30-5635

AIR MAIL

September 30, 1975

Mr. Melvin Shupe
Radioisotopes Licensing Branch
Division of Materials and Fuel Cycle
Facilities Licensing
USNRC
Washington, D.C. 20555

Amend #6

Dear Sir:

This is to elaborate on the submittal of July 23, 1975 and clarify some points that may be in question.

We desire to continue to have the option of using the source holders previously approved in the models BG-9G and BGOM-9G while adding the option of using the rotary source shutter described.

Label P/N 38-25863 is worded in accordance with amendment #5 (corrected corrected copy) of our license number 34-00639-03G. The amendment is dated November 8, 1974. The enclosed section 10A contains elaboration to clarify the meaning of the statements contained in this label. Two versions of this section are included. One version requires testing of the ON-OFF mechanism by a specifically licensed person. The other provides instructions by which the user, without radiological training, may assure that the ON-OFF mechanisms and indicator are functioning properly and record the result of the test. Although 10CFR31.5 (c)(2)(i) excludes devices containing Krypton from leak testing, the text of section 10A contains recognizable symptoms the licensee may observe to conclude that the source is, or is not, leaking gas.

Based on years of experience with our own people who install and service devices on a continuing basis and are constantly called upon to make leak tests and radiation surveys and to make repairs, as required to source holders, it is extremely unlikely that any person using a device with a radiation level of not more than 5 mR/hr at 12 inches from the device would receive a dose in excess of 10% of the limits specified in 10CFR20.101. An analysis conducted some time ago of the film badge reports covering the doses received by our field service personnel substantiates this. The analysis, which provided an average for 39 man years of service, showed that the average accumulated dose per man year was 97 millirems. This corresponds to a quarterly dose of 25 mrem, less by a

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ctor of 5 than the quarterly limit of 125 mrem. Thus, it is obvious that the General Licensee under any "ordinary condition of use" could not be expected to be exposed to anything approaching the limit dose for General Licensees.

In case of fire or explosion the maximum damage that might be expected would be rupture of the source container (capsule) and escape of the Kr-85 into the atmosphere. Under such conditions, the Kr-85 would be carried away and dispersed rapidly. Lesser damage which might cause malfunction of the source shutter mechanism would not increase the radiation level and temperatures which would melt lead shielding might also be expected to rupture the capsule window due to the approximate doubling of the internal pressure.

Instructions covering maintenance of legibility of labels is contained in section 10A of the instruction manual and also instructions for replacing defaced and/or illegible labels is included. The label design used is such as to assure maximum legibility under very adverse conditions. A copy of the actual label used is enclosed.

We trust the foregoing plus enclosures elaborate adequately on our submittal of July 23, 1975. Should there be further questions, please call on the writer.

Sincerely,

THE OHMART CORPORATION

G. A. Kelly
Staff Engineer

GAK:jt

Enclosures: (Section 10A)
Label 38-25863

CC: HLC

3949

SECTION 10A-0
GL 097-8
Label 38-25863 Kr-85
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USNRC REGULATIONS FOR

GENERALLY LICENSED GAGES

1.0 GENERAL

This device is distributed under the terms of a General License, the conditions of which are covered in USNRC Regulations 10CFR31.5. (USNRC was formerly USAEC.) A copy of these regulations is included. The regulations of states (called Agreement States) which have entered into an agreement with the U.S. Nuclear Regulatory Commission to take over regulation of radioactive material closely parallel those of the USNRC.

Although General Licensees are not required to be as cognizant of other federal regulations for nuclear devices, or of radiological safety practices, due to the sharply defined conditions for use by the General Licensee, The OHMART Corporation believes General Licensees may be interested in learning more about regulations. 10CFR 19, 20 and 30 are included for that purpose.

State Boards of Health usually require registration of radiation producing devices. The appropriate state agency, whether Agreement State or not, should be contacted to learn the registration requirements of the particular state.

Devices distributed to General Licensees are designed and manufactured in accordance with information submitted to, and approved by, the USNRC. Designs are such that under approved conditions of use the radioactive material will not be lost and no one under ordinary conditions of use, will receive a dose in excess of 0.125 rem per calendar quarter. The rem is the unit of radiation exposure which takes into account the Relative Biological Effect (RBE) on man. For Beta and Gamma radiation, the roentgen (the measure of ionizing capability in air) and the rem are numerically equal. The prefix "milli" means "1/1000 of" (1 millirem (mrem) = 0.001 rem).

