

March 27, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/  
Executive Director for Operations

SUBJECT: FINAL RULE: REVISION OF 10 CFR 32.14(d) TO PLACE TIMEPIECES CONTAINING GASEOUS TRITIUM LIGHT SOURCES ON THE SAME REGULATORY BASIS AS TIMEPIECES CONTAINING TRITIUM PAINT

## PURPOSE:

To obtain the Commission's approval for publication of a final rule amending 10 CFR Part 32.

## BACKGROUND:

By negative consent, the Commission approved a proposed rule to amend the prototype testing requirements for hands, dials, and pointers containing tritium (used primarily in timepieces) contained in Part 32. This proposed rule was in response to a petition received from mb-microtec, Inc. (PRM-32-4), and noticed for public comment (56 FR 53670; October 29, 1993). The petition, which requested that timepieces containing gaseous tritium light sources (GTLS), have their distribution regulated on the same basis as those timepieces that contain tritium paint. No comments were received on the notice for public comment. Three comments were received on the proposed rule, all approving going forward with the rule. One commenter suggested that the U.S. Nuclear Regulatory Commission (NRC) should begin using the international SI units, and recommended that the exemption activity for tritium be changed to 27 mCi (1 GBq) instead of 25 mCi (0.925 GBq) to conform more closely to the exemption activity of 1 Gbq (27 mCi) in the IAEA Safety Series No.115. A second commenter indicated that the language of 32.14(d)(2) of the proposed rule was confusing, and proposed clarifying language. The third commenter, noting that specific tests had been removed from 32.14(d)(1), requested that the final promulgation of the rule be coincident with the issuance of the appropriate final guidance document, NUREG-1562, which is to contain the necessary tests.

CONTACT: Donald O. Nellis, NMSS/IMNS  
(301) 415-6257

## DISCUSSION:

To respond to the intent of the petitioner, this action would amend Part 32 to remove specific prototype testing requirements for hands, dials, and pointers using tritium from 32.14(d)(1) and to modify, but not change, the intent of, the existing performance standard in 32.14(d)(1). In addition, the clarifying language for 32.14(d)(2) has been incorporated in response to one commenter's request. Guidance on testing to meet the standard will be provided in an appendix to NUREG-1562, "Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License," which was published as a draft for public comment in January 1997. The final NUREG-1562 is scheduled for publication by the effective date of this final rule, which is 60 days after publication. These modifications will provide increased flexibility to licensees, and should accommodate any future developments in technology and design of tritium illuminated timepieces. The guidance will not be incorporated into a regulatory guide, as the staff had previously stated, since the Office of Nuclear Material Safety and Safeguards plans to use the NUREG series to provide guidance to applicants and licensees on the preparation of license applications.

Currently, NRC requires applicants for a license to commercially distribute GTLS to apply for a license in accordance with 32.22. To distribute timepieces under this provision an applicant must submit detailed analyses of the product. The proposed amendment would simplify the licensing process for distributors of timepieces containing GTLS that contain no more than 25 mCi (0.925 GBq) of tritium by allowing them to apply for a distribution license in accordance with 32.14. Thus, timepieces using GTLS containing small quantities of tritium would be distributed and used in accordance with the same sections of the regulations as timepieces using luminous tritium paint, e.g. 32.14 and 30.15(a)(1). Vendors who desire to continue marketing self-luminous watches containing greater than 25 mCi of tritium could continue to do so in accordance with the provisions of 32.22.

## COORDINATION:

The Office of the General Counsel has no legal objection to this final rulemaking. The Office of the Chief Financial Officer has no objection to the resource estimates associated with the rulemaking. The Office of the Chief Information Officer concurs that there will be no information technology impacts.

## RECOMMENDATION:

That the Commission:

1. Approve the Notice of Final Rulemaking for 10 CFR Part 32 (Attachment 1).
2. Note:
  - a. That a final Regulatory Analysis will be available in the NRC Public Document Room (Attachment 2);
  - b. No Environmental Assessment has been prepared for this rulemaking. The NRC has determined that the final rule is the type of action described as a categorical exclusion in 51.22(c)(2);
  - c. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required

by the Regulatory Flexibility Act, 5 U.S.C. 605(b);

- d. 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;
- e. The appropriate Congressional committees will be informed of this action (Attachment 3);
- f. A press release will be issued (Attachment 4);
- g. Copies of the *Federal Register* notice of final rulemaking will be distributed to all 10 CFR Part 32 licensees. The notice will be sent to other interested parties upon request;
- h. The staff has determined that this is not a "major" rule as defined in the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804(2), and has confirmed this determination with OMB. The appropriate Congressional and General Accounting Office contacts will be informed (Attachment 5).

