15070 Avenue of Science San Diego, CA 92128 Bus: 858-217-2200 Fax: 858-217-2203

www.sabiainc.com

February 24, 2009

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Mr. Elmo E. Collins Regional Administrator US NRC Region IV 612 East Lamar Blvd, Suite 400 Arlington, Texas 76011-4125

Subject: Reply to Your letter of January 29, 2009, EA-08-237 "Notice of Violation..."

Dear Mr. Collins,

Attached please find the response to your letter of January 29, 2009, and the Reply to Notice of Violation that has also been sent to U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738. A check for the amount of the imposed fine has been sent to U.S. Nuclear Regulatory Commission, License Fee and Accounts Receivable Branch, P.O. Box 954514, St. Louis, MO 63195-4514.

Your letter indicated that SABIA, Inc. had not been responsive to the Predecisional Enforcement Conference Summary. We have attempted here to provide the information that was considered missing and to respond to the comments in your letter of January 29, 2009.

A summary of the Company-Wide Safety Review is attached.

The new and revised radiological procedures were used as the training materials and each procedure was covered item-by-item. A copy the training meeting records is attached; however, the names of the attendees have been removed and only the total number attending is given. The names of the persons trained in each meeting are available for review in our radiation safety records files.

Procedure 1002002, ALARA Practices Policy, did not include a prohibition that the user refrain from further handling a source until the results of a leak test are obtained, but that has been added. However, that prohibition had been included in each of the procedures for leak-testing of sources, installation of sources, and maintenance of gauges. These will continue to include that prohibition because they govern those activities.

Procedure 1002000, Emergency Procedures, Nuclear Gauges, has been revised to include a discussion on the availability of decontamination supplies. Decontamination of personnel, if required, is also discussed, but comprehensive and complete decontamination is left to trained medical professionals after initial decontamination has been completed.

Any non-routine work with radioactive sources will be reviewed by the SABIA Radiation Safety Committee prior to the activity commencing to ensure that proper procedures are in place and that the personnel who will do the work have adequate training and understanding of the task.

SABIA, Inc. is submitting for inclusion in its Radioactive Materials License current issues of radiological procedures that have been written or revised since it was last amended and will continue to submit all radiological procedures to the NRC for inclusion in the SABIA Radioactive Materials License within 30 days after they are written or revised.

We believe we have addressed the concerns that were expressed in your letter. If we can provide additional clarifications or information, please contact me.

Respectfully,

Clinton Lingren President/CEO

Attachments:

Reply to a Notice of Violation Summary of the Company-Wide Safety Review Training meeting records

CC:

James F. Miller, Radiation Safety Officer SABIA, Inc. 15070 Avenue of Science San Diego, California 92128

Clinton Suray

Mark Dietrich Technical Services Administrator Idaho Dept. of Environmental Quality 1410 North Hilton Boise, Idaho 83706

David Jones State of Idaho Department of Environmental Quality 900 North Skyline Drive, Suite B Idaho Falls, Idaho 83402

Mike Taysom Bonneville County Emergency Management 605 North Capital Ave. Idaho Falls, Idaho 83402

Steven Morreale
Regional Response Coordinator
U.S. Department of Energy
Idaho Operations Office
1955 Freemont Avenue
Idaho Falls, Idaho 83401

Reply to a Notice of Violation; (EA-08-237)

(1) admission or denial of the alleged violation;

SABIA, Inc. acknowledges the decision of the NRC concerning the violation and admits that the violation occurred.

(2) the reason for the violation if admitted, and if denied, the basis for denying the validity of the violation;

SABIA, Inc. did not conduct adequate planning and training for the project of disassembling the radiation gauges in preparation for source disposal. The program was relying on the experience of those doing the work and the company procedures, which had been submitted to the NRC as part of planning for the work. However, the experience of the personnel and the completeness of the procedures proved inadequate for magnitude of the task and the event that was encountered. The source that leaked was the only beta source in the possession of the company and the personnel had no previous experience with beta sources.

