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RECORD #136

TITLE: Letter Dated Feb. 6, 1978 ... Regarding Redistribution of
Backlighted Dials

FICHE: 66183-076

MAY 3 1 1978

MEMORANDUM FOR: G. Wayne Kerr, Assistant Director
for State Agreements Program, OSP

FROM: Jane R. Mapes, Attorney
Regulations Division, OELD

SUBJECT: LETTER DATED FEBRUARY 6, 1978 FROM DAVID D. SNELLINGS,
JR., DIRECTOR, DIVISION OF RADIOLOGICAL HEALTH,
BUREAU OF ENVIRONMENTAL HEALTH SERVICES, ARKANSAS
DEPARTMENT OF HEALTH REGARDING REDISTRIBUTION OF
BACKLIGHTED DIALS

ISSUES:

Your memorandum of February 14, 1978 requests our comments on the following questions contained in Mr. Snellings' letter of February 6, 1978, concerning the licensing requirements applicable to the repair and redistribution of watches containing approximately 200 millicuries of tritium enclosed in three glass vials. These watches are generally described as liquid crystal display watches back lighted by tritium activated luminous sources. The tritium used in the luminous sources is byproduct material within the meaning of section 11e of the Atomic Energy Act of 1954, as amended.

1. Is the TIMEX Repair Facility in Little Rock, Arkansas, required to have an NRC distribution license to return repaired watches which contain the original tritium sources to the owners?
2. Is an NRC distribution license required when the original tritium source is replaced with a new source and returned to the owner?
3. Is it necessary for an individual offering repair services on watches containing 200 millicurie tritium sources to be licensed by the NRC or an Agreement State?

ANALYSIS:

Section 81 of the Atomic Energy Act of 1954, as amended, states in part:

"No person may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, own, possess, import, or export any byproduct material, except to the extent authorized by this section or by section 82. The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, for medical therapy, industrial uses, agricultural uses, or such other useful applications as may be developed. . . . The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission. The Commission is authorized to establish classes of byproduct material and to exempt certain classes or quantities of material or kinds of uses or users from the requirements for a license set forth in this section when it makes a finding that the exemption of such classes or quantities of such material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. (Emphasis supplied.)

Pursuant to this authority, the Commission has promulgated regulations (10 CFR §§ 32.22-32.25) which specify the conditions under which it will issue specific licenses authorizing the manufacture, processing, production and/or initial transfer for sale or distribution of self-luminous products containing tritium.

The Commission has also promulgated regulations (10 CFR § 30.19 ^{1/}), which exempt self-luminous products containing tritium from the licensing

1/ Section 30.19 states in part:

"(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, . . . and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in Parts 20 and 30-35 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, . . . in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific (continued p. 3)

requirements of section 81 of the Act and the regulations in 10 CFR Parts 20 and 30-35 if those products have been manufactured, processed, produced or initially transferred in accordance with a specific license issued pursuant to 10 CFR § 32.22.

The Commission's regulations in 10 CFR § 150.15(a)(6) ^{2/} provide that the NRC shall exercise exclusive regulatory authority over all transfers of possession and control by manufacturers, processors or producers of products containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons is exempted from the Commission's licensing and regulatory requirements under 10 CFR Parts 30 and 40. Retention of this authority has enabled the Commission to maintain a vantage point from which it can exercise continuous surveillance over the safety of products containing radioactive material which are intended for general use and can, at the same time, assess the effect from the standpoint of radiological health and safety of the uncontrolled addition of radioactive material to the environment resulting from the distribution of those products for general use.

1/ (continued)

license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section. . . .

"(c) The exemption in paragraph (a) of this section does not apply to tritium, . . . used in products primarily for frivolous purposes or in toys or adornments."

2/ 10 CFR § 150.15(a)(6) provides in part:

"Persons in Agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to . . . [t]he transfer of possession or control by the manufacturer, processor, or producer of any . . . device, commodity, or other product containing . . . byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter. . . ."

For a discussion of 10 CFR § 150.15(a)(6) and its statutory basis, see Memorandum on Licensing of Dial Painting Activities by Jewelers and Watch Repairers, Dorian to Kerr, April 1976, copy attached.

Products qualifying for the class exemption in 10 CFR § 30.19 are those which the Commission has determined meet the safety criteria for that class regardless of the manner in which or the type of person by whom they may be used. (Under section 81 of the Act, the Commission is authorized to grant an exemption only if it is able to find that the contemplated use of a specific quantity of byproduct material "will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public." Absent such a finding, an exemption would be invalid. In the statement of considerations which accompanied the rule establishing the class exemption in 10 CFR § 30.19, the Commission stated that it ". . . has concluded that the overall benefits to be derived from the use of radioactive materials in self-luminous products covered by the amendments, as a class of products, offset the small risk as reflected in the safety criteria." 34 FR 9025, June 6, 1969.) Assurance that a product will not constitute an unreasonable risk to the health and safety of the public rests primarily on the regulatory requirement that the product must be manufactured in accordance with the provisions of the specific license in 10 CFR §§ 32.22-32.25 in order to qualify for the exemption.

