

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-122-D-101-B

DATE: November 1, 1996

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DEVICE TYPE: Transmission Gauge

MODEL: MK 1.0

DISTRIBUTOR: Betacontrol
(formerly Baumer of America, Inc.)
P.O. Box 235
435 route 202
Towaco, NJ 07082

MANUFACTURER: Betacontrol GMBH
P.O. Box 1225, Am Weidekamp 10
D-5905 Freudenberg, Germany

SEALED SOURCE MODEL DESIGNATION:
Amersham Buchler VZ-337 (Sr-90)
Amersham Corp. SIF.D1 (Sr-90)
Institute National de Radioelements
700-052.002/4 (Kr-85)
Amersham Corp. KAC.D1 (Kr-85)
Amersham Corp. KAC.D3 (Kr-85)
Amersham Corp. AMC.17 (Am-241)
Amersham Corp. 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, D3)
Americium-241	300 millicuries (11.1 GBq)
Promethium-147	50 millicuries (1.9 GBq)

LEAK TEST FREQUENCY: 6 Months (Not required for Kr-85)

PRINCIPAL USE: (E) Beta Gauge or (D) Gamma Gauge

CUSTOM DEVICE: _____ YES X NO

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DESCRIPTION:

The MK 1.0 is used for the measurement of the thickness of various material. The device can be mounted in an O-Frame, C-Frame or Fixed Head configuration. Air gaps vary according to the application with typical ranges between 0.37" (0.95 cm) to 1.97" (5.0 cm). However, in some applications the air gap may be as large as 13.2" (33.5 cm). The radioactive source is mounted in the base of the device and is fixed in place by a source holder which is specifically manufactured for the installed source.

While in the "measuring off" position, a shutter with 0.08" (2 mm) of lead covers the source. When in the "measuring on" position the shutter is positioned out of the radiation beam by a electric magnet. If current is interrupted, a spring will automatically return the shutter to the "measuring off" position. A limit switch is connected to the magnet and indicates the position of the shutter by a red, "Attention, radiation", source unshielded lamp and a green, "Radiation Screened", source shielded lamp. The green lamp will only illuminate when the shutter is in the fully closed position. The lamps are mounted on either side of the device frame.

The MK 1.0 sensor transmission gauge may contain either a promethium-147, krypton-85, strontium-90, or americium-241 source, depending on the end user's specific needs. The type of source used is directly related to the material measured. The Institute National de Radioelements, krypton-85 source and the Model VZ-337 strontium-90 source incorporate radioactive material contained in a sealed silverfoil into a sealed welded stainless steel capsule. These sources are not currently registered by the NRC on any other certificate. Sufficient information has been submitted to allow use of these sources in the Model MK 1.0 device. The KAC.D1 and KAC.D3 sources contain krypton-85 hermetically sealed in a titanium capsule. The promethium-147

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DESCRIPTION (cont.):

and americium-241 sources contain radioactive material incorporated in a ceramic enamel which is sealed in a welded stainless steel capsule. The Model SIF.D1 source contain a Sr-90 compound incorporated on a ceramic pellet sealed in a stainless steel capsule. Each source is contained in a custom source holder and mounted on a steel carrier. The source holders contain the source with walls of 1.97" (5 mm) steel or 3.94" (10 mm) brass, except in the area of the radiation window which is only shielded by the shutter.

There are two design modifications made to the units distributed for use under a general license. Tamper-resistant screws are installed on the outer case to prevent access to the source by users, and an additional label is attached that meets the requirements listed in the regulations.

DIAGRAM:

See attachments 1, 2, and 3.

LABELING:

Devices distributed for use under a specific license are labeled in accordance with Section 20.1904, 10 CFR Part 20. Two labels are attached to the device. One label identifies the device by the model number, manufacturer, and year of construction. The other label identifies the isotope, activity, date, and contains the trefoil symbol. The manufacturer states they are unsure whether the date on units distributed prior to September 27, 1996, is the date of assay or the date of construction. The date on units distributed after September 27, 1996, is the date of assay.

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LABELING (cont.):

Device distributed for use under a general license are labeled in accordance with Section 32.51, 10 CFR Part 20. The devices contain the above two labels and one additional label. The date listed on the activity label for all units distributed for use under a general license is the date of assay. The additional label identifies the leak-test frequency, on/off test frequency, directions for safe use, serial number, and contains the statement required in 32.51(a)(3)iii.

The labels are made of stainless steel or aluminum and are permanently attached by rivets to the device.