The device registration and the source registration of the DuPont-Merck source described the source material as "strontium/yttrium-90 fused in a glass disc and sealed by welding in a 316L stainless steel capsule." Based on that description, there should not have been the risk of so extensive an exposure to personnel nor contamination of the facility as did occur. Handling a source of the form that was encountered (with a significant amount of fine powder) should have been done only in a specially prepared facility equipped to prevent spread of the radioactive material.

(3) the corrective steps that have been taken and the results achieved;

SABIA, Inc., with the approval of the NRC, contracted with a company for cleaning up and disposing of the contamination from the leaking source. The decontamination was completed and the report submitted to the NRC.

SABIA, Inc. reviewed the planning and organization of the source disposal project that was being conducted when the Sr-90 leak was encountered and reviewed the procedures that were used. It was determined that the procedures should be upgraded to be more thorough and better organized. One of the methods used to review the event was a root cause analysis using the program Apollo Root Cause Analysis. The results of that analysis were used in evaluating what corrective actions should be taken.

A team was formed of those individuals in the company that were trained to use or work around radioactive sources, and they were given the task of upgrading all procedures and processes associated with working with radioactive sources, with special emphasis on ensuring that occupational doses are ALARA.

New procedures were prepared, older procedures were revised to increase clarity and completeness, and all procedures were re-formatted for providing a uniform presentation to the reader to avoid misunderstanding.

On September 29, 2008, all SABIA employees received three hours of training on radiation safety. On October 3, 2008, the Radiation Safety Committee (RSC) met to review the status of corrective actions. The RSC reviewed the status of procedure revision and preparation, radiation safety training, radiation safety records retention, and radioactive source disposal.

On October 13, 2008, the first of the new and revised procedures were released and training was held with employees to ensure that they understood the changes that had been made and the content of the new procedures. Following receipt of the January 29, 2009, letter from the NRC, SABIA, Inc. has made additional revisions to some of the procedures in response to those comments and is submitting the procedures under separate cover to the NRC for inclusion in its license.

SABIA, Inc. reviewed its practice of accepting unwanted sources from customers for disposal and made the determination that it would receive from customers only those radioactive sources associated with its own instruments that it provides to its customers.

SABIA, Inc. has continued with the disposal of the sources that were at its facility, has had the remaining gauges disassembled and has the sources in shielded containers ready for shipping for final disposal. Quotations have been received for receiving those sources and a contract is being established. The sources will be encased in concrete for shipping and will be shipped to their final destination after 30 days of the concrete curing. The final disposal will be complete by April 30, 2009.

SABIA, Inc. is preparing other procedures for conducting licensed activities, such as non-routine maintenance on specific models of radioactive devices referenced in the SABIA Radioactive Materials License. They will be submitted for inclusion in the SABIA Radioactive Materials License as they are prepared.

(4) the corrective steps that will be taken to avoid further violations; and

Any non-routine work with radioactive sources will be reviewed by the SABIA Radiation Safety Committee prior to commencing the activity to ensure that proper procedures are in place and that the personnel have adequate training and understanding of the task.

SABIA, Inc. will ensure, whenever a leak test is performed on a radioactive source, that no further work or operations with that source will be performed until it is established that the radioactive source is not contaminated and is not leaking. That prohibition has been included in the appropriate procedures.

SABIA, Inc. will submit all radiological procedures to the NRC for inclusion in the SABIA Radioactive Materials License within 30 days after they have been written or revised.

(5) the date when full compliance will be achieved.

The procedure and policy changes are in place and the current procedures have been submitted for inclusion into the SABIA Radioactive Materials License.

SABIA, Inc. will request amendments to the Radioactive Materials License within 30 days of the generation of any new or revised SABIA Radiological procedure, ALARA procedure or Emergency procedure for its inclusion in the license.

SABIA, Inc. will complete the disposal of all radioactive sources that are now in the final stages of preparation for disposal by April 30, 2009.

Company-Wide Safety Review

SABIA, Inc. reviewed the planning and organization of the source disposal project that was being conducted when the Sr-90 leak was encountered and reviewed the procedures that were used. It was determined that the procedures should be upgraded to be more thorough and better organized. One of the methods used to review the event was a root cause analysis using the program Apollo Root Cause Analysis. The results of that analysis were used in evaluating what corrective actions should be taken.

