

November 5, 1998

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: POLICY CONCERNING BUNDLING OF EXEMPT QUANTITIES

PURPOSE:

To request Commission approval, by negative consent, to issue a generic letter describing a revised Office of Nuclear Material Safety and Safeguards (NMSS) decision regarding the bundling of exempt quantity byproduct material.

BACKGROUND:

A 1994 staff decision transmitted in a letter dated June 3, 1994 ([Attachment 1](#)), to allow Ronan Engineering Company (Ronan) to instruct its customers to bundle 10 exempt quantity byproduct material sources into a Ronan designed gauge has been interpreted by some licensees to mean that an unlimited number of exempt sources can be bundled together in their gauging devices. Specifically, an application submitted by Berthold Systems, Inc. (BSI) in January of this year, for an exempt distribution license, disclosed their plans to place as many as 70 exempt sources in gauging devices of their design. This request represented a significant departure from the staff's previous position allowing up to 10 sources to be bundled together in an unlicensed gauging device and presented a potential safety concern not previously envisioned with the bundling of 10 or less exempt sources. Both the State of Iowa and the Organization of Agreement States have also expressed their safety concerns over the bundling of large numbers of exempt sources.

DISCUSSION:

Since conferring with the Office of the General Counsel (OGC) in June of this year, the staff informed Ronan and BSI to discontinue advising their customers to bundle exempt sources. BSI initially expressed concern about this change in NRC policy, but subsequently decided to have its device design evaluated and registered with the NRC to allow for distribution to general licensees. Ronan has also filed for general licensing of its devices with the State of Kentucky.

The basis for NRC concern in this matter centers on the issue that the numbers of individual exempt sources bundled in such devices would reach some point where a general or specific license would normally be required. Given that the bundled exempt sources remained exempt, NRC would have no mechanism to regulate their safe possession, use, and disposal.

The staff has drafted a generic letter ([Attachment 2](#)) for distribution to all materials licensees. This paper informs the Commission of the staff's actions thus far, our proposed generic communication and possible actions to ultimately address this issue.

At this time, devices already in use, having multiple exempt quantities of byproduct material, may continue to be used. The staff plans to reexamine this process following the ongoing risk assessment to determine if there are any public safety concerns with these devices and whether any further action is warranted. Depending on the outcome of this examination, the staff will examine alternatives, including rulemaking to authorize distribution of these devices to persons exempt from licensing. This overall process may take 2 to 3 years.

The State of Iowa and the Organization of Agreement States will be made aware of this action and will be provided with a copy of the attached Generic Letter once published.

COORDINATION:

OGC has reviewed this paper and has no legal objection.

RECOMMENDATION:

That the Commission note that, unless directed otherwise, the staff will issue a generic letter to all materials licensees. We consider this action to be within the delegated authority of NMSS/Division of Industrial and Medical Nuclear Safety. Staff requests action within 10 days. Action will not be taken until an SRM is received.

William D. Travers
Executive Director for Operations

CONTACT: Anthony S. Kirkwood, NMSS/IMNS
(301) 415-6140

Attachments: 1. Letter dtd 6/3/94
2. Draft Generic Letter

ATTACHMENT 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

NRC GENERIC LETTER 98-##: RECENT NUCLEAR MATERIAL SAFETY AND SAFEGUARDS DECISION ON BUNDLING EXEMPT QUANTITIES

Addressees: All materials licensees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this generic letter to notify addressees about a recent Office of Nuclear Material Safety and Safeguards decision concerning bundling exempt quantities. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate. However, no specific action nor written response is required.

Discussion:

Section 30.18 of 10 CFR Part 30 exempts any person from the requirements for a license to the extent that such person possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity in 10 CFR 30.71, Schedule B. A person wishing to commercially distribute or initially transfer products containing byproduct material, such as check sources, to persons exempt from licensing, must obtain an exempt distribution license from NRC. The product information to be submitted for an exempt distribution license is outlined in 10 CFR Part 32 and, specifically for exempt quantities, is outlined in 10 CFR 32.18, 32.19, and 32.20. Pursuant to 10 CFR 32.18(c), NRC will not approve a license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material to persons exempt pursuant to 10 CFR 30.18 if the exempt quantities are incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

An earlier NRC position that was transmitted in a June 3, 1994, letter in response to a request to put multiple exempt quantities in a tube inside a mold housing opposite a radiation detector, was based upon the circumstances presented that were limited in nature. However, based upon additional requests of a much more extensive nature, NRC now finds that combining any exempt sources is inconsistent with the regulations, pursuant to 10 CFR 30.18, 32.18, 32.19, and 32.20. Instructing persons exempt from licensing to combine exempt quantities, and providing devices for them to do so, is in direct conflict with NRC's requirements for labeling of exempt sources. Section 32.19 specifically instructs persons not to combine exempt quantities, since the exemption provided in 10 CFR 30.18 is applicable only as long as no individual nor discreet quantity of the byproduct materials exceeds the quantity limits specified in 10 CFR 30.71, Schedule B, and as long as the quantities set out in that schedule are originally received and remain separate and distinct from other quantities of exempt byproduct materials. The labeling requirements in 10 CFR 32.19, which address shipments to exempt persons, instruct 10 CFR 32.18 licensees to label the "immediate container" with information identifying the radioisotope and the quantity of radioactivity, and in addition to that information, the container ". . . shall also bear the words . . . 'Exempt Quantities Should Not Be Combined.'" Therefore, although the exemption in 10 CFR 30.18 provides for persons without a license to possess and use a wide variety of byproduct materials, and to possess and use specific byproduct materials without restriction as to the total quantity that may be possessed and used at any one time, the regulations do not authorize, but rather discourage, grouping exempt quantities of byproduct material.

The basis for NRC concern in this matter centers on the issue that the individual numbers of exempt sources bundled in such devices would reach some point where a general or specific license would normally be required. In the case where the bundled exempt sources remained exempt, NRC would have no mechanism to regulate their safe possession, use, and disposal.

Please be advised that the bundling of exempt quantities of byproduct material, any program of advising persons to combine exempt quantity sources, as well as the possession and use of bundled exempt sources in unregistered devices by persons exempt from licensing, are not authorized by NRC. Only those persons specifically authorized, by license, to distribute devices containing, or designed to contain, bundled exempt quantity sources, to specific or general licensees, may do so. However, to do so, they must first have the device designs evaluated and registered with NRC or an Agreement State, and obtain appropriate manufacturing and distribution licenses or amendments to their current manufacturing and distribution licenses, before distributing devices to specific or general licensee's.

At this time, devices, already in use, having multiple exempt quantities of byproduct material, may continue to be used. NRC does not plan to take any action regarding these devices or users unless a radiological safety hazard is identified. NRC plans to perform a risk assessment to determine if there are any public safety concerns with these devices and whether any further action is warranted. Depending on the outcome of the risk assessment, NRC will examine alternatives, including rulemaking to authorize the distribution of these devices to persons exempt from licensing. It is anticipated that the risk assessment and rulemaking process will take 2 to 3 years.

If you have any questions about this matter, please call the technical contact listed below or the appropriate regional office.

Frederick C. Combs, Acting Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

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Attachment: List of Recently Issued NRC GL's.