



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
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ARLINGTON, TEXAS 76011-4125

July 30, 2009

EA-08-237
CAL 4-08-001
NMED 080128

Mr. Clinton Lingren, President
SABIA, Inc.
15070 Avenue of Science
San Diego, CA 92128

SUBJECT: NRC REVIEW OF CORRECTIVE ACTIONS TAKEN BY SABIA (CONFIRMATORY ACTION LETTER 4-08-001 AND NRC INSPECTION REPORT 030-35997/2008-001 AND NOTICE OF VIOLATION)

Dear Mr. Lingren:

The purpose of this letter is to summarize NRC's review of: (1) SABIA's actions in response to Confirmatory Action Letter (CAL) 4-08-001, and (2) SABIA's responses and corrective actions related to NRC Inspection Report 030-35997/2008-001 and Notice of Violation.

On February 29, 2008, SABIA reported to NRC a strontium-90 contamination event at its Idaho Falls, Idaho, facility. Several Federal, State, and local agencies, including NRC, responded onsite to the event. The event resulted in extensive contamination of SABIA's facility. In addition, SABIA personnel were externally contaminated and one individual received a measureable intake of strontium-90. On March 5, 2008, the NRC issued a CAL to SABIA that confirmed SABIA would take specific actions including, but not limited to: taking actions to implement security requirements at the Idaho Falls facility; making arrangements for dose assessments for all workers potentially exposed to strontium-90; obtaining the services of an appropriately licensed service provider to decontaminate the Idaho Falls facility; providing for the removal and disposal of contaminated materials; and providing a written report to the NRC detailing its corrective actions.

SABIA's actions related to dose assessments, decontamination of its facility, and disposal of contaminated materials, is already adequately addressed on the docket and in NRC Inspection Report 030-35997/2008-001. SABIA's corrective actions as described in their June 4, 2008, written report to the NRC pursuant to the CAL were also described in the subject inspection report.

With respect to implementing the security requirements discussed in the CAL, during NRC's onsite event response, the inspection revealed that certain security measures had not been completely implemented by SABIA as a result of the event. However, it was also recognized that, had SABIA employees attempted to implement the facility's security plan, they would have exposed themselves to an additional radiation hazard and would have made themselves vulnerable to additional external contamination and intakes of radioactive material. NRC acknowledges that there is a connection between security and safety and that implementation of one should not compromise the other. Because SABIA's security plan could not be

implemented as originally intended, the CAL prompted SABIA to implement appropriate compensatory measures to address the security requirements. These security measures, including SABIA's coordination with two local law enforcement agencies, were inspected during the onsite event response and again during subsequent NRC follow-up inspections, and were found to be adequate. The decontamination of SABIA's facility, removal of contaminated materials, and transfer and disposal of large quantities of licensed materials has allowed SABIA to return to a normal security mode without the need for enhanced security measures.

On October 18, 2008, NRC issued Inspection Report 030-35997/2008-001. On November 10, 2008, a predecisional enforcement conference was held with SABIA to discuss the findings identified in the inspection report. Following the NRC's deliberations on the matter, on January 29, 2009, NRC issued a Notice of Violation and proposed imposition of civil penalty. The Notice of Violation issued a Severity Level III violation for SABIA's failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

By letter dated February 24, 2009, SABIA provided the NRC with its response to the Notice of Violation. NRC reviewed the response and found that there was insufficient information to make a determination regarding the appropriateness and comprehensiveness of SABIA's corrective actions. As a result, by letter dated March 25, 2009, SABIA was requested to provide the NRC with additional details and documentation regarding its corrective actions.

By letter dated April 8, 2009, SABIA provided the NRC with the requested information regarding its corrective actions. In its letter, SABIA further elaborated that its causal factor analysis determined the root cause of the event to be the information contained in the Sealed Source and Device Registry (SSDR) safety evaluation for the gauge and source that were involved in the event. In its causal factors analysis, SABIA presented their position that it was unreasonable to think that a strontium-90 source composed of oxide/silicate fused in a glass disk was capable of being readily dispersed and thus they did not implement or exercise any special precautions in handling the source. SABIA further explained that, based on their review of the information contained in the SSDR safety evaluation, they saw no need to have additional planning, preparation, or training to handle the strontium-90 source contained in the gauge.

