



UNITED STATES
NUCLEAR REGULATORY COMMISSION


WASHINGTON, D.C. 20555-0001

June 6, 1997

MEMORANDUM TO:

Stuart A. Treby
Assistant General Counsel for
Rulemaking and Fuel Cycle, OGC

FROM:

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Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT:

REQUEST FOR RESPONSE TO QUESTIONS RELATED TO
EXEMPT DISTRIBUTION OF DEVICES, ELEMENTS OF THE
DEPARTMENT OF DEFENSE, AND HOLDERS OF MASTER
MATERIALS LICENSES

The Department of the Army, through the Tank - Automotive and Armaments Command, Armament and Chemical Acquisition and Logistics Activity (ACALA), has requested a custom device safety evaluation for the model Advanced Chemical Agent Detector/Alarm (ACADA) chemical agent detector. ACALA currently holds 4 specific licenses issued by Region III. The Army has requested that the device be used under a specific license. ACALA plans to distribute these devices to other elements of the Army as well as to other elements of the Department of Defense (DOD). However, during a recent meeting with representatives from the Army, Air Force, and the manufacturer, the issue of whether these devices could be registered and distributed for possession and use under an exemption in accordance with 10 CFR 32.26 was raised. Devices with activities and uses similar to these have been approved for exempt distribution under 10 CFR 32.26, however, not by an element of the DOD.

We are unsure of the regulatory position on several issues related to exempt distribution of products with respect to the various elements of the DOD and holders of master materials licenses. Therefore, we request that you address the following questions. We have included a proposed response to most questions which includes our understanding of the current regulations and policies as they relate to distribution of products for possession and use under an exemption from the requirements for a license.

1. Can the Army, through an exempt distribution license held by ACALA, distribute products intended to be possessed and used by persons under an exemption from the requirements for a license to: (a) other elements of the Army; (b) other elements of the DOD; or (c) any member of the public?

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Background: The Army has numerous commodities licenses throughout the United States. The DOD currently contracts for the manufacture of certain devices through the Army for distribution and use for all elements of the DOD. The Army, due to the fact that the devices are purchased and distributed by the Army, maintains accountability for all these devices under its various commodities licenses. The Army would like to change this practice and the other elements of the DOD would also like to reduce the level of accountability and control of these devices. This is due to the large numbers of devices, in the tens of thousands, and the minimal radiation hazard associated with the possession and use of the devices.

Position: (a), (b), and (c) It is our understanding that the Army could obtain an exempt distribution license and distribute products to separate entities within the Army, other elements of the DOD, and any member of the public and these products would be possessed and used under an exemption from the requirements for a license. However, the entity within the Army possessing the exempt distribution and possession licenses for these products (i.e., ACALA) would not be able to possess and use these products under the exemption; these products would be required to be treated as specifically licensed devices.

2. Can the Army, if it had a broad scope license, distribute products intended to be possessed and used by persons under an exemption from the requirements for a license to: (a) other elements of the Army; (b) other elements of the DOD; or (c) any members of the public?

Background: The Army has numerous commodities licenses throughout the United States and is currently considering combining these into either one or a few broad scope licenses.

Position: (a) It is our understanding that other elements of the Army could receive, possess, and use these products only if the facility that is considered the initial distribution point (i.e., ACALA) is not covered under the broad scope license and that facility obtains exempt distribution and possession licenses for the products. The approved initial distribution point must control the devices as specifically licensed devices. The Army could do this if it were to structure its broad scope license(s) in a similar manner, i.e., if ACALA or some other entity were not covered under the broad scope license(s). Otherwise, each element within the Army would be covered under the broad scope license as one entity and the products would have to be handled as specifically licensed devices.

(b) and (c) It is our understanding that the Army could obtain an exempt distribution license and distribute these products to other elements of the DOD and any members of the public and these products would be possessed and used under an exemption.

3. Can the Army, if it had a master materials license like the Air Force and the Navy, distribute products intended to be possessed and used by persons under an exemption from the requirements for a license to: (a) other elements of the Army; (b) other elements of the DOD; or (c) any member of the public?

Background: The Army has numerous commodities licenses through out the United States and is currently considering combining these into either one or a few broad scope type licenses and then later merging all existing licenses, including the medical licenses, into a master materials license.