A team was formed of those individuals in the company that were trained to use or work around radioactive sources, and they were given the task of upgrading all procedures and processes associated with working with radioactive sources, with special emphasis on ensuring that occupational doses are ALARA.

New procedures were prepared, older procedures were revised to increase clarity and completeness, and all procedures were re-formatted for providing a uniform presentation to the reader to avoid misunderstanding.

SABIA, Inc. conducts an annual Radiological Program Audit. The last audit that was performed prior to the February 29, 2008, Sr-90 contamination event was conducted on December 28, 2007. Soon after the decontamination of the manufacturing facility was complete, another audit was conducted on July 9, 2008. An audit was again conducted on February 13, 2009. Those completed audits are filed with the SABIA radiation safety records.

In addition, two employees from the SABIA San Diego office were sent to Idaho Falls to assist with manufacturing for a period of time with the specific instructions to review jointly with the staff in Idaho Falls all manufacturing processes and practices from a safety standpoint. Several modifications to processes were made to improve safety, primarily in the areas of handling manufacturing materials. No formal audit checklist was used and a formal audit report was not prepared. However, an agenda item was added to the company weekly staff meeting to review any safety concerns from any part of the company. That practice has continued since mid-year, 2008.



Radiation Safety Training was presented on September 29, 2008.

The subject of the meeting was training in the SABIA radiological procedures.

The meeting was held in the San Diego office with the employees outside the San Diego office participating via teleconference and www.gotomeeting.com

Items discussed included 10CFR regulations, 49 CFR regulations, CFR definitions Governing Agencies (NRC, California, Agreement States, CNSC, Queensland Health), the SABIA Radioactive Materials Licenses, Device Registrations, a review of the SABIA radioactive materials licenses, a review of the SABIA radiological procedures, and the SABIA Radiation Safety Committee.

Training was presented by a PowerPoint presentation titled, "SABIA Inc. Radiation Safety Training, Sep 2008.

Present were SABIA employees who work with radioactive materials or in the area where radioactive materials are used or stored and SABIA field service employees.

Training was presented to 17 employees. Training Roster is attached with trainer's signature.



Radiation Safety Training was presented on October 13, 2008.

The subject of the meeting was training in the SABIA radiological procedures.

The meeting was held in the San Diego office with the employees outside the San Diego office participating via teleconference and $\underline{www.gotomeeting.com}$

Items discussed included the new SABIA radiological procedures, with focus on radiation safety. Procedures included:

1002000, Emergency Procedures, Nuclear Gauges,

1002003, Inspection and receiving procedure, Radioactive Materials,

1002004, Packing and Transportation of Sealed Radioactive Sources,

1002015, XC-5000 Source Shutter, Analyzer Leak Test procedure with forms,

1002016, XL-5000 Source Shutter, Analyzer Leak Test procedure with forms,

1002007, Nuclear Source Leak Test and Inventory Certification,

1002008, Physical Inventory of Sealed Radioactive Sources,

1002009, Nuclear Source Leak Test Calculation Sheet,

1002010, Nuclear Source Leak Test Report

Training was presented by computer and projector utilizing the PDF copies of the radiological procedures.

Present were members of the SABIA Radiation Safety Committee and supervisors for the SABIA field service teams responsible for work with coal and with cement.

Training was presented to 6 employees. Training Roster is attached with trainer's signature.



Radiation Safety Training was presented on January 12, 2009.

The subject of the meeting was Radiation Safety Refresher Training and training in SABIA radiological procedures.

The meeting was held in the SABIA San Diego office.

Reviewed documents of the NRC inspection at Farmersburg and Sommerville. Reviewed Safety Inspection report and Compliance inspection from the NRC to Black Beauty Coal Company. Reviewed SABIA Documents and Radiological procedures, including 1002000, Emergency Procedures, Nuclear Gauges, including decontamination procedure, and 1002002, ALARA Practices Policy.

Training was presented by PowerPoint presentation, using "Safety training 2009 with OSHA.pptx" (41 slides)

Present were SABIA employees working with radioactive materials, employees working near areas having radioactive materials, and SABIA field service employees.

Training was presented to 24 employees. Training Roster is attached with trainer's signature.