CONDITIONS OF NORMAL USE:

The MK 1.0 transmission gauge will be used in industrial applications for the contactless measurement of the thickness of foils, plates or tubes of paper, rubber, plastic, metal, glass, coatings on foils and textiles, and the amount of color and impregnated materials on textiles and other porous materials.

PROTOTYPE TESTING:

In the original application, Baumer of America, Inc., did not supply prototype test results regarding mechanical operation (e.g., no specific data on retention of the source when the device is subjected to mechanical stimuli). In lieu of such submission, Baumer relied on the ANSI-N542 Classification of the sources and the past use of the device in Europe and the USA in industrial environments since 1985 without operational problems causing unnecessary radiation exposure to users.

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PROTOTYPE TESTING (cont.):

Additionally, Baumer of America, Inc., provided the following ANSI-N538 Classifications for the device:

1. with source Kr-85, 60 mCi (2.2 GBq),
0.37 in (9.5 mm) gap: ANSI-33-355-775-R1
2. with source Kr-85, 150 mCi (5.6 GBq),
0.37 in (9.5 mm) gap: ANSI-33-245-665-R1
3. with source Sr-90, 10 mCi (0.37 GBq),
1.3 in (33 mm) gap: ANSI-33-344-885-R1
4. with source Am-241, 300 mCi (11.1 GBq),
13.2 in (335 mm) gap: ANSI-33-564-985-R1
5. with source Am-241, 300 mCi (11.1 GBq),
1.97 in (50 mm) gap: ANSI-33-775-985-R1

These devices were distributed under an NRC specific license by Baumer of America, Inc., from 1985 to June, 1993, at which time the name was changed to Betacontrol. Baumer of America Inc., stated that no incidents of failure of the device causing a radiological hazard had been reported as of July 8, 1992.

Betacontrol stated that they were aware of no problems or failures of any safety components or loss of source containment as of August 12, 1996. Betacontrol also stated that three devices were involved in a fire and sustained no safety related damage.

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EXTERNAL RADIATION LEVELS:

The following are the dose rates reported by the manufacturer for the Model MK 1.0 transmission gauge.

Sr-90, 50 mCi (1.9 GBq), 1.3 in (33 mm) gap.

<u>Distance (in/cm)</u>	<u>Max. Radiation Level (mrem/hr)/(mSv/hr)</u>	
	<u>Shutter open</u>	<u>Shutter closed</u>
1.97/5	90.0/0.900	7.4/0.074
11.81/30	12.0/0.120	1.5/0.015
39.37/100	1.6/0.016	0.5/0.005

Kr-85, 500 mCi (18.5 GBq), 0.37 in (9.5 mm) gap.

<u>Distance (in/cm)</u>	<u>Max. Radiation Level (mrem/hr)/(mSv/hr)</u>	
	<u>Shutter open</u>	<u>Shutter closed</u>
1.97/5	500.0/5.000	9.5/0.095
11.81/30	15.0/0.150	2.5/0.025
39.37/100	0.6/0.006	0.4/0.004

Am-241, 300 mCi (11.1 GBq), 13.2 in (335 mm) gap.

<u>Distance (in/cm)</u>	<u>Max. Radiation Level (mrem/hr)/(mSv/hr)</u>	
	<u>Shutter open</u>	<u>Shutter closed</u>
1.97/5	5.0/0.050	0.10/0.001
11.81/30	1.0/0.010	Background
39.37/100	0.3/0.003	Background

Pm-147, 50 mCi (1.9 GBq), 0.71 in (18 mm) gap.

<u>Distance (in/cm)</u>	<u>Max. Radiation Level (mrem/hr)/(mSv/hr)</u>	
	<u>Shutter open</u>	<u>Shutter closed</u>
19.69/50	0.4/0.004	n/a
39.37/100	0.1/0.001	n/a

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QUALITY ASSURANCE AND CONTROL:

Betacontrol (Germany) does not manufacture the components of the device or source, but rather receives them from sub-contractors and performs the final assembly of the device and installation of the source. Betacontrol's quality control (QC) procedures, therefore, consist of checking the various components for proper fit, rejecting non-conforming components, assembly checks during installation of the source, and a one week full operational check.

Betacontrol performs installation and servicing of the device if requested, but relies on the manufacturer's QC program for product conformance. The installation consists of QC procedures equivalent to those mentioned above.

For devices distributed for use under a specific license, the end user is responsible for performing an initial quality check of the device upon receipt, as well as assuring that the device is properly maintained and serviced. The initial check consists of comparing the device to a design drawing (supplied by Betacontrol), performing a full operational check and measuring external radiation levels and external contamination levels.