L. Joseph Callan  
Executive Director for Operations

Attachments:        1. [Federal Register Notice](#)  
                          2. [Regulatory Analysis](#)  
                          3. [Congressional Letters](#)  
                          4. [Press Release](#)  
                          5. [Small Business Regulatory Enforcement Fairness Act of 1996 Letters](#)

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 32

RIN 3150-AF76

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.

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

FOR FURTHER INFORMATION CONTACT: Donald O. Nellis, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555, Telephone (301) 415-6257 (e-mail address don@nrc.gov).

SUPPLEMENTAL INFORMATION:

- [I. Background](#)
- [II. Public Comments on the Proposed Rule](#)
- [III. Response to Public Comments](#)
- [IV. Agreement State Compatibility](#)
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- [VIII. Regulatory Flexibility Certification](#)
- [IX. Backfit Analysis](#)
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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:

- (i) 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 \_\_\_\_\_ day of \_\_\_\_\_, 1998.

For the Nuclear Regulatory Commission.

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John C. Hoyle,  
Secretary of the Commission.

REGULATORY ANALYSIS

FINAL RULEMAKING

"LICENSE APPLICATIONS FOR CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL"

10 CFR PART 32

**1. Background**

**1.1 Statement of the Problem**

On August 9, 1993, the Commission docketed a petition for rulemaking (Docket No. PRM-32-4) from mb-microtec, Inc. (microtec). In a letter dated July 30, 1993, microtec petitioned the NRC to amend its regulations "to put watches with gaseous tritium light sources (GTLS) on the same regulatory basis as watches with luminous tritium paint regarding the requirements for their distribution."

In the July 30, 1993, petition, the petitioner stated the following:

Over time, improvements in the design of these tubes (GTLS) have increased the efficiency so that less tritium is required for a given luminosity, and as a result, an effective self-luminous timepiece using GTLS, rather than paint, can be manufactured using 25 mCi of tritium.

The current requirements for GTLS are more stringent than requirements for watches with the same millicurie amounts of tritium paint.

With today's newer technology, an analog watch can be well illuminated with 14 GTLS having a total activity of 25 mCi, the same activity presently admitted for tritium painted watches. Moreover, today's production techniques permit GTLS manufacture of small, efficient sources with perfect seals. Only minute amounts of tritium diffusing through the glass walls can escape.

**1.2 Current NRC Regulations**

In 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Materials," 32.14(d)(1) contains the standard of performance for prototype testing of timepieces and other devices and specific prototype test procedures for tritium on dials, hands and pointers. The prototype tests were developed to ensure that under normal use, tritium paint would remain bound to the dials and hands of timepieces and thermostat dials and pointers.

### 1.3 Earlier NRC Actions

Following the receipt of the petition, a "Notice of receipt of petition for rulemaking" was published for public comment in the *Federal Register* on October 29, 1993 (58 FR 52670). No public comments were received on the notice published concerning the petition.

### 2. Objective

By negative consent, the Commission approved a rule plan to amend the prototype testing requirements for hands, dials, and pointers containing tritium (used primarily in timepieces) contained in Part 32. This rule plan was submitted to the Commission on February 4, 1997, SECY-97-028.

The objective of the rulemaking is to amend 10 CFR Part 32 to remove the specific prototype testing procedures for hands, dials, and pointers using tritium from 32.14(d)(1). Guidance on the specific requirements for prototype testing will be included as an appendix in NUREG-1562, "Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License," which will be available on the effective date of this final rule.

### 3. Alternatives

Three alternatives have been considered: no action, except to deny the petition; amend the regulations; or use an information notice, generic letter, or regulatory guide.

#### 3.1 No Action. Except to Deny the Petition

Not changing the regulations would maintain the current situation, which is: because the bending test requirement of 32.14(d)(1)(ii) is not appropriate for GTLS, commercial distributors must apply for and obtain a license amendment in accordance with 32.22 for watches using GTLS, with the attendant cost in time and expense of performing detailed safety analyses not considered necessary for watches employing the same quantities of tritium but in the form of paint. The cost for distributors to initially obtain a distribution license under 32.22 rather than under 32.14 is an unnecessary expense without commensurate health and safety benefit.

