

ATTACHMENT III

September 20, 1995

Steve Baggett
U.S. Nuclear Regulatory Commission
Mail Stop T8F5
Washington, DC 20555

RE: Amendment to Registration for Registry #NR-122-D-101-S

Dear Mr. Baggett:

We wish to amend our Registry of Radioactive Sealed Sources and Devices for the following Betacontrol Gauges for distribution as general licensed gauges:

Registry #: NR-122-D-101-S

Device Type: Transmission Gauge

Model: MK 1.0

Distributor:

Betacontrol
P.O. Box 235
435 Route 202
Towaco, New Jersey 07082

Manufacturer:

Billing Address:
Betacontrol
P.O. Box 1225
Freudenberg, Germany 57252

Delivery Address:
Betacontrol
Am Weidekamp 10
Freudenberg, Germany 57258

Sealed Source Designation:

Amersham Buchler VZ-337 (Sr-90)
Institute National de Radioelements 700-052.002/4 (Kr-85)
Amersham Corporation KAC.D1 (Kr-85)
Amersham Corporation KAC.D3 (Kr-85)
Amersham Corporation AMC.17 (Am-241)
Amersham Corporation PHC.C1 (Pm-147)

<u>Isotope:</u>	<u>Maximum Activity:</u>
Strontium-90	50 millicuries (1.9 GBq)
Krypton-85	60 millicuries (2.2 GBq) (700-052.002/4)
Krypton-85	500 millicuries (18.5 GBq) (KAC.D1, KAC.D3)
Americium-241	300 millicuries (11.1 GBq)
Promethium-147	50 millicuries (1.9 GBq)

The following information is being submitted in addition to the previous registration information per the requirements in 10 CFR 32.51.

- 32.51(a): An amendment to our specific license will be submitted to the NRC Region 1 Office upon your approval of registry.
- 32.51(a)(2):
- 1) The information relating to the design, manufacturer, and prototype testing has not changed from previously submitted information, therefore, no additional information is being submitted.
 - 2) For quality control purposes gauge housings are received in the United States through Betacontrol or the nuclear gauge housings are drop shipped to the client facility where it will be installed. The client is informed not to open the package. Betacontrol personnel will open the packages containing the gauge housings when they install the device. Upon opening the package Betacontrol will ensure that the correct device, isotope and activity was received in the U.S. The device will be inspected for damage and malfunctions by Betacontrol personnel.
 - 3) In addition to the labels indicated in the previous registration, the information in Attachment I will be included on the source housing label. This label fulfills the requirements of 10 CFR 32.51(a)(3)(i)(ii) and (iii). Labels are made of stainless steel or aluminum and are permanently attached by rivets or screws to the source housing. We confirm that any previously purchased gauging devices will have this label attached, if the customer changes possession from a specific license to a general license.
 - 4) The proposed use of the gauging devices has not changed.

- 5) The installation and servicing of these source housings shall only be performed by individuals specifically licensed by the NRC or an Agreement State to perform these operations. This is indicated to the general licensee in the amendment to the Operation Manual which is supplied to the general licensee (see Attachment II).
- 6) The leak testing of these source housings shall be performed on a six (6) month frequency except for Krypton-85. The general licensee may perform the wiping of the device following the procedure indicated in the amendment to the Operation Manual (see Attachment II). The general licensee is not authorized to perform analysis of leak test samples.
- 7) Any additional operating and safety instructions other than those previously submitted are included in the amendment to the Operation Manual (see Attachment II).
- 8) Following the Operation Manual with amendments, the byproduct material contained in these source housing devices will not be released or be inadvertently removed from the device during ordinary conditions of handling, storage, and use of the device.

The following assessments indicate that no individual will receive in one (1) year a dose in excess of 10 percent of the annual limits specified in 10 CFR 20.1201(a) under ordinary conditions of handling, storage, and use of the source housing.

- a. Each source housing is mounted on a production line which does not allow access to the device during ordinary operation.
- b. When the source housing is switched off or in the "Measuring 0" mode, the source is turned into the shielded position, away from the radiation exit port or a shutter block shields the radiation exit port.
- c. The source is automatically shielded in the event of power failure.

