

February 9, 2005

Rad Ware
Attn: Dixie J. Wells-O'Dou
Radiation Safety Officer
6461 Plumcrest Rd.
Las Vegas, NV 89108-5309

Dear Ms. Wells-O'Dou:

This is in response to your letter dated December 5, 2004, in which you seek clarification of why a Nuclear Regulatory Commission (NRC) license is required, rather than an Agreement State license, in order for a company to distribute tritium gunsights.

Because you referenced 10 CFR 30.19, it appears that you are particularly interested in distribution to persons exempt from licensing. However, there seems to be some misunderstanding regarding transfers in general, as you note that some Agreement State licensees are authorized to transfer large quantities of tritium without the need for an NRC license. First though, you should note that 10 CFR 30.19 provides an exemption from the requirements to obtain a specific license, as established in 10 CFR 30.3, to possess certain byproduct materials in products which have been authorized for distribution pursuant to a license issued by NRC under 10 CFR 32.22. This exemption only applies to persons within NRC's jurisdiction. Each of the Agreement States must establish their own regulations to provide this exemption to persons within their jurisdiction. Thus, the language in 10 CFR 30.19(b) regarding equivalent regulations.

There are three methods by which a licensee may be authorized to transfer radioactive material: (1) to other specific licensees, (2) to general licensees, and (3) to persons exempt from licensing. The authorization to transfer to specific licensees can be granted by both NRC and the Agreement States and is established by both regulation (such as 10 CFR 30.41) and as a license condition. The allowance to transfer to general licensees can be authorized by both NRC and the Agreement States and is permitted through the issuance of a license that specifically authorizes such transfers (see 10 CFR 32.51 and 10 CFR 31.5). Generally speaking, the authorization to permit transfers to persons exempt from licensing has been reserved by the Commission and is permitted through the issuance of a license that specifically authorizes such transfers (such as 10 CFR 32.22). To some extent, the basis for these transfer authorities can be found in the Statements of Consideration supporting 10 CFR Part 150, which provides the following.

Public Law 86-373, dated September 23, 1959, amended the Atomic Energy Act of 1954 (the Act) by the addition of a new section 274, "Cooperation With States." One purpose of that legislation was to clarify the respective responsibilities under the Act of the Commission and the States with respect to the regulation of byproduct, source, and special nuclear materials. Under section 274b. of the Act the Commission is authorized to enter into an agreement with any State providing for discontinuance of the regulatory authority of the Commission with respect to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. Subsection (c) of section 274 of the Act specifically excludes from such agreements the

discontinuance of any Commission authority with respect to certain activities, such as nuclear reactors, import and export, and some disposal activities. In addition, pursuant to this subsection, the Act states the Commission is authorized by rule, regulation, or order 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.

On September 29, 1961, the Commission published for public comment a draft of a proposed 10 CFR Part 150, which would relinquish certain licensing authority to agreement States and exempt persons in those States from Commission licensing requirements. The publication noted that the Commission had not taken a position as to whether it should retain or relinquish to the States its authority to license the distribution of products containing atomic energy materials; and specifically invited public comment. Comments were received from fifty organizations and individuals. The proposed rule was also discussed with the Commission's Advisory Committee of State Officials. Based on the comments and advice received, the Commission decided against blanket reservations of control over the transfer of manufactured products.

In the final rule (10 CFR Part 150) published February 14, 1962, (27 FR 1351), the Statements of Consideration (SOC) notes that with respect to whether the Commission should retain or relinquish authority to license the transfer by manufacturers, processors or producers of equipment, devices, commodities or other products containing atomic energy materials, Part 150 provides for state regulatory control in this area except those items intended for use by the general public. As a result, control over consumer type devices, such as luminous watches, was retained by the Commission. The SOC further explains that the uncontrolled distribution of atomic materials in products designed for distribution to the general public and the ultimate uncontrolled release of these materials into the environment, involve questions of national policy, which have not yet been resolved. It was for this reason that the Commission retained control over such products.