#### 3.2 Amend the Regulations

Revision of the testing requirements of 32.14(d) to accommodate GTLS containing no more than 25 mCi of tritium would permit simplification of the licensing process for timepieces containing GTLS. For vendors who want to continue marketing self-luminous timepieces containing GTLS with greater than 25 mCi tritium, the provisions of 32.22 would remain.

Watches using GTLS can be produced without exceeding the quantities of tritium specified in 30.15(a)(1). Further, an appropriate test can be devised, and has been proposed by the petitioner<sup>(1)</sup>, that would demonstrate that a watch employing GTLS illumination would meet the requirement in 32.14(d)(1) that "... the method of containment or binding is such that it is unlikely that the radioactive material will be released or be removed from the product under the most severe conditions which are likely to be encountered in normal use and handling..,"

Within the alternative of rulemaking to accommodate GTLS, a variant to the specific proposal of the petitioner has been considered. Thus, the alternatives considered are:

- (a) revise the regulations to incorporate the prototype test specified by the petitioner to accommodate GTLS;
- (b) remove specific prototype testing procedures from the regulations and place both the test proposed by the petitioner and the current prototype test for painted hands, dials, etc., in an appropriate guidance document, but maintain the overall performance standard in the regulations. Note that the requirement to submit information on the procedures and results of prototype testing remain in 32.14(b)(4).

Although either approach will grant the intent of the petitioner's request, the second is a performance-based approach which would better accommodate future developments in luminous technology. Specifically, even though the prototype testing procedure proposed by the petitioner is considered acceptable and reasonable for GTLS on watches, other methods or applications may arise where it may not be optimal or appropriate. Hence, with this variant, the NRC staff can approve new or different applications and methods without need for either an amendment to or exception from existing regulations, and yet continue to ensure that "...the method of containment or binding of the byproduct material in the product is such that the radioactive material will not be released or be removed from the product under the most severe conditions which are likely to be encountered in normal use and handling." The language used in this final rule represents only a small modification to the existing text of the performance standard.

#### 3.3 Use an Information Notice, Generic Letter, or Regulatory Guide

These alternatives would be inappropriate because they cannot be used to amend what is currently required by the regulations. The rule would still require the use of specific prototype testing procedures. Use of any of these alternatives could not negate the existing rule requirements.

In consideration of the above, the NRC staff has chosen to proceed with alternative 3.2(b): amending the regulations to accommodate watches employing GTLS by removing the prescriptive prototype testing specification for tritium paint from the existing regulations and placing both that specification and the prototype test proposed by the petitioner, in an appendix to NUREG-1562, "Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License," which will be issued by the effective date of the final rule.

### 4. Value-Impact Analysis

#### 4.1 The Petitioner's Assessment

In the letter dated July 30, 1994 the petitioner stated:

Over time, improvements in the design of these tubes have increased the efficiency so that less tritium is required for a given luminosity, and as a result, an effective self-luminous timepiece using GTLS, rather than paint, can be manufactured using 25 mCi of tritium.

The current requirements for GTLS are more stringent than requirements for watches with the same millicurie amounts of tritium paint.

With new technology, greater illumination could be achieved with less radioactivity than needed previously, but the additional requirements to get a GTLS watch approved for distribution results in manufacturers not using this technology.

#### 4.2 The NRC's Assessment

##### (a) Cost Savings Associated with Amendment to 10 CFR Part 32

The final rule does not present a new cost burden to applicants or licensees, but should reduce cost burdens associated with the licensed distribution of timepieces using GTLS containing 25 mCi or less of tritium. There would also be some regulatory savings because the NRC would not have to expend resources reviewing new applications for licenses to manufacture and distribute timepieces containing tritium in accordance with 32.22, which include device evaluations.

The value-impact analysis focuses on the benefits of granting relief consistent with Alternative 3.2 (b) specified in Section 3 above. The analysis looks solely at changes relative to applying for a license in accordance with 32.22 and applying for a license in accordance with 32.14.

The following table gives the previous and current fees associated with licensing products containing GTLS in U.S. dollars.