- d. If any individual needs to perform maintenance in the vicinity of the source housing, the source housing would be in the shielded position. The following dose assessments are based on the dose rates at 100 cm from the source. The source housing can safely be moved along the glide, to provide distance between the worker and the source housing, so 100 cm is a practical distance. The worker time in the area near the source housing used for these calculations is one (1) hour per week. We believe this is an over estimate of time because these source housings are positioned on continuous process machines and are not accessible except when the process machine is not operating. Also, the general licensee's personnel will not be servicing these devices (source housings). Attachment III has the dose rate assessments with the source shielded (shutter closed) for your reference. The maximum exposure rate at 100 cm was used for these dose assessments.

Krypton 85, 18.5 GBq (500 mCi)

Skin Dose to the Whole Body

$$0.4 \text{ mR/hr} \times 52 \text{ hr/yr} = 20.8 \text{ mRem/yr}$$

Whole Body Dose

$$0.4 \text{ mR/hr} \times 52 \text{ hr/yr} = 20.8 \text{ mRem/yr}$$

Krypton-85, 11.1 GBq (300 mCi)

Skin Dose to the Whole Body

$$0.26 \text{ mR/hr} \times 52 \text{ hr/yr} = 13.52 \text{ mRem/yr}$$

Whole Body Dose

$$0.22 \text{ mR/hr} \times 52 \text{ hr/yr} = 11.44 \text{ mRem/yr}$$

Krypton-85, 3.7 GBq (100 mCi)

Skin Dose to the Whole Body

$$0.2 \text{ mR/hr} \times 52 \text{ hr/yr} = 10.4 \text{ mRem/yr}$$

Whole Body Dose

$$0.2 \text{ mR/hr} \times 52 \text{ hr/yr} = 10.4 \text{ mRem/yr}$$

Americium-241, 11.1 GBq (300 mCi)

At 100 cm, with the shutter closed, this device is at background radiation levels and therefore, below 10% of the limits in 10 CFR 20.1201(a).

Strontium-90, 1.9 GBq (50 mCi)

Skin Dose to the Whole Body

$$0.5 \text{ mR/hr} \times 52 \text{ hr/yr} = 26 \text{ mRem/yr}$$

Whole Body Dose

$$0.5 \text{ mR/hr} \times 52 \text{ hr/yr} = 26 \text{ mRem/yr}$$

Promethium-147, 1.9 GBq (50 mCi)

The maximum exposure rate at 50 cm from the source with the shutter closed is background, therefore no assessment is needed for this device.

The dose rates for the Sr-90 and Pm-147 are from the previously submitted registry information.

These calculations demonstrate it is unlikely that any person will receive in the one (1) year a dose in excess of 10 percent of the annual limits specified in the 10 CFR 20.1201(a) during ordinary conditions of handling, storage, and use of these gauges (source housings).

- 9) Under accident conditions (such as fire or explosion) associated with handling, storage, and use of these gauges it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in 10 CFR 32.24 for the following reasons:
 - a. The gauges (source housings) are mounted on production lines for thickness detection where the potential of an explosion in the area of the gauge is very unlikely to happen, so no serious damage to the gauge should occur. This fact along with the steel or brass construction of the gauge housing should avoid the rupture of the welded stainless steel capsule.

- b. The radioactive material contained in these gauges are used mainly for emitting Beta and low energy gamma radiation, therefore, the potential of large external exposures to the body should not occur during an explosion or fire, because the exposure rate at 10 feet from the source with the shielding gone will be very low (well below any exposure rates that have the potential to deliver an exposure in excess of the levels indicated in Column IV of the table in 10 CFR 32.24).
- c. Kr-85 is not absorbed into the body and will not be retained in the lung, if inhaled, therefore, the total internal exposure and external exposure would be below the levels in Column IV of the table in 10 CFR 32.24.

The Pm-147 and Am-241 sources contain radioactive material incorporated in a ceramic enamel which is sealed in a welded stainless steel capsule. The Sr-90 source incorporates radioactive material contained in a sealed silver foil into a sealed welded stainless steel capsule. The make up of these sources will avoid the potential airborne contamination that may occur during a fire or explosion and therefore, internal contamination is highly unlikely.

