JUN 2 6 1998

Berthold Systems, Inc.
ATTN: G.M. (Bud) Smith
President
101 Corporate Drive
Aliquippa, Pennsylvania 15001

Dear Mr. Smith:

Please be advised that Berthold Systems, Inc. (BSI) must discontinue its program of advising its customers to combine exempt quantity sources. As discussed during the June 19, 1998, telephone conversation between you and Mr. Lubinski, Nuclear Regulatory Commission (NRC), the NRC Office of General Counsel (OGC) has determined that the NRC position that was transmitted in a June 3, 1994, letter to Ronan Engineering Company, was in error. Specifically, NRC now finds that combining of exempt sources is inconsistent with the regulations pursuant to 10 CFR 30.18, 32.18, 32.19 and 32.20. Because the exemption provided in 10 CFR 30.18, as set out in the regulation itself, is applicable only as long as no individual or discreet quantity of the byproduct materials exceeds the quantity limits specified in 10 CFR 30.71, Schedule B, and as long as the quantities set out in that schedule are originally received and remain separate and distinct from other quantities of exempt byproduct materials, Ronan's instructions and the jig that it provides to its customers is in direct conflict with the NRC's requirements for labeling of exempt sources which instruct persons not to combine exempt quantities. The labeling requirements in section 32.19, which address shipments to persons exempt, instruct 32.18 licensees to label the "immediate container" with information identifying the radioisotope and the quantity of radioactivity, and in addition to that information, "shall also bear the words ... 'Exempt Quantities Should Not Be Combined.'" Therefore, while the exemption in section 30.18 provides for persons without a license to possess and use a wide variety of byproduct materials, and to possess and use specific byproduct materials without restriction as to the total quantity which may be possessed and used at any one time, the regulations do not authorize, but rather prohibit, grouping exempt quantities of byproduct material.

BSI may distribute these devices to specific or general licensees. However, in order to do so, BSI must have the device design evaluated and registered with the NRC and if distributed to general licensees BSI must have its general distribution license amended.

In an application dated January 10, 1998, you requested a specific license pursuant to 10 CFR 32.18 to distribute exempt quantities of specified byproduct material to persons exempt from licensing under 10 CFR 30.18. However, we understand you want to change your application to request both a license to manufacture and distribute a generally licensed device and a NRC device registry review.

To distribute a generally licensed gauging device pursuant to 10 CFR 31.5, the requirements in 10 CFR 32.51 must be met. Based on our initial review of your application you must submit sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and

However, as discussed during the June 22, 1998, meeting between you and Mr. Steven Baggett, because of the low risk associated with a device containing 500 microcuries of cesium-137, flexibility in the device review will be considered. I have enclosed a copy of the handout from this meeting detailing the usual requirements for a NRC generally licensed device review. In short, however, the following information should be provided:

1. For all models please supply a set of drawings that adequately describe the construction of the devices.

2. Provide the maximum number and activity of the sources to be used in the device.

3. Please explain how you will prevent access to the sources by the general licensee.

4. Please describe how the labels will meet the requirements in Section 32.51(a)(3), 10 CFR 32.

5. Please confirm that dose levels on contact will not exceed 0.5 millirem per hour.

6. Dose assessments must be provided that demonstrate that the device meets Section 32.51, 10 CFR Part 32 safety criteria, i.e., it is unlikely that a person will receive in 1 year a dose in excess of 10 percent of the annual limits in 10 CFR 20.1201(a) or the internal organ dose limit of Column IV of the table in 10 CFR 32.24. Please provide adequate dose scenarios based on the radiation levels around the device.

7. Results of prototype testing or engineering analysis to demonstrate device maintain its integrity during likely conditions of use.

8. Provide a description of your Quality Assurance program including a commitment to verify radiation levels and test for removable contamination.

9. Describe servicing that you will provide and that general licensee's may perform. In doing so, please provide safety instructions that will be provided to the general licensee's.

At this time, devices already in use having multiple exempt quantities of byproduct material may continue to be used. NRC does not plan to take any action with respect to these devices or users unless a radiological safety hazard is identified. In addition, as discussed during our meeting of June 22 and during your meeting with NRC in your congressional representative's office on June 23, 1998, NRC will allow BSI to continue to distribute devices having multiple exempt quantities of byproduct material for a period of 60 days from the date of this letter.

NRC plans to perform a risk assessment to determine if there are any public safety concerns with these devices and whether any further action is warranted. If the risk assessment demonstrates a low risk to the public, NRC would initiate rulemaking to authorize the distribution of these devices to persons exempt from licensing. It is anticipated that the risk assessment and rulemaking process will take 2 to 3 years.

