



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

AUG 17 1994

MEMORANDUM FOR: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

FROM: Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

SUBJECT: REQUEST FOR RULEMAKING--EXEMPTION FROM LICENSING
OF CERTAIN PRODUCTS CURRENTLY COVERED UNDER
SPECIFIC OR GENERAL LICENSES

The Commission, on August 13, 1990, in a Staff Requirements Memorandum (SECY-90-175), advised the staff that it concurs with the staff's recommendation to proceed with rulemaking to establish separate exemptions for certain devices which are currently used under specific or general licenses. However, the Commission indicated that the staff should incorporate its proposal into the Below Regulatory Concern (BRC) implementation plan. Since initiation of the BRC policy program has been suspended and the Enhanced Regulatory Participation program is currently being developed, the Office of Nuclear Material Safety and Safeguards (NMSS) request that the Office of Regulatory Research (RES) proceed with this rulemaking as an independent action.

Enclosure 1 includes a first draft of proposed changes to 10 CFR Parts 30 and 32. The changes would exempt persons from licensing for possession, use, transfer and disposal of certain devices. We believe the requirements for either a specific or general license concerning possession, use, transfer and disposal of the devices is excessively burdensome considering the devices pose little or no potential for causing a significant exposure. We request that RES obtain the services of a contractor to examine the effects of the exemptions and ensure adequate protection of people and the environment.

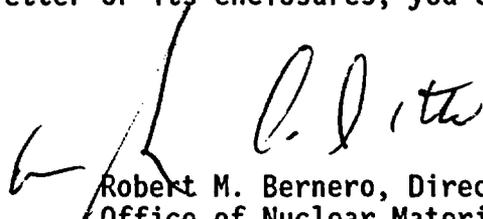
The proposed changes would provide an exemption from licensing to certain users of electron capture detectors, X-ray fluorescence analyzers, static eliminators, static monitors, beta backscatter gauges and calibration and reference sources, which meet certain design and safety criteria. This would relieve the users of the reporting, record keeping, testing and disposal requirements associated with use of the devices under specific or general licenses, and would relieve persons using the devices under a specific license from additional technical and financial burdens. These burdens are not necessary given the low hazards associated with the devices. The change would require an amendment to 10 CFR Part 32 to impose adequate requirements on the vendors of the products.

To assist RES in developing the rulemaking package, we are providing a draft justification for rulemaking (Enclosure 2) and a list of the approximate number of devices currently used by general licensees which would qualify for the exemption based on activity (Enclosure 3).

One item not addressed in the draft proposed changes is a grandfather clause. We request that RES have a contractor examine the effects of exempting persons using devices that fall in the general category but do not meet all of the design criteria listed in the rule. If a grandfather clause is not appropriate, the statements of consideration for the proposed rule should address how existing devices could be modified to meet the requirements of the proposed exemption.

We request that RES assign a high priority to the rulemaking.

Mr. John W. Lubinski is the NMSS point of contact for the rulemaking. If you have any questions concerning this letter or its enclosures, you can contact him at 415-7868.



Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

ENCLOSURE 1
PROPOSED CHANGES

§ 30.21 Certain devices containing small quantities of byproduct material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution certain devices containing byproduct material, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in parts 20 and 30-36, 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires such devices provided that the devices have been initially transferred in accordance with a specific license issued pursuant to § 32.30 of this chapter, which license authorizes the initial transfer of the devices for use under this section.

(b) Any person who desires to initially transfer devices for use pursuant to paragraph (a) of this section, should apply for a license, pursuant to § 32.30 of this chapter, which states that the device may be transferred by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section or equivalent regulations for an Agreement State.

§ 32.30 Distribution of certain devices containing small quantities of byproduct material.

(a) An application for a specific license to initially transfer devices for use pursuant to § 30.21 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirement of § 30.33(a)(2) and (3) do not apply to an application for a license to transfer devices manufactured, processed, or produced pursuant to a license issued by an Agreement State;

(2) The NRC has issued a registration certificate pursuant to § 32.210 of this chapter and such registration specifies that the design of the device is

appropriate for distribution pursuant to this section.

(3) The device is designed and manufactured:

(i) such that it does not contain more than 20 mCi of Ni-63, 50 mCi of Cd-109, 40 mCi of Fe-55, or 200 mCi of Po-210, or the sum of the quantity of each isotope divided by the quantity set forth in § 30.71, Schedule B for each isotope does not exceed 10^1 .

(ii) for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition or the byproduct material is used for internal calibration or standardization of the device.

(iii) such that the byproduct material is contained in a source housing which cannot be opened without destroying the mechanism designed to seal the housing;

(iv) such that a rod 0.25" (0.635 cm) in diameter by 6" (15.24 cm) in length cannot be inserted into any aperture in the source housing and contact the sealed source used in the device; and

(v) such that the device would maintain its integrity and the radiation levels around the device would not be substantially increased after the device is subjected to the following tests:

Temperature. The device is held at -40°C (-40°F) for 20 minutes and then held at a temperature of 180°C (365°F) for 1 hour.