- d. If power to the gauge is cut-off due to an accident (fire or explosion) the shutter mechanism automatically closes.
 - e. The emergency procedures we have incorporated into the amendment to the Operation Manual should avoid any internal or external exposure to any person in the event of any accident condition.
10. Please reference Attachment II for the general license and amendment to the Operation Manual.

If you have any question concerning this application for registration, please contact me at (201) 263-4243. Thank you for your prompt attention to our request.

Sincerely,

George R. Stoddard
National Sales Manager

/jjz

ATTACHMENT I

Label for General Licensed Gauges

For installation, operation, and servicing of the device, reference the operating and service manuals.

Leak Testing Frequency: 6 months (not required for Kr-85)

On-Off Mechanism and Indicator Test Frequency : 6 months

The receipt, possession, use and transfer of this device Model _____, Serial Number _____ are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

Caution - Radioactive Material

(Name of Manufacturer, or Initial Transferor)

ATTACHMENT II

General License Document Amendment to Operations Manual

Dear Customer:

A general licensee has been granted to you for the use of this device (gauge). Under this general license you must follow the requirements of the Nuclear Regulatory Commission's 10 CFR 31.5 or Agreement State's regulations equivalent to 10 CFR 31.5. We are furnishing you with a copy of the general license in 10 CFR 31.5. If you are in one of the Agreement State's listed below, this device is regulated by the Agreement State under requirements substantially the same as those in 10 CFR 31.5. We recommend contacting your Agreement State Office to obtain a copy of these regulations.

Agreement State Contact List

Alabama

Division of Radiation Control
Department of Public Health
434 Monroe Street
Montgomery, AL 36130-1701

California

Environmental Health Division
State Department of Health Services
714/744 P Street
Post Office Box 942732
Sacramento, CA. 94234-7320

Arizona

Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, AZ 85040

Colorado

Radiation Control Division 20/82
Department of Health
4300 Cherry Creek Drive South
Denver, CO 80220

Arkansas

Division of Radiation Control and
Emergency Management
Department of Health
4815 West Markham Street, Slot 30
Little Rock, AR 72205-3876

Florida

Office of Radiation Control
Department of Health and Rehabilitative
Services
1317 Winewood Boulevard
Tallahassee, FL 32399-0700

Georgia

Radioactive Materials Program
Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, GA 30354

Illinois

Department of Nuclear Safety
1035 Outer Park Drive
Springfield, IL 62704

Iowa

Bureau of Environmental Health
Iowa Department of Public Health
Lucas State Office Building
Des Moines, IA 50319

Kansas

X-ray & Radioactive Materials
Control Section
Department of Health & Environment
Bureau of Environmental
Health Service
109 SW 9th Street
Topeka, KS 66612

Kentucky

Radiation Control Branch
Cabinet for Human Resources
275 East Main Street
Frankfort, KY 40621-1000

Louisiana

Radiation Protection Division
Office of Air Quality and
Radiation Protection
7290 Bluebonnet Road
Post Office Box 82135
Baton Rouge, LA 70884-2135

Maryland

Radiological Health Program
Office of Toxics, Environmental Science
and Health (TESH)
Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Mississippi

Division of Radiological Health
State Department of Health
3150 Lawson Street
Post Office Box 1700
Jackson, MS 39215-1700

Nebraska

Division of Radiological Health
Department of Health
301 Centennial Mall South
Post Office Box 95007
Lincoln, NE 68509

Nevada

Radiological Health Section
Health Division
Department of Human Resources
505 East King Street
Carson City, NV 89710

New Hampshire

Radiological Health Bureau
Division of Public Health Services
Health and Welfare Building
6 Hazen Drive
Concord, NJ 03301-6527

New Mexico

Bureau of Hazardous and
Radioactive Materials
Water and Waste Management Division
Department of Environment
Post Office Box 26110
Santa Fe, NM 87502

New York

Bureau of Environmental
Radiation Protection
Department of Health
2 University Place
Albany, NY 12203

