

February 4, 1997

FOR: The Commissioners

FROM: Hugh L. Thompson, Jr. /s/  
Acting Executive Director for Operations

SUBJECT: 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 TRITIUM PAINT

## PURPOSE:

To inform the Commission that the EDO intends to approve a rulemaking plan to amend 10 CFR 32.14(d)(1) relating to the prototype testing requirements for hands, dials, and pointers containing tritium (used primarily in timepieces). The rulemaking would grant mb-microtec's petition to allow distribution of a new technology in self-illuminated timepieces.

## CATEGORY:

This paper covers a minor policy question requiring Commission consideration.

## BACKGROUND:

A petition from mb-microtec was received and noticed for public comment (58 FR 52670; October 29, 1993). The petitioner requested that timepieces with gaseous tritium light sources (GTLS) be placed on the same regulatory basis as timepieces with luminous tritium paint. A GTLS consists of a sealed glass tube internally coated with a phosphor and may contain up to 200 mCi gaseous tritium. The petitioner stated that design improvements have enabled the use of less tritium.

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Timepieces using up to 25 mCi of tritium for illumination have been distributed for use by the general public since the 1961 amendment to Part 30 which allows the possession, use, and transfer of such timepieces without a license. Prototype testing requirements applicable to the licensee distributor of timepieces and other devices containing tritium were established in 10 CFR 32.14(d)(1). 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.

Timepieces containing greater than 25 mCi of tritium in the form of GTLSs have more recently been distributed for use under a different exemption from licensing contained in 10 CFR 30.19, Self-luminous products. Licensing for distribution of self illuminated products under 10 CFR 30.19 is approved on a case-by-case basis, and is therefore more burdensome on licensees and NRC. Because of improvements in the design of GTLSs, timepieces using GTLSs can now be produced using quantities specified in 10 CFR 30.15(a)(1), i.e., less than 25 mCi. However, the requirements for distribution under this section specify a prototype bending test. This is an appropriate test for hands and pointers painted with tritium paint, but not for the inflexible glass tubes that are the GTLSs. Because another licensing path is available to licensees, the staff has been reluctant to approve any individual exemptions from this specified test (authority to grant exemptions provided in 10 CFR 30.11). Therefore, no timepieces using GTLSs have been distributed for use under 10 CFR 30.15(a)(1).

## DISCUSSION:

Because of the requirements to distribute products for use under 10 CFR 30.19, the licensing process is more burdensome to the potential distributor of timepieces than is the case with an application to distribute timepieces for use under 10 CFR 30.15(a)(1). A simple change to the prototype testing requirements in 10 CFR 32.14(d)(1) would simplify the licensing process for distributors of timepieces containing GTLSs 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 sections of the regulations as timepieces using tritium paint.

Rather than revise the specific testing requirements in the regulations as proposed by the petitioner to accommodate both tritium paint and GTLSs, the staff plans to take a more performance-based approach and remove the existing specific testing procedures from the regulations and provide guidance on the appropriate procedures in a regulatory guide. The existing general performance standard that the tritium must be properly contained in the product would not be changed. The planned action will not change the level of radiation protection provided to users of tritium illuminated timepieces.

This action involves no resource adjustments to the NRC Five-Year Plan.

## COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The staff does not intend to coordinate this rule plan with the Agreement States because the licensing of manufacturers and initial distributors of watches and other products for use under exemption is reserved to NRC by 10 CFR 150.15.

## RECOMMENDATION:

Note that it is my intention to implement the Rulemaking Plan within 10 days from the date of this paper unless otherwise directed by the Commission.

Hugh L. Thompson, Jr.  
Acting Executive Director for Operations

Enclosures: 1. PRM-32-4  
2. Plan for Rulemaking  
3. Regulatory Agenda Entry

ENCLOSURE 2

## PLAN FOR RULEMAKING

### A. THE ISSUE TO BE ADDRESSED BY THE RULEMAKING

A petition from mb-microtec was received and noticed for public comment (58 FR 52670; October 29, 1993). The petitioner requested that timepieces with gaseous tritium light sources (GTLS) be placed on the same regulatory basis as timepieces with luminous tritium paint. A GTLS consists of a sealed glass tube internally coated with a phosphor and may contain up to 200 mCi gaseous tritium. eta particles emitted by the tritium interact with the phosphor which subsequently emits visible light. The petitioner stated that, 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 petitioner stated that the current requirements for GTLSs are more stringent than requirements for watches with the same millicurie amounts of tritium paint. The petitioner further stated 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. No public comments were received on the notice published concerning the petition.

