November 10, 2004

James F. Miller, RSO
Sabia, Inc.
7944 Convoy Court
San Diego, CA 92111

Dear Mr. Miller:

This letter is in reference to your application dated August 26, 2004, requesting registration for Sabia, Inc. Model K-1000 materials analyzer. In order to complete our review, please provide the additional information requested in the Enclosure.

We will continue our review upon receipt of this information. We request that you provide the additional information in 30 days. If we do not receive a response, we will consider your request as having been abandoned and void the active control for your request. This action would be without prejudice to the resubmission of another request. If you need additional time, please contact me.

If you have any questions, please contact me at (301) 415-7637.

Sincerely,

/RA/

Nima Ashkeboussi, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As Stated

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ENCLOSURE

Additional Information Required

1. Source Holder/Source

Please provide or describe:

1.1 How the sources are mounted and secured in the source holder and state the height in the source housing at which the source holder is located. How the source holder will remain in the source housing if the lock is removed, and how access is controlled to the source holder and lid lock key.

1.2 Page 10 of your application shows the drawing of the source holder. The drawing shows spaces for 4 sources; however, Page 6 of your application states that up to five sources may be used. Please explain these discrepancies.

1.3 State clearly the maximum activity per source, the maximum number of sources that will be used in the K-1000, and the maximum activity of the device.

1.4 The application refers to the device as “K-1000 Series”. Please describe the differences between the models in the K-1000 Series.

1.5 Step 3 on Page 23 of your application instructs the technician to withdraw the source holder at least 12 inches from the steel drum to perform leak testing. Please describe the safety features of the design that would prevent accidental removal of the source holder beyond the 12 inch distance and expose the source.

2. Prototype Testing

2.1 Please provide mounting details of this device and the maximum height of installation. Also, demonstrate how the source would maintain its integrity in case of a drop from the maximum height.

2.2 Page 6 of your application states that the temperature of the material running through the pipe may be up to 80E C continuously and up to 1000E C for up to 10 minutes. Please provide the material used for the 6 inch pipe and demonstrate that it can withstand these conditions and that there is sufficient clearance between the pipe and the device to allow for temperature differential expansion. Also confirm that the borated polyester will not be adversely impacted by the high temperatures. Demonstrate what temperature gradient will be reached in the source holder at the end of a temperature surge of 1000E C for a 10 minute duration.

2.3 Under corrosion on Page 12 of your application, you state that the device was periodically hosed. Please be more specific in the time intervals, duration of hosing, and the temperature of the water and demonstrate how this covers the expected conditions of use and the working life of the device.

2.4 Under vibration on Page 12 of your application, you state the prototype was subjected to vibrations estimated to be between 10 Hz to 50 Hz at an amplitude of 0.05 inches. Please explain your basis for determining how these parameters satisfy the actual conditions experienced by the device.

2.5 Please describe any operational incidents that have occurred with the Model K-1000 device in Canada.

Radiation Profiles

3.1 Page 15 of you application provides a radiation profile for an activity of 595 MBq. Your application indicates that the maximum activity you will have up to 4995 MBq (5 source @ 27mCi each). Please provide radiation profiles that are reflective of the maximum activity for the device.

3.2 Page 3 of your application states that the dose rate to a person near the housing assembly is 500 mrem per year and Page 6 of your application states that maximum personnel radiation exposure is 60 mrem per year. Please explain the discrepancies and provide expected dose rates and how they were calculated.

3.3 Provide the annual dose rate to servicing personnel performing the procedures specified for the user on Page 8. Specifically, please address the dose rate for servicing personnel in terms of the regulatory requirements for generally licensed devices per 10CFR 32.51.

3.4 Please provide practices and procedures that you will implement to ensure radiation exposure below the limits allowable to members of the public and untrained nuclear workers per 10 CFR 20.1301 (100 mrem per year; 2 mrem per hour).

3.5 Please provide the radiation profile for the device, loaded with maximum activity sources, around the source holder when the source holder is withdrawn 12 inches from the device, as the maintenance procedures under Step 3 on Page 23 require for the leak test.

4. Labeling

4.1 Please note the label on page 5 identifies Sabia Inc. San Diego, CA as the manufacturer of the device. Please submit a corrected label to indicate that Sabia Inc., Idaho Falls is the manufacturer.

5. Quality Assurance

5.1 Under quality assurance on Page 7 of your application, you state that the assembly of the drum is by means of welded construction. Please state the welding process to be used and the weld testing acceptance criteria. Please also state if the drum is designed to any industrial standards and provide the drum material specifications and wall thickness.

5.2 Please state the scope of inspection and the type of inspection to be conducted on receipt of the devices in California.

6. Clarifications

Please explain or clarify:

6.1 The discrepancies between the statements made on the label on page 5, “Installation, relocation, and maintenance....shall only be performed by persons specifically licensed” and the statements made on page 6 of the application “The device will not be moved from its location with sources installed; the sources will be moved and reinstalled by Sabia” and “The installation of the sources is specifically performed by Sabia, Inc. personnel”. Specifically clarify what activities only Sabia can do and what the gauge user can do.

6.2 On Page 12 of your application, you note that the maximum operating temperature is 55E C, however the ANSI N-43.8 temperate 2nd classification is 50E C. Please note that we will be limiting the operating conditions to levels that will not exceed ANSI N-43.8 classification.

6.3 Your device in Canada was installed indoors, please clarify if you want the device to be registered for indoor and outdoor use.