RULEMAKING ISSUE
(Notation Vote)

July 7, 1997 SECY-97-139

FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations

SUBJECT: PROPOSED RULE: LICENSE APPLICATIONS FOR CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL (10 CFR PART 32)

PURPOSE:

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

BACKGROUND:

By negative consent, the Commission approved a rulemaking plan to amend the prototype testing requirements for hands, dials, and pointers containing tritium (used primarily in timepieces) contained in Part 32. This rulemaking plan was submitted to the Commission on February 4, 1997, SECY-97-028, "Rulemaking Plan for Revision of Prototype Testing Requirements for Hands, Dials, and Pointers Using Tritium; Response to PRM-32-4 to Put Timepieces with Gaseous Tritium Light Sources on the Same Regulatory Basis as Timepieces with Luminous Paint." The proposed rule responds to a petition received from mb-microtec, Inc., docketed on August 9, 1993, that requested timepieces containing gaseous tritium light sources (GTLS) be regulated on the same basis as timepieces containing tritium paint in regard to their distribution.

DISCUSSION:

In response to the petitioner's request Part 32 would be amended 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). Guidance on meeting the standard will be provided in an appendix to draft NUREG-1562, "Standard Review Plan for Applications for Licenses to Distribute Byproduct Material to Persons Exempt from the Requirements for an NRC License." This guidance will be

CONTACT:
Mary L. Thomas, RES
415-6230

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

available for use by licensees at the time the rule becomes final. These modifications will provide increased flexibility to licensees, and will accommodate any future developments in technology and design of tritium illuminated timepieces. The guidance will not be incoporated into a regulatory guide, as the staff had previously stated, since NMSS plans to use the NUREG series to provide guidance to licensees on the preparation of license applications.

Currently, NRC requires licensees who commercially distribute gaseous tritium light sources 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 gaseous tritium light sources (GTLS) that contain no more than 25 mCi of tritium by allowing them to apply for a distribution license in accordance with § 32.14, which would only require the applicant to demonstrate that a prototype would meet the performance standard in § 32.14(d)(1). Thus, timepieces using GTLSs 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, that is, § 30.15(a)(1). Vendors who desire to continue marketing self-luminous watches containing greater than 25 millicuries 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 the proposed 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 for publication in the Federal Register the proposed amendments to 10 CFR Part 32 (Enclosure 1).

2. Note:

   a. That the proposed amendments will be published in the Federal Register allowing 75 days for public comment.

   b. 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).

   c. A draft regulatory analysis has been prepared for this rulemaking (Enclosure 2).

d. An Environmental Assessment has not been prepared for this rulemaking. The NRC has determined that the proposed rule is the type of action described as a categorical exclusion in § 51.22(c)(2).

e. The appropriate Congressional committees will be informed of this action (Enclosure 3).

f. The proposed rule modifies existing information collection requirements that are subject to review by OMB. Upon approval, request for review and clearance will be sent to OMB.

g. That a public announcement will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register (Enclosure 4).

h. That resources to complete and implement this rulemaking are included in the current budget.

L. Joseph Callan
Executive Director
for Operations

Enclosures: As stated (4)

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Tuesday, July 22, 1997.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT July 15, 1997, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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[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: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is resolving a petition for rulemaking submitted by mb-microtec, Inc. (PRM-32-4) by proposing to amend 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. The proposed rule would remove from the regulations the specific requirements for prototype testing of these products containing tritium, and provide guidance for prototype testing in a separate document. If adopted, this proposed amendment would simplify the licensing process for distribution of certain timepieces containing tritium and would facilitate the use of a new technology in self-illuminated timepieces.

DATES: Submit comments by [Insert the date 75 days after publication in the Federal Register]. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001. ATTN: Rulemaking and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm, Federal workdays.

Examine comments received, the regulatory analysis, and other documents related to this rulemaking at the NRC Public Document Room, 2120 L Street NW., (Lower Level), Washington, DC.

Single copies of this proposed rulemaking may be obtained by written request or telefax ((301) 415-5389) from Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. These same documents also may be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this rulemaking as indicated in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001, telephone (301) 415-6230, e-mail MLT1@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Background

The Petition for Rulemaking

In a letter dated July 30, 1993, mb-microtec, Inc. petitioned the NRC to amend its regulations "to include timepieces containing gaseous tritium light sources (GTLS) on the same regulatory basis as those with tritium paint in regard to their distribution exempt from the requirements of 10 CFR 32.14(d)."