Position: (a) It is our understanding that the holder of a master materials license could distribute these products to persons exempt, if those persons are within separate entities and only if the facility that is considered the initial distribution point is not covered under their master materials license and that facility obtains exempt distribution and possession licenses. The approved initial distribution point must control the products as specifically licensed devices. The Army could do the same if it were to structure its master materials license in a similar manner, i.e., if ACALA or some other entity were not covered under the master materials license. Otherwise, each element within the Army would be covered under the master materials license and the products would have to be handled as specifically licensed devices.

(b) and (c) It is our understanding that the Army could obtain an exempt distribution license and distribute these products to other elements of the DOD and any member of the public and these products would be possessed and used under an exemption.

4. If an individual or entity receives a product under an exemption, such as the ACADA or a smoke detector, and the individual or entity currently possesses a specific license or a permit issued by a master materials licensee that includes the isotope contained in the product, does the individual or entity have to control the product as a specifically licensed device? What if the individual or entity possesses a specific license, but the specific license does not include the isotope contained in the product?

Background: The Navy and Air Force both have master materials licenses. The Army currently has specific licenses which include the isotope contained in the ACADA. In addition, the Army, as well as other elements of the DOD, has internal regulations which require them to track, inventory, and dispose all radioactive material in the same manner irregardless of how it is licensed.

Position: It is our understanding that the individual or entity would possess and use the product under an exemption and would not have to treat it as a specifically licensed device. The individual or entity would not have to perform leak tests or inventories and there would be no restrictions on the disposal of the product. Whether the specific license or permit contains that specific isotope is irrelevant. With respect to the Army and other elements of the DOD, they could possess these products under an exemption under NRC regulations. Any additional controls placed on these products by the elements of the DOD are not required under NRC regulations.

5. Can an international manufacturer, with an initial distributor licensed for distribution of products to persons exempt from the requirements for licensing in the United States, ship these products to a military base located outside the United States and the products upon entry into the United States be considered to be covered under the exemption? What if the contract for the purchase of some products is held with a facility

in the United States, which pays for them, and the delivery point is a military base outside the United States?

Background: The Army, through Aberdeen Proving Grounds, has a contract with a company located outside the United States to manufacture the ACADA. For economical reasons, the Army would like to ship the devices directly from the manufacturer to military bases outside the United States for use. These devices could subsequently be imported into the United States.

Position: It is our understanding that, for a product to be distributed for use under an exemption as recognized under NRC regulations, the product must be distributed through a location that has been authorized to make the initial transfer. This authorized initial transfer point must always be within the United States (i.e., NRC jurisdiction). For products which are initially transferred from a vendor outside the United States to locations outside the United States, when these are brought into the United States, they must be controlled as specifically licensed devices. Once the product is in the United States, an application may be filed requesting that the product be registered and found as acceptable for distribution for possession and use under an exemption. The fact that a contract is in place with an entity located within the United States is irrelevant.

6. There are two questions related to question 5 that we do not have a position and we request clarifications: (1) How does the North American Free Trade Agreement (NAFTA) between the United States, Canada, and Mexico impact the above position; and (2) can an international manufacturer "drop ship" products within the United States without the product going through the authorized initial distributor and still be covered by the exemption?
7. For the holder of either a broad scope or master material license, what degree of separation is needed between licensed entities (e.g., Branch, Division, military post, Command, location, etc.) for the distribution of products to be possessed and used by the broad scope or master materials licensee under an exemption?

Based on our understanding of the regulations, we plan on advising the Army, through ACALA, that they could, if adequate information is provided such that a registration certificate and exempt distribution license could be completed, be approved for an exempt distribution license for the ACADA chemical agent detector under 10 CFR 32.26. The Army would be able to distribute the ACADA to other entities within the Army for possession under an exemption as long as the entity does not fall under the control of ACALA. The Army would also be able to distribute to other elements of the DOD and any member of the public as well. The Army would be advised that if reorganizations were to effect ACALA, all new entities falling under the control of ACALA would have to control these devices as specifically licensed devices and conversely, if current entities are removed from under the control of ACALA, those entities could treat them as if they were possessed under an exemption. In addition, if the Army were to consolidate their commodities licenses into one or more broad scope or master materials licenses, the Army would be advised of our positions as stated in questions 2 and 3 above.

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