OCT 16 1986

AB34-1 PDR

MEMORANDUM FOR: James M. Taylor, Director
Office of Inspection and Enforcement

G. Wayne Kerr, Director
Office of State Programs

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Patricia G. Norry, Director
Office of Administration

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: OFFICE CONCURRENCE REQUEST: AMENDMENT OF 10 CFR PARTS 30 AND 32

The concurrence of your Office is requested in the enclosed documents for amendment of 10 CFR Parts 30 and 32 to provide for pre-marketing radiation safety evaluation and registration of sealed sources and devices used under specific license. The following is a summary of this request:

1. Title: Registration of Sources and Devices

2. NMSS Project Manager: Steven Baggett (x79005)

3. NMSS Task Number: TFC 86-3

4. Cognizant Individuals: J. Metzger, IE
L. Bolling, SP
M. Lesar, ADM
Undesignated, RES

5. Requested Action: Office Concurrence

6. Requested Completion Date: OCT 31 1986

7. Background:

NRC regulations clearly provide for pre-marketing approval of certain sealed sources of radioactive material and devices which incorporate those sources. Examples are: smoke detectors used under an exemption

from regulations, gauges used under a general license, and certain medical devices used under specific license. The regulations are less clear with respect to pre-marketing evaluation of other products, e.g. industrial radiographic devices and in-plant gauging devices which are used under specific license.

The proposed rule would clearly state the procedures for manufacturers and distributors of sources and devices to obtain pre-marketing evaluation and registration of products to be used under specific license. Consistent with present practice, the rule would require the applicant to submit for evaluation specified radiation safety information about the product.

The proposed rule would assure that all manufacturers and distributors are informed of NRC's program for evaluation and registration of radiation safety information on sources and devices used under specific license. The rule also would state the registrant's responsibility to ensure that distributed products meet the radiation safety related specifications filed with the NRC.

This rulemaking was approved by the EDO and transferred from RES to NMSS on November 29, 1985. The attached draft amendments differ from earlier drafts by RES. Those earlier drafts would have established a class concept for sources and devices used under specific license whereby, for example, a specific licensee who was approved to possess a gauge would also be approved to receive any gauge that had been registered. The attached draft is more limited in scope and is intended to formalize the established practice for evaluation and registration of sources and devices used under specific license.

8. Division Level Review and Responses:

On 9/4/86 a draft of the enclosed documents was circulated for Division level review by IE, SP, ADM, RES, and PA. IE and SP responded with Division level concurrence. OGC and PA responded with Office level concurrence. RES did not respond. ADM's Division of Rules and Records responded with suggestions for more closely conforming with regulation drafting guidelines set out in NRC Regulations Handbook (NUREG/BR-0053).

These suggestions have been followed in preparing the enclosed documents. ADM also noted the need to forward to OMB the new information collection requirement (§ 32.210) on or before the date the proposed rule is published in the Federal Register. The request with supporting statement for OMB approval is being prepared by NMSS.

(SIGNED) Donald B. Mausshardt

John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards

Enclosure:
Proposed memorandum to Victor Stello, Jr.
fm. John G. Davis w/encl.

MEMORANDUM FOR: Victor Stello, Jr.
Executive Director for Operations

FROM: John G. Davis, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: PROPOSED AMENDMENTS TO 10 CFR PARTS 30 and 32 - MANUFACTURERS' REGISTRATION OF SAFETY INFORMATION ON RADIATION SOURCES AND DEVICES

Enclosed for your signature is a notice of proposed rulemaking which would amend 10 CFR Parts 30 and 32 to provide for manufacturers' registration of radiation safety information about sources and devices containing radioactive material.

This rulemaking activity will result in regulations that clearly provide for the long standing practice whereby manufacturers of sealed sources of radioactive material and devices containing sealed sources file radiation safety information about their products with the NRC. The information is evaluated and, when referenced in specific license applications by the manufacturers' customers, is used by the NRC and the Agreement States in determining that an applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property.

This practice is currently conducted under a general provision in the regulations (§30.32(a)) that allows an applicant for a specific license to incorporate by reference information contained in previous reports filed with the Commission.

The practice is extensively used. The NRC maintained sealed source and device registry contains information on approximately 3,000 models of sources and devices from about 400 manufacturers/distributors (vendors). Both the NRC and the 28 Agreement State licensing groups contribute data to and use the registry.