In the petition, the petitioner stated the following:

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

On August 9, 1993, the NRC docketed the letter as a petition for rulemaking (Docket No. PRM-32-4). 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 concerning the petition.

Current NRC Regulations for Certain Items Containing Byproduct Material

Section 30.15(a)(1) states that if a timepiece containing byproduct material is to be distribu ed to persons exempt from the NRC's licensing requirements, it may not contain more than 5 millicuries per hand, not more than 15 millicuries in the dial, and not more than 25 millicuries of tritium in total. Section 32.14(d)(1) contains overall performance requirements for the binding of tritium to watch hands, pointers, and dials, as well as specific prototype testing requirements for tritium-painted watch hands, pointers, and dials. Although 10 CFR 30.15(a)(1) does not specify a form for tritium in timepieces, the prototype testing requirements in 10 CFR 32.14(d)(1) -- the section of the NRC's regulations under which a specific license to distribute watches exempt under 10 CFR 30.15(a)(1) is granted -- are only applicable to timepieces employing tritium paint.

Watches containing greater than 25 millicuries of tritium in GTLSs may be distributed to persons exempt from licensing requirements in accordance with 10 CFR 30.19, "Self-luminous products containing tritium, krypton-85, or promethium-147," which, unlike 10 CFR 30.15(a)(1), specifies neither a limit on the amount of tritium that may be incorporated into self-luminous products nor the end use of the product. However, to distribute a self-luminous watch containing tritium to persons exempt from licensing requirements in 10 CFR 30.19, a specific license must be obtained in accordance with 10 CFR 32.22. To manufacture, process, produce, or initially transfer self-luminous products containing unrestricted amounts of tritium under 10 CFR 32.22(a)(2), the applicant must submit detailed information and analyses concerning the particular product in order to obtain approval for distribution. The information required by 10 CFR 32.22 must be sufficient to demonstrate that the product meets a number of specific safety

criteria, including dose criteria for use and disposal. The application must include proposed prototype testing procedures, which must be approved by the NRC. Further, the evaluations conducted by both the licensee and the staff, as well as the prototype testing proposed, apply to the entire product rather than its components. Conversely, approval for distribution of timepieces containing less than 25 millicuries of tritium to persons exempt from licensing requirements in 10 CFR 30.15(a)(1)(i) requires a specific license under 10 CFR 32.14, but only requires satisfaction of the prototype testing requirements contained in 10 CFR 32.14(d). Consequently, it is less burdensome upon a licensee to distribute watches employing tritium illumination under 10 CFR 32.14 than under 10 CFR 32.22.

Proposed Amendments

The NRC has carefully reviewed the arguments presented by the petitioner. The NRC is proposing to resolve the petition by initiating this rulemaking. This rulemaking incorporates the petition in part. Rather than revise the specific testing requirements in the regulations as proposed by the petitioner to accommodate both tritium paint and GTLSs, the NRC is proposing a more performance-based approach by removing the existing specific testing procedures from the regulations. Guidance on specific prototype testing procedures will be provided in draft 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 for public comment. Further, the proposed rule would modify but not change the intent of the existing general performance standard. This modification will state that the method of containment or binding of the byproduct be 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. By making these modifications to § 32.14(d), increased flexibility in the regulations will be provided and future developments in technology and design of tritium illuminated timepieces will be accommodated. These modifications will not decrease the level of radiation protection provided to users of tritium illuminated timepieces.

Rationale

The licensing process is more burdensome to potential distributors of timepieces under 10 CFR 30.19 than with an application to distribute timepieces for use under 10 CFR 30.15(a)(1). Changing the prototype testing requirements in 10 CFR 32.14(d)(1) would simplify the licensing process for distributors of timepieces containing small quantities of tritium in the GTLS form by allowing them to apply to distribute these timepieces for use under 10 CFR 30.15(a)(1). Thus, timepieces using GTLSs would be distributed and used under the same requirements of the regulations as timepieces using tritium paint.

Effects of the Proposed Amendments

The effect of this proposed amendment would facilitate distribution of self-illuminated timepieces that utilize a new technology.

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect

format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the rulemaking are also available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number (800) 303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial phone number for the main FedWorld BBS, (703) 321-3339, or by using Telnet via Internet: fedworld.gov. If using (703) 321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC Online Main Menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems,

but you will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules Menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules Menu.

You may also access the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the same access as the FedWorld bulletin board, including the facility to upload comments as files (any format), if your web browser supports that function.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@NRC.GOV. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301)415-6215; e-mail CAG@NRC.GOV.

