SAIC Application dated February 26, 2013
Information Needed for Registration of Xpose Series
and for Exempt-Distribution License

A. Questions Regarding Registration Certificate Application Request

SAIC application dated February 26, 2013, contained insufficient information as required by 10 CFR 32.30 and described in the relevant guidance document NUREG-1556 Vol. 3 titled "Applications for Sealed Source and Device Evaluation and Registration." Specific deficiencies include:

1. Description/Construction:

1.1 Please submit a full set of engineering drawings and a detailed description of the construction of the device. The design and data should be sufficient to allow the reviewer to fully understand the construction, operations of the product and its components and safety features and to allow the evaluation of the product's safety, security and integrity.

You should include, as a minimum, complete annotated engineering design and/or construction drawings showing assembly of components, exterior construction of the final product, operation of the shutter, location and mounting of the sources. Please provide details of source holder, dimensions, shield assembly and beam geometry. Address the tamper proofing features of the device, and provide the relevant drawings. Please clarify the statement that "the source disc cannot be inadvertently removed…" (Page 2 of 5).

1.2 The application indicates that series of products is to be manufactured. Please provide drawings requested above in Section 1.1 for all models in the series. Please summarize the differences between the various models; you may use a table to indicate the differences.

1.3 Please confirm that SAIC will be both the manufacturer and the distributor of the Xpose devices.

1.4 Please provide the description and location of the on-off switch and any indicator which may show the shutter position. Clarify when one or multiple switches are to be used. Provide the drawings for the different configurations.

1.5 Address the issue of potential corrosion between the aluminum source containment and other components.

1.6 Source:

1.6.1 Please confirm that Spectrum Techniques will be the sole supplier of the sources to be used in the Xpose devices.

1.6.2 Please specify the "precise SAIC specifications" (Page 2 of 5) in terms of physical, chemical and engineering parameters.

1.6.3 Specify the properties of the epoxy which is to be used in the source. Please address the issue that the epoxy will maintain its properties in a radiation environment for the duration of the working life of the device.

1.6.4 Describe how SAIC will assure that the source vendor maintains proper quality assurance measure of the production of the sources.

1.6.5 Clarify source distributor and exactly which sources will be used in Xpose devices. Please provide reference to the appropriate SSD registrations.

1.7 The Principle use code stated in your application is (D) Gamma Gauge. We think that the code (N) Ion Generators, Chromatography is more appropriate. Please confirm.

1.8 Please provide more information on the Source Disc, Source Heart, Tungsten Wedge design as discussed in the description section of the application (Page 2 of 5). In particular, discuss in further detail the significance of the parts in the operation on the device (i.e. the shield/shutter mechanism) and the actual construction and assembly of the parts.

1.9 Please provide more detail with regard to the operation of device as dosimetry pager, radiation field detector, and isotope identifier.

1.10 Please clarify the following statement: “These additional features may not require the use of the Ba-133 source – shield/shutter mechanism to function” (Page 3 of 5, Description Section).

1.11 Please clarify the following statement: “Additional lead shielding may be added as needed depending on specific Xpose product specifications and customer needs” (Page 2 of 5, third Paragraph).

2. Labeling:

2.1 Please state the label location, and visibility to users, of the various models in the series.

2.2 The text of the label provided in the application is not in compliance with the requirements of 10 CFR 32.32. Please provide the appropriate label/labels which are in compliance with the regulations.

2.3 Provide the labels which will be used under various models in the series.

2.4 Provide the materials, dimensions, color and method of attachment for the labels.

3. Conditions of Use:

3.1 Please quantify with physical parameters the environmental conditions which were referred to as “normal weather conditions…” (Page 3 of 5). Address the conditions of use such as temperature, vibration and shock in terms of physical parameters.

3.2 Please quantify the “corrosive atmosphere or excessive vibration” in physical terms (Page 3 of 5).

4. Prototype Testing:

4.1 Provide test method, specifications, conditions and results.

4.2 Provide properties of the "hard surface" which was used for the prototype drop tests.

5. Radiation Profiles:

5.1 The application provides the maximum radiation levels at 5, 30 and 100 centimeter distances from the device. However, the maximum reading locations were not provided.

5.2 Provide the model of the instrument for the survey which was used to take the measurements, as well as the dates of the calibration. Please provide the dates of the survey readings.

6. Quality Assurance:

6.1 Please provide a copy of the quality assurance program which you refer to as "on file with the NRC."

7. Operation and Maintenance Manual:

7.1 Please provide a final copy of the operation and maintenance manual.

B. Questions Concerning Exempt-Distribution License Application

Your application does not sufficiently address the following requirements in 10 CFR 32.30, "Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer," and 10 CFR 32.31, "Certain industrial devices containing byproduct material: Safety criteria."

1. 10 CFR 32.30(b)(7) requires the applicant to submit sufficient information relating to the degree of access of human beings to the device during normal handling and use to demonstrate that the device will meet the safety criteria set forth in 10 CFR 32.31.

   To demonstrate that your device meets this requirement, you provided the following statement:

   "The Xpose device is designed to be handled and used by law enforcement. Accessibility will be such that it is typically worn in a utility belt by officers. Due to the source-shield/shutter mechanism, users will not have access to the source during handling and use."

   Although the device is designed to be handled and used by law enforcement, please indicate what controls, if any, exist to ensure that the device will not be distributed to the general public.

2. 10 CFR 32.30(b)(14) requires a determination that the probabilities with respect to the doses referred to in 10 CFR 32.31(a)(4) meet the criteria of that paragraph.

To demonstrate that your device meets this requirement, you provided the following statement:

"Xpose will be distributed to a select group of individuals that have training and a history of using this type of device. Other similar devices used by law enforcement have a long history of safe use with no failures."

Your response does not address the requirement of 10 CFR 32.30(b)(14). You are required to provide an assessment of potential doses that might occur if the safety features of the device fail. For convenience, the requirement is repeated here:

- 10 CFR 32.31(a)(4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater.

  (The footnote to this section provides the following additional information: It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria: Low— not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible— not more than one such failure/incident per year for each one million exempt units distributed.)

In demonstrating that you meet this requirement, it is not necessary to evaluate every possible scenario. It is acceptable to choose one scenario that maximizes external dose, and one that maximizes internal dose, and if the result is well under 500 mrem (for external) and 100 mrem (for internal), it can be assumed that all eventualities will meet the accident criteria.

Given that you expect to distribute a relatively small number per year, you could assume only a few hundred are ever in the distribution chain to be involved in a single accident. If you can show that 10,000 of your product cannot result in more than 500 mrem, then the exact number at one place is not critical.

3. 10 CFR 32.31(b) requires that an applicant for a license under 10 CFR 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

To demonstrate that your device meets this requirement, you provided the following statement:

“Given the small amount of activity (10 pCi) of byproduct material, the dose rate at 1 meter from the source is calculated to be 2 μR/hr. The external radiation dose is then 2 mR for 1000 hrs of exposure. At a distance of 1 cm, the calculated dose rate is 2.0 E+4 μR/hr giving a dose to localized areas of skin over an 80 hr period of 1.6 rem.”

You used a distance of 1 centimeter to demonstrate that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem). A distance of 1 centimeter does not appear to be appropriate for a source carried in the pocket of a shirt or trousers. Please provide justification for your use of 1 centimeter, or, if this distance cannot be justified, recalculate the dose averaged over areas no larger than 1 square centimeter using a realistic distance between source and skin.