### B. RELEVANT REGULATORY FRAMEWORK

Section 30.15(a)(1) states that if a timepiece containing byproduct material is to be distributed to persons exempt from the Commission'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 total. Section 32.14(d)(1) contains an overall performance requirement 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 relevant section of the Commission'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 tritium in GTLSs may be distributed as exempt by meeting the requirements of 10 CFR 30.19, "Self-luminous products," 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 under 10 CFR 30.19 a specific license must be obtained under 10 CFR 32.22. The requirements to manufacture, process, produce, or initially transfer self-luminous products containing unrestricted amounts of tritium under 10 CFR 32.22(a)(2) require the licensee to 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. It must include proposed prototype testing procedures, which in turn must be approved by the Commission. Further, the evaluations conducted both by the licensee and the staff, as well as the prototype testing proposed, apply to the entire product rather than components. Conversely, approval for distribution of timepieces containing less than 25 millicuries tritium under 10 CFR 30.15(a)(1) only requires satisfaction of the prototype testing requirements contained in 10 CFR 32.14(d), along with some general requirements applicable to all specific byproduct material licensees. Consequently, it is less burdensome upon a licensee to distribute watches employing tritium illumination under 10 CFR 32.14 than 10 CFR 32.22.

### C. ALTERNATIVES FOR RESOLUTION

- 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 32.22 rather than under 10 CFR 32.14 is an unnecessary administrative expense without commensurate health and safety benefit.
- 2. Amendment of 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 will remain.

As noted above, 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,<sup>(1)</sup> 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 a regulatory guide, but maintain in the regulations the overall performance criterion: that the Commission determine that the method of containment or binding 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.

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 test 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 without need for either an amendment to or exception from existing regulations, and yet continue to assure 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. Use of **Information Notices**, **Generic Letters**, and **Regulatory Guides** - These alternatives would be inappropriate since they cannot be used to override what's required by the regulations.

In consideration of the above, the NRC staff intends to proceed with alternative 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 a regulatory guide.

#### **D. COST EFFECTIVENESS**

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 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.

#### **E. BACKFIT ANALYSIS**

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

#### **F. OGC LEGAL ANALYSIS**

OGC advises that, to achieve the regulatory objective of the petition, it would be necessary to amend 10 CFR 32.14 in either of the manners described under C.2(a) or 2(b) or promulgate a new rule specifically for GTLS. OGC has reviewed the rulemaking plan including the proposed approach under NEPA and the Paperwork Reduction Act. OGC believes that an Environmental Assessment will need to be prepared in support of the proposed rule because it is not covered under any of the categorical exclusions described under 10 CFR 51.22. There does not exist any known basis for objection to promulgation of a rule drafted in accord with C.2(b).

Since the proposed rulemaking plan would also address issues related to the petition for rulemaking, the staff will need to assure that appropriate procedural actions are taken to close the actions associated with that petition. These actions included specifically denying or granting the petition for rulemaking, either in the Federal Register notice associated with the proposed rulemaking or in a separate Federal Register notice, and informing the petitioner of the Commission's decision. The detailed procedures for responding to the rulemaking petition are contained in Part 11 of the Regulations Handbook (NUREG/BR-0053), Rev. 3).

#### **G. IMPLEMENTATION BY THE AGREEMENT STATES**

The licensing of manufacturers or initial distributors of watches and other products distributed for use under exemption is reserved to NRC by 10 CFR 150.15.

#### **H. SUPPORTING DOCUMENTS**

This rulemaking will require a simple Regulatory Analysis that will show no impact to licensees. No backfit analysis will be needed. However, an OMB Paperwork analysis and under alternative 2(b), a regulatory guide will need to be prepared. OGC believes that an Environmental Assessment may be needed.

**I. RESOURCES**

The estimated resources to complete this rulemaking, alternative 2(b) would be about 0.9 staff-year. Approximately, 70 percent of this effort would come from RES and about 30 percent divided among NMSS, OSP, OGC, and ADM. Although alternative 2(b) does include the preparation of a regulatory guide, preparation of the guide should require little more effort than amending the regulations to incorporate the petitioner's proposed test, alternative 2(a), since the contents of the guide would be the test in the current regulation and the petitioner's test.

