RECORD #203

TITLE: Transfer of Reactor Activated Materials to Person's Exempt

FICHE:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

July 21, 1988

Not in HPP

MEMORANDUM FOR: Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial
and Medical Nuclear Safety

FROM: Stuart A. Treby
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for Rulemaking and Fuel Cycle
Office of the General Counsel

SUBJECT: TRANSFER OF RADIOACTIVE MATERIAL TO PERSONS EXEMPT

In your memorandum concerning the subject above, dated July 7, 1988, you requested our views on whether a possession or distribution license under Part 32 is required under two separate fact situations. The first situation concerns the irradiation of electronic components for the purpose of determining their "hardness" against radiation exposure. This irradiation results in various components of the electronic devices being activated, i.e., induced radioactivity. As stated in your memorandum, some of the staff believes that because exempt quantities (10 CFR 30.18) would be present, no Part 32 license would be necessary in order to transfer the components to DOD after irradiation. On the other hand, some of the staff believe that a license pursuant to § 32.11 would be necessary to transfer the exempt concentrations.

The answer to the question lies, in large part, as to whether the situation involves an exempt "concentration" or an exempt "quantity." Subsection 30.14(a) provides, in pertinent part, that a person is exempt from the license requirement of section 81 of the Atomic Energy Act "to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70." (Emphasis added.) However, subsection 30.14(d) specifically prohibits the introduction of byproduct material into a product or material knowing that it will be transferred to persons exempt under § 30.14 "except in accordance with a license issued pursuant to § 32.11..." This prohibition is repeated almost verbatim in § 32.13.

This office has previously addressed the issue of induced radiation in another context (irradiated gems) and reads the term "introduction" to be interpreted as encompassing not only the introduction of byproduct material into another product but the activation of material within a product or material, thereby transforming it into byproduct material. An additional question to be initially answered is whether the activated material is in fact "byproduct material." It appears from the facts presented that it is

because the material is "made radioactive by exposure to the radiation incident to the process of...utilizing special nuclear material." 42 U.S.C. 2014(e)(1), 10 CFR 30.4(d). Having said this, it appears to us that the regulations under discussion really do not contemplate the situation presented, particularly within the context presented. Nevertheless, if the activated material within the electronic devices being irradiated is in exempt concentrations, it may be possessed and transferred pursuant to the exemption provided under § 30.14. But, the irradiator introducing the byproduct material must be licensed pursuant to § 32.11 if the material is to be transferred to an exempt person under § 30.14.

In contrast to the discussion above, § 30.18 provides exemption from licensing requirements for possession and transfer of byproduct material if the "individual quantities" of byproduct material, each does not exceed the applicable quantity set forth in § 30.71, Schedule B. The prohibitions contained in subsections 30.18(c) and (d) do not appear to apply because, in our opinion, the transfer to DOD (or its contractor under this circumstance) is not for the purpose of "commercial distribution," i.e., introduction into the market place. Therefore, because § 32.18 addresses the need for a specific license to possess or transfer byproduct material for "commercial distribution" to persons exempt under § 30.18, it appears that no license would be required under § 32.18 in this circumstance.

However, when originally promulgated, the Statement of Consideration for the proposed § 30.18 (33 FR 11414, August 10, 1968) included the following language:

> "Persons holding an AEC (now NRC) byproduct material license or an Agreement State license for manufacture, processing, or production of byproduct material would be authorized to make transfers, on a noncommercial basis, of exempt quantities of byproduct material possessed under the license. This provision is designed to accommodate the occasional transfers between laboratories of small quantities of byproduct material in tissue samples, tagged compounds, counting standards, etc., which involve a negligible risk." (Emphasis added.)

In the final rule (35 FR 6426, April 22, 1970), the Commission reiterated this position verbatim. While it can be argued that the byproduct material resulting from the "testing" of the "radiation hardness" of the tested electronic equipment should fall within the "etc." list of authorized transfers between laboratories, the context of the § 30.18 exemption seems to be oriented toward pre-existent byproduct material used as a marker. Accordingly, we believe the better view to be that the induced radiation byproduct material should be looked at in terms of whether the radioactivity so produced is within the exempt concentration levels listed in § 30.70.

Thus, based on the above, we believe the key to the answer to this question to lie within the resolution of whether we are talking about exempt concentrations of byproduct material introduced into a product or material

(§ 30.14); or whether we are talking about the possession and transfer of exempt quantities of byproduct material that are within the limits of § 30.71, Schedule B, for distribution purposes, but as to which the associated licensing provisions of § 32.18 appear inapplicable. From the facts available, it appears to us, from the legal perspective, that we are talking about the introduction of byproduct material into another material or product, which leads to the conclusion that §§ 30.14 and 32.11 are the applicable licensing provisions. It may be appropriate under this circumstance to exempt DOD and its contractor from this licensing requirement under the authority of § 30.11(a).

The second situation raised in your memorandum concerns the distribution by an x-ray equipment manufacturer of a small number of exempt quantity "check sources." The position of the manufacturer is that because it distributes the sources to its customers "free," (that is, without a separate charge), it is not commercially distributing them. We do not agree. The manufacturer is interpreting the term "commercial distribution" in a far too limited manner. We view the meaning of this term to mean the introduction of a material into the market place, whether or not a charge is assessed for that distribution. Given the mandate of the NRC to protect the public health and safety from radiation hazards, it would be nonsensical to determine the protection of the public on the basis of whether a charge was made for a quantity of byproduct material distributed into the public domain, i.e., the market place. In addition, as pointed out by your staff, it is logical to assume that the manufacturer expects to gain a monetary return on the x-ray equipment because of this "free" distribution of byproduct material, the "check source." Accordingly, we concur with the view that this distribution is a "commercial distribution" type of transfer and, as such, must be licensed pursuant to §§ 30.18(d) and 32.18.

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