We believe that the practice has now sufficiently matured and is used to the extent that it warrants a specific provision in the regulations. The proposed rule would continue the practice of manufacturers filing information and, in effect, receiving pre-marketing approval of their products for purposes of specific licensing. Publication as a rule will assure that all vendors of sealed sources and devices are informed of this practice and will clearly state that manufacturers registering their products with NRC have a responsibility to ensure that the distributed products meet the radiation safety related specifications filed with the registry.

I recommend that you sign (under authority delegated in 10 CFR 1.40(c) and (d)) the enclosed notice of proposed rulemaking that would amend 10 CFR Parts 30 and 32. The appropriate Congressional committees will be informed of these proposed changes. A notice regarding publication of the proposed rule will be included in the next Weekly Report to the Commission.

Coordination: The Offices of Nuclear Regulatory Research, State Programs, Inspection and Enforcement, and Administration concur in the enclosed amendments to 10 CFR Parts 30 and 32. The Office of the General Counsel has reviewed this paper and concurs in it. The Office of Public Affairs concurs that a public announcement need not be issued.

John G. Davis, Director
Office of Nuclear Material
Safety and Safeguards

Enclosures:
A. FR Notice of Proposed Rulemaking
B. Draft Regulatory Analysis
C. Draft Congressional Letter

Approved for Publication

The Commission delegated to the EDO (10 CFR 1.40(c) and (d)) the authority to develop and promulgate rules as defined in the APA (5 U.S.C. 551(4)) subject to the limitations in NRC Manual Chapter 0103, Organization and Functions, Office of the Executive Director for Operations, paragraphs 0213, 038, 039, and 0310.

The enclosed proposed rule, entitled "Manufacturers' Registration of Radiation Safety Information for Certain Devices and Sealed Sources," amends 10 CFR Parts 30 and 32 to provide clearly for manufacturers of radiation sources and devices containing radiation sources to file with NRC radiation safety information about their products for evaluation and subsequent use in NRC's consideration of applications for specific licenses authorizing use of the products.

This proposed rule does not constitute a significant question of policy, nor does it amend regulations contained in 10 CFR Parts 7, 8, or 9 Subpart C concerning matters of policy. I therefore find that this rule is within the scope of my rulemaking authority and am proceeding to issue it.

_____
(Date)

_____
Victor Stello, Jr.,
Executive Director for Operations

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

Manufacturers' Registration of
Radiation Safety Information for
Certain Devices and Sealed Sources

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing regulations that would formalize current administrative practice under which manufacturers of radiation sources and devices containing radiation sources file safety information about their products with the NRC. The NRC evaluates and uses the information in its issuance of specific licenses to users of the products. Filing of information by a manufacturer (called registration) avoids multiple filings of the same information by the customers and thus expedites NRC's issuance of licenses. The proposed amendments, directed toward manufacturers, describe the information that the NRC needs for its evaluation of a source or device and state the registrant's responsibility to ensure that distributed products meet radiation safety specifications filed with the NRC.

DATES: Submit comments by _____. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

Enclosure A

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch.

Hand deliver comments to: Room 1121, 1717 H Street NW, Washington, DC between 8:15 a.m. and 5:00 p.m. weekdays.

Examine comments received at: The NRC Public Document Room, 1717 H Street NW, Washington, DC.

Obtain single copies of the draft regulatory analysis on this proposed regulation from Steven Baggett, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-9005.

FOR FURTHER INFORMATION CONTACT: Steven Baggett, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 427-9005.

SUPPLEMENTARY INFORMATION:

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Enclosure A

I. Purpose of Proposed Rule.

Current NRC regulations clearly provide for the issuance of specific licenses which reference so-called "pre-marketing" evaluations and registrations of radiation safety information on certain sealed sources of radioactive material and on devices which incorporate those sources. Examples include smoke detectors used under an exemption from regulations, gauges used under a general license, and certain medical devices used under a specific license.

The regulations are less clear about pre-marketing evaluation of other products such as industrial radiographic devices and industrial gauging devices which are used under a specific license. For these products, the NRC has developed and implemented an administrative procedure for the pre-marketing evaluation and registration of radiation safety information under general provisions of its regulations.

The proposed rule would add specific provisions to the regulations for this established administrative procedure at 10 CFR 32.210. The proposed rule would describe NRC's evaluation and registration criteria and would clarify the regulatory responsibility of manufacturers of products for which the NRC evaluates and registers radiation safety information. In particular, the proposed rule would clearly state that the registrant is required to manufacture and distribute its product in accordance with its request for evaluation and registration and with the terms of NRC's registration certificate. Additionally, the registrant's quality control procedures would be expected to ensure that its product meets the specifications it furnished to the NRC.

