

DLD (SP05)

OSP Action - 65-248
(LAB)



Angus S. King, Jr.
Governor

Kevin W. Concannon
Commissioner

STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
AUGUSTA, MAINE 04333
October 4, 1996

Paul H. Lohaus, Deputy Director
Office of State Programs (03D23)
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Lohaus;

This letter is in reference to a phone call with Lloyd Bolling and Craig Gordon on 10/2/96 regarding the interpretation of the regulations that is evidenced by the enclosed letter dated 5/6/96 from Larry Camper of NMSS.

Mr. Camper states that Oxford Instruments is not authorized to distribute under its license number 41-14168-01E radioactive sources to individuals if those said individuals intend to redistribute said sources with all the original labeling and in the original container. Mr. Camper stated that the above redistribution would be in direct violation of 10 CFR 30.18(d). While I do agree that the regulation denies redistribution I question the interpretation of 30.18 (d). It states, paraphrased; no distribution except in accordance with a license issued under 32.18. I interpret 10 CFR 32.18 to limit the number of sources per transaction (10) which implies a control for any attempt at redistribution but does not state it. The next question is if Oxford follows all the regulations pertaining to themselves and their license (10 sources per single transaction) at what point do these sources become non-exempt? If they send say 100 orders over a year to a single address? Since NRC keeps all the exempt distribution information are there any other companies in Maine that appear on your lists numerous times? How is this information reviewed? How else do you propose we regulate this community? **Can Maine issue a specific license that only authorizes redistribution of licensed exempt sources? Or is this a NRC "E" license?** Is it the original manufacturers responsibility to make sure that an exempt source is only purchased by exempt people for exempt purposes? Stated another way, is the fact that the source is exempt not enough?

Maine has two companies, that I know of, that purchase exempt sources and redistribute. One company I just found out about due to the above situation (they redistribute 0.1 microCurie Pb-210 sources) and one company I was told a year ago (by NRC staff) could redistribute sources (0.23 microCurie C-14) from Isotope Products as long as the labeling and the source were not changed. The reason being once the source was distributed as exempt it is exempt. The latter appears to make more sense but these interpretations obviously conflict, which is correct? **I'd like to point out that these sources are not "introduced into products" (10 CFR 32.19(d)) they are distributed to be used with a manufactured product.**

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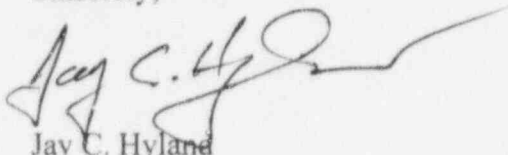
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My next questions pertain to smoke detectors (32.26). Manufacturers send thousands (legally) to all the departments stores and hardware stores, which are all unlicensed redistributors. Americium-241 has no exempt amount listed in 30.70 Schedule A and smoke detectors distributed as exempt contain 20 times the quantity defined as exempt in 10 CFR 30.15(a)(9). Furthermore, A memorandum to Donald Nussbaumer from Richard Cunningham dated February 11, 1986 regarding disposal of smoke detectors stated "It would not seem practical or enforceable to attempt to impose legal restrictions on disposal of smoke detectors by retailers or consumers" and went on to state that there were no legal restrictions on disposal. If someone wanted to recycle smoke detectors as a disposal option and redistribute the sources would this still be exempt? Why are smoke detectors more exempt than other exempt sources?

We seem to be second guessing the levels of exempt sources, is it exempt or isn't it? If the levels aren't low enough, change them, or limit the total Curie content that anyone can possess at one time but let's do it from the licensed side of the house (the manufacturer) and not "sweat" the small stuff.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jay C. Hyland", with a long horizontal flourish extending to the right.

Jay C. Hyland
Environmental Specialist
Radiation Control Program

cc: Craig Gordon, NRC RI
Lloyd Bolling, NRC OSP
Paul Rogers, The Science Source
Joe O'Donnell, IDEXX

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 6, 1996

Oxford Instruments, Inc.
Analytical Systems Division
ATTN: Mr. John B. Cox, Manager
Radiochemistry Laboratory
P.O. Box 2560
Oak Ridge, Tennessee 37831-2560

Dear Mr. Cox:

I am responding to your facsimile dated March 20, 1996, requesting licensing information about Spectrum Techniques, Inc. and clarification/interpretation of the restrictions in 10 CFR 30.18.

Section 30.18(a) of 10 CFR Part 30 (enclosed), provides that, except for paragraphs (c) and (d) of this section, any person is exempt from the regulatory requirements for a license and Parts 30 through 34, 36, and 39 to receive, possess, use, transfer, own or acquire byproduct material in individual quantities that do not exceed the quantities listed in 10 CFR 30.71, Schedule B. Section 30.18(c) does not authorize for commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of such material into products intended for commercial distribution. This means that any person who manufactures or processes and then transfers for commercial purposes products containing exempt quantities of radioactive material must be authorized to do so pursuant to an exempt distribution license issued by the NRC under 10 CFR 32.18.

Our records indicate that NRC received a license application from Spectrum on April 16, 1996. However, until such time as NRC issues a license to Spectrum, any transfer or redistribution by Spectrum (for commercial purposes) of products received from Oxford would not be authorized and would be treated as noncompliance with the provisions of 10 CFR 30.18(c). The information you provided was forwarded, with Spectrum's licensing status, to NRC's Region II Office for follow-up.

Section 30.18(d) of 10 CFR Part 30, states that, "No person may, for purposes of commercial distribution, transfer byproduct material... knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section... except in accordance with a license issued under 10 CFR 32.18...." The regulations are clear that a licensee should not transfer or distribute products to someone without a distribution license when it is known or believed by the licensee that these products will be transferred or redistributed to persons exempt under this section. As to Oxford's responsibility in this instance, if, as you state, Oxford is aware that Spectrum is redistributing sources purchased from Oxford and Oxford continues to distribute to Spectrum with this knowledge, then Oxford would be considered in noncompliance with the provisions of 10 CFR 30.18(d) and would also be subject to investigation and enforcement by the NRC.

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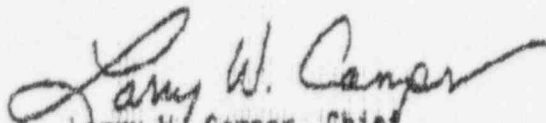
J. B. Cox

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for possible willful disregard of the regulations. If Oxford believes that Spectrum is redistributing sources received from Oxford without the benefit of a distribution license, then Oxford would be well advised to cease distribution to Spectrum until such time as Spectrum obtains the requisite distribution license or it is concluded that Spectrum is not distributing in noncompliance with 10 CFR 30.18.

If you have any additional questions, please contact Susan Greene of this office at (301) 415-7843.

Sincerely,



Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: 10 CFR Part 30