External Pressure. The device is subjected to an external pressure of 3.6 pounds per square inch absolute (24.82 pascals).

Impact. A 50 g (1.8 ounces) steel hammer, 2.5 cm (0.98 inch) in diameter, is dropped from a height of 1 m (3.3 feet) on to the device. The device is then dropped 10 times to a steel surface from 1.5 m (4.92 feet).

Vibration. The is subjected to a vibration from 25 to 500 Hz at a 5 g peak amplitude for 20 minutes.

Puncture. A 1 gram (0.04 ounce) hammer and pin, 0.3 cm (0.1 inch) in diameter, is dropped from a height of 1 m (3.3 feet) onto the

¹ The contractor would need to assist in the determination of the maximum activity of Po-210 allowed to be used in the devices.

device.

The Commission may require the device to survive more stringent testing if the foreseen uses of the device are likely to subject the device to harsh environments.

(4) The device is manufactured and distributed in accordance with a quality assurance program which assures that the quality control standards approved by the Commission are implemented.

(5) The applicant submits sufficient information relating to the:

(i) Degree of access of human beings to the device during normal handling and use.

(ii) Total quantity of byproduct material expected to be distributed in the device annually.

(6) The applicant demonstrates that the radiation exposures which result from the distribution of this device will be as low as practicable.

(7) The device is not used for frivolous purposes or in toys or ornaments.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the device cannot be reasonably foreseen.

§ 32.32 Same: conditions of licenses issued under § 32.30; labeling.

Each person licensed under § 32.30 shall:

(a) Label or mark each device and its point-of-sale package on its external surface with a durable, legible, easily visible label or marking containing:

(1) The following statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.30. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.";

(2) The name of the radionuclide and quantity of activity;

(3) An identification of the person licensed under § 32.30 to transfer the device for use pursuant to § 30.21 of this chapter or equivalent regulations of an Agreement State; and

(4) The model number of the device as listed on the distribution license.

§ 32.33 Same: records and material transfer reports.

Each person licensed under 32.30 shall maintain records and file a report to the NRC Document Control Desk with a copy to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(a) The report must include the following information on products transferred to other persons for use under § 30.21 of this chapter or equivalent regulations of an Agreement State -

- (1) the quantity of each model device distributed; and
- (2) the quantity of activity of each radionuclide contained in each device.

(b) The licensee shall file the report within 30 days following -

- (1) Five years after filing the preceding report; or
- (2) Filing an application for renewal of the license under § 30.37; or
- (3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized pursuant to the license issued under § 32.26.

(c) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (b)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate.

(d) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

ENCLOSURE 2

DRAFT

JUSTIFICATION FOR RULEMAKING: EXEMPTING USERS OF CERTAIN DEVICES FROM LICENSING REQUIREMENTS

1. THE ISSUE TO BE ADDRESSED BY THE RULEMAKING AND THE PROBLEM TO BE CORRECTED.

BACKGROUND

On February 12, 1959 (24 FR 1089), the Atomic Energy Commission amended its regulations to provide a general license for the use of byproduct material contained in certain luminous, measuring, gauging, or controlling devices. Under the current requirements for possession of byproduct material under a general license, certain persons may receive and use devices containing byproduct material if the device has been manufactured and distributed in accordance with the specifications contained in a specific license issued by the NRC or by an Agreement State. A specific license is issued based upon a determination by a regulatory authority that the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee is required to comply with the safety instructions contained in or referenced on the label of the device and to have the testing or servicing of the device performed by an individual authorized to manufacture, install, or service these devices. A device used under a general license is a "black box," that is, the radioactive material is contained in a sealed source usually within a shielded device. The device is designed with inherent radiation safety features so that it can be used by persons with no radiation training or experience. Thus, the general license policy is a mechanism to simplify the licensing process so that a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

Other devices which are designed with the same inherent safety features as the devices used under the general license are required to be used under a specific license issued by the Commission or an Agreement State. As such, the user is subject to certain reporting, record keeping, testing, transfer and disposal requirements and, in some cases, additional technical and financial burdens, which are not warranted given the safe design of the device and low activity of the radionuclides.

On August 13, 1990, Staff Requirements Memo (SECY-90-175) required the staff to proceed with rulemaking for exemptions for certain devices currently used under specific or general licenses. This proposed rulemaking was to be in accordance with the Below Regulatory Concern (BRC) implementation program. These certain devices present little or no potential for radiological hazard during possess, use, transfer or disposal. Subsequently, initiation of the BRC program, and the subject proposed rulemaking, has been suspended. However, the subject proposed rulemaking is not part of the BRC policy program and should be continued. The devices to be covered under this proposed rule include electron capture detectors, X-ray fluorescence analyzers, static eliminators, static monitors, beta backscatter gauges, and calibration and reference sources. Currently, users of these devices must either obtain a specific license to possess these devices or use them under a general license. The proposed rulemaking would relieve the users of the reporting, record keeping, testing, transfer and disposal requirements associated with use of the devices under specific or general licenses and would relieve persons using the devices under a specific license from the additional technical and financial burdens. These burdens are not necessary given the low hazards associated with the devices.