On February 24, 1968, the Commission published (33 FR 3346) a proposed amendment to 10 CFR Part 150 which would redefine the category of products containing radioactive materials over whose transfer by the manufacturer, processor, or producer in an Agreement State the Commission retains jurisdiction. The SOC accompanying the final rule published April 16, 1969 (34 FR 6517), recalls that in issuing 10 CFR Part 150, the Commission exercised its authority under subsection 274c of the Act by providing that persons in Agreement States are not exempt from the Commission's licensing requirements with respect to the transfer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public. The SOC further recalls that in retaining regulatory over transfer of products "intended for use by the general public," the Commission was seeking to maintain surveillance of the safety of products containing radioactive, without the imposition of regulatory controls, and to be able to assess the effect of the addition of these radioactive materials to the environment. The SOC goes on to explain that the purpose of the amendment to 10 CFR Part 150 was a result of the "... increasing difficulty in determining whether or not such products are intended for use by the general public...." Therefore, the Commission adopted an amendment to 10 FR 150(a)(6) deleting the phrase "product ... intended for use by the general public" and substituting the phrase "product ...

whose subsequent possession, use, transfer and disposal by all other persons are exempted from the licensing and regulatory requirements of the Commission....”

The SOC further explains that while the use, possession of the radioactive materials and the manufacturing, processing, and production of such products in an Agreement State is subject 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 the transfer of such products to exempt persons. The SOC also explains that the Commission has confined its regulation of exempt products to specifications for the products, quality control procedures, requirements for testing, and labeling. The SOC notes that the authority of Agreement states to regulate any radiation hazards that might arise during the manufacture of such products is not affected by the amendment and, accordingly, dual regulation is avoided.

I hope this information adequately responds to you questions. Enclosed is language from the Atomic Energy Act and Part 150 of NRC regulations, which we believe are pertinent to your question. If you need further clarification, I suggest you speak with Bruce Carrico of my staff at 301-415-7826.

Sincerely,

/RA/

Richard P. Correia, Acting Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure: Atomic Energy Act and
Part 150 of NRC regulations

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Enclosure: Atomic Energy Act and
Part 150 of NRC regulations

Distribution:
IMNS/ r/f

ML050400249

*see previous concurrence

OFFICE	MSIB	MSIB
NAME	THarris*	RCorreia*
DATE	2/7/05	2/9/05

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Atomic Energy Act and Part 150 Language

Atomic Energy Act

Sec. 274. Cooperation With States.

b. Except as provided in subsection c., the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under chapters 6, 7, and 8, and section 161 of this Act, with respect to any one or more of the following materials within the State –

(1) byproduct materials as defined in section 11e.(1);272

(2) byproduct materials as defined in section 11e.(2);273

(3) source materials;

(4) special nuclear materials in quantities not sufficient to form a critical mass

Notwithstanding any agreement between the Commission and any State pursuant to subsection b., the Commission is authorized by rule, regulation, or order 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.

10 CFR Part 150

150.10 Persons exempt.

Except as provided in § 150.15, 150.16, 150.17, 150.17a, 150.18, and 150.19, any person in an Agreement State who manufactures, produces, receives, possesses, uses, or transfers byproduct material, source material, or special nuclear material in quantities not sufficient to form a critical mass is exempt from the requirements for a license contained in Chapters 6, 7, and 8 of the Act, regulations of the Commission imposing licensing requirements upon persons who manufacture, produce, receive, possess, use, or transfer such materials, and from regulations of the Commission applicable to licensees. The exemptions in this section do not apply to agencies of the Federal government as defined in § 150.3.

§ 150.15 Persons not exempt.

(a) Persons in agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to the following activities:

(6) The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or 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.

Enclosure

(b) Notwithstanding any exemptions provided in this part, the Commission may from time to time by rule, regulation, or order, 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 or an exemption from licensing issued by the Commission.