In reviewing applications for specific licenses to manufacture, process or produce self-luminous products containing tritium or to transfer such products for use, the NRC evaluates data relating to the handling, storage, use, and disposal of the product in order to ascertain the likelihood that the external radiation dose or the dose commitment resulting from intake of radioactive material from the product will or will not exceed the limits specified in 10 CFR § 32.24 during conditions of normal use, disposal, handling and storage, including normal accumulation of quantities of exempt units in one location during marketing, distribution, installation and servicing of the product. (Emphasis supplied. Servicing of a product may include repair.) The NRC also evaluates the effectiveness of the containment, shielding and other safety features of the product under normal conditions of use, handling, storage and disposal and under the most severe conditions such as accidents or fires. A specific license authorizing the manufacture, processing or production of the product or its initial transfer for sale or distribution is issued only after the Commission is satisfied that under both normal and accident conditions the probability of failure of the containment, shielding or safety features of the product in a manner which would cause persons to receive doses in excess of the applicable limits is low 3/ and that under these same conditions the

3/ "Low" means not more than one such failure per year for each 10,000 exempt units distributed. 10 CFR § 32.23(d), footnote 2.

probability that persons would receive doses in excess of other applicable limits is negligible. 4/

Briefly summarized, the Commission's regulations implementing section 81 of the Act now provide that once a product has qualified for a § 30.19 exemption by virtue of having been manufactured, processed or produced or initially transferred for sale or distribution in accordance with a specific license issued pursuant to § 32.22 or, in the case of manufacture, equivalent regulations of an Agreement State, it is no longer necessary for any person, including a person engaged in repair of the product, to obtain a license authorizing the receipt, possession, use or transfer of the product.

Review of safety evaluations 5/ prepared by NRC staff in connection with applications for licenses authorizing distribution of liquid crystal

4/ "Negligible" means not more than one such failure per year for each 1 million exempt units distributed. 10 CFR § 32.23(d), footnote 2.

5/ The following NRC staff safety evaluations were reviewed:

Safety Evaluation, dated April 1, 1977, for License Issued to National Semiconductor Corporation Authorizing Distribution of Model Designations DAA5Y, DAB5W, DAB5Y, DAC5W, DAC5Y, CAA5YW, CAB5Y, CAB5W, and CAC5YW Watches to Persons Exempt from the Requirements for a License Pursuant to Section 30.19 of 10 CFR Part 30.

Safety Evaluation, dated June 2, 1977, for a License Issued to Fairchild Camera and Instrument Corporation Authorizing Distribution of Liquid Display Watches Backlighted with Tritium Activated Luminous Sources to Persons who are Exempt from the Requirements for a License Pursuant to Section 30.19 of 10 CFR Part 30.

Safety Evaluation, dated June 3, 1977, for License Issued to Texas Instruments, Inc. Authorizing Distribution of Liquid Crystal Display Watches Back Lighted by Tritium Activated Luminous Sources to Persons Exempt from the Requirements for a License Pursuant to Section 30.19 of 10 CFR Part 30.

Safety Evaluation, dated November 9, 1977, for License Issued to Self-Powered Lighting, Limited Authorizing Distribution of Liquid Crystal Display Watches Backlighted by Tritium Activated Luminous Sources to Persons Exempt from the Requirements for a License.

display watches backlighted by tritium activated luminous sources to persons exempt from the requirements for a license pursuant to 10 CFR § 30.19 6/ indicates that these watches are subject to two general types of repairs: (1) repairs which do not involve removal, replacement or disassembly of the tritium light source or tritium time module, such as battery replacements and minor electronic circuit adjustments; and (2) repairs which do involve the tritium light source or tritium time module, such as repair or replacement of a non-functioning or damaged liquid crystal display assembly. Under the present state of the art, it is anticipated that the latter type of repair will usually involve replacement of the original module with a new module rather than disassembly, reconstruction and reinsertion of the original module. It is also anticipated that this type of repair will, in most instances, be carried out by the manufacturer or under his auspices. We are under the impression that the manner in which the module containing the tritium source is inserted into the watch case is one aspect of the manufacture, processing and production of these watches which must be evaluated in order to determine whether the watch does or does not constitute an unreasonable risk to public health and safety.