North Carolina

Division of Radiation Protection
Department of Environment, Health
and Natural Resources
Post Office Box 27687
Raleigh, NC 27611-7687

North Dakota

Division of Environmental Engineering
Department of Health
1200 Missouri Avenue, Room 304
Post Office Box 5520
Bismarck, ND 58502-5520

Oregon

Radiation Control Section
State Health Division
Department of Human Resources
800 NE Oregon Street #21
Portland, OR 97214-0450

Rhode Island

Division of Occupational and
Radiological Health
Department of Health
203 Cannon Building
3 Capital Hill
Providence, RI 02908-5097

South Carolina

Bureau of Radiological Health
Department of Health and
Environmental Control
2600 Bull Street
Columbia, SC 29201

Tennessee

Division of Radiological Health
L&C Annex, Third Floor
401 Church Street
Nashville, TN 37219-5404

Texas

Bureau of Radiation Control
Department of Health
1100 West 49th Street
Austin, TX 78756-3189

Utah

Division of Radiation Control
Department of Environmental Quality
168 North 1950 West
Post Office Box 144850
Salt Lake City, UT 84114-4850

Washington

Division of Radiation Protection
Department of Health, LE-13
Airdustrial Center Building #5
Post Office Box 47827
Olympia, WA 98504-7827

The following is the general license as written in 10 CFR 31.5:

- (a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provision of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.
- (b) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specification contained in a specific license issued pursuant to Part 32.51 of this chapter or in accordance with the specifications contained in a specific license issued by an Agreement State which authorizes distribution of the devices to persons generally licensed by the Agreement State.
- (c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:
 - (1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;
 - (2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other interval as are specified in the label; however
 - (i) Devices containing only Krypton need not be tested for leakage of radioactive material, and
 - (ii) Devices containing only Tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

- (3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:
 - (i) In accordance with the instructions provided by the labels; or
 - (ii) By a person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to perform such activities;
- (4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding containment. The licensee shall retain these records as follows:
 - (i) Each record of a test for leakage of radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed.
 - (ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed.
 - (iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed.
- (5) Upon the occurrence of failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcuries or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license pursuant to Parts 30 and 32 of this chapter or from an Agreement State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the byproduct material contained in the device and, within 30 days, furnish to the Administrator of the appropriate Nuclear Regulatory Commission, Regional Office listed in appendix D of Part 20 of this chapter, a report containing a brief description of the event and the

- remedial action taken;
- (6) Shall not abandon the device containing byproduct material;
 - (7) Shall not export the device containing byproduct material except in accordance with Part 110 of this chapter;
 - (8) Except as provided in paragraph (c)(9) of this section, shall transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device is transferred to the specific licensee in order to obtain a replacement device;
 - (9) Shall transfer the device to another general licensee only:
 - (i) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this section and any safety documents identified in the label of the device and within 30 days of the transfer, report to the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the Commission and the transferee; or
 - (ii) When the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.
 - (10) Shall comply with the provision of parts 20.2201 and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21 of this chapter.
- (d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

The following procedures and information is provided to you to ensure the safe use of this device.

Installation and Servicing

Initial installation of the source housing must be completed by Betacontrol. After initial installation the source housing must only be removed, installed or serviced by individuals specifically authorized by the NRC or an Agreement State to perform these services. This general license does not authorize installation or servicing of this device.

Labelling

The labels affixed to the device at the time of installation must be maintained in a legible and visible manner.

Leak Testing

The device must be leak tested on a six (6) month frequency as indicated by the general license (except for Krypton-85 devices)

Leak test kits can be obtained through Betacontrol

The following procedures should be followed when wiping the gauge housing:

1. De-energize the device, so the shutter closes and shields the source. The green light will indicate that the shutter is in the closed (off) position.
2. Using the wiping material supplied with the kit, wipe the external surface of the source holder where contamination would be expected (shutter window, weld seams, edge of bolted plates).
3. Place the wiping material in the appropriate container (being careful not to touch the wiping area to other objects because this would spread contamination, if present).
4. Provide the supplier with the requested information about the source.
5. Send the leak test kit to the supplier for analysis.
6. If results indicate 0.005 uCi or more contamination take device out of service and immediately contact one of Betacontrol's service representatives. Also, a report to the NRC and/or Agreement State Office will need to be filed, if the removable contamination exceeds these levels.