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. Hence, the proposed rule, if adopted, would be a Division 4 matter of compatibility with regard to the manufacture and initial distribution of watches and other products for use. Division 4 rules address those regulatory functions which are reserved to NRC pursuant to the Atomic Energy Act and 10 CFR Part 150. Under the new Commission Policy on Agreement State Compatibility, this rule would be treated in the same manner but the category previously known as Division 4 will have a different designation.

Environmental Impact: Categorical Exclusion

The NRC has determined that the proposed 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 proposed rule.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden reduction for this information collection is estimated to average 54 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and

reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of burden accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the collections of information or on the above issues should be submitted by [insert date 30 days after publication in the Federal Register]. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

If a document does not display a currently valid OMB control number the NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis for the proposed amendment. The analysis examines the benefits and impacts considered by the NRC. The draft regulatory analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies may be obtained from Mary L. Thomas, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 2055-0001, telephone 301-415-6230 or e-mail at MLT1@NRC.GOV.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact upon a substantial number of small entities. Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size and how the regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee.

(b) How the regulations could be modified to take into account the licensee's differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the regulations were modified as suggested by the licensee.

(d) How the regulation, as modified, would more closely equalize the impact of regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group.

(e) How the regulation, as modified, would still adequately protect public health and safety.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule, and therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

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 proposing to adopt the following amendment 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, (42 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.

* * * * *

(d) The Commission determines that:

(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.

(2) Prototype tests for automobile lock illuminators are prescribed by 10 CFR 32.40, Schedule A.

Dated at Rockville, Maryland, this ____ day of_____, 1997.

For the Nuclear Regulatory Commission.

_____
John C. Hoyle,
Secretary of the Commission.

DRAFT REGULATORY ANALYSIS

FOR PROPOSED 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 include timepieces containing gaseous tritium light sources on the same regulatory basis as those with tritium paint in regard to their distribution exempt from the requirements of 10 CFR 32.14(d)."

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

> 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 GTLSs 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 for a painted watch but that the additional requirements to get a GTLS watch approved for distribution results in manufacturers not using this technology.

1.2 Current NRC Regulations

In 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Materials," 10 CFR 32.14, "License Applications for Certain Items Containing Byproduct Material," paragraph (d)(1) requires prototype testing of timepieces and other devices containing tritium. The prototype tests were developed to ensure that under normal use tritium paint would remain bound to the dials and hands of timepieces, 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 (1) amend 10 CFR Part 32 to remove the prototype testing requirements for hands, dials, and pointers using tritium from 10 CFR 32.14(d)(1) and (2) to provide guidance on the specific requirements for prototype testing in draft 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 again be issued for public comment.

3. Alternatives

Three alternatives have been considered in the regulatory analysis: no action, except to deny the petition; amend the regulations; 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: since the bending test requirement of 10 CFR 32.14(d)(1)(ii) is not appropriate for GTLS, commercial distributors must apply for and obtain a license amendment in accordance with 10 CFR 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 10 CFR 32.22 rather than under 10 CFR 32.14 is an unnecessary expense without commensurate health and safety benefit.

3.2 Amend the Regulations

Revision of the testing requirements of 10 CFR 32.14(d) to accommodate GTLS containing no more than 25 mCi of tritium would permit simplification of the licensing process for watches containing GTLS. For vendors who want to continue marketing self-luminous watches containing GTLS with greater than 25 millicuries tritium, the provisions of 10 CFR 32.22 would remain.

Watches using GTLS can be produced without exceeding the quantities of tritium specified in 10 CFR 30.15(a)(1). Further, an appropriate test can be devised,

and has been proposed by the petitioner[1], that would demonstrate that a watch employing GTLS illumination would meet the requirement in 10 CFR 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 requirements 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.

While either approach will grant the intent of the petitioner's request, the second is a more performance-based approach that 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 staff can approve new or different applications and methods

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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.

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."

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

These alternatives would be inappropriate since they cannot be used to amend what is currently required by the regulations. The rule would still require prototype testing procedures and results to be submitted in a license application. Use of any of these alternatives could not negate the existing rule requirements.

In consideration of the above, the NRC staff intends 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 draft 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 again be issued for public comment.

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 GTLSs 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 for a painted watch but that 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 proposed rule would not present a new cost burden to applicants or licensees, but could eliminate 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 10 CFR 32.22, which include device evaluations.

The value-impact analysis focuses on the benefits of granting relief consistent with Alternative 2 as specified in Section 3 above. The analysis looks solely at changes relative to applying for a license in accordance with 10 CFR 32.22 and applying for a license in accordance with 10 CFR 32.14.

