



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20655

PDR

OFFICE OF THE
CHAIRMAN

March 18, 1983

The Honorable Tony Coelho
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Coelho:

In my letter of November 23, 1982, I informed you that a proposed rule was to be published concerning annual reports of distribution of consumer products containing byproduct material. That proposed rule would replace the existing annual reporting requirement by a requirement that reports be submitted (1) every five years, or (2) at the time of application for renewal of the specific license, or (3) at the time the licensee notifies the Commission that it is discontinuing distribution of these consumer products. Since licenses for distribution of consumer products are routinely issued and renewed for periods of five years, the report can be submitted as a part of the application for renewal of the license.

The proposed rule was published in the Federal Register (47 FR 52719) on November 23, 1982 allowing for a 30-day public comment period. Eleven letters of comment were received. Most commenters supported the Commission's effort to reduce the reporting burden on licensees but varied in their views as to which alternative action should be taken. A summary of the comments and the NRC's responses is included in the preamble of the final rule.

The Commission concludes that relatively current and accurate data on distribution of consumer products should be collected. The information collected under these reporting requirements provides the NRC and other interested parties with information concerning the extent and pattern of consumer products distribution. The NRC has also used this information to perform periodic assessments of public exposure to radiation from these products. The Commission also concludes that the reporting burden of the licensees can be significantly reduced without affecting the usefulness of the data. This rule, which substitutes a requirement to submit a report every five years for the annual reporting requirement, appears to provide the best balance between reducing the burden and maintaining a useful data base. Therefore, the Commission adopted the proposed rule, without change, as the final rule. Enclosed for your information is a copy of a Notice of Final Rulemaking to be published in the Federal Register.

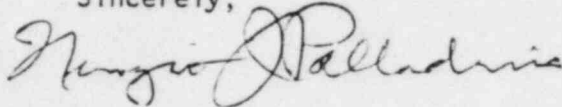
We believe this reduction of reporting burden for businesses that distribute consumer products will improve efficiency without losing the effectiveness of our regulatory program for consumer products.

The Honorable Tony Coelho

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As I previously stated, I appreciate your bringing this matter to my attention. I believe the action we have taken is appropriate and will improve our program.

Sincerely,

A handwritten signature in cursive script that reads "Nunzio J. Palladino". The signature is written in dark ink and is positioned above the typed name and title.

Nunzio J. Palladino
Chairman

Enclosure: Notice of Final Rulemaking

NUCLEAR REGULATORY COMMISSION
10 CFR Part 32
Consumer Products Containing Small Quantities of
Radioactive Material; Modified Reporting and
Recordkeeping Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to modify the reporting and recordkeeping requirements imposed on persons specifically licensed to distribute consumer products containing byproduct material. The existing annual reporting requirements are amended to require that reports be submitted (1) every five years, or (2) at the time of application for renewal of the specific license, or (3) at the time the licensee notifies the Commission that it is discontinuing distribution of these consumer products. The amendment is intended to reduce the number of reports submitted to the Commission. This amendment pertains only to the submission of reports and recordkeeping requirements and will not affect the safety properties of the products that are distributed.

EFFECTIVE DATE:

FOR FURTHER INFORMATION CONTACT:

Dr. Anthony N. Tse
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555 (301-443-5825)

SUPPLEMENTARY INFORMATION:

Background

On November 23, 1982, the NRC published in the Federal Register (47 FR 52719) a Notice of Proposed Rulemaking to amend 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." The proposed amendments to Part 32 suggested modifications to the reporting and recordkeeping requirements imposed on persons licensed to distribute consumer products containing small quantities of byproduct material (exempt items).

These regulations required licensees to submit an annual report to the NRC specifying the total quantity of byproduct material transferred in each type of consumer product and the total number of each product transferred during the reporting period. An annual report was required even if a licensee made no transfers during the reporting period. This process provided the NRC and other interested parties with information concerning the extent and pattern of consumer product distribution. The NRC has also used this information to estimate the exposure of the general public to radiation from these products.

After reviewing these reporting requirements, the NRC proposed a minor change to the requirements that would reduce paperwork burdens on the affected licensees and the agency without diminishing the value of these reports to the NRC's regulatory program. The NRC proposed that the licensees be required to submit a report every 5 years, or at the time of application for renewal of the specific license, or at the time the licensee notifies the Commission that it is discontinuing distribution of these consumer products. In the notice of proposed rulemaking, the NRC also sought public comment on two alternative actions: (1) eliminating reporting requirements completely, and (2) establishing a threshold such that if less than 1000 units were distributed annually, a report would not be required. However, the NRC has decided to adopt the approach set out in the proposed rule. The reason for this decision is outlined in the NRC's response to comments received on the proposed rule and the suggested alternatives.