Testing of On-Off Mechanism

The shutter (on-off mechanism) along with the indicators (lights) must be tested at a six (6) month frequency. The results of these tests must be recorded. When the red light is lit, this indicates the device is in the ON or exposed position. When the green light is lit the device is in the OFF or shielded position. You should record the functioning of the shutter, the lights, the date performed and the individual performing the tests. If a malfunction with the shutter or lights occur, contact one of Betacontrol's service representatives. The changing of a burned out light bulb can be performed by your personnel.

Emergency Procedures

To ensure all employees at your facility are safe from any possible radiation hazard during an accident (fire, explosion, etc.) directly or indirectly involving this device the following procedures should be posted and followed:

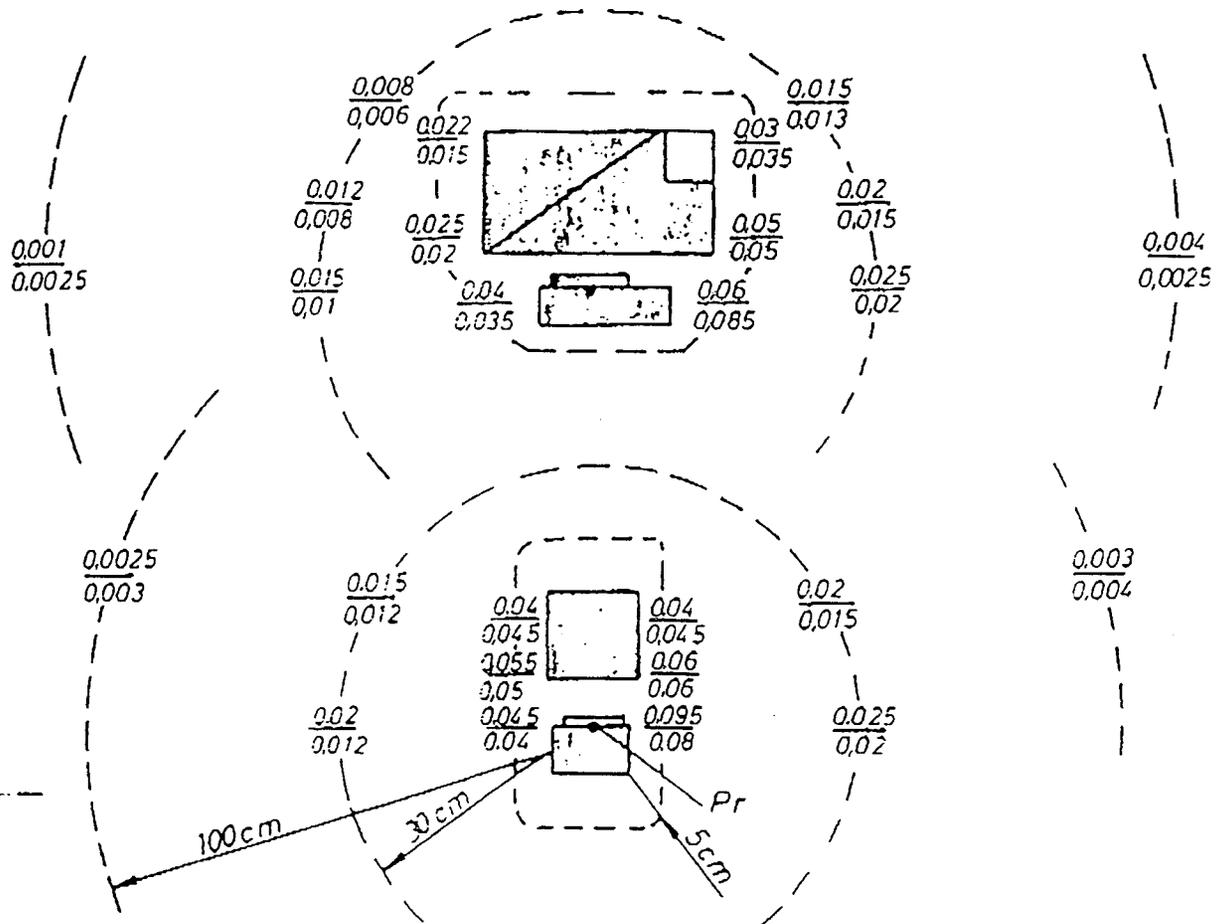
If a malfunction, accident, or damage occur to a nuclear gauge take the following steps:

1. Cease work immediately.
2. If the gauge has been partially damaged or destroyed, keep people at least 20 feet away or rope off the area at 20 feet.
3. Notify the Radiation Safety Officer or supervisor, immediately after isolating the area.
4. Contact one of Betacontrol's service representatives for additional assistance.
5. In the case of a fire or explosion inform the fire department personnel of the presence of the nuclear gauge.
6. In the case of any accident or fire, do not use the gauge until any damage or damage to the gauge is assessed.
7. If required, notify the NRC and/or Agreement State.

This information has been provided to assist your facility in maintaining exposures "as low as is reasonably achievable" ALARA. If at anytime you have questions or concerns please contact one of our service representatives.

Sincerely,

George R. Stoddard
National Sales Manager



Pr: Strahlenquelle
radiation source
source rayonnement

Meßspalt
gap : 9,5 mm
fente libre

Strahler : Krypton 85, 18,5 GBq (500 mCi)
source

Strahlerfenster : geschlossen
source window : closed
fenêtre du port source : fermée

Meßgerät : Babyline 31
survey meter : Babyline 31
appareil de mesure

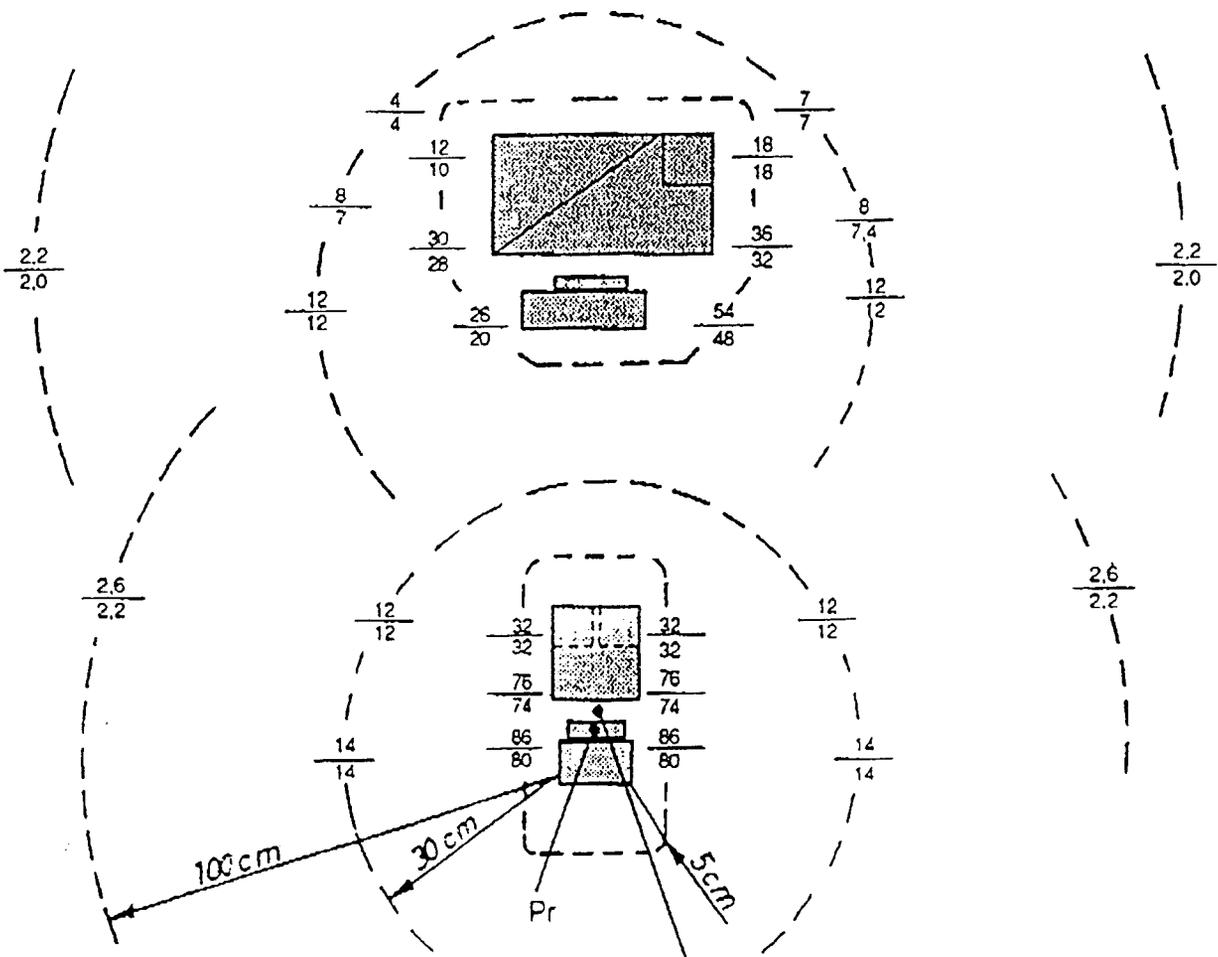
Dosisleistung : mit Absorber : 7 mg/cm²
dose rate (mSv/h) : with absorber : 300 mg/cm²
intensité du rayonnement : avec absorbeur

