

September 19, 1996

Michele Burgess
U.S. Nuclear Regulatory Commission
Mail Stop T-8F5
Washington, DC 20555
(11545 Rockville Pike
Rockville, MD 20852)

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

Dear Ms. Burgess:

This is the response to your request dated September 17, 1996 for additional information for the amendment to the above referenced documents. Each item is addressed in the same order as your letter.

1. We verify that tamper proof fasteners that are a TORX head with an additional pin in the recess will be used. These cap screws require a special bored TORX key and are similar in construction to allen cap screws described in attachments 1 & 2.
2. The cover film provides only environmental protection and provides no screening effect. The dose rates are the same with and without the cover film. However to limit exposure to the user we verify that the above mentioned tamper proof fasteners will also be used to secure the holding ring (item #14 on attachment #3). and we will remove from page 17 of our application the allowing of the GL user to replace the cover film. (see attachment #5).

3. Attachment #6 indicates the position of the warning panels on both sides of the scanning frame. The triangular construction allows viewing from all directions. When "C" frames or fixed point sensors are used the mounting positions of the warning panels is installation dependent. Each panel contains four (4) lamps, two (2) for the ON indication and two (2) for the OFF indication. Each pair of lamps is wired in parallel to allow a functioning lamp in the event one lamp of a pair fails.
4. We verify that the GL user will not have to remove any tamper proof fasteners to perform any allowable service.
5. The source on/off function is verified via the lamps in the warning panels and is also indicated by LED on the operator keypad. Shutter function is tested/verified each time the shutter is opened or closed. Following is the description of the warning panel lamps operation which is a positive indication of shutter position:

Switch S1 (attachment #7) is actuated by an arm which is physically attached to the shutter mechanism and only contacts the switch when fully closed. The shutter is closed by the absence of power to the rotary solenoid (item #7 attachment #3) and pulled to the closed position by a spring. With the shutter closed power is supplied to terminal 7 through terminal 9 to energize relay 6K2 (attachment #8). The contacts of this relay (attachment #8) close providing 24vac to terminal 11 through cable #10 (attachment #9) to terminal 11 to the warning panel OFF lamps (attachment #10). When power is applied to the rotary solenoid (item #7 attachment #3) the arm attached to the shutter moves off the switch S1 (attachment #7). This allows power from terminal #7 through terminal 8 to energize relay 6K1 (attachment #8). The contacts of this relay (attachment #8) close providing 24vac to terminal 10 to the warning panel ON lamps (attachment #10). Additional sets of contacts on relays 6K1 and 6K2 provide digital input signals to the processor which signals the keypad LED to illuminate when the shutter is open and extinguish when the shutter is closed.

6. Attachment #4 is a key to the "bubble" numbers on drawing 700-5652/3 (attachment #3). Additionally a clear drawing is supplied.
7. We verify that this paragraph will be removed from the GL operation and service manuals.

#6

Drawing to be
received from
factory & will
follow shortly

8. The operation manual and service manual provided to a GL user or SL user contains the information about the specific isotopes used by that specific user, thus each manual is user specific. The operation manual and service manual examples provided with our license application are only representative of the content of our manuals. We verify that each GL or SL user receives the information and dose rate tables only for the specific isotope and equipment they receive.
9. We verify that when a SL user changes to a GL user the amendment contained in our application as attachment #2 will be included in the SL user's operation manual. This will result in this amended SL user operation manual being identical to the GL user operation manual.
10. GL users will receive a different service manual than SL users. In the case where a SL user changes to a GL user, all SL service manuals will be collected and destroyed and new GL service manuals will be supplied. The "Checklist for changing a specific licensed device to a generally licensed device" will be changed to include verification that the SL service manuals were collected and destroyed and new GL service manuals issued (see attachment #11).
11. We verify that the paragraph in question will be changed in both the operation manual and service manual to read "Should the radiation shutter become damaged the area should be secured and *betacontrol* service should be immediately notified."
12. We verify that service manual supplied to GL users or to SL users that change to GL users will contain only those operations which the GL user is permitted to perform.
13. The services that the GL user is authorized to perform are: adjust friction safety clutch, service lamps in warning panels, perform on/off test and wipe test. The dose calculations provided in the attachment #3 of the license application would apply to the services of adjusting friction safety clutch, servicing lamps in the warning panels and performing on/off testing as each of these operations can be performed with distances greater than 100 cm between the individual and the source. Only the wipe testing would involve different dose calculations. For wipe testing the following dose assessments would be applicable based on the shutter closed and a worker time near the source of 30 minutes every 6 months. Only the forearms are at a distance of 5 cm between the individual and the source and the whole body dose rate would be at a distance of 30 cm:

All Krypton-85 activities

No Wipe Testing Required

Americium-241, 11.1 GBq (300 mCi)

Skin Dose to the Forearms

$0.15 \text{ mR/hr} \times 1 \text{ hr/yr} = 0.15 \text{ mRem/yr}$

Whole Body Dose

The maximum exposure rate is at background

Strontium-90, 1.9 GBq (50 mCi)

Skin Dose to the Forearms

$7.4 \text{ mR/hr} \times 1 \text{ hr/yr} = 7.4 \text{ mRem/yr}$

Whole Body Dose

$1.6 \text{ mR/hr} \times 1 \text{ hr/yr} = 1.6 \text{ mRem/yr}$

Promethium-147, 1.9 GBq (50 mCi)

Skin Dose to the Forearms

$0.08 \text{ mR/hr} \times 1 \text{ hr/yr} = 0.08 \text{ mRem/yr}$

Whole Body Dose

The maximum exposure rate is at background

These calculations, along with previous calculations contained in the above mentioned attachment #3 of the license application, demonstrate it is unlikely that any person will receive in one (1) year a dose in excess of 10% of the annual limits specified in the 10 CFR 20.1201 (a) during ordinary conditions of servicing these gauges (source housings).