The proposed rule would ensure that all manufacturers, applicants for specific licenses, and other interested persons are informed of and comply with the NRC's procedures and requirements for pre-marketing registration of radiation safety information on sealed sources and devices.

II. Background.

Section 30.33 of Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 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, particularly sealed sources of byproduct material and devices containing sealed sources, applicants for specific licenses frequently describe that equipment by referring to data already filed with the NRC by the equipment manufacturer under a practice of direct communication between the NRC and the manufacturer.

This practice is administratively convenient to the NRC, manufacturers, and to applicants because it reduces and simplifies paperwork. A single submission by a manufacturer is evaluated by the NRC and the results of the evaluation are used in NRC's review of multiple applications for specific licenses, thus avoiding repetitive submissions by applicants and reviews by the NRC. This practice is provided for under the general provision of § 30.32 of Part 30, whereby "information contained in previous applications, statements or reports filed with the Commission ... may be incorporated by reference, provided that the reference is clear and specific."

The following sections explain the key terms "sealed source" and "device" and describe the program for registration of radiation safety information on this equipment.

A. Sealed Sources.

Byproduct material used by a specific licensee often is contained in a sealed capsule, held between layers of non-radioactive metal foil, or firmly fixed to a non-radioactive surface by electroplating or other means. The byproduct material with its capsule or other confining barrier is termed a "sealed source." The confining barrier prevents dispersion of the byproduct material under normal and most accident conditions related to use of the source.

There is a wide range in the amount of byproduct material used in sealed sources under a specific license. For example, (1) the sealed sources used in industrial gauges frequently contain several millicuries of byproduct material, (2) the sealed sources used in industrial radiography may contain tens of curies of byproduct material, and (3) a sealed source used in a teletherapy unit for treatment of cancer may contain several thousand curies of byproduct material.

Radiation safety programs for the use of byproduct material as a sealed source are structured on the presumption that the byproduct material will not leak from the sealed source and contaminate the environment or expose individuals to radiation. This presumption depends upon the adequacy of the containment properties of the sealed source to withstand the stresses imposed by the environment in which the source is used.

Before authorizing the distribution and use of a sealed source containing byproduct material, the NRC determines the adequacy of its containment and other radiation safety features. This determination is based on radiation safety information submitted by the manufacturer or distributor of the sealed source or by

the applicant for a specific license that authorizes its use. The NRC uses its regulations and radiation safety criteria set out in industry standards in making this determination.

B. Devices.

Frequently, the byproduct material is contained in a sealed source that, in turn, is contained in a shielded source housing. The source housing may have a shutter mechanism that allows an operator to greatly reduce the shielding in a particular direction so that a beam of radiation can exit the housing. The radiation beam is then available for such purposes as the treatment of cancer or for the examination of flaws in metal castings.

The source housing, together with its shutter mechanism and other radiation control mechanisms (if any), is commonly called a "device." Examples of devices are teletherapy units, industrial radiographic equipment, and industrial thickness and density gauges.

Before authorizing the distribution and use of byproduct material in a device, the NRC determines the adequacy of the radiation safety features of the device. This determination is based on information submitted by the manufacturer or distributor of the device or by the applicant for a specific license that authorizes use of the device containing byproduct material. The NRC uses its regulations and radiation safety criteria set out in industry standards in making this determination.

C. Sealed Source and Device Registration.

1. Nationwide Registry.

Manufacturers and distributors of sealed sources and devices subject to NRC regulation routinely submit radiation safety information about their products directly to the NRC. This system avoids multiple and time consuming submission of the same detailed information by each applicant for a specific license that proposes to obtain and use those products.

The NRC maintains a nationwide registry of radiation safety information on sealed sources and devices containing byproduct material. Regulatory authorities in the Agreement States (where NRC has relinquished its regulatory jurisdiction) also provide information to the NRC for the registry on their radiation safety evaluations and have access to all the information contained in the registry. Thus, when a manufacturer or distributor of products within either an Agreement State or in NRC's regulatory jurisdiction provides detailed information about its sealed source or device to its regulatory agency, the results of the radiation safety evaluation will be available for use in granting licensing approval to users of the sealed source or device throughout the United States, its territories and possessions, and in Puerto Rico.

