Enclosure 3 lists those source models that do not meet the requirements of Section 39.41 or the generic exemption. When a sealed source is contained (and normally stored) within a device (logging tool), the sealed source manufacturer and model number is shown below the entry. When NRC has been able to determine that a sealed source model was manufactured/distributed by another company, or more than one model designation may have been used, this information is shown in parentheses below the entry. Neutron generators are shown by the designation "Nu GEN." An asterisk (*) indicates that the source is used within the logging tool's electronics package.

We do not intend to update these lists in the future. Due to the time which has passed, we believe that all questions concerning sources identified on the unapproved list should have been answered. Any new well logging source introduced by source manufacturers must be designed to meet the criteria specified in 10 CFR 39.4[illegible]. Therefore, it will not be necessary to update the list to include a new source, as the NRC or Agreement State registration sheet for the source will indicate that use of the source in well logging operations is acceptable.

If you have any questions, please contact Torre Taylor at (301) 492-0611 or J. Bruce Carrico at (301) 492-0634.

John E. Glenn

John E. Glenn, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosures: As stated

WELL LOGGING SEALED SOURCES APPROVED
UNDER PART 39 REQUIREMENTS

MANUFACTURER	MODEL
AMERSHAM CORPORATION	AMN.CYn (n = 1 to 14)
AMERSHAM CORPORATION	AMN.CY1
AMERSHAM CORPORATION	AMN.PEn (n = 1 to 4)
AMERSHAM CORPORATION	CDC.CYn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.CDn (n = 2 to 12)
AMERSHAM CORPORATION	CKC.800 SERIES
AMERSHAM CORPORATION	CVN.CYn (n = 2 to 12)
AMERSHAM CORPORATION (GAMMA INDUSTRIES, GENERAL NUCLEAR)	VD(HP)
AMERSHAM CORPORATION	CVN.CY2
ANADRILL, INC.* ISOTOPE PRODUCTS MODEL 274 SEALED SOURCE	SGS-AA,SGS-BA, OR SGS-CA
COMPROBE, INC.	1203 DENSITY PROBE
GAMMA INDUSTRIES MODEL VD-HP SERIES SOURCE	
GULF NUCLEAR, INC. MODEL VL-1 SEALED SOURCE	
DRESSER INDUSTRIES INC (Nu GEN)	C-58301, C-107298
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-571
GEARHART INDUSTRIES, INC. (Nu GEN)	013-1004-000
GENERAL ELECTRIC. CO.	GE(N)-Cf-100 SERIES
GULF NUCLEAR, INC. (NEEI)	VL-1
GULF NUCLEAR, INC. (NEEI)	71-1 (NEEI-AMBE-71-1)
KAMAN SCIENCES CORPORATION (Nu GEN)	A-3061
KAMAN SCIENCES CORPORATION (Nu GEN)	A-920
KAMAN SCIENCES CORPORATION (Nu GEN)	A-520
KAMAN SCIENCES CORPORATION (Nu GEN)	E-3010 AND E-3020
MONSANTO CO., DAYTON LABORATORY	H-245258 (NSR-M)
MONSANTO CO., DAYTON LABORATORY	24113
MONSANTO CO., DAYTON LABORATORY	24154-C
MONSANTO CO., DAYTON LABORATORY	24174
MONSANTO CO., DAYTON LABORATORY	24181
MONSANTO CO., DAYTON LABORATORY	24183

Enclosure 1

WELL LOGGING SEALED SOURCES APPROVED
UNDER PART 39 REQUIREMENTS (cont'd)

MANUFACTURER	MODEL
P.A. INCORPORATED (MONSANTO)	H-243258 (NSR-M)
P.A. INCORPORATED*	P-194693
SCHLUMBERGER (MONSANTO, NUMEC)	DWG H-115686
SCHLUMBERGER	DWG H-142108
SCHLUMBERGER	DWG H-239681
SCHLUMBERGER WELL SERVICES*	P-194693
SCHLUMBERGER WELL SERVICES	NSR-R
UNC NUCLEAR INDUSTRIES	PA2A, PA2B, PT2A, PT2B, PS2A, PS2B (OLD: SM-100)
E.I.DUPONT DE NUMOURS & CO. (NEN)	MODEL 478C SEALED SOURCE
US DEPARTMENT OF ENERGY	SR-CF-100 SERIES