The requirements for the type of records that must be kept is not changed although in certain cases the length of time that these records must be stored is modified to conform with the 5 year reporting period. This is necessary to facilitate the licensee's preparation of summary reports.

Comments

Interested persons were invited to submit written comments. The 30-day comment period expired on December 23, 1982. Eleven letters of comment were received: ten from private industry and one from a state agency.

Most commenters supported the Commission's effort to reduce the reporting burden on licensees. However, the commenters varied in their views as to which alternative action should be taken. One suggested that the NRC terminate licensing for small distributors of consumer products; four favored complete elimination of reporting requirements; three supported the 5-year reporting period but two of these three also favored eliminating the reporting requirements; two preferred a threshold number and one opposed any change to the existing regulations.

Copies of the comments may be examined in the Commission's Public Document Room at 1717 H Street NW, Washington, DC. A summary of the comments and the NRC staff's responses to these comments is presented below.

1. Most commenters supported complete elimination of reporting requirements because (1) the public exposure to radiation from consumer products is very small and (2) the data contained in the reports could be obtained by other means, such as literature searches or discussions with product manufacturers. Although the public exposure to radiation from consumer products is very small, the Commission must, from time to time, reassess the exposure and verify that the public exposure remains small. Relatively current and accurate data on the types and quantities of products and radionuclides distributed are necessary to inform the Commission of the extent of the distribution of these products and to provide data for performing adequate assessments of public exposure to

radiation from these products. Thus, the Commission believes a reasonably accurate data base should be collected by the Commission.

The Commission considered alternative ways of collecting the necessary data. Some data may be collected by literature search or by discussions with product distributors or manufacturers. However, these methods may have the following drawbacks (1) certain information, such as the number of products distributed in a year, might not be available in the literature because of its proprietary nature, (2) the data collected could have a large degree of uncertainty unless information from all licensees who distribute the products is included, and (3) the efforts spent by licensees to locate and report distribution data in response to an unscheduled data collection survey might be more burdensome than the efforts required to prepare one report every five years. Therefore, the Commission believes the data obtained from reports submitted at 5-year intervals is more accurate than data collected from literature search or by discussion with manufacturers.

2. One commenter suggested that the NRC should terminate licensing small distributors of consumer products containing byproduct materials. The principal issue in this rulemaking is not whether the NRC should continue to license consumer product distributors; the issue is whether the NRC should modify its existing reporting requirements applicable to this group of licensees. Thus, this comment is not relevant to the issue in this rulemaking proceeding.

3. Two commenters preferred the alternative that would establish a threshold number for the submission of an annual report. Another commenter, on the other hand, stated that a 1000-unit threshold plan would eliminate very few smoke detector manufacturers because it is unlikely that someone would handle such a small number of products. Although the 1000-unit threshold option would result in about 30% reduction in the number of reports, it would also have three major drawbacks: (1) the data would be relatively inaccurate, because it is uncertain what percent of the total would be reported, (2) the licensees would still have to summarize product distribution data at the end of a reporting period so that they could determine whether the distribution exceeded the threshold number, and (3) lack of the report from a specific licensee

would lead to the uncertainty whether the threshold had not been exceeded or the licensee had neglected to file the report. On the other hand, the 5-year reporting option, as compared to the existing annual reporting requirements, would provide 80% reduction in the number of reports a licensee must submit. Therefore, the Commission believes the threshold option is not as effective in reducing the reporting burden as the the 5-year reporting option.

4. One commenter suggested that the existing reporting requirements not be changed. He doubted the efficacy of the change in reducing paperwork. In addition, the turnover in personnel would make the information on a 5-year reporting interval not as valuable as it is on a yearly basis. The Commission believes that, if the reporting period is extended from 1 year to a 5-year period, there would be a significant reduction (by a factor of 5) in the number of reports that must be prepared by licensees. Although the Commission agrees that the information obtained at 5-year reporting intervals would not be as current as the information contained in annual reports, the lack of data on the yearly basis would have little impact in the NRC's effort in assessing of public exposure to radiation from these products because the period between assessments is usually greater than 5 years. Considering the significant reduction in the number of reports, the Commission believes it is cost effective to extend the reporting period from 1 year to 5 years.

5. Several commenters are concerned with extending the recordkeeping requirements. Two stated that the retention of records for another year would impose an additional and unwarranted cost. Another, however, stated that they keep records as live records for a year or two before these records are transferred to archival storage and that there is little difference between the storage of archival records for 3 or 6 years as long as these records do not have to be retrieved on a regular basis. This amendment requires that the record be maintained one year after that record was used in preparation of the 5-year report submitted to the Commission. The average record retention period would be 3 years. This replaces the existing record retention period of 2 years for about 25 licensees and five years for about 175 licensees or an average record retention period of 4.5 years, thereby resulting in an overall reduction

in recordkeeping requirement. The Commission believes that, although each licensee may have different recordkeeping systems and the changes in recordkeeping requirements will have a different impact on various licensees, the burden on recordkeeping averaged over all the affected licensees would result in a slight reduction in the record retention periods.