We look forward to receiving the required information as soon as possible. If you have any questions, please contact me at (301) 415-6140 or Mr. John Lubinski at (301) 415-7868.

Sincerely,

Original Signed By:
Anthony S. Kirkwood

Anthony S. Kirkwood
Materials Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

Control No. 021947

Enclosures: As stated

cc: Mary Keller, Berthold Systems, Inc.
George Kury, Berthold Systems, Inc.
Tom Combs, NRC/OCA
John McGrath, RI
Vickie Jeffs, State of Kentucky

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OFC	MSB NMSS	E	MSB NMSS	E	MSB NMSS	E	OGC	
NAME	ASKirkwood:ask		SLBaggett		LWCamper		SATerby	
DATE	06/25/98		06/26/98		06/26/98		06/26/98	

OFC	IMNS NMSS							
NAME	FCCombs							
DATE	06/25/98							

OFFICIAL RECORD COPY

ITEM 1 - LICENSE INFORMATION

This is a request to amend BSI's current license, most of the licensing information should be there already.

Applicant and Contact
BSI

Device type
Photon Gauge

Model

NW-XXXX Series (-2100 Density Gauge, -3200 Point Level, -3100 Continuous Level)
notify us of additional models for information purposes only

Radioactive Source Model Designation

Need to use BSI drawing number for source design

Radionuclides and Maximum Activity

Cesium-137 - 500 microcuries
(no single source to exceed an exempt quantity unit as defined in 10 CFR 30.70 schedule B)

Leak-Test Frequency

The NRC does not require periodic leak testing of a device during use if the device contains only (1) hydrogen-3, (2) radioactive material with a half-life of less than 30 days, (3) radioactive material in the form of gas, (4) less than 100 microcuries of beta- or gamma-emitting material, or (5) less than 10 microcuries of alpha-emitting material. Therefore, not required if no source exceeds 10 CFR 30.70 quantities.

Written Description

Provide a brief written description of the nature and intended purpose of the device (e.g., what it is and how it is to be used.) State whether the device is portable or installed in a fixed location. Describe the radiation safety features of the device, including dimensions, materials of construction, methods of assembly and attachment, and external radiation levels. Include a description of the shielding and the method of securing the source in the device. Describe how the device is installed for use (e.g., bolted to a pipe).

Drawing

Provide an isometric projection drawing or sketch showing components pertinent to radiation safety such as shielding material, shielding thickness, label location, and approximate dimensions of the device. The drawing, sketch, or photograph should be no larger than about 8-1/2 in. by 11 in. and should be clear, legible, and suitable for photocopying.

Conditions of Use

Describe the planned use of the device and describe the extremes of environmental and operating conditions (e.g., temperature, humidity, corrosive atmosphere, vibration) that the device is designed to operate within and to which the device will be exposed during use, shipment and storage. Include descriptions of the types of users, the locations of use within a customer's facility, the frequency when persons will be near the device, and the possibility that the device may be used as a component in other products. State the expected useful life of the device.

Details of construction

Submit annotated, scaled drawings of the device that describe all materials of construction, dimensions, methods of fabrication, means for mounting the source and source holder in the device, and means of securing the device in it's installed position. Note that ranges of dimensions, materials and methods of construction may be provided in lieu of exact dimensions. Describe in detail all design features that protect the source from environmental extremes and abuse, ensure that the source will not be released or inadvertently removed from the device, control the hazard from direct or scattered radiation, and discourage unauthorized access to the source. There should be design features or assembly techniques which discourage disassembly and access to the source. Some common practices are (1) use of special "one-way" screws, (2) epoxy or paint sealant on heads of source access screws, (3) wire or strap security seals,(4) spot welds or (5) a don't touch or disassemble label. Describe clearly the accessibility of the radiation beam during use. Specify the size of openings or gaps that could allow any part of a human body to enter the radiation beam.

Labeling

Submit samples or facsimiles of the labels or describe the labeling for the device. State methods used and how and where the label is attached to the device. The label or marking should be sufficiently durable to remain legible for the useful life of the device and should be located in a clearly visible place on the device. Labeling requirements are set out in §32.51(a)(3). You should review these requirements and ensure that your proposed labels for devices distributed to general licensees are consistent with the requirements. The Label must clearly state the device is exempt from leak test requirements.

Testing of Prototypes

Describe tests performed on each prototype device and submit test results establishing that the integrity of the radiation safety features of the device will be maintained under the most extreme conditions of use to which the device is likely to be subjected.