If you have any questions please contact me.

Sincerely,



Ray Santoianni
Service Manager

FABORY

FABORY **TAMPER PROOF** (THEFT PROOF) - HEXAGON SOCKET BUTTON HEAD CAP SCREWS - STEEL
 FABORY ANTI VOL - VIS A TETE BOMBEE A SIX PANS CREUX - ACIER
 FABORY ANTI ROBO - TORNILLOS DE CABEZA ABOMBADA CON HUECO EXAGONAL - ACERO
 FABORY ANTI DIEBSTAL - FLACHRUNDKOPFSCHRAUBEN MIT INNENSECHSKANT - STAHL

		DIN : - NEN : - ANSI : - B.18.3.4M ISO : - 7380	CODE STEEL 07143	 Ordering example: 07143 M8 x 20
		K 91		

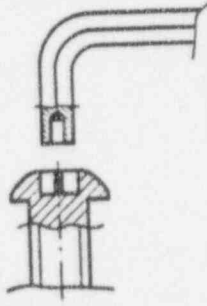
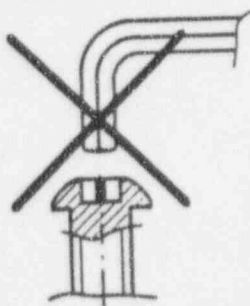
d	M4	M5	M6	M8
P	0.7	0.8	1	1.25
dk	max. 7.6	9.5	10.5	14
	min. 7.24	9.14	10.07	13.57
k	max. 2.2	2.5	3.3	4.4
	min. 1.95	2.5	3	4.1
s	nom. 2.5	3	4	5

d x L	STEEL 07143	≥	d x L	STEEL 07143	≥	d x L	STEEL 07143	≥
M4X10	040.010	200	M5X25	050.025	200	M6X50	060.050	200
M4X12	040.012	200	M5X30	050.030	200	M8X10	080.010	200
M4X16	040.016	200				M8X12	080.012	200
M4X20	040.020	200	M6X10	060.010	200	M8X16	080.016	200
M4X25	040.025	200	M6X12	060.012	200	M8X20	080.020	200
M4X30	040.030	200	M6X16	060.016	200	M8X25	080.025	200
			M6X20	060.020	200	M8X30	080.030	200
M5X10	050.010	200	M6X25	060.025	200	M8X40	080.040	200
M5X12	050.012	200	M6X30	060.030	200	M8X50	080.050	200
M5X16	050.016	200	M6X40	060.040	200			
M5X20	050.020	200						

FABORY TAMPER PROOF SCREWS

Normal socket key

Special socket key with hole boring



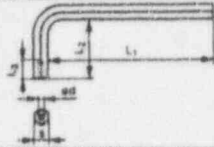
- theft proof
- vandal proof
- only to assemble/dis-assemble with special key
- also available in stainless steel (see section 9)

For special socket keys see elsewhere in this section.

WARNING: Zinc plating of these products may cause hydrogen embrittlement

FABORY

HEXAGON SOCKET SCREWS KEYS WITH HOLE BORING - FOR **TAMPER PROOF** SCREWS - STEEL - YELLOW PASSIVATED
 CLES MALES COUDEES POUR VIS A SIX PANS CREUX TROUE - POUR ANTI VOL VIS A TETE - ACIER - PASSIVEE JAUNE
 LLAVES PARA TORNILLOS CON HUECO EXAGONAL CON AGUJERO - PARA ANTI ROBO TORNILLOS - ACERO - PASSIVADO AMARILLO
 WINKEL SCHRAUBENDREHER FÜR INNENSECHSKANTSCHRAUBEN MIT LOCH - FÜR ANTI DIEBSTALTSCHRAUBEN - STAHL - GELB PASSIVIER



DIN : - 911
 NEN : -
 ANSI : -
 ISO : - 2936

D 91

CODE

YELL. PASS. **07751**



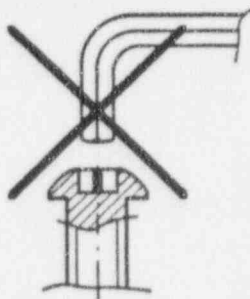
Ordering example:
 07751 2,5mm

s (width across flats)	2,5	3	4	5
L1	56	63	70	80
L2	18	20	25	28
L3	*	*	*	*
d	1,3	1,5	1,8	2,3

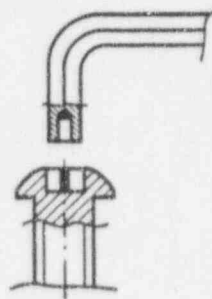
s	YELL. PASS. 07751	☒	s	YELL. PASS. 07751	☒	s	YELL. PASS. 07751	☒
2.5MM	025.001	1	4MM	040.001	1			
3MM	030.001	1	5MM	050.001	1			

SPECIAL SOCKET KEYS WITH HOLE BORING FOR FABORY TAMPER PROOF SCREWS

Normal socket key