ISSUES ADDRESSED

The proposed rule would address relieving users of certain devices containing byproduct material from burdensome cost from licensing requirements which are not justified considering the inherent safety design of the devices. The rule would also relieve NRC and Agreement States of cost associated with licensing the users of the device and some of the cost associated with licensing the manufacturers of the equipment.

With respect to the problem to be addressed, the proposed rule would exempt users of the devices from regulatory requirements based on the design of the devices and the activity of the radioactive material contained in the device.

2. THE NECESSITY AND URGENCY OF ADDRESSING THE ISSUE.

If the rulemaking is pursued, it will allow certain specific and general licensees to use byproduct without having to satisfy existing regulatory requirements. Considering the low potential for radiation exposure associated with the products, the current regulations governing use of the devices covered by this rulemaking is unnecessarily burdensome. Therefore, promulgation of the rule would alleviate the industry of unnecessarily burdensome requirements and would allow NRC and the Agreement States to focus its resources on higher priority issues rather than regulating the possession, use, transfer and disposal of the devices covered by the rulemaking.

3. ALTERNATIVES TO RULEMAKING.

The only alternative to rulemaking is to maintain the status quo. Maintenance of the status quo would continue to impose burdensome specific and general licensing requirements on industry and the would require NRC to continue to expend resources to regulate the possession, use, transfer and disposal of certain devices that pose little or no threat to public health and safety or to the environment. Therefore, the proposed rulemaking is the only viable alternative to addressing the possession, use, transfer and disposal of the devices.

4. HOW THE ISSUE WILL ADDRESSED THROUGH RULEMAKING.

10 CFR Part 30 will be amended to provide an exemption from licensing for the possession, use, transfer and disposal of certain devices containing byproduct material. The exemption is based on the fact that the design of the device is such that it will pose little or no threat to people or to the environment.

10 CFR Part 32 will be amended to provide the specifications that the devices used under the exemptions in 10 CFR 30 must meet to be considered safe.

5. HOW THE PUBLIC, INDUSTRY, THE STATES, AND NRC WILL BE AFFECTED BY THE RULEMAKING, INCLUDING BENEFITS, COSTS, OCCUPATIONAL EXPOSURE, AND RESOURCES.

The rule has the potential to result in four distinct benefits. The first is the financial savings to users of the devices in both NRC and Agreement States. Persons currently using the devices under specific or general licenses would no longer be subject to costs associated with license requirements which include reporting, record keeping, testing, performing inventories, and cost associated with transfer and disposal of the devices.

The second benefit would be to the distributors of the devices, located in both NRC and Agreement States. They too would no longer have to adhere to certain license conditions and would not have to provide certain services nor provide certain information to their customers upon transfer of the devices. However, the distributors would incur a one time cost of applying for an exempt distribution license which would allow for the distribution of devices to persons exempt from licensing under the new rule.

The third benefit would be to the Agreement State programs. They would no longer incur costs associated with specifically or generally licensing persons who could be exempt from licensing requirements under the rule change. In addition, certain distributors of devices would terminate their distribution licenses and obtain an NRC exemption distribution license. Therefore, the Agreement State would save the costs associated with maintaining the distribution licenses.

The final benefit would be to NRC. NRC would no longer incur the costs associated with specifically or generally licensing persons who could be exempt from licensing requirements under the rule change and certain distributors would convert their current distribution licenses to exempt distribution licenses. Inspection and enforcement of the exempt distribution licenses would cost NRC less because there are less requirements on the licensees. The number of NRC distribution licensees would increase as a

result of Agreement State licensees applying for exemption distribution licenses. However, the cost of issuing the new licenses and for inspection and enforcement of the licenses would be more than offset by the savings incurred by NRC.

All of the benefits of the rule change are achieved with little or no effect on the protection of people or the environment because of the low potential for exposure associated with the devices.

6. NRC RESOURCES AND TIMETABLE FOR THE RULEMAKING.

[The development of a timetable and calculation of the resources necessary to develop the proposed and final rule will have to be accomplished as a joint effort between RES and NMSS.]

7. THE PRIORITY OF THE RULEMAKING.

High.

ENCLOSURE 3

	Number of Devices Containing 10 Times the Limits in 10 CFR 30.71B or Less Used by General Licensees	Additional Number of Devices Containing the Limits Specified in the Proposed 10 CFR 32.30 Used by General Licensees
Ba-133	715	NA
Cd-109	6	1,541
C-14	477	NA
Cs-137	4,664	NA
H-3	2,797	NA
I-129	30	NA
Fe-55	218	678
Kr-85	84	NA
Ni-63	77	6,684
Po-210	0	36,584
Pm-147	2,218	NA
Sr-90	5	NA
Tl-204	3,129	NA
Total:	14,420	45,487