2. NARM.

Radioactive material includes "byproduct material" which is radioactive material derived from the production or use of special nuclear material, see e.g., 10 CFR 30.3(d), and subject to regulation by the NRC and the Agreement States. Another class of radioactive material called "NARM," naturally occurring and accelerator-produced radioactive materials, is not subject to regulation

under the Atomic Energy Act of 1954, as amended, but is regulated by the States. As a general rule, the NRC does not accept applications for radiation safety evaluation and registration of sealed sources or devices that will contain NARM. There are two exceptions to this general rule. One exception is if the radionuclide used in the source or device is available from either a reactor, and thus defined as byproduct material, or from an accelerator and thus defined as NARM. Cadmium-109 is an example of such a radionuclide. NRC will accept applications concerning Cd-109 assuming, for purposes of source or device evaluation and registration, that the Cd-109 will be produced in a reactor. The other exception is if the NARM is commingled with byproduct material.

3. Devices and Sealed Sources Manufactured Outside the United States.

A source or device manufactured outside the United States may be registered with the NRC if the appropriate information is supplied and if NRC's administrative requirements are satisfied. Additionally, the registrant must establish an address or representative in the United States where papers may be served, where records required by the NRC will be maintained, and where the NRC can inspect the registrant's activities as necessary to fulfill the requirements of NRC's regulations.

D. Requests for Registration.

Requests for evaluation and registration of sealed sources and devices must contain sufficient information for an NRC determination that the radiation safety properties of the product are adequate to protect health and minimize danger to life or property. This general guidance on the expected content of a request is supplemented by detailed guidance in two NRC docu-

ments: (1) Draft Regulatory Guide FC 603-4, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material," and (2) Draft Regulatory Guide FC 601-4, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material."[1] These documents discuss the expected technical content of a request and offer a suggested format. Included in each document is a checklist that may help an applicant to assure that it submits adequate information for NRC's radiation safety evaluation and determination of the conditions under which the source or device will be authorized for distribution and use. Manufacturers and distributors of sealed sources and devices are encouraged to consider these documents when preparing requests for registration.

E. Certificate of Registration.

Following a determination of the adequacy of the radiation safety properties of a sealed source or device, the NRC or an Agreement State issues a numbered certificate of registration to the manufacturer or distributor. This certificate, among other things, summarizes the submitted radiation safety information and specifies the limitations and conditions of use of the sealed source or device, such as requirements for periodic leak tests and restrictions on environmental conditions of use. Although the certificate of registration is, in effect, a

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1. Free single copies of Draft Regulatory Guides FC 603-4 and FC 601-4, to the extent of supply, may be obtained by writing to the Publications Services Section, Information & Records Management Branch, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies are also available for inspection and/or copying for a fee in the NRC Public Document Room, 1717 H Street, NW, Washington, DC 20555.

pre-marketing approval of the source or device, its issuance does not constitute a commitment to issue a specific license authorizing use of the source or device. Approval of an application for a specific license also requires satisfaction of other requirements listed in § 30.33 of 10 CFR Part 30 such as the training and experience qualifications of the applicant.

Copies of the registration certificate are provided to regulatory authorities in the Agreement States for their use in granting specific licensing approval to users within their jurisdictions.

III. The Proposed Rule.

The proposed rule in 10 CFR 32.210 would formalize this practice. Manufacturers and distributors would file radiation safety information about their sealed sources and devices with the NRC and NRC would evaluate that information, provide registration certificates, and use that information in the issuance of specific licenses to users of the sources and devices. To date, this practice has been carried out under general provisions of NRC's regulations. The proposed specific regulatory provisions for the practice are intended to ensure that manufacturers, distributors, NRC's licensees, and the public are informed of (1) the opportunity for NRC's pre-marketing evaluation and registration of sealed sources and devices intended for use under specific licenses and (2) the criteria that are used by the NRC in making its evaluations.

However, there are two additional important reasons for the proposed rule. First, it would specifically require the manufacturer or distributor (i.e., the registrant of the radiation safety information) to manufacture and distribute the product in accordance with representations made in the request for evaluation

and with the provisions of the registration certificate. Under this requirement, if the registrant states a particular limit for radiation levels at a specified distance from its device, and NRC accepts that limit in its evaluation and issuance of the registration certificate, the registrant is required to follow that limit notwithstanding any specific provision in NRC's rules for a higher limit on devices used under specific license. Second, the registrant's quality control program would be expected to ensure that each sealed source or device meets the specifications that it has furnished to the NRC.