For devices distributed for use under a general license, Betacontrol performs the initial quality check during installation. In addition, Betacontrol verifies that device contains the appropriate tamper-resistant screws and labels, and that the user is supplied with the appropriate documentation.

For devices being changed from specifically licensed use to generally licensed use, Betacontrol verifies that the appropriate changes have been made to the devices, and that the documentation currently possessed by the user is replaced with the appropriate documentation.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Devices intended for distribution to persons specifically licensed by the NRC or an Agreement State shall be labeled in accordance with 10 CFR Part 20.
- Devices intended for distribution to persons generally licensed pursuant to Section 31.5, 10 CFR Part 31 shall be labeled in accordance with Section 32.51, 10 CFR Part 32.
- Devices intended for use under a general license shall be installed and initially tested for external radiation levels, required labels and documentation, and leakage-contamination of radioactive material by Betacontrol or other persons specifically licensed by the NRC or an Agreement State to perform such activities.
- Handling, storage, use, transfer and disposal: for devices used under specific license will be determined by the licensing authority. For devices used under a general license are covered by the requirements of 10 CFR 31.5 or Agreement State equivalent.
- The device shall be serviced only by Betacontrol or persons specifically licensed to do so by the NRC or an Agreement State, with the exception that the user may collect wipe test samples.
- REVIEWER NOTE: For devices distributed for use under a specific license, if the end user is to initially install and/or service the device, then the licensee must have an adequate radiation safety program to ensure the device is properly installed and serviced and that adequate emergency procedures are in place.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (cont.):

- Devices initially distributed for use under a general license must be installed by Betacontrol.
- The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The Model MK 1.0 devices have been in use in the US and Europe since 1985 with no reported incidents of failure.

Betacontrol has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- 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 source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20. During typical use, the device is installed in a process line and is not easily accessible while the device is in operation.

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SAFETY ANALYSIS SUMMARY (cont.):

- Under accident conditions associated with handling, storage, and use of the source housing, 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 the following chart:

PART OF BODY

DOSE

Whole body; head and trunk;
active blood-forming organs;
gonads; or lens of eye

15 rem (0.15 Sv)

Hands and forearms; feet and
ankles; localized areas of skin
averaged over areas no larger
than 1 square centimeter

200 rem (2.0 Sv)

Other organs

50 rem (0.50 Sv)

Based on this information, the test data referenced below and the claimed ANSI-N538 ratings, we continue to conclude that the device is acceptable for licensing purposes as specified in this certificate.

Furthermore, we continue to conclude that the Model MK 1.0 transmission gauge would be expected to maintain its integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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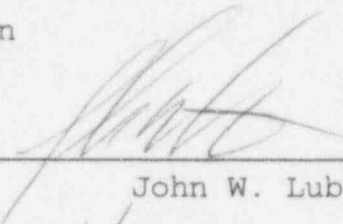
REFERENCES:

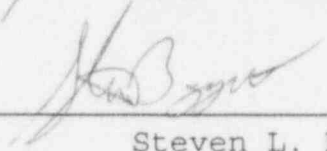
The following supporting documents for the Model MK 1.0 are hereby incorporated by reference and are made a part of this registry document.

- Baumer of America, Inc. letters dated March 5, 1984, April 2, 1984, April 13, 1984, July 16, 1984, November 1, 1984, November 26, 1984, February 22, 1985, February 26, 1985, August 5, 1991, February 7, 1992, February 10, 1992, February 11, 1992, May 28, 1992, June 8, 1992, June 17, 1992, and June, 25, 1992, with enclosures thereto.
- Betacontrol letters dated September 20, 1995, May 1, 1996, June 17, 1996, August 7, 1996, August 12, 1996, September 19, 1996, September 20, 1996, and October 4, 1996, with enclosures thereto.
- Betacontrol facsimile dated July 15, 1996, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: November 1, 1996 Reviewer: 
John W. Lubinski