In some instances, engineering analyses may be an acceptable alternative to the testing of prototypes. If engineering analyses are used, consideration should be given to testing particular prototype components of the device and to observation of performance during early use of the device.

Quality Assurance and Control

BSI should review its current program and either commit to it or submit revised program as it relates to fabrication and service of these product lines. In addition the program must include a check of the radiation level for each product distributed and determine that each device distributed is free from contaminations. Otherwise BSI will need to describe the quality assurance and control (QA/QC) program and procedures to be followed to ensure that each finished device meets specifications furnished to the NRC. The QA/QC Program should provide control over all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the devices to ensure compliance with the representations made in the registration or license application or with the regulations. This program should include provisions for evaluating complaints from users of the device if the complaints relate to radiological protection properties of the device.

Radiation Profiles

If the user is not installing the sources into the device, commit to distributing devices that have a maximum surface dose rate of 0.5 mrem/hour.

Otherwise submit radiation profiles of a prototype or production model of the device. Radiation levels should be determined using the maximum activity of each nuclide expected to be used in the device. Measure and submit the radiation levels for conditions at 5 cm, 30 cm, and 100 cm from the nearest accessible surfaces of the device. A description of the method and instrumentation used to measure the radiation levels should be included. The method and instrumentation should produce measurements which can be used in determining satisfaction of the dose limits in §32.51(a)(2)(ii) for (1) extremities at a tissue depth of 0.007 cm, (2) for eye dose equivalent at a tissue depth of 0.3 cm, and (3) for deep dose equivalent at a tissue depth of 1 cm.

Installation

If the device is to be mounted in a fixed position, describe the manner in which it is to be installed. Include a description of any extra shielding, barriers, or limited accessibility inherent in each type of installation and possible commitments on maximum radiation levels in accessible areas. If barriers, locks, signs, etc., are used to restrict access to certain areas (e.g., to control access to an air gap on a gauge) these areas and control mechanisms should be described.

Specify who will install the device if installation is required and describe the training and qualifications of the installer. For example, would you as the distributor install the device? If you plan for the general licensee to install or service the device, you must request such an arrangement. This request must be made pursuant to §32.51(c) and must include instructions to the general licensee and likely doses during installation.

Radiological Safety Instructions

Submit a copy of the safety instructions to be furnished with the device, including any precautions or warnings on labels attached to the device. The instruction should be simple and straight forward using easy to read language. Unless the type of device causes sufficient reasons to do otherwise, the radiological safety instructions should include:

- Specific instructions for safe operation and maintenance of the device.
- Recommended procedures to control radiation hazards in case of damage or malfunction of the device.
- A radiation profile of the device describing radiation levels external to the device, including those in any beam of radiation that may be accessible with the device in normal operation.
- A caution against tampering with or modifying the device or removal of the source contained in the device. If the user is expected to install or remove the device, collect leak test samples, or check for proper operation of the on-off mechanism, specific instructions for these operations should be provided.
- Recommendations and authority for disposal of the device.

Documentation to Accompany the Device

In addition to the radiological safety instructions , you should submit samples of or describe other radiation-safety-related documentation that you will supply with the device. Examples of such documentation are a copy of §31.5 of 10 CFR Part 31 or if the device is to be sent to a comparable general licensee in an Agreement State, a copy of that Agreement State's regulation equivalent to §31.5, or alternatively, a copy of §31.5 and a note explaining that use of the device is regulated by the Agreement State under requirements essentially the same as those in §31.5 (see paragraph 32.51a(b) of 10 CFR Part 32), and a copy of the documentation of the tests on the shipping container demonstrating that it meets the requirements of a DOT Specification 7A package (see paragraph 173.415(a) of 49 CFR Part 173).

Servicing

Describe the type and extent of the services that will be offered to the customer or services that the customer can perform (e.g., device installation, relocation, repair, and servicing including radiation surveys of devices; storing and transferring for disposal of devices returned from customers; and field demonstration of your devices).

Safety Analysis

Provide a paragraph that summarizes the important facts about the device and source pertaining to safety and the results of a safety analysis of the device and source performed by the manufacturer, independent testing facility or vendor. Include references to appropriate industry or consensus standards (ANSI, etc.). The application should reference and include comments on the three specific points in paragraph 32.51(a)(2):

(I) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in §20.1201(a) of 10 CFR Part 20. (Thus the doses will not exceed a total effective dose equivalent or 500 millirems or eye dose equivalent of 1.5 rems, or shallow dose equivalent of 5 rems to the hands, etc.)