The proposed rule would require the request for review of a sealed source or device to include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing and, additionally, in the case of a device, sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life or property.

The NRC normally evaluates a sealed source or a device using radiation safety criteria set out in industry standards. If existing industry standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The standards and criteria used must be sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life or property.

IV. ENVIRONMENTAL IMPACT: CATEGORICAL EXCLUSION.

The NRC has determined that this proposed regulation is the type of action described in the categorical exclusion set out in 10 CFR 51.22(c)(3)(i). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

V. PAPERWORK REDUCTION ACT STATEMENT.

This proposed amendment contains revised information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

VI. REGULATORY ANALYSIS.

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the analysis may be obtained from Mr. Steven Baggett (see "For further information contact:" heading).

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

VII. REGULATORY FLEXIBILITY ACT CERTIFICATION

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. The Sealed Source and Device Registry now contains approximately 3,000 certificates of registration which have been issued to about 400 manufacturers and distributors. These totals include actions both by the Agreement States and by the NRC. NRC's current rate of issuance of certificates is about 100 per year to an estimated 40 manufacturers and distributors. From year to year, there is some turnover among the manufacturers and distributors. Although a substantial number would be considered small entities, the proposed rule is not expected to have a significant impact on them.

Under present practice, the estimated average technical time (in addition to time spent on laboratory work and engineering analysis) required by the manufacturer or distributor to prepare a request for evaluation of a sealed source is 10 hours and for evaluation of a device is 30 hours. The proposed rule would not change the technical time needed for the preparation of a request for an evaluation and registration.

Use of the Sealed Source and Device Registry under present practice and as provided in the proposed rule results in savings to manufacturers and distributors and to applicants for specific licenses in the following manner. The NRC annually processes about 1500 applications for specific licenses, or amendments thereto, which reference safety information contained in the Registry. If, in lieu of referring to information in the Registry, each license applicant submitted com-

plete safety information for the source or device, the increased technical time needed by the applicant for license is estimated to be 5 hours for a source and 15 hours for a device. These estimated times assume that the license applicant obtains needed test and engineering data and some assistance from the manufacturer or distributor. The increased assistance provided to each of multiple customers by the manufacturer or distributor is estimated to be 2 hours for a source and 6 hours for a device.

The NRC has determined that the proposed rule would not impose an additional burden on any manufacturer or distributor of sealed sources and devices. However, it is seeking comments on suggested modifications, especially from small entities, because of the widely differing conditions under which many of them operate.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The manufacturer's or distributor's size in terms of annual income or revenue and number of employees;

(b) How the proposed regulation would result in a significant economic burden upon it as compared to that on a large entity; and

(c) How the proposed regulations could be modified to take into account its differing needs or capabilities.

VIII. BACKFIT

The NRC has determined that the backfit analysis provisions in 10 CFR 50.109 do not apply to this proposed rule because these amendments apply to materials licenses issued under Parts 30 and 32. These amendments do not apply to licenses under 10 CFR Part 50.

LIST OF SUBJECTS IN 10 CFR PARTS 30 AND 32

Part 30 - Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Part 32 - Byproduct material, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 30 and 32.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 is revised to read as follows:

AUTHORITY: Sections 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

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

For purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b) and (c), 30.41(a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.36, 30.51, 30.52, 30.55, and 30.56(b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 30.32 is amended by adding a new paragraph (g) to read as follows:

§ 30.32 Application for specific license.

* * * * *

(g) An application for a license to receive and possess byproduct material in the form of a sealed source or in a device that contains the sealed source must either - -

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

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

PART 32 - SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

3. The authority citation for Part 32 is revised to read as follows:

AUTHORITY: Sections 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 32.13, 32.15(a), (c), and (d), 32.19, 32.25(a) and (b), 32.29(a) and (b), 32.54, 32.55(a), (b), and (d), 32.58, 32.59, 32.62, and 32.210 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 32.12, 32.16, 32.20, 32.25(c), 32.29(c), 32.51a, 32.52, 32.56, and 32.210 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In § 32.1, paragraph (a) is revised to read as follows:

§ 32.1 Purpose and scope.

