



California Department of Health Services

SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Services

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ARNOLD SCHWARZENEGGER
Governor

June 3, 2004

Mr. Paul Lohaus
U.S. Nuclear Regulatory Commission
Office of State and Tribal Programs
Washington, D.C. 20555

SUBJECT: REGULATORY INTERPRETATION RELATED TO CAL 4-04-001

Dear Mr. Lohaus,

On May 20, 2004, my staff received a call from the U.S. Nuclear Regulatory Commission (NRC), Region IV office (NRC-RIV) to inform us of a pending Confirmatory Action Letter (CAL) to be sent by NRC-RIV to a California specific and NRC general (reciprocity) licensee. California Department of Health Services, Radiologic Health Branch (DHS/RHB) staff questioned the appropriateness of the cited regulatory basis in the proposed CAL. The CAL was issued without resolution of the DHS/RHB concerns. We are requesting a regulatory interpretation pertaining to this matter so that we can ensure that we understand NRC's regulatory basis for the actions specified in the CAL.

Our understanding of the situation that precipitated the CAL is as follows: One of California's radioactive materials licensees, Sabia, Inc., manufactures devices containing californium-252 for use in coal mines for elemental coal analysis, and transferred the devices, containing californium-252 sources, to three NRC coal-mine licensees (RAG Emerald Resources, LP, NRC License No. 37-20567-02; McElroy Coal Company, NRC License No. 37-25561-01; and Black Beauty Coal Company, NRC License No. 13-26785-01). Sabia, Inc. has applied to NRC for Sealed Source and Device (SS&D) registration for the transferred device, but as yet no SS&D registry sheet has been issued for the device. The neutron sources used in the devices have been issued a SS&D registry sheet (# NR-298-S-102-S).

The CAL documents agreement by Sabia, Inc. with an NRC/RIV request to "[i]mmediately cease distribution of unapproved devices...that contain byproduct material until a device registry sheet has been issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State." The CAL further states "[n]ote that before commencing distribution of approved devices, Sabia, Inc., must obtain a license authorizing distribution of such devices from the NRC or an Agreement State." According to Sabia Inc., NRC informed them that they needed to take these actions in order to bring themselves into conformance with NRC regulatory requirements. DHS/RHB expressed concern to NRC-RIV that these actions may not be supported by appropriate regulations. We continue to have this concern.

Radiologic Health Branch, MS 7610, PO Box 997414, Sacramento, CA 95899-7414
(916) 327-5106

Internet Address: www.dhs.ca.gov/rhb

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It appears to us that the language in 10 CFR 32.210 is permissive, not compulsory. It states "Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license *may* submit a request to NRC for evaluation of radiation safety information about its product and for its registration" (emphasis added). It is our understanding that issuance of a SS&D registry sheet is a convenience, rather than a necessity, for transfer of radioactive devices from a manufacturer to a specific licensee (as opposed to such transfer to a general licensee or to persons exempt from licensing). Issuance of a SS&D registry sheet at a manufacturer's request appears to be a convenience to the manufacturer and the manufacturer's customers in that it allows the manufacturer's customers to expedite receipt of a specific license for use of the device from NRC or an Agreement State because it foregoes the need of the customer to demonstrate to their licensing organization that the device meets the criteria of 10 CFR 32.210, since this was already done by the manufacturer. Our understanding in this regard emanates from 10 CFR 30.32(g), et seq.

We also question the regulatory requirement for a "license authorizing distribution" if the distribution occurs from one specific licensee to another specific licensee. It is DHS/RHB's understanding that a specific licensee may transfer material to any other specific licensee authorized to receive the type, form and amount of material to be transferred in accordance with 10 CFR 30.41, without specific license authorization to distribute such material.

Although not addressed in the CAL, we reviewed whether Sabia, Inc. complied with the requirements of 10 CFR 30.41 for their transfer of the device to the three coal-mine specific licensees. Under 10 CFR 30.41, it appears Sabia, Inc. would be required to verify that the transferee was authorized to receive the type, form, and amount of material to be transferred, but not the use to which the material was being put. The latter appears to be the receiving (coal mine) licensee's regulatory responsibility. All three of the coal-mine companies possess licenses that authorize possession of californium-252, in the form of Frontier Technology Corporation Model 100 series sealed sources, and with activity in conformance with that specified by an appropriate SS&D registry sheet. It is DHS/RHB's understanding that Sabia, Inc. met these regulatory requirements in that they transferred californium-252 in the form of a Frontier Technology Corporation Model 100 series sealed source, which had a SS&D registry sheet (#NR-298-S-102-S), and the transferred activity adhered to that specified in the SS&D registry sheet.

It appears to us that the coal-mine licensees are responsible, upon receiving the californium-252 sources, to utilize the sources in accordance with their licenses. Their licenses require that they utilize the source in a device for which a SS&D registry sheet has been issued. Since Sabia, Inc. did not have a SS&D registry sheet for the devices they transferred, it appears to us that the coal-mine licensees would be required to provide the information required in 10CFR 32.210 in support of an amendment to use the device manufactured by Sabia, Inc. Failure to get such a license amendment would appear to constitute a regulatory violation by the coal-mine licensees, not by Sabia, Inc. As a separate issue, we are not certain whether the coal-mine licensees are authorized to receive and possess the californium-252 sources, as long as they comply with license conditions #6, #7, and #8 of their licenses, even though they could not use the sources in accordance with license condition #9 of their licenses. We do not believe that 10 CFR 30.34(c) is sufficiently clear in this latter regard.

In summary, we are requesting regulatory interpretations as follows:

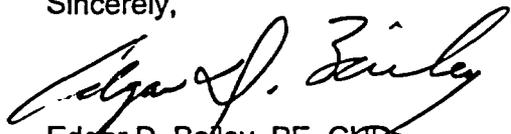
1. Must devices have an SS&D registry sheet in order to be legally transferred to a specific licensee?

2. Must a license specifically authorize distribution in order for a specific licensee to transfer radioactive material to another specific licensee?
3. Is the responsibility to use radioactive material in accordance with license condition #9 "Authorized use" of the transferee's license the responsibility of the transferor or the transferee licensee?
4. Can the coal-mine licensee in the above examples possess the californium sources authorized by license conditions #7 and #8 without using them, if the sources are not contained in the devices specified in license condition #9?

In responding to the above questions, we request that you provide a regulatory analysis in support of your responses. We would appreciate NRC's prompt attention to this request for regulatory interpretations affecting our licensee, Sabia Inc. We note that Sabia, Inc. is constrained by the NRC issued CAL to take action within 45 days of issuance of the May 20, 2004 CAL issuance.

We would like to thank you in advance for providing the requested regulatory interpretations to us. If you require additional information from DHS/RHB concerning this matter, please do not hesitate to contact me (916-440-7899 or 7897).

Sincerely,



Edgar D. Bailey, PE, CHP
Chief, Radiologic Health Branch
California Department of Health Services

C: Mr. Linda McLean
U.S. Nuclear Regulatory Commission
Region IV Office
Texas Health Resources Tower
611 Ryan, Suite 400
Arlington, Texas 76011-4005