Repairs of the first type do not present radiological health and safety issues. They are similar in many respects to the kinds of repairs to which watches, irrespective of whether they do or do not contain radioactive material, would normally be subject. In our opinion, repairs of this type constitute the kind of use which properly falls within the scope of the exemption in 10 CFR § 30.19.

Repairs of the second type necessitate handling the tritium source and/or the time module containing the tritium source and involve such processes as removal, disassembly, reconstruction, reinsertion or replacement of the original source or module. These processes are similar in many respects (they may, in fact, be identical) to the processes used in the initial manufacture of an LCD watch. Repairs of this type do present issues of radiological health and safety, issues which are essentially indistinguishable from the radiological health and safety issues addressed at the time of the initial manufacture of the LCD watch and evaluated in making the statutory finding on which the decision to exempt such products from regulation must be based.

Taking the language in 10 CFR § 30.19 at face value, there would seem to be no basis for distinguishing between repairs of watches which

6/ It is assumed for the purpose of this analysis that the exempt product is the LCD watch (i.e., a watch case containing a LCD time module back lighted with a tritium source) as distinct from the time module alone.

involve handling, including removal and reinsertion, of the original tritium source and/or tritium time module and those which involve removal of the original tritium source and/or tritium time module and replacement of that source and/or module with a new source and/or module. Both types of repairs appear to be uses of exempt products within the meaning of the regulation which places no restriction on the persons by whom or manner in which such products are used except to require persons who manufacture, process, produce or initially transfer self-luminous products containing tritium for sale or distribution to do so under a specific license issued pursuant to 10 CFR § 30.22.

Nevertheless, a persuasive argument can be made that the exemption in 10 CFR § 30.19 does not extend to repairs of LCD watches in which the original tritium source or tritium time module is removed and replaced with a new tritium source or time module. This conclusion rests on the premise that a watch from which the original tritium source or tritium time module has been removed can no longer be considered an exempt item within the meaning of 10 CFR § 30.19 because the requirement on which that exemption is based, namely that the self-luminous product be manufactured or initially transferred in accordance with a specific license issued pursuant to 10 CFR § 30.22, cannot be met by an empty watch case.

CONCLUSION

On the basis of this analysis, we are of the opinion that under the Commission's existing regulations, the questions posed by Mr. Snellings should be answered as follows:

Question 1: Is the TIMEX Repair Facility in Little Rock, Arkansas, required to have an NRC distribution license to return repaired watches which contain the original tritium sources to the owners?

Question 1 should be answered in the negative. Since repaired watches containing original tritium sources do not lose their status as exempt products under 10 CFR § 30.19, an NRC distribution license is not required to return these watches to their owners.

Question 2: Is an NRC distribution license required when the original tritium source is replaced with a new source and returned to the owner?

Question 2 should be answered in the affirmative. When an LCD watch is repaired by replacing the original tritium source or tritium time module with a new source or time module, the repairer must obtain a

specific NRC or Agreement State byproduct material license authorizing the repair and a specific NRC distribution license authorizing the return of the watch to the owner.

Question 3: Is it necessary for an individual offering repair services on watches containing 200 millicurie tritium sources to be licensed by the NRC or an Agreement State?

The answer to question 3 depends on the type of repair service offered. A person performing repairs which do not involve replacement of the original tritium source or tritium time module is not required to be licensed. That same person, however, must obtain a specific byproduct material license either from NRC or from the appropriate Agreement State in order to perform repairs which do involve replacement of the original tritium source or tritium time module with a new tritium source or time module. Persons making such repairs are also required to obtain an NRC distribution license authorizing the return of repaired watches to their owners.

The preceding analysis and conclusions leave one problem unresolved. If the manner in which a tritium source and/or tritium time module is inserted into a LCD watch is significant from the radiological health and safety standpoint, 7/ there would appear to be no justifiable basis for distinguishing between repairs which involve removal and reinsertion of the original tritium source or tritium time module and repairs which involve replacement of the original tritium source or tritium time module with a new tritium source or time module. 8/ This concern raises the question of the propriety of treating any repairs of LCD watches involving the tritium source or tritium time module as exempt "uses" within the meaning of 10 CFR § 30.19.

The propriety of authorizing distribution of these items as exempt from further regulation in the face of a safety evaluation which virtually calls for (i.e., "anticipates") certain repairs to be done

7/ Statements in the NRC staff safety evaluation reports noting that all watch repairs involving tritium sources or tritium time modules will be handled by the manufacturer tend to support the view that this process is significant from the radiological health and safety standpoint.