(a) This part prescribes requirements for the issuance of specific licenses to persons who manufacture, or initially transfer items containing byproduct material for sale or distribution to (1) persons exempted from the licensing requirements of Part 30 of this chapter, or (2) persons generally licensed under Part 31 or 35 of this chapter. This part also prescribes certain regulations governing holders of such licenses. In addition, this part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of the licensee or another and regulations governing holders of such licenses. Further, this part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources which are to be used by persons specifically licensed under Part 30 of this chapter or equivalent regulations of an Agreement State.

* * * * *

5. Subpart D is added as follows:

Subpart D - Specifically Licensed Items

§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be made in duplicate and sent to the U.S. Nuclear Regulatory Commission, Division of Fuel Cycle and Material Safety, Material Licensing Branch, Washington DC 20555.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, additionally, in the case of a device, sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with - -

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

Dated at Bethesda, Maryland this _____ day of _____, 1987.

For the Nuclear Regulatory Commission.

_____

Victor Stello, Jr.,
Executive Director for Operations.

DRAFT REGULATORY ANALYSIS

FOR TASK-TFC 86-3

NOTICE OF PROPOSED RULEMAKING -

Manufacturers' Registration of
Radiation Safety Information for
Certain Devices and Sealed Sources

INTRODUCTION

The purpose of a regulatory analysis is to ensure that NRC regulatory decisions are based on adequate information concerning the need for and consequences of a proposed regulatory action and to ensure that cost effective regulatory actions, consistent with providing the necessary protection of the public health and safety and common defense and security, are identified.

The procedures followed by NRC staff in preparing regulatory analyses are set out in NRC's published document, "Regulatory Analysis Guidelines" (NUREG-0058). Those procedures require a comprehensive analysis for a rule that is likely to result in:

a. An annual effect on the economy of $100,000,000 or more in direct and indirect costs, or

b. A significant impact on health, safety or the environment, or

c. A substantial increase in cost to NRC licensees, permit holders or applicants, to Federal, state or local governments, and geographical regions.

The procedures in NUREG-0058 also provide for preparation of analyses for rules that will likely result in lesser impacts than identified in a, b and c. For such rules, the evaluations are not as extensive or detailed as rules which result in impacts a, b or c. The proposed rule considered in

this analysis, "Manufacturers' Registration of Radiation Safety Information for Certain Devices and Sealed Sources," is in this category.

Interested persons are encouraged to comment on this analysis and those comments will be considered in determining further NRC action on the proposed rule. Comments should be sent to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. ATTN: Docketing and Service Branch.

1. STATEMENT OF PROBLEM

The NRC maintains a nationwide registry of radiation safety information on sealed sources of radioactive material and devices containing sealed sources. Manufacturers or distributors of sealed sources and devices voluntarily submit product information for the registry and that information is then incorporated by reference into applications for specific licenses by persons desiring to use the products.

The registry contains approximately 3,000 models of sources and devices that have been registered by about 400 manufacturers or distributors. Input to and use of the registry is shared by NRC and the Agreement States.

As administered, the registry system, in effect, constitutes a system for pre-marketing clearance or approval for licensing purposes of radiation safety properties of sealed sources and devices that are used under specific licenses issued by NRC and the Agreement States.

The operation and use in licensing of the registry is currently guided by 10 CFR 30.32 whereby an applicant for a specific license may incorporate by reference "information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission ... ." The absence of a more specific regulatory provision for the registry raises several questions: (1) has adequate notice of its existence and operation been provided so that all manufacturers and distributors, particularly those entering the sealed source and device business, have fair opportunity to register their products; (2) does the manufacturer have to assure that the distributed products meet the radiation safety related specifications filed with the registry; (3) does the manufacturer have to follow some sort of

quality assurance requirements for its products; and (4) what criteria does NRC use to evaluate the radiation safety aspects of a manufacturer's product.

2. OBJECTIVES

In consideration of the above statement of the problem, the proposed rule has the following objectives:

A. To provide a continuing notice to all interested persons:

(i) that the NRC maintains a nationwide registry of radiation safety related information on sealed sources and devices,

(ii) that manufacturers or distributors of sealed sources and devices may file product information with the registry,

(iii) as to the general areas of safety information to be covered when registering a sealed source or device,

(iv) as to the criteria used by NRC in evaluating a sealed source or device, and

(v) that the registered information is available and is used in the issuance of specific licenses.

B. To clearly establish that registrants of product information have a responsibility to the NRC to implement quality control programs and thus ensure that distributed products meet the product specifications that are filed with NRC, evaluated for adequacy, and relied on in the issuance of specific licenses which authorize use of the products.