There are two (2) labels affixed to each device. One label, bearing the legend "Caution Radioactive Material", gives the appropriate details of the device. The other gives the conditions governing the use of the device.

The second label spells out in brief exactly what the General Licensee may or may not do with the device. Reference may be made on the label to instructions contained in the manual supplied with the device. The governing regulations are contained in 10CFR31.5, previously mentioned.

The text of Label 38-25863 appears below. Paragraphs are numbered for purposes of explanation.

1. RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR EQUIVALENT AND REGULATIONS OF THE U.S. NRC OR AN AGREEMENT STATE.

2. ABANDONMENT OR DISPOSAL PROHIBITED UNLESS TRANSFERRED TO PERSONS SPECIFICALLY LICENSED BY THE NRC OR AN AGREEMENT STATE.

3. OPERATION PROHIBITED IF THERE IS INDICATION OF FAILURE OF OR DAMAGE TO SHIELDING, OR CONTAINMENT OF RADIOACTIVE MATERIAL.

4. INSTALLATION, DISMANTLING, RELOCATION, MAINTENANCE AND TESTING INVOLVING THE RADIOACTIVE MATERIAL SHIELDING OR CONTAINMENT SHALL BE PERFORMED BY PERSONS SPECIFICALLY LICENSED BY THE NRC OR AN AGREEMENT STATE.

5. DEVICE SHALL BE TESTED FOR PROPER FUNCTIONING OF THE ON-OFF MECHANISM AND INDICATOR AT INTERVALS NOT TO EXCEED 6 MONTHS.

6. LOSS, THEFT OR TRANSFER OF THIS DEVICE AND FAILURE OF OR DAMAGE TO THE SHIELDING, OR THE SOURCE CONTAINMENT, MUST BE REPORTED TO THE NRC OR AN AGREEMENT STATE.

7. REMOVAL OF THIS LABEL IS PROHIBITED.

Para. #1. This refers to the content of 10CFR31.5.

2. This limits transfer of this device to persons who possess a "Specific" USNRC or Agreement State license. When transferring you must have a copy of the transferees license to possess it. 10CFR30.41 in the included Section 10 describes transfer regulations and information that the transferor must have before transferring. Note from paragraph #4 that the General Licensee may not dismantle the gage.

3. Self-explanatory. (The ON-OFF mechanism must be considered part of shielding.)

4. This is largely self-explanatory. "Testing" refers to making radiation surveys at initial start-up of the device. The test of the ON-OFF mechanism, periodically as stipulated in paragraph #5, may be performed by the General Licensee following procedures outlined below. Routine replacement of indicator lights may be performed by the General Licensee. All other maintenance involving the source holder, source containment, or ON-OFF mechanism must be performed by persons specially

5. Self-explanatory. Procedures for testing operation of the ON-OFF mechanism are outlined below.

6. This is self-explanatory except that failure of the ON-OFF mechanism due to corrosion or other causes should be included in "Failure of or damage to the shielding".

7. This label may only be removed permanently when the gage has been added to a Specific License and then only with permission of the licensing agency. The label must not be defaced or removed otherwise. Should the label become defaced or illegible, it must be replaced. A new label may be obtained from OHMART.

The wording of the text of the label is a condition of the license authorizing distribution of the device to General Licensees and carries the specific authorized conditions of use by the licensee.

The attached 10CFR31.5 part of the regulations are very important and should be carefully studied. Should there be any question, The OHMART Corporation should be contacted.

2.0 TESTING (ON-OFF MECHANISM)

1. Turn the keylock switch on the control panel to SOURCE ON. Observe the indicator lights on the control panel and at the gage. The red lights should be ON. Turn the switch to SOURCE OFF. The green lights should be ON.

2. With the gage in a measuring condition, turning the keylock switch to SOURCE OFF should result in a sharp, beyond full scale reading due to the shutter cutting off most of the radiation. If this does not happen, place a sheet of approximately 16 gauge steel in the measuring gap. If this causes the meter to read beyond full scale, the ON-OFF mechanism is malfunctioning. The OHMART Corporation should be contacted for service and the device taken out of use until repairs are made. The results of the test should be recorded together with the date made, and kept on file for inspection.

3.0 TESTING (LEAKAGE)

Although formal testing for leakage is not required for Kr-85 sources since a chemically inert gas cannot be tested by wiping, it is useful to be able to recognize that a source may be leaking gas. Loss of gas will result in a lack of sensitivity of the gage to changes in product being measured. A slow leak will result in upscale drift