The Regulation

The final rule is the same as the proposed rule. It modifies the reporting and recordkeeping requirements in 10 CFR 32.12, 32.16, 32.20, 32.25, and 32.29.

Paperwork Reduction Act Statement

The rule was submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (Pub. L. 96-511; 42 U.S.C. Ch. 15). The information collection requirements contained in this regulation were approved by OMB. OMB approval no. 3150-0001.

Regulatory Flexibility Certification

Since these amendments generally would reduce present recordkeeping and reporting requirements, the Commission, in accordance with sec. 605(b) of the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. Persons specifically licensed to distribute consumer products containing byproduct material will no longer be required to submit an annual report to the Commission but will be required to submit reports covering periods of approximately five years. An estimated reduction of about 80 percent of the approximately 200 reports currently submitted annually is expected.

List of Subjects in 10 CFR Part 32 .

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting requirements.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and section 553 of title 5 of the United States Code the following amendment of title 10 chapter 1, Code of Federal Regulations, Part 32, is published as a document subject to codification.

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

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

AUTHORITY: Secs. 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, and 32.62 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 and 32.56 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. The authority citations at the end of the following sections in Part 32 are removed: §§ 32.1, 32.14, 32.15, 32.16, 32.17, 32.18, 32.22, 32.25, 32.26, 32.29, 32.40, 32.51, 32.52, 32.53, 32.54, 32.56, 32.57, 32.61, 32.62, 32.71 and 32.110.

3. Section 32.12 is revised to read as follows:

§ 32.12 Same: records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission,

Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(b) The report must identify the--

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c) 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 under the license issued under § 32.11.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report shall so indicate.

(e) 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.

4. Section 32.16 is revised to read as follows:

§ 32.16 Certain items containing byproduct material: records and reports of transfer.

(a) Each person licensed under § 32.14 or § 32.17 shall maintain records of transfer of material and report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission,

washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(b) The report must include the following information on items transferred to other persons for use under § 30.16 of this chapter or equivalent regulations of an Agreement State--

- (1) A description or identification of the type of each product;
- (2) For each radionuclide in each type of product, the total quantity of the radionuclide; and
- (3) The number of units of each type of product transferred during the reporting period.

(c) The licensee shall file the report within 30 days after--

- (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 under the license issued under § 32.14 or § 32.17.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.14 or § 32.17 during the reporting period, the report must so indicate.

(e) 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.

5. Section 32.20 is revised to read as follows:

§32.20 Same: records and material transfer reports.

(a) Each person licensed under § 32.18 of this part shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds and quantities of byproduct material transferred. The licensee shall maintain the record of a transfer for a period of one year after the event is included in a summary report to the Commission.

(b) The licensee shall file a summary report stating the total quantity of each isotope transferred under the specific license with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(c) The licensee shall file the summary 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 under the license issued under § 32.18.

(d) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

6. In § 32.25, paragraph (c) is revised to read as follows:

§ 32.25 Conditions of licenses issued under §32.22: quality control, labeling, records, and reports of transfer.

Each person licensed under §32.22 shall:

* * * * *

(c) Maintain records and file reports with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.19 of this chapter or equivalent regulations of an Agreement State--

- (i) A description or identification of the type of each product;
- (ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

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

(i) Five years after filing the preceding report; or

(ii) Filing an application for renewal of the license under § 30.37;

or

(iii) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.22.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2)(i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under 32.22 during the reporting period, the report must so indicate.

(4) 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.

7. In § 32.29, paragraph (c) is revised to read as follows:

§32.29 Conditions of licenses issued under §32.26: quality control, labeling, records, and reports of transfer.

Each person licensed under § 32.26 shall:

* * * * *

(c) Maintain records and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with copies to the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter.

(1) The report must include the following information on products transferred to other persons for use under § 30.20 of this chapter or equivalent regulations of an Agreement State--

(i) A description or identification of the type of each product;

(ii) For each radionuclide in each type of product, the total quantity of the radionuclide; and

(iii) The number of units of each type of product transferred during the reporting period.

- (2) The licensee shall file the report within 30 days following--
 - (i) Five years after filing the preceding report; or
 - (ii) Filing an application for renewal of the license under § 30.37;

or

(iii) 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.

(3) The report must cover the period between the filing of the preceding report and the occurrences specified in paragraphs (c)(2)(i), (ii), or (iii) of this section. If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(4) 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.

Dated at Bethesda, Maryland this 4th day of MARCH, 1983.

For the Nuclear Regulatory Commission



William J. Dircks
Executive Director for Operations