3. ALTERNATIVES

Alternative 1: Issue a proposed rule that clearly would provide for the voluntary registration with NRC of radiation safety information on sources and devices to be manufactured and distributed for use under specific license. The rule would state the information to be submitted for NRC's evaluation, the standards and criteria used in NRC's evaluation, and the registrant's responsibility to assure that distributed products conform to the registered information.

Alternative 2: No rulemaking action but continue the voluntary registry; Rely on regulatory guides and branch positions to explain the operation of the registry, what information should be registered, and how to register information.

Alternative 3: Issue a proposed rule that would replace the "voluntary" registry by a "mandatory" registry. The manufacturer or distributor would be required to register radiation safety information before receiving authority to transfer the sealed source or device for use under specific license.

Alternative 4: Discontinue the voluntary registry of information by manufacturers and distributors and require the first applicant for a specific license authorizing use of a particular source or device to submit design and construction data. When clearly and specifically referenced by subsequent applicants, the initially submitted information could be used in issuance of additional specific licenses.

4. CONSEQUENCES

Alternative 1: This action is consistent with accomplishing the objectives stated above in section 2. This action also is consistent with the continued operation of the established and matured registration program that is administered by NRC and the 28 Agreement States. Licensing authorities in these jurisdictions accept and evaluate radiation safety information that is filed by their respective manufacturers and distributors of sources and devices. Summaries and evaluations of filed information are placed in the central registry that is maintained by NRC and is accessible to all 29 regulatory groups. Because of sharing of registered information and acceptance by all the 29 regulatory groups of evaluations performed by any one of the 29 groups, a manufacturer or distributor needs to submit detailed safety information to only a single regulatory group in order for that information to be available for use in issuing specific licenses throughout the U.S.

Alternative 2: This alternative would maintain the status quo. It allows continued operation of the administratively efficient registry system for radiation safety information on sources and devices. However, it would not adequately answer the several questions presented above in section 1. It would not provide clear notice of the registry system to all persons and would not increase the probability of early communication between NRC and persons entering the business of manufacturing or distributing sources and devices for use under specific licenses. These early communications are useful in directing the attention of new manufacturers and distributors to particular regulatory requirements and pertinent regulatory guides and branch positions. Also, this alternative would not provide a clear statement of a registrant's

responsibility to assure that distributed sources and devices satisfy the radiation safety related specifications on file in the registry.

Alternative 3: This alternative is consistent with accomplishing the objectives stated above in section 2. Also, it would be consistent with the NRC's regulation of products used under an exemption from regulatory requirements (e.g., smoke detectors) or under a general license (e.g., luminous safety devices for use in aircraft). However, it would not be consistent with NRC's and Agreement States' practice for regulating the use of sources and devices under specific license. That practice allows the applicant for specific license either to file information directly or to refer to information filed by the manufacturer when demonstrating that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This flexibility with respect to which party directly submits information for use in approval of an application for specific license is useful when considering one-of-a-kind products and when considering users' modifications of standard designs to satisfy unique conditions of use. In these cases, the applicant for license may choose to use the services of a manufacturer who has little interest in registering information directly with the NRC. That choice could be compromised by requiring "mandatory" registration by the manufacturer. Further, and perhaps more important, we are not aware of compelling health and safety reasons to change the established "voluntary" registry to a "mandatory" registry.*

*NOTE: Persons with information that is important to consideration of this alternative of "mandatory" registration are encouraged to comment.

Alternative 4: This alternative would appear to unnecessarily complicate the filing of radiation safety information for sources and devices. Direct communication between the regulatory authority and the manufacturer can be convenient and effective in clarifying submitted information. To require that information which may be known only to the manufacturer must always be funneled to NRC through the first license applicant would add to the paperwork burden of NRC, users and manufacturers. The staff does not consider this to be a viable alternative in view of the extensive and effective use of the voluntary registry system by NRC, the States, manufacturers and users.

5. DECISION RATIONALE

Under present practice, the estimated average technical time (in addition to time spent on laboratory work and engineering analysis) required by the manufacturer or distributor to prepare a request for evaluation and registration of a sealed source is 10 hours. The NRC professional staff spends an average of 6 hours on the safety evaluation of a sealed source. The estimated average technical time required to prepare a request for evaluation and registration of a device is 30 hours and the NRC professional staff spends an average of 27.6 hours on the safety evaluation. The proposed rule would not change the time needed for the preparation and the review of a request for evaluation and registration nor the economic impact on specific licensees.