**Table - Comparison of Previous and Current Fees (\$)**

Previous Regulatory Citation	Previous Fees	Previous Annual Fees Discounted Over 10 Years	Current Regulatory Citation	Current Fees	Current Annual Fees Discounted Over 10 Years
170.31(3)(H) Initial Application	2,400		170.31(3)(I) Initial Application	4,400	
171.16(d)(3)(H) Annual License	4,600	2,335	171.16(d)(3)(I) Annual License	8,200	4,162
170.31(9)(A) Application - each device	3,400				
171.16(d)(9)(A) Annual Device Registration	6,700	3,401			

It can be seen from the table that the total fees before this final rule can vary from \$12,500 for an initial application package which includes a \$2,400 initial application fee, a \$3,400 device application fee, and a \$6,700 device registration fee; to \$11,300 for an annual license which includes a \$4,600 annual license fee and a \$6,700 device registration fee. The fees under this final rule could vary from \$4,400 for an initial application package to \$8,200 for an annual license. This results in a cost savings to the applicant/licensee of \$8,100 (\$12,500 - \$4,400) for an initial application package and \$3,100 (\$11,300 - \$8,200) in annual license and device registration fees. The discounted annual savings over 10 years would be \$1,574 ((\$2,335 + \$3,401) - \$4,162) expressed in constant dollars. The current number of licensees that would be affected by this rule is 10. The total resultant annual cost savings for this particular industry would be \$15,740. The annual values were discounted over 10 years to correspond with the time period for which a license is first issued.

NRC would save costs by no longer having to review device registration documents for licensed distribution of timepieces using GTLS containing 25 mCi or less of tritium. However, a one-time cost to NRC would result from the NRC staff costs involved in terminating a device registration for licensees already distributing such timepieces in accordance with 32.22, but who by distributing in accordance with 32.14, could eliminate annual NRC device registration fees. The one-time cost incurred by the NRC would be \$700 (10 hr X \$70/hr) per licensee for a total cost of \$7,000 (\$700/licensee X 10 licensees).

##### (b) Health and Safety Effects

Existing data indicate that the tritium leak rate for timepieces containing 25 mCi of tritium paint or 25 mCi of tritium gas vary considerably. These data suggest that the tritium leak rate from timepieces containing 25 mCi of tritium gas in GTLS is considerably lower than timepieces containing the same amount of tritium paint. In addition, these data suggest that the individual and collective doses from GTLS timepieces during the distribution, use, and disposal are significantly lower than from timepieces containing equal amounts of tritium paint. Finally, the data suggests that the health risk from the

accidental breakage of the glass vials and the release of gaseous tritium from timepieces is not significant. The NRC has concluded that the manufacture and use of timepieces containing GTLS would result in insignificant exposures. By adopting this final rule, the cost savings would be maximized without any measurable adverse effect on public health and safety.

## 5. Decision Rationale

Based on the above analysis, the NRC believes that the proposed rule, if adopted, would provide both the manufacturers and initial distributors of products containing GTLS and the NRC significant savings. Also, it has been determined that the radiological risk from distribution of such devices is negligible and the radiation skin dose from timepieces containing GTLS is significantly less, per millicurie of tritium used, than that from timepieces containing tritium paint.

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The Honorable James M. Inhofe, Chairman  
Subcommittee on Clean Air, Wetlands, Private  
Property and Nuclear Safety  
Committee on Environment and Public Works  
United States Senate  
Washington, DC 20510

An identical letter was sent to  
The Honorable Dan Schaefer

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a notice of a final rule to be published in the *Federal Register* and a copy of a press release. The rulemaking is in response to a petition for rulemaking (PRM-32-4) submitted by mb-microtec, Inc.

The U.S. Nuclear Regulatory Commission is amending its regulations to permit the distribution of timepieces containing gaseous tritium light sources (GTLS) to be regulated in accordance with the same requirements as timepieces containing tritium paint. This amendment simplifies the licensing process and facilitates, the use of a new technology in self-illuminated timepieces.

Sincerely,  
Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Senator Bob Graham

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The Honorable Dan Schaefer, Chairman  
Subcommittee on Energy and Power  
Committee on Commerce  
United States House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee is a copy of a notice of a final rule to be published in the *Federal Register* and a copy of a press release. The rulemaking is in response to a petition for rulemaking (PRM-32-4) submitted by mb-microtec, Inc.