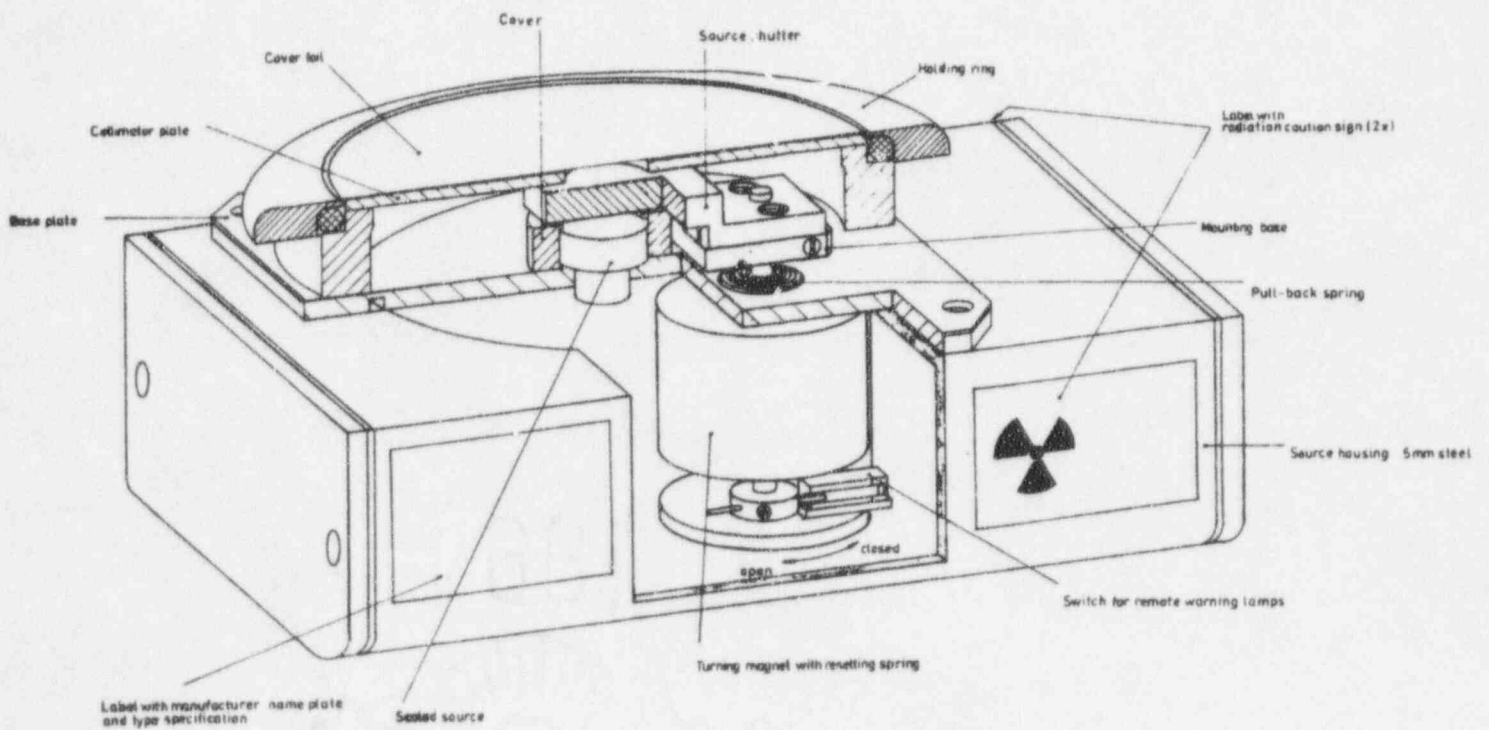
Date: November 1, 1996 Concurrence: 
Steven L. Baggett

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ATTACHMENT 1



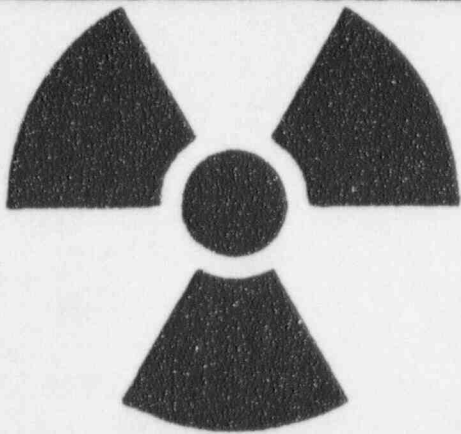
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ATTACHMENT 2

betacontrol	
D-5905 FREUDENBERG	
Type	<input type="text"/>
Baugr.	<input type="text"/>
Fabr.Nr.	<input type="text"/>
Korn.Nr.	<input type="text"/>
<input type="text"/>	
Made in Western Germany	

	CAUTION
	RADIOACTIVE MATERIAL
	ISOTOPE <input type="text"/>
	ACTIVITY <input type="text"/>
	DATE <input type="text"/>
	HALF LIFE <input type="text"/>

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ATTACHMENT 3

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

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

On-Off Mechanism and Indicator Test Frequency: 6 month

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.