The NRC annually processes about 1500 applications for specific licenses, or amendments thereto, which reference safety information contained in the Registry. If, in lieu of referring to information in the Registry, each license applicant submitted complete safety information for the sealed source or device, the applicant would have an increased technical effort in preparing the appli-

cation, the manufacturers and distributors would spend more time in assisting customers in the preparation of applications for specific licenses, and the NRC professional staff would spend more time reviewing the applications.

If the Registry is not used, the increased technical time to prepare an application for specific license is estimated to be 5 hours for a source and 15 hours for a device. These estimated times assume that the license applicant obtains the needed test and engineering data and some assistance from the manufacturer or distributor and, with additions or modifications as appropriate, forwards that data as part of the license application. The increased assistance provided to each of multiple customers by the manufacturer or distributor is estimated to be 2 hours for a source and 6 hours for a device.

If the Registry was not used, the technical time that would be spent by manufacturers and distributors in assisting their customers in preparation of applications for specific licenses is estimated to be an order of magnitude greater than the total time now spent on such assistance and on preparing requests for evaluation and registration.

The NRC saves professional staff time through use of the Registry. If 1500 applicants for specific licenses annually submitted detailed safety information in lieu of referring to information in the Registry, the NRC professional staff time spent on source and device reviews would be multiplied by a factor of 15. About 22 man-years annually would be required for NRC's reviews instead of the present 1.5 man-year.

The proposed action of issuance of a proposed rule to provide clearly for the voluntary registration with NRC of radiation safety information on sources and devices is recommended because: (1) the proposed rule permits continued operation of the efficient and effective registry system that has been developed and implemented by NRC and 28 Agreement States, and (2) the proposed rule would answer the several questions about the registry system, i.e., have all interested parties been informed about the system, what criteria are used by NRC in its evaluations, and what responsibility does the manufacturer have to assure that distributed products satisfy the specifications that have been registered?

In addition, the proposed action provides opportunity for public comment on the Commission's program for evaluation and registration of radiation safety information on devices and sources used under specific license. This opportunity, which may result in an improved program, would not be provided by Alternative 2 (status quo).

6. IMPLEMENTATION

The notice of proposed rulemaking would be published in the Federal Register and the public would be provided a period of 60 days to comment. Following evaluation of the comments and assuming that the proposed action is still warranted, a final rule would be published, to be effective 30 days after publication in the Federal Register.

The proposed rule is not expected to change the operation and use of the existing sealed source and device registry system. The proposed rule should assist in early recognition by new manufacturers and distributors of the opportunity to register their products. Implementation of the rule may result in NRC's increased attention to review of manufacturers' quality control programs. This action would occur during routine inspections of manufacturers' in-plant radiation safety programs and possibly also would occur if users encounter safety problems that are attributable to poor quality. This attention to quality control is intended to make sure that distributed products satisfy the radiation safety related specifications that are on file in the sealed source and device registry.

DRAFT CONGRESSIONAL LETTER

Enclosed for the information of the subcommittee are copies of a Notice of Proposed Rulemaking to be published in the Federal Register.

The proposed amendments to 10 CFR Parts 30 and 32 will provide clearly in the regulations for the long standing practice whereby manufacturers of sealed sources of radioactive material and devices containing sealed sources file radiation safety information about their products with the Nuclear Regulatory Commission. The information is evaluated and when referenced in specific license applications by the manufacturers' customers, is used by the NRC and the Agreement States in determining that an applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property.

This practice is currently conducted under a general provision in the regulations that allows an applicant for specific license to incorporate by reference in an application information contained in previous reports filed with the Commission.

The practice is extensively used. The NRC maintained sealed source and device registry contains information on approximately 3,000 models of sources and devices from about 400 manufacturers and distributors (vendors). Both the NRC and the 28 Agreement State licensing groups contribute data to and use the registry.

We believe that the practice has now sufficiently matured and is used to the extent that it warrants specific provision in the regulations. Publication of the rule will assure that all vendors of sealed sources and devices are informed of this practice and will clearly state that manufacturers registering their products with the NRC have a responsibility to ensure that the distributed products meet the radiation safety related specifications filed with the registry.

In view of the minor nature of the proposed amendments which merely formalize present practice, the Commission considers that issuance of a public announcement is not warranted.

Enclosure C