No contractor support dollars will be expended. No additional resources are anticipated to implement the rule. A slight reduction in resources might occur in that new models of watches containing GTLS which could be distributed under a 10 CFR 32.14 license would require less administrative effort than if approved under a 10 CFR 32.22 license.

Resources to complete and implement the rule are included in the current budget. A copy of the rulemaking concurrence package will be forwarded to the Office of the Controller for coordination of resource issues per EDO Memorandum of June 14, 1991.

**J. ENHANCED PUBLIC PARTICIPATION**

This rulemaking is a minor revision which does not warrant an enhanced public participation.

**K. ISSUANCE BY EDO IN ACCORDANCE WITH MD 9.17**

This rule would not constitute any major policy change; rather it would update prototype testing requirements pertaining to the use of tritium on dials, hands, and pointers contained in 10 CFR 32.14. For this reason, it falls within the authority delegated to the EDO to issue this rule in accordance with paragraph 0213 of Management Directive 9.17.

**L. LEAD OFFICE STAFF AND KEY STAFF FROM OTHER OFFICES**

- Research - Mary L. Thomas
- NMSS - Steven L. Baggett
- OGC - Robert L. Fonner
- SP - Dennis M. Sollenberger

**M. STEERING/WORKING GROUP**

No steering group will be used on this rulemaking. The working group is identified above.

**N. SPECIAL MEASURES & INFORMATION**

There were no public comments on the notice published concerning the petition.

An expansion of this exemption could also include other uses of GTLS such as compasses, thermostats, and gun sights. However, this is both outside the scope of the petitioner's request and would require further study to either assure the appropriateness of the petitioner's proposed test, or develop appropriate prototype tests. Hence, this alternative would take more resources and time to complete. It is considered more responsive to the petitioner to limit this particular rulemaking to a simple change in the testing requirements of 10 CFR 32.14(d) as requested by the petitioner. Further improvements in the licensing of distribution of exempt products/materials could be considered in the future as part of the ongoing program to reevaluate the exemptions. In addition to considering rulemaking, the staff may review the licensing practices implementing Part 32 with respect to exempt distribution, such as providing for a more generic product approval for distribution under 10 CFR 30.19.

**O. SCHEDULING**

Proposed rule	3 months after approval of the Rulemaking Plan
Final rule	6 months after proposed rule published

TITLE: Revision of Prototype Testing Requirements for Dials, Hands, and Pointers Containing Tritium

RIN: To be determined

CFR CITATION: 10 CFR 32.14, Certain items containing byproduct material; requirements for license to apply or initially transfer.

**ABSTRACT:**

Resolution of a petition received from mb-microtec to amend 10 CFR 32.14 to include watches containing gaseous tritium light sources (GTLSs) on the same regulatory basis as luminous tritium paint. Since the application of tritium luminescent technology has changed sufficiently, a modification of the regulation is warranted. Although the exemption in 10 CFR 30.15(a)(1) puts no restriction on the form of tritium in timepieces, the prototype testing requirements of 10 CFR 32.14 were designed for luminous tritium paint and preclude distribution of timepieces containing gaseous tritium light sources (GTLSs) for use under this exemption. Currently, timepieces containing GTLSs must be approved for distribution under 10 CFR 32.22 for use under 10 CFR 30.19, the class exemption for self-luminous products. The licensing process in this case is

more complex. Exposures to the public are very low from watches using either GTLSs or luminous tritium paint, with watches using GTLSs generally resulting in lower exposures. In this case, the more burdensome process involved in obtaining authorization to distribute this product under 10 CFR 32.22 is unnecessary. Revision of the prototype testing requirements will allow distribution on the same regulatory basis as watches containing luminous tritium paint. These prototype testing requirements also apply to thermostat dials and pointers, which may also be affected.

TIMETABLE:	Office concurrence	3 months after EDO approval
	Final rule published	6 months after proposed rule published

LEGAL AUTHORITY: 42 USC 2201; 42 USC 5841

EFFECTS ON SMALL BUSINESS AND OTHER ENTITIES: None.

AGENCY CONTACT:

Mary L. Thomas, Office of Nuclear Regulatory Research, (301) 415-6230.

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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.