WELL LOGGING SEALED SOURCES APPROVED
UNDER THE GENERIC EXEMPTION

MANUFACTURER	MODEL
COMPROBE, INC. GULF NUCLEAR, INC. MODEL CSV SEALED SOURCE	2103 DENSITY PROBE
COMPROBE, INC. GAMMA INDUSTRIES (GAMMATRON) MODEL AN-HP SEALED SOURCE	2103 DENSITY PROBE
E.I.DUPONT DE NUMOURS & CO. (NEW ENGLAND NUCLEAR)	NER-572, NER-582
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	CS-1000 (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB (HP)
GAMMA INDUSTRIES	NB (HP)
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	NHP-A-#
GAMMA INDUSTRIES	WLG-1
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	AN-HPG, RN-HP
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-20
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	DA-5
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-GHP
GULF NUCLEAR, INC. (NEEI)	AMBC-71-2A
GULF NUCLEAR, INC. (NEEI)	C-73-2
GULF NUCLEAR, INC. (NEEI)	CS-2
GULF NUCLEAR, INC. (NEEI)	CSV
MONSANTO CO., DAYTON LABORATORY	24112
MONSANTO CO., DAYTON LABORATORY	24120
PARKWELL LABORATORIES, INC. (US NUCLEAR)	PL-104

Enclosure 2

KNOWN SEALED SOURCES NOT APPROVED
FOR USE IN WELL LOGGING

MANUFACTURER	MODEL
AMERSHAM CORPORATION	CD CO 5987
AMERSHAM CORPORATION	CDC.600 SERIES (.801 TO .811)
DRESSER ATLAS	B89596, B89597, B89598
FRONTIER TECHNOLOGY CORP.	100
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-DL-4
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	GNI-NB-S-5.0
GAMMA INDUSTRIES	NB-S-5, NB-S-20
GAMMA INDUSTRIES (GENERAL NUCLEAR, INC.)	PL-AMBE-2.7
GAMMA INDUSTRIES	RC-1 (HP)
GAMMA INDUSTRIES	S-14
GAMMATRON, INC. (NUCLEAR SOURCES AND SERVICES, INC.)	GT-G
GENERAL NUCLEAR, INC.	GNI-C(G)M-5
GULF NUCLEAR, INC. (NEEI)	CO-50
GULF NUCLEAR, INC. (NEEI)	CS-50
GULF NUCLEAR, INC. (NEEI)	TG-1
GULF NUCLEAR, INC. (NEEI)	72-CO-200
HASTINGS RADIOCHEMICAL WORKS	CS-III-A-100
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	373
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	374
ICN PHARMACEUTICAL, INC. (US NUCLEAR)	376
ICN PHARMACEUTICAL, INC.	J146

Enclosure 3

KNOWN SEALED SOURCES NOT APPROVED
FOR USE IN WELL LOGGING (cont'd)

MANUFACTURER	MODEL
ISOTOPES SPECIALTIES	C-0037
LFE CORPORATION (TRACERLAB)	CS-15
MINNESOTA MINING AND MANUFACTURING	4F6B
MINNESOTA MINING AND MANUFACTURING	4F6H (REDESIGN OF MODEL 4F6B)
MINNESOTA MINING AND MANUFACTURING	4F6S
MINNESOTA MINING AND MANUFACTURING	4P6F
MINNESOTA MINING AND MANUFACTURING	4P6U
MINNESOTA MINING AND MANUFACTURING	4P6W
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As part of its redesign of the materials licensing process, NRC is consolidating and updating numerous guidance documents into a single comprehensive repository as described in NUREG-1539 and draft NUREG-1541. NUREG-1556, Vol. 3, is intended for use by applicants, registrants, and NRC staff in applying for and evaluating applications for registration of sealed sources and devices. The final version of this document is intended to supercede guidance provided in NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations," Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," and Regulatory Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material."

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