



DOCKET NUMBER

PROPOSED RULE

PR

(45 FR 20493)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL RESOURCES

Post Office Box 2063

Harrisburg, Pennsylvania 17120

November 26, 1982

Nunzio J. Palladino, Chairman
U.S. Nuclear Regulatory Commission
Mail Stop H-1149
1717 H Street, N.W.
Washington, DC 20555

Dear Dr. Palladino:

RE: Proposed Amendment to No. 10 CFR 20 Requiring
Accreditation of Personnel Dosimetry Services

We strongly endorse the referred proposal which would mandatorily require licensees to use personnel dosimetry services which are accredited by the National Voluntary Laboratory Accreditation Program, a part of the National Bureau of Standards.

There are significant detrimental disparities between methods of calibrating or standardizing of both the dosimeter processing equipment and the respective dosimeters. These result in disparate interpretation of personnel dose among the dosimetry services whether they are commercial suppliers, or of governmental or private industrial in-house origin. It is difficult to reconcile a comparative dose from the same exposure which could vary, for example, from 3 to less than 30 millirems as determined by several services.

The proposed amendment, which we support, is apparently the only way to have personal dosimetry systems tested, evaluated, and accredited so that more uniform and meaningful dose reporting might be realized in that important area of personal radiological health.

Very truly yours,

Tom

THOMAS M. GERUSKY, Director
Bureau of Radiation Protection

DS10: add: Robert Alexander
5650 NL

to recordkeeping and the submission of reports and would have no effect on safety properties of the products that are distributed.

DATES: Comment period expires December 23, 1982. Comments received after December 23, 1982 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 that date.

ADDRESS: All interested persons who desire to submit written comments or suggestions for consideration in connection with the proposed amendment should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments on the proposed amendment may be examined at the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. Donovan A. Smith, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-443-5825).

SUPPLEMENTARY INFORMATION: Sections 32.12, 32.16, 32.20, 32.25, and 32.29 of the Nuclear Regulatory Commission's regulations in 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," include certain reporting requirements applicable to licensees who transfer byproduct material for use under the exemptions from Commission licensing requirements set in §§ 30.14, 30.15, 30.16, 30.18, 30.19 and 30.20.

The licensees are required to report annually to NRC the total quantity of each byproduct material transferred in each type of exempt item, and the total number of each exempt item transferred during the reporting period. An annual report is required even if no transfers were made during the reporting period.

The Commission recently reviewed the reporting requirements and is considering a minor change that would reduce administrative burdens for the Commission without greatly changing the value of the reports to the regulatory program.

The reporting requirements are used to collect information about the extent of use of products for which NRC has exempted the user from regulatory controls. That information has been used in estimating exposure of the general public. For example, over 30,000,000 smoke detectors, each containing a small amount of byproduct material, have been distributed; and the

estimated annual radiation dose to the U.S. population from smoke detectors is about 1,000 person-rem.

Upon consideration of (1) The relative values to the regulatory program of approximate numbers and of relatively current and exact numbers of exempt items (also called "consumer products") transferred to the general public and (2) a desire to reduce unnecessary paperwork, the Commission is proposing to require that the reports be submitted at approximately five-year intervals. Since the specific licenses authorizing distribution of consumer products usually are issued for a period of five years, the report of the numbers of products and the quantities of radioactive materials transferred can be submitted as a part of the application for renewal of the license.

At the present time, persons specifically licensed to distribute consumer products containing byproduct material are required to maintain records of transfers for periods of two or five years (§§ 32.20 and 30.51(c)(3)). Since the proposed amendments would require summary reports of transfers over periods of five years, the length of time for maintaining a record of a transfer would be changed to facilitate the licensee's preparation of summary reports and to allow verification of the accuracy of the reports. As modified, a record of a transfer would have to be maintained until one year after that record was used in preparation of the summary report submitted to the Commission. Thus, records maintained by the licensee could reflect transfers which occurred up to six years ago and, assuming a uniform rate of distribution, the average record would be three years old.

The effects of the proposed changes in recordkeeping requirements would be the following. The approximately 25 specific licensees now required by § 32.20 to maintain records of transfers of material for a period of two years after any transfer would be required to maintain records of transfers for one to six years and the average period would be three years. These 25 specific licensees would have an increased recordkeeping burden. The other approximately 175 specific licensees affected by the proposed rule and now required by § 30.51(c)(3) to maintain records of transfers for a period of five years, would need to maintain records for one to six years and the average period would be three years. These 175 specific licensees would have a reduction in recordkeeping burden. Thus, collectively, the proposed

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

Consumer Products Containing Small Quantities of Radioactive Material; Modified Recordkeeping and Transfer Reporting Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering amending its regulations to modify the recordkeeping and annual reporting requirements imposed on persons specifically licensed to distribute consumer products containing small quantities of byproduct material. The proposed amendment would replace the annual reporting requirements by requirements that reports be submitted every five years or at time of application for renewal of the specific license or at time of notification of the Commission of a decision to discontinue distribution of consumer products. The proposed amendment is intended to reduce the number of reports submitted to the Commission. The proposed amendment pertains only

amendments should cause a slight reduction in the number of records maintained by the specifically licensed distributors of consumer products containing byproduct material.