The following table gives the current and proposed fees associated with licensing products containing gaseous tritium light sources in U.S. dollars.

Regulatory Citation	Current Fees	Annual Fees Discounted Over 10 Years	Regulatory Citation	Proposed Fees	Annual Fees Discounted Over 10 Years
10 CFR 170.31(3)(H). Initial Application	2.400		10 CFR 170.31(3)(I). Initial Application	4.400	
10 CFR 171.16(d)(3)(H) Annual License	4.600	2.335	10 CFR 171.16(d)(3)(H) Annual License	8.200	4.162
10 CFR 170.31(9)(A) Application - each device	3.400				
10 CFR 171.16(d)(9)(A) Annual Device Registration	6.700	3.401			

It can be seen from the table that the current total fees 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 proposed fees 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 13. The total resultant annual cost savings for this particular industry would be $20,462. The annual values were discounted over a time period of 10 years to correspond with the time period for which a license is first issued.

NRC would save staff hour 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 staff costs involved in terminating a device registration any licensees already distributing such timepieces in accordance with 10 CFR 32.22, but who by distributing in accordance with 10 CFR 32.14, could eliminate annual NRC device registration fees. The cost incurred by the NRC would be $1200 (10h X $120/hr) per licensee.

(b) Health and Safety Effects

The leak rate of tritium from GTLS incorporated into timepieces is lower than that from an equivalent Curie amount of tritium paint incorporated into timepieces; thus, the exposures from timepieces using GTLS less than 25 mCi are lower than those from timepieces using tritium paint. In fact, ORNL recently reported that the potential skin dose from a GTLS watch containing 50 millicuries (50 millirem) is four-fold lower than a watch containing 2 millicuries tritium paint (200 millirem). Moreover, the health risk from the

release of 25 mCi of gaseous tritium in the event of breakage of the glass vials is not significant.

The NRC has concluded that the manufacture and initial distribution of products containing gaseous tritium light sources results in insignificant exposures. Therefore, by adopting the proposed 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 or initial distributors to distribute products containing gaseous tritium light sources and the NRC significant savings with respect to licensing such devices with negligible radiological risk from distribution of such devices.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

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 are copies of a public announcement and a Federal Register notice concerning a proposed amendment to 10 CFR Part 32. This rulemaking is being undertaken in response to a petition for rulemaking PRM-32-4 submitted by mb-microtec, Inc.

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to permit the distribution of timepieces containing gaseous tritium light sources to be regulated in accordance with the same requirements as timepieces containing tritium paint. If adopted, this proposed amendment would simplify the licensing process and facilitate the use of a new technology in self-illuminated timepieces.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Representative Ralph Hall

Draft press release, 6/26/97, 2:30 p.m.

NRC CONSIDERS CHANGES TO REGULATIONS ON WATCHES AND CLOCKS CONTAINING RADIOACTIVE TRITIUM

The Nuclear Regulatory Commission is considering amending its regulations to simplify the licensing process for timepieces containing tritium. It would permit timepieces containing gaseous tritium to be licensed under the same regulatory requirements as those containing tritium paint.

The proposed revisions are in response to a petition for rulemaking submitted by mb-microtec, Inc, of North Tonawanda, New York.

Tritium, a self-luminescent radioactive material, is used in watches and clocks to make their hands, numbers or other parts visible in the dark. It may be either in the form of a gas--contained in tiny sealed tubes--or in paint. The planned revisions would not change the level of radiation protection provided to users and wearers of tritium-illuminated timepieces.

Currently timepieces containing tritium paint may be licensed under a section of the regulations that contains specific prototype testing requirements. License applications that meet those tests, and that do not exceed limits on the total amount of tritium permitted per timepiece, can meet NRC licensing requirements. However, some of the tests, such as a bending test designed to show that paint will not crack off, are probably not suitable for gaseous tritium. Therefore applicants for a license to manufacture watches and clocks containing gaseous tritium cannot apply under this section of the regulations and must apply for an NRC license under a

separate section of the regulations that requires submittal of much more detailed information (such as engineering drawings containing the overall dimensions, minimum and maximum dimensions of each model or series, and description of construction materials).

The proposed rule would remove from the regulations the specific requirements for prototype testing but would continue to contain requirements for overall product performance. Where appropriate, the NRC staff, as part of its review of license applications, will impose testing requirements for watch hands and dials through license conditions.

Interested persons are invited to submit written comments on the proposed changes to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff, within 75 days after publication of a Federal Register notice. This notice is expected to be published shortly.

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