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in §32.24. (Thus the doses will not exceed 15 rems whole body, 200 rems to the hands, etc.)

Safety Analysis for Applicant's Gamma Gauge

The below analysis could be used to support BSI conclusion that the doses associated with its device will not exceed the limits prescribed in §32.51(a)(2)(ii) and (iii) if it is modified to reflect the activity, dose rates and other assumption unique to this device design and use.

sample safety analysis

This determination of doses under normal conditions of use of the applicant's L Series Gamma Gauges is based on maximum radiation levels of 100 mrem/hr on the surface of the shielding, 5 mrem/hr at 30 cm, 2.5 mrem/hr at 60 cm, and 1 mrem/hr at 100 cm. These are conservative levels. Each level exceeds the calculated highest level for any of the four housings with its maximum proposed activity. At the surface, the highest calculated value (90 mrem/hr) occurs with the 120 mm housing containing 4 mCi Co-60. At 30 cm, the highest calculated value (4.9 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60. At 60 cm, the highest calculated value (1.6 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60. At 100 cm, the highest calculated value (0.6 mrem/hr) occurs with the 200 mm housing containing 100 mCi Co-60.

The calculated highest level in the primary beam at 100 cm from the housing is 220 mrem/hr. This level occurs for the 150 mm housing containing 1000 mCi Cs-137. No one is expected to be in the primary beam prior to the beam reaching the detector. The gauge will be installed such that there will not be an accessible air gap. In the projected path of the primary beam after striking the detector, radiation levels will be very low.
For purposes of evaluation of a worker's annual exposure, we made the below assumptions and obtained the stated calculated doses.

1. At the start of the work shift the worker unlocks the shutter and turns it to the "on" position. At the end of the shift, the worker turns the device "off" and locks the shutter. Each of these 2 acts is performed 240 times per year and each requires 1 min. to perform. During these acts, the worker's hands are at an average distance of 5 cm and the worker's body is at 60 cm from the device surface. The total calculated doses for these activities are:

   240 mrem to the hands
   20 mrem to the body

2. once a month for a total of 12 times per year, the worker cleans accumulated material (dirt, grease, dust, etc.) from the device, including the labels. Each act requires 5 minutes with the worker's hands in contact with the shielding and the worker's body at 30 cm. The total calculated doses for cleaning activities are :

   100 mrem to the hands
   5 mrem to the body

3. For each of 240 work days per year the worker is assumed to spend 1 hour at an average distance of 3 m. The other 7 hours, the worker is at an average distance of 6 m. The calculated doses for presence in the general area:

   73 mrem to the hands
   73 mrem to the body

The total dose from the above 3 dose contributing activities* of manipulating the shutter, cleaning the device, and being present in the general area is calculated to be 413 mrem to the hands and 98 mrem to the body of the worker.

The accident scenario considered is a fire. Here the primary concern is the potential release of the Co-60 or Cs-137. Such a release is not expected in a fire because of the high temperature resistance of the source capsules (ISO/C 66646) and because of the non-dispersible form of the Co-60 and the Cs-137. The Co-60 and Cs-137 are in the non-dispersible forms, respectively, of cobalt-nickel alloy wire and solid ceramic or glass, respectively.

The other major concerns in the event of fire are:

1. The possible melting and loss of the lead shielding;
2. The removal of the device from its installed position with the shutter in the open position.

In either situation, radiation levels as high as 45 rem/hr may be present at the surface of the 150 mm shielding with its 1000 mCi Cs-137 source. The radiation level at 30 cm may be 1.8 rem/hr and at 1 m may be 220 mrem/hr. If during clean-up after the fire a worker were to handle the gauge (absent its lead shielding or with the shutter open) his/her hands could be exposed at the rate of 45 rem/hr and the body, assumed at 30 cm, at 1.8 rem/hr.

For purposes of this scenario, it is assumed that the worker picks up the device and places it in a wheelbarrow (2 min contact exposure to hand and 2 min whole body exposure at 30 cm). He/she then pushes the wheelbarrow (at a distance of 1 m from the source to hands and body) for 5 minutes to a dump truck where it deposited and shielded by other debris until recovered by trained radiation safety personnel. The worker would receive a total hand dose of 1.5 rem + 0.018 rem or 1.52 rem. The worker's whole body dose would be 60 mrem + 18 mrem or 78 mrem.

A member of the public, perhaps acting as a scavenger at the site of the fire, is unlikely to receive a greater dose than the worker.

The above are believed to be conservatively calculated doses and are within the limits of section 32.51(a)(2).