

July 16, 2004

Mr. Edgar D. Bailey, CHP, Chief
Radiological Health Branch, MS 7610
California Department of Health Services
P. O. Box 997414
Sacramento, CA 95899-7414

Dear Mr. Bailey:

I am responding to your June 3, 2004 letter which asks questions and expresses concerns regarding the United States Nuclear Regulatory Commission (NRC) confirmatory action letter (CAL) number 4-04-001. Your letter indicated that the CAL was issued without resolving the issues California raised during a May 20, 2004 call from the NRC. At the time of the call, the NRC had already issued the CAL to Sabia, Inc.; therefore, there was no opportunity to address the State's concerns raised during the call.

The NRC CAL dated May, 20, 2004, to Sabia, Inc. was an administrative step. The CAL formalizes commitments made by Sabia, Inc. to NRC to take prompt action to address circumstances where immediate safety issues existed at locations in NRC jurisdiction. NRC had become aware that devices containing Cf-252 sources supplied by Sabia, Inc. were in use at several locations in NRC jurisdiction in apparent non-compliance with the conditions of the NRC general license. The NRC license issued to Sabia, Inc. for use of radioactive material in NRC regulatory jurisdiction (Region I) was an NRC general license under 10 CFR 150.20 to conduct Research and Development (R&D) activities. Terms of the California license, which apply under NRC's general license, require Sabia, Inc. staff to be present during use of the material at specific temporary job sites. Sabia, Inc. did not comply with the NRC general license. The NRC's CAL was issued to ensure that Sabia was aware of, and would comply with, this requirement in its license. In addition, the CAL was issued to effect an immediate removal of the sources to an authorized licensed location and to have Sabia, Inc. cease any further activities under the NRC general license. NRC staff is still reviewing whether an actual transfer of radioactive material or devices occurred.

Before finalizing the actions in the CAL, NRC conducted in-depth discussions with Sabia, Inc. to ensure that we had an accurate understanding of the facts involved in order to provide the most appropriate actions Sabia, Inc. could promptly take to address the immediate safety issues. NRC considered other regulatory actions (e.g., license amendments) but considered these alternatives to be untimely in dealing with the immediate safety issues. Accordingly, the CAL only addressed NRC's immediate safety concerns, and did not articulate all the regulatory or licensing options which might ultimately be used. The NRC is continuing to investigate these matters and has not yet reached any final conclusions.

In accordance with 10 CFR 2.790 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and

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Management System (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm.html> (the Public Electronic Reading Room).

Your letter also requested a response to several specific questions on regulatory interpretation. Enclosed please find our responses to your questions. If you have any additional questions, please contact me at 301-415-3340 or Mr. Osiris Siurano of my staff at 301-415-2307 or e-mail: OSP@NRC.GOV.

Sincerely

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

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RESPONSES TO CALIFORNIA'S SPECIFIC QUESTIONS

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

Response: No, devices are not required to have a Sealed Source and Device (SS&D) registry sheet in order to be transferred from one specific licensee (i.e., the transferor) to another specific licensee (i.e., the transferee) which is authorized to receive the device. However, the transferee must have specific authorization in its license to use the device. The provisions of 10 CFR 30.32(g) specify that the application for a specific license to use byproduct material in the form of a sealed source or a device, must either identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of Chapter 10 of the Code of Federal Regulations or an Agreement State; or contain the information identified in § 32.210 sufficient to evaluate the device. For unique applications, either the NRC or an Agreement State performs a "custom" evaluation of the source and/or device. A custom registration is usually issued for unique designs used by a single user; in fact, there are no examples where an identical design has been distributed to numerous users and designated for each user as a custom registration. The applicable guidance in NUREG-1556, Vol. 3, Rev. 1, Section 5.2, specifies that "[t]he request for the safety evaluation and registration of the product may be made by the custom user or vendor." Because a single end user is considered to be a "custom" user, the authorization for using the device would only apply to that custom user.

In the instant case, if Sabia, Inc. (Sabia) intended to transfer the device to the coal mine licensee, Sabia did not have an approved SS&D registry sheet for the device in question; nor did Sabia provide the necessary information to the coal mine licensee so that the coal mine licensee could obtain a custom review before acquiring the device from Sabia. Sabia had filed with NRC an original and revised application (April and May of 2004, respectively) for an SS&D review of its device (Model S-3, source holder to be used with a Elemental Analyzer); therefore, Sabia should have been aware that even though the coal mine licensee had a specific license to use various devices, it could not have been authorized to use the device in question because the device had neither an SS&D registry sheet nor a custom registration.

Question 2: Must a license specifically authorize distribution in order for a specific licensee to transfer radioactive material to another licensee?

Response: No, a specific license does not need to contain any specific "distribution" authority which allows a specific licensee to transfer radioactive material to another specific licensee. The Commission's regulations at 10 CFR 30.41(c) provide this authority which requires the transferor to verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred. See response to Question 3 below for information on how this section should be implemented.

Question 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?

Response: It is the responsibility of the holder of an NRC or Agreement State license to comply with the license conditions contained in its license. However, 10 CFR 30.41(c) and equivalent Agreement State regulations require that "[b]efore transferring byproduct material to

a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred." Therefore, if a transferee's license conditions #7 and # 9 do not provide the appropriate authorization to use a particular sealed source or device, a transferor cannot legally transfer that sealed source or device until the transferee obtains the appropriate authorization.

Question 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?

Response: If the coal-mine licensee is authorized to possess the californium sources, it may do so; however, when the sources are placed into a device, the device must be authorized for use in license condition #9, as discussed above, which requires an SS&D registration or custom approval/registration for the device before the licensee can use the device containing the sources.