8/ The absence of a justifiable basis for such a distinction is also evidenced by the marked similarity between the process used during initial manufacture of the watch and the repair process.

by the manufacturer can also be questioned. How can radiological health and safety be assured when the item (or its user) is exempt from regulation? In the absence of such assurance, how is the exemption justified? Perhaps a definitive health physics analysis may be needed to answer these questions. In any event, some further thought on this matter seems to be called for.

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Jane R. Mapes, Attorney
Regulations Division, OELD

Attachment:
As stated

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April, 1976

Letter sent
9/27 1976

Memorandum for: G. Wayne Kerr, Chief.
Agreements and Exports Branch

From: Thomas F. Dorian
OELD

Subject: LICENSING OF DIAL PAINTING ACTIVITIES BY JEWELERS
AND WATCH REPAIRS

Re: Letter of April 5, 1976, from
G. W. Kerr to J. M. Becker

NRC has retained the authority under 10 CFR §150.15(a)(6) to license under 10 CFR §§32.14 and 30.15(a)(1) watch repairers and jewelers which strip radium paint from dials and hands of watches and reapply tritium paint.

Subsection 274c. of the Atomic Energy Act of 1954, as amended, provides that notwithstanding any agreement between the Commission and any State, the Commission is authorized to require that "the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license issued by the Commission."

In issuing 10 CFR Part 150, which implemented certain provisions of subsection 274 of the Act, in 1962, the Commission exercised its authority under subsection 274c. of the Act by providing (§ 150.15(a)(6)) that persons in Agreement States are not exempt from the Commission's licensing requirements with respect to * * *

(6) The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public. (Emphasis added.)

With respect to the meaning of "products intended for use by the general public," the Statement of Considerations accompanying Part 150 read, in part, as follows:

"Control over consumer type devices, such as luminous watches, would be retained by the Commission. The uncontrolled distribution of atomic materials in products designed for distribution to the general public, such as consumer type devices, and the ultimate uncontrolled release of these materials into

the environment, involve questions of national policy which have not yet been resolved. It is for this reason that the Commission is retaining control over such products. The Commission recognizes that the phrase 'products designed for distribution to the general public' is not precise. The purpose of the provision, however, will be discussed with each agreement State; serious difficulties in interpretation of the phrase are not anticipated." (Emphasis added.) (See Howard K. Shapar's memo. of Oct. 23, 1962, on "Transfer of Licensing and Regulatory Authority to the States," at p. 2.)

In his memorandum, Shapar, however, added, "The retained AEC jurisdiction Section 150.15(a)(6) over products intended for use by the general public relates not to the manufacture or other use of the material in the Agreement State, but only to the transfer of possession or control by the manufacturer, processor, or producer." (Supra, at p. 4.) (Emphasis added.)

On May 16, 1969, NRC amended § 150.15(a)(6). The Statement of Considerations accompanying the amendment, in part, read as follows:

"In retaining regulatory authority over transfer of products 'intended for use by the general public' the Commission was seeking to maintain surveillance over the safety of products containing radioactive materials, without the imposition of regulatory controls, and to be able to assess the effect of the attendant uncontrolled addition of these radioactive materials to the environment.

In view of the increasing difficulty in determining whether or not such products are intended for use by the general public, the Commission has adopted the amendment of Part 150 set out below, which changes § 150.15(a)(6) by deleting the phrase 'product * * * intended for use by the general public' and substituting therefor the phrase 'product * * * whose subsequent possession, use, transfer and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter.'

Under Part 150 as amended below the transfer of possession or control by a manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material or source material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from Commission licensing and regulatory requirements under Parts 30 and 40, is not subject to the licensing and regulatory authority of an Agreement State even though the product is manufactured, processed, or produced pursuant to an Agreement State license. The manufacturer of such products in an Agreement State is subject to the Commission's regulatory authority with respect to transfer of any product which has been so exempted from the Commission's licensing and regulatory requirements. The Commission has confined its regulation of the transfer of exempt products to specifications for the products, quality control procedures, requirements for testing, and labeling. The authority of Agreement States to regulate any radiation hazards that might arise during manufacture of such products is not affected by the amendment. Accordingly, dual regulation will continue to be avoided." (Emphasis added.)

NRC retains control over luminous watches and tritium paint to the extent that that control involves the "transfer of possession or control by the manufacturer, processor, or producer" of those watches or of tritium paint to certain exempt persons.

Watch repairers and jewelers engaged either in stripping radium paint from a dial and hands of a watch and reapplying tritium paint or in repairing and reconditioning a timepiece and reapplying tritium paint, can be called processors, ~~etc.~~, for example, 10 CFR §32.22. This interpretation matches the emphasized portions in the Statement of Considerations accompanying the amendment to §150.15(a)(6) quoted earlier.

Thomas F. Dorian
Attorney - OELD