Stückzahl	Benennung	Teil	Werkstoff	Rohmaterial Zeich. Nr. Modell Nr.	DIN, Bemerkung
Gezeichnet	Datum	Name	Das Urheberrecht an dieser Zeichnung bleibt uns. Jede Vervielfältigung ohne Mitteilung an diese Personen unzulässig und strafbar.		
Geprüft	17.02.'89	O. Brühl			

ALBRECHT BÄUMER
Freudenberg, Kreis Siegen

Maßstab
Strahlenbelastung
Radiation dose rates

700-103-220 Bl. 23



Pr:
Strahlenquelle
radiation source
source de rayonnement

Meßspalt
gap : 9,5 mm
fente de mesure

Strahler
source : Krypton 85; 11,1 GBq (300 mCi)

Strahlerfenster
source window : geschlossen / closed
fenêtre de la source : fermée
Meßgerät
survey meter : Babyline 31
appareil de mesure

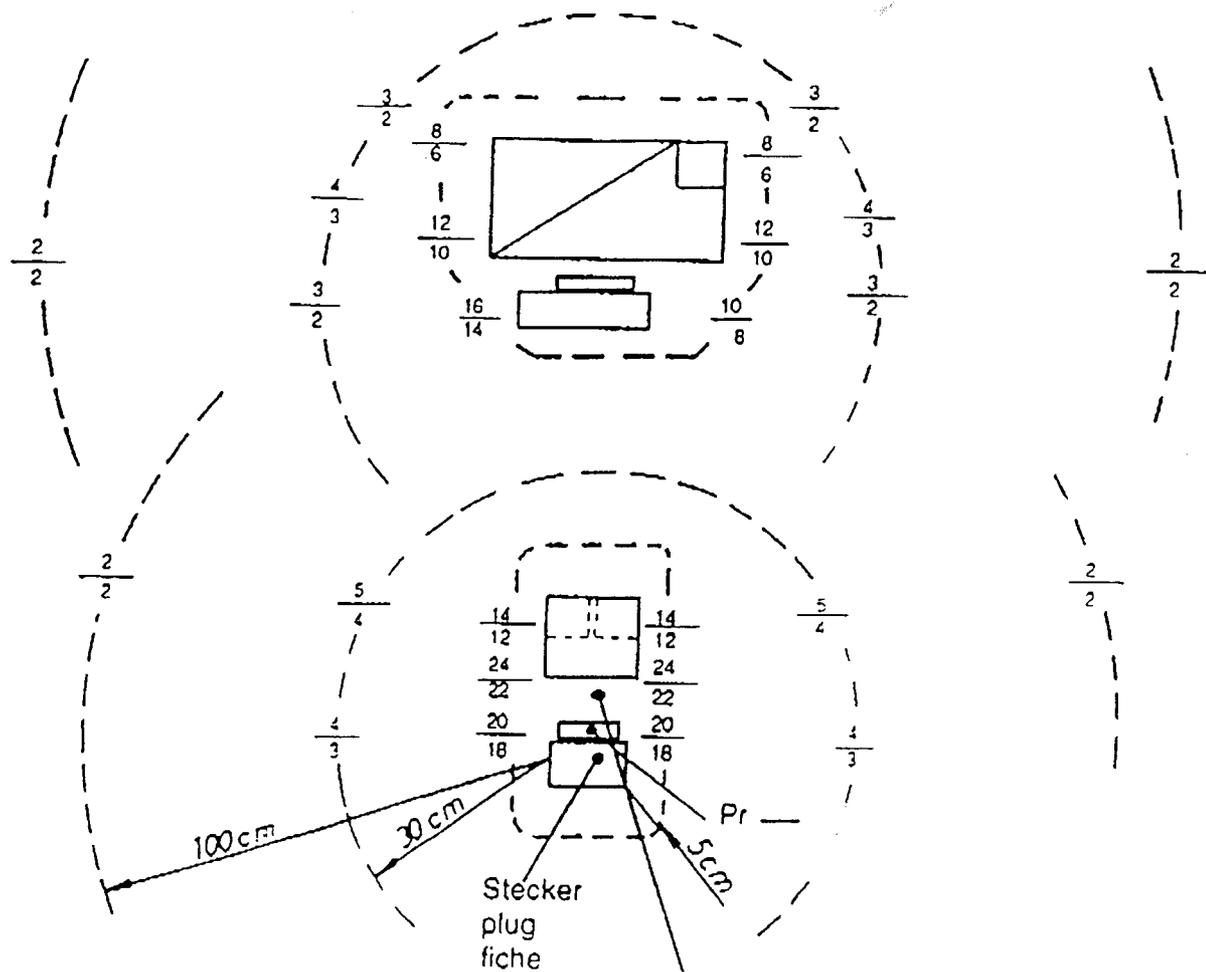
Dosisleistung
dose rate : (µSv/h) mit Absorber / with absorber : 7 mg/cm²
débit de dose : avec absorbeur : 300 mg/cm²

Typ / type: X 1114 Schlitzkollimator 10 * 35 / X 1114 slotted collimator 10 * 35 / X 1114 colimateur à fente 10 * 35

	Datum	Name	Das Urheberrecht an dieser Zeichnung gehört uns. Laut Gesetz ist Vervielfältigung oder Mitteilung an dritte Personen unzulässig und strafbar.	 gmbh meß- und regeltechnik, D-57258 Freudenberg
