

DOCKET NUMBER
PROPOSED RULE **32**

(62FR49173)

DOCKETED
[7590-01-P] UCN70

NUCLEAR REGULATORY COMMISSION

'98 JUN 10 A10:04

10 CFR Part 32

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RIN 3150-AF76

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License Applications for Certain Items Containing Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations that govern licensing requirements for persons who incorporate byproduct material into certain items or who initially transfer certain items containing byproduct material. This action is being taken in response to a petition for rulemaking submitted by mb-microtec, Inc. (PRM-32-4), to allow the distribution of timepieces that contain less than 25 mCi of gaseous tritium light sources (GTLS) to be regulated according to the same requirements that regulate timepieces containing tritium paint. This final rule simplifies the licensing process for distribution of certain timepieces containing tritium paint and accommodates the use of a new technology for self-illuminated timepieces.

August 17, 1998

EFFECTIVE DATE: (~~60 days after publication in the Federal Register~~)

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L-4-1P732

Pub. on 6/17/98
at 63FR32969

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I. Background

A petition for rulemaking was received from mb-microtec, Inc. (PRM-32-4), and noticed for public comment on October 29, 1993 (58 FR 53670). This petition requested that those timepieces having GTLS be placed on the same regulatory basis as timepieces with luminous tritium paint. No public comments were received on the notice.

NRC regulations that are relevant to this petition are the following:

1. Under 10 CFR 30.15(a)(1), persons who receive, possess, use, transfer, own, or acquire timepieces containing byproduct material are exempted from NRC's licensing requirements provided that not more than the following quantities of byproduct material are contained in the timepiece or hands or dials:

- (1) 25 mCi of tritium per timepiece;

- (ii) 5 mCi of tritium per hand;
- (iii) 15 mCi of tritium per dial (bezels, when used, shall be considered part of the dial).

Quantity limits for timepieces containing promethium-147 are also included.

2. Broad general requirements in § 32.14(d)(1) are applicable to the method of containment or binding of the byproduct material incorporated into the products specified in 10 CFR 30.15. Specific prototype testing requirements for tritium-painted dials, watch hands, and pointers are also provided in § 32.14(d)(1). No prototype testing procedures are provided for timepieces containing GTLS.

3. An exemption from licensing requirements in § 30.19 is similar to that found in 10 CFR 30.15(a)(1) with respect to self-luminous products containing tritium, krypton-85, or promethium-147; but unlike § 30.15(a)(1), it does not limit the quantity of these radionuclides that may be incorporated into various parts of the product. However, it does require persons who manufacture, process, produce, or initially transfer such products to apply for a specific license under § 32.22.

4. An extensive list of requirements in § 32.22 must be met in order to obtain a specific license to distribute such products, and § 32.23 and § 32.24 provide safety criteria that must be demonstrated prior to issuance of a license to distribute such products.

The petitioner stated that current regulations were overburdensome and counterproductive, and that watch manufacturers do not want to become involved with the present licensing procedures required under § 32.22 concerning GTLS watches.

The NRC believes that the health and safety impact from using timepieces with GTLS would likely be positive because the radiation dose to the public from the use, storage, distribution, etc., of timepieces using GTLS is less than the dose to the public from timepieces

containing tritium paint if the same amount of tritium is used in both types of timepieces. This is because the tritium leak rate from timepieces using GTLS is lower than from timepieces using tritium paint because of significantly lower tritium leak rates from sealed glass tubes than from timepieces containing the same amount of tritium as paint. Thus, allowing the exempt distribution of timepieces using GTLS under the same regulatory requirements as those used for timepieces containing tritium paint could result in a lower dose to an individual and a lower collective dose to the public. The distribution of timepieces containing larger quantities of gaseous tritium (up to 200 mCi) has been approved for use under § 32.22, "Self-luminous products." These timepieces have been evaluated against the safety criteria specified in §§ 32.22, 32.23, and 32.24 and have been found acceptable.

The NRC believes that including GTLS in § 32.14(d) to allow their exempt distribution for use under § 30.15 would reduce unnecessary burdens for both the licensees and the NRC. Without the adoption of this alternative, licensees have to manufacture timepieces under the stringent criteria in §§ 32.22, 32.23, and 32.24. The NRC must also review product design against these requirements. Because these stringent requirements are not deemed necessary for smaller quantities of tritium, these burdens could be avoided without affecting public health and safety. Based upon the foregoing, the NRC has concluded that the distribution under § 30.15 and § 32.14 should be allowed.

On September 19, 1997 (62 FR 49173), the NRC published a proposed rule that incorporated the petition in part, by removing the existing specific testing procedures for tritium from the regulations and leaving only a modified first sentence in § 32.14(d)(1):

- (1) The method of containment or binding of the byproduct material in the product is such that the radioactive material will be bound and will not become detached from the

product under the most severe conditions which are likely to be encountered in normal use and handling.

This modification of § 32.14(d)(1) represented a performance-based approach by removing the existing specific testing procedures from the regulations and was expected to provide increased flexibility in the regulations and the accommodation of future developments in the technology of tritium illuminated timepieces, as well as other products exempt from the requirements for a license under § 30.15.

II. Public Comments on the Proposed Rule

The comment period on the proposed rule closed December 3, 1997. Three comment letters pertaining to the proposed rule were received, each addressing a different element of the rule. These comments are discussed in the following section.

III. Response to Public Comments

The first commenter approved the changes made in § 32.14(d)(1) but requested, as a step toward international harmonization, that the NRC adopt the International System of Units (SI) in prescribing the quantities of byproduct material incorporated into products distributed to persons exempt from licensing as specified in § 30.15. In addition, the commenter requested that the quantity limit for tritium specified in § 30.15(a)(1)(i), 25 mCi, be changed to read 27 mCi (1 GBq) to correspond to the exempt activity of tritium specified in the IAEA Safety Series No. 115 standard.

NRC practice is to use a dual system in describing units; the quantities are given in the SI system, followed by the quantities in parentheses in conventional units. This system of units is used in this final rule wherever radiation quantities are specified. However, no change in § 30.15 is being made at this time so that the quantity limit will remain as 25 mCi. Regarding the request to change the total exempt activity for timepieces to 27 mCi in place of the 25 mCi now in use, the NRC is currently involved in an overall reevaluation of the exemptions from licensing in 10 CFR Parts 30 and 40, including § 30.15(a)(1)(i), and will consider the issue during that process.

The second commenter stated that the language of § 32.14(d)(1) of the proposed rule appeared to require 100% containment of the tritium in watches using tritium paint. The commenter proposed alternative text that would remove this inconsistency and provide text equally applicable to watches that utilize either tritium paint or GTLS as to other exempt products under § 30.15. This commenter's suggestion has been adopted. Section 32.14(d)(1) has been revised in this final rule. As revised, the rule requires that the tritium be properly contained. The commenter also noted that § 32.14(d)(2) of the proposed rule did not make sense as presented and proposed amendatory language that contains the same concept. The language proposed by this commenter has been adopted in the final rule. Accordingly, the codified text in § 32.14(d)(2) has been modified to refer more correctly to existing prototype testing requirements for automobile lock illuminators.

The third commenter remarked that the wording of the first sentence of the proposed § 32.14(d)(1) was similar to the opening sentence of the existing rule, and that the remainder of the language of § 32.14(d)(1), which stated that the performance standard is satisfied if certain prototype tests (applicable only to tritium paint) are satisfied, has been removed. The commenter noted that the proposed rule also stated that guidance on specific prototype testing

procedures would be provided in NUREG-1562, "Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License." The commenter indicated support for the increased flexibility provided by the proposed rule and for the need for clear and unambiguous means to satisfy stringent performance requirements established in the previous § 32.14(d)(1). The commenter also noted that the relevant modifications to the guidance document have not yet been made and requested that the final promulgation of the rule be coincident with the issuance of appropriate guidance. Also this commenter requested that, because many timepieces are manufactured abroad, the NRC acknowledge explicitly in its guidance that compliance with relevant international standards is sufficient to ensure compliance with the NRC performance standard.

The NRC intends to have the revised guidance document completed by the time this rule becomes effective. Regarding the requirement that timepieces manufactured abroad should meet NRC requirements, those timepieces should fulfill the criteria specified in NUREG - 1562 or its equivalent.

IV. Agreement State Compatibility

Under the Atomic Energy Act, certain regulatory functions are reserved to the NRC. Among these are the distribution of products to persons exempt from licensing, as discussed in 10 CFR Part 150. Therefore, this final rule will be an "NRC" Category of compatibility with regard to the manufacture and initial distribution of watches and other products for use under an exemption for licensing. NRC Category rules address those regulatory areas which are reserved to the NRC pursuant to the Atomic Energy Act and 10 CFR Part 150.

V. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

VI. Paperwork Reduction Act Statement

This final rule reduces the burden to applicants for licenses to distribute timepieces by allowing them to file an application under the provisions of § 32.14 rather than under the provisions of § 32.22 that, in practice, also requires that the applicant obtain a registration certificate. The reduction in burden is estimated to be 21 hours per response. Because the application requirements contained in § 32.14 and § 32.22 are not being substantively changed, no Office of Management and Budget (OMB) clearance is required. Part 32 requirements are approved by the OMB approval number 3150-0001.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

VII. Regulatory Analysis

The NRC has prepared a regulatory analysis on this final rule. The analysis examines the costs and benefits of the revisions provided by the rule and indicates an annual total cost

saving to the industry to be approximately \$15,000. This regulatory analysis is available for inspection at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, D.C.

VIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. The NRC has prepared a regulatory analysis that includes consideration of the impact of this final rule on small entities. A copy of this regulatory analysis is available for inspection or copying at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, D.C. The analysis states that this regulation would currently affect 10 licensees and would result in a cost savings for the industry of approximately \$15,000 per year.

IX. Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule and, therefore, a backfit analysis is not required for this final rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

X. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, 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 adopting the following amendments to 10 CFR Part 32.

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

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

Authority: Secs. 81, 161, 183, 186, 68 Stat. 935, 948, 953, 954, as amended, (43 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. In § 32.14, paragraph (d) is revised to read as follows:

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

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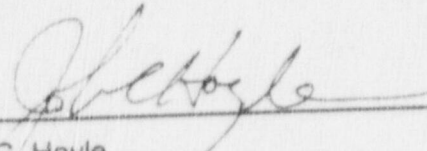
(d) The Commission determines that:

(1) The byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

(2) For automobile lock illuminators, the product has been subjected to and meets the requirements of the prototype tests prescribed by § 32.40, Schedule A.

Dated at Rockville, Maryland, this 9th day of June, 1998.

For the Nuclear Regulatory Commission.



John C. Hoyle,
Secretary of the Commission.