The NRC staff's independent review of the causes of the event determined that SABIA's causal factor analysis is incorrect. Based on our independent assessment, it is unreasonable to attribute the cause of the event to be the information contained in the SSDR safety evaluation because the individual that handled the gauge and strontium-90 source did not review the SSDR safety evaluation prior to handling the gauge or source, nor did he possess a copy of the SSDR safety evaluation for reference during his gauge dismantlement activities. SABIA's Radiation Safety Officer, who was not present when the gauge and source were dismantled and the contamination event occurred, previously stated to NRC that he had last reviewed the SSDR in the 2002 time frame, well before the gauge dismantlement activities took place in 2008. Therefore, we have concluded that the information contained in the SSDR safety evaluation did not influence how SABIA chose to handle the gauge and source because SABIA personnel handled the gauge and source in the absence of that information. A careful review of the SSDR safety evaluation would have revealed valuable information including, but not limited to: (1) the dimensions of the source holder (so that an appropriately sized container could have been staged by SABIA personnel for storage of the source holder); (2) the specifications of the thin

window that separated the source from the user (so that SABIA personnel would not have been inclined to subject the window to damage by impacting it with a screwdriver); and (3) the configuration of the source and source holder, which indicated that the source was an integral part of its source holder (so that it would have been evident that it was incorrect to attempt to remove the source from its source holder). Although we disagree with SABIA's determination of the root cause, we are not requesting any additional response related to SABIA's causal factors analysis and consider this item closed.

SABIA's April 8, 2009, letter also provided additional information regarding the training that was provided to SABIA employees as part of SABIA's corrective actions. Based on our review of SABIA's various training agendas and training materials, it appears that the training provided by SABIA addressed the conditions of SABIA's NRC license, NRC regulatory requirements, and a discussion of SABIA's new/revised operating and emergency procedures. In our reviews, we noted that the training materials submitted by SABIA did not explicitly address the contamination event. SABIA's radiation safety training, although not specifically required, could be enhanced by a discussion of the contamination event, its causes, SABIA's corrective actions, and lessons learned. In addition, the NRC staff has noted that SABIA has occasionally allowed non-SABIA employees to be involved in licensed activities as authorized users. Authorized users who are non-SABIA employees should be provided with the level of training required for all authorized users, as specified in SABIA's NRC license. Based on the training rosters submitted to NRC, it appears that many individuals were provided with the additional training. During future NRC inspections, inspectors will review training records and interview personnel to verify that all appropriate individuals (SABIA employees and non-SABIA employees) have been provided the training as part of your corrective actions.

In electronic mail dated May 6, 2009, SABIA was asked to provide the NRC with additional information regarding certain corrective actions. Specifically, SABIA was asked to provide the NRC with records of disposal or transfer related to the sealed sources that had been in storage at SABIA's Idaho Falls facility at the time of the event. By letter dated June 4, 2009, SABIA provided the NRC with a record that described the disposal or transfer of all 179 sources that had been in storage at the time of the event. This submitted information, together with information gathered during an NRC inspection performed on April 13, 2009, is sufficient to demonstrate that SABIA has completed this particular corrective action.

One item that remains under review by the NRC is related to SABIA's operating and emergency procedures. On November 21, 2008, the NRC received 14 radiological operating and emergency procedures from SABIA for the NRC's review and approval. These procedures were inappropriately marked by SABIA and were resubmitted to NRC on January 28, 2009, with appropriate markings. These procedures were reviewed by the NRC staff and several deficiencies were identified and discussed with SABIA's Radiation Safety Officer. On March 6, 2009, SABIA resubmitted its procedures to the NRC for review and approval. The submission contained revisions to the 14 originally submitted procedures as well as 18 new procedures for the NRC's review and approval. SABIA's March 6, 2009, submission is currently under review by the NRC staff. The results of this review will be provided to SABIA in a separate communication because these procedures are being reviewed as part of a license amendment request.

In summary, NRC has reviewed the actions taken by SABIA in response to CAL 4-08-001, NRC Inspection Report 030-35997/2008-001, and the subject Notice of Violation. The NRC's reviews

of SABIA's actions consisted of both onsite inspections as well as in-office reviews of SABIA's submittals to the NRC. Our review has concluded that SABIA has completed the actions outlined in the CAL. As a result, we consider the CAL to be closed. In addition, we have reviewed your reply and additional submissions related to the concerns raised in our Notice of Violation and find your actions to be responsive to those concerns. Although we disagree with your determination of root cause, we are not requesting any additional response from SABIA on this matter. We will continue to review the implementation of your corrective actions during future inspections to determine that full compliance has been achieved and will be maintained.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this letter, please contact Mr. Jack Whitten at 817-860-8197.

Sincerely,

/RA/

Arthur T. Howell III, Director
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ADAMS	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> SUNSI Rev Complete	Reviewer Initials:	JFK
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