Gezeichnet	31.08.1992	Lorch		
Geprüft	31.08.1992	A. vom Bruch		

Strahlenbelastung
Radiation dose rates
Valeurs d'Irradiation

700-103-220 Bl. 45



Pr:
Strahlenquelle
radiation source
source de rayonnement

Meßspalt
gap
fente de mesure : 33 mm

Strahler : Krypton 85; 3,7 GBq (100 m Ci)
source

Strahlerfenster : geschlossen
source window : closed
fenêtre de la source : fermetée

Meßgerät : Babyline 31
survey meter :
appareil de mesure

Dosisleistung : mit Absorber
dose rate (μ Sv/h) : with absorber : $\frac{7 \text{ mg/cm}^2}{300 \text{ mg/cm}^2}$
débit de dose : avec absorbeur

Typ: X 1114		Siebkollimator	
Gezeichnet	Datum 25.06.1992	Name Lerch	Das Urheberrecht an dieser Zeichnung gehört uns. Laut Gesetz ist Vervielfältigung oder Mitteilung an dritte Personen unzulässig und strafbar.
Geprüft	25.06.1992	H. Schemm	
Maßstab	Strahlenbelastung Radiation dose rates Valeurs d'irradiation		betacontrol gmbh meß- und regeltechnik, 5905 Freudenberg 700-103-220 Bl. 42