During the review of the present reporting requirement and the preparation of the proposed amendment, the staff also considered two other alternative actions. These alternative actions were (1) completely eliminating the reporting requirements, and (2) establishing a threshold number for submission of annual reports so that a report would be required only if the distributor transferred more than 1,000 units (e.g., 1,000 smoke detectors) during the year. These two alternative actions are briefly discussed below.

The alternative action of completely eliminating the reporting requirements could be justified by the extensive data collected during the last ten years. These data indicate that the total contribution to the exposure of the general public to radiation from the use of byproduct material in consumer products is less than 0.001 of background radiation or of limits recommended for exposure to radiation from all sources. In the absence of major changes in the Commission's regulation of consumer products and in the public's acceptance of consumer products containing radioactive material, their contribution to future exposure of the public is unlikely to be significantly greater than during the past ten years.

If the reporting requirements were eliminated and a need developed for information about the extent of distribution of consumer products containing byproduct material, that information could be obtained in the same manner as is used now for obtaining information about products containing source material.

Although Commission regulations have required annual reports from distributors of consumer products containing byproduct material (smoke detectors, self-luminous timepieces, etc.), no similar requirement has been imposed on distributors of consumer products containing source material (gas mantles, welding rods, etc.). The absence of a reporting requirement for source material is a result of specific provision in Section 65 of the Atomic Energy Act of 1954, as amended, that the Commission shall not require reports with respect to unimportant quantities of source material.

Absence of regulatory reporting requirements for consumer products containing source material has not prevented the staff from developing estimates of exposures to the public from these products. Approximately

25 000,000 gas mantles, each containing a very small amount of source material, are distributed annually in the U.S., and their use results in an annual population dose of about 1,200 person-rem.

The staff has developed estimates of the number of distributed consumer products containing source material by literature searches and by discussions with manufacturers. The same approach can be used in the future for consumer products containing byproduct material without decreasing the protection afforded the public health and safety.

The alternative action of establishing a threshold number for submission of annual reports would relieve the small-volume distributor of paperwork but would not significantly affect the reported total number of products distributed. Under this alternative, if a licensee distributes less than 1,000 units during the reporting period, the annual report would not be required. If the licensee distributes more than 1,000 units during the reporting period, a report would be required.

A review of 1,500 reports which were submitted during the last ten years showed that, if a 1,000-unit threshold had been in effect, there would have been a one-third reduction in the number of reports submitted and less than a one-tenth reduction in the total number of units that were reported transferred.

Interested persons are encouraged to comment on the proposed amendment and also on the alternative actions of (1) eliminating the reporting requirements and (2) establishing a threshold number for submission of annual reports. Either of the alternative actions may be adopted by the Commission instead of the proposed amendment.

Paperwork Reduction Act Statement

This proposed amendment would modify the requirement for certain specific licensees to file an annual report with the Commission about products and byproduct material transferred for exempt use. As modified, reports covering five-year periods would be required and there would be a reduction in the number of reports submitted to the Commission. The proposed amendment also would provide a net reduction in the number of records required to be maintained by those specific licensees.

Pursuant to the Paperwork Reduction Act of 1980 (Pub. L. 96-511), this proposed rule will be submitted to the Office of Management and Budget for clearance of the net reduction in recordkeeping and information collection requirements.

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, if promulgated, will not have a significant economic impact on a substantial number of small entities. Persons specifically licensed to distribute consumer products containing byproduct material would no longer be required to submit an annual report to the Commission but would be required to submit reports covering periods of approximately five years. NRC estimates that the average licensee would require about one hour to prepare and submit a report. An estimated reduction of about 80 percent of the approximately 200 reports currently submitted annually would be 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, notice is hereby given that adoption of the following amendments to 10 CFR Part 32 is contemplated.

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. 161c, 68 Stat. 950, as amended (42 U.S.C. 2201 (c)).

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 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.

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 § 30.19 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 occurrence 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:

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(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 occurrence 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 occurrence 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 Washington, D.C., this 17th day of November, 1982.

For the Nuclear Regulatory Commission,
John C. Hoyle,

Acting Secretary of the Commission.

[FR Doc. 82-32064 Filed 11-22-82; 8:45 am]

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Scott M. Matheson
Governor



James O. Mason, M.D., Dr.P.H.
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December 1, 1982

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Washington, D.C. 20555

GOVERNMENT OF UTAH
PROCESSED RULE 20

(76)
(45 FR 20493)

Dear Mr. Palladino:

It has been our experience that personnel dosimetry services have been unreliable in the low dose range. We have not tried to check accuracy by submitting a dosimeter with a calibrated exposure, but the reported exposures did not always coordinate with our activities. While our reported exposures have been less than 20 mrem/month, we have wondered how reliable the dosimetric services are even at higher doses.

We would like to go on record in support of a federal requirement that providers of Personnel Dosimetry Services must show evidence of reliability such as certification by a national laboratory.

Sincerely,

Darrell M. Warren
Darrell M. Warren, Director
Bureau of Radiation Control

and

Blaine N. Howard
Blaine N. Howard, Health Physicist
Bureau of Radiation Control

BNH:kn

DSIO
add:

Robert Alexander
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Acknowledged by 12/10/82 emp