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Sincerely,  
Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure: *Federal Register* Notice

cc: Representative Ralph Hall

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NRC AMENDS REGULATIONS

GOVERNING TIMEPIECES CONTAINING TRITIUM

The Nuclear Regulatory Commission is amending its regulations to simplify the licensing process for timepieces containing tritium. The amended regulations will permit timepieces containing Gaseous Tritium Light Sources (GTLS) to be licensed under the same regulatory requirements as timepieces

containing tritium paint. These amended regulations are in response to a petition for rulemaking submitted by mb-microtec, Inc. of North Tonawanda, New York.

Tritium, a radioactive material, interacts with various radioluminescent materials incorporated in hands, numbers or other parts of timepieces to produce luminescence (light) which makes the dials and hands visible in the dark. The tritium may be either in the form of a gas contained in tiny sealed tubes -- or in a luminescent paint. The amendments will not change the level of radiation protection provided to users and wearers of tritium illuminated timepieces.

Under existing regulations, timepieces containing tritium paint may be licensed under a section of the regulations that contains specific prototype testing requirements. License applicants able to meet these prototype tests, and whose products do not exceed the quantity limits per timepiece are able to meet the NRC licensing requirements. Some of these prototype tests however, are not suitable for testing gaseous tritium (GTLS) timepieces, so that applicants for a license to manufacture timepieces containing gaseous tritium cannot apply under this section of the NRC regulations. They must now apply for a license under a separate section of the regulations that requires submittal of much additional information, such as detailed drawings, dimensions, materials of construction and so forth for each model or series.

The revised regulations removes the specific requirements for prototype testing from the regulations but does not change the intent of the existing product performance standard. Specific tests applicable to timepieces containing either tritium paint or gaseous tritium light sources are incorporated in the NUREG document for license applications for distribution of such products.

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Mr. Robert P. Murphy  
General Counsel  
General Accounting Office  
441 G. St., NW  
Washington, DC 20548

Identical letters sent to:  
The Honorable Al Gore and  
The Honorable Newt Gingrich

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the U.S. Nuclear Regulatory Commission is submitting a final rule amending its regulations governing licensing requirements for persons who incorporate byproduct material into certain items, or who initially transfer certain items containing byproduct material. This final rule is in response to a petition for rulemaking submitted by mb-microtec, Inc. (PRM-32-4) to allow distribution of timepieces containing less than 0.925 GBq (25 mCi) of gaseous tritium light sources (GTLS) to be regulated according to the same requirements that regulate timepieces containing tritium paint.

The amended regulations would permit exempt distribution of timepieces using GTLS that contain less than 0.925 GBq (25 mCi) of tritium per timepiece, and would reduce unnecessary licensing burdens, for both licensees and the NRC associated with the licensing of timepieces containing greater than 0.925 GBq (25 mCi) of tritium. In addition, the dose to the public from timepieces using GTLS is expected to be less than from timepieces using the same quantity of tritium as paint, because the tritium leak rate from sealed glass tubes is significantly lower than from paint.

Enclosed is a copy of the final rule that is being transmitted to the Office of the *Federal Register* for publication. The Regulatory Flexibility Certification is included in the final rule. This final rule is scheduled to become effective 60 days after publication in the *Federal Register*.

Sincerely,  
Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure: Final Rule

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The Honorable Al Gore  
President of the United  
States Senate  
Washington, DC 20510

Dear Mr. President:

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Sincerely,  
Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure: Final Rule

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The Honorable Newt Gingrich  
Speaker of the United States  
House of Representatives  
Washington, DC 20515  
Dear Mr. Speaker:

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Sincerely,  
Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosure: Final Rule.

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1. The petitioner has proposed substituting a vibratory test, similar to that specified for painted dials, in place of the bending test for hands and pointers in the case of timepieces using GTLS, to ensure the unit integrity of the GTLS, pointers, and hands. As pointed out by the petitioner, this would be consistent with the comparable but somewhat more flexible prototype testing requirements described in IAEA Safety Series 23, "Radiation Protection Standards for Radio Luminous Timepieces." Attaching only the hub end of the hands and pointers to a fixture and subjecting them to vibration as proposed by the petitioner would involve smaller forces than the bending test but would still exceed the forces these elements would encounter under the most severe conditions expected in normal use. The NRC staff has reviewed the petitioner's proposed test and agrees that the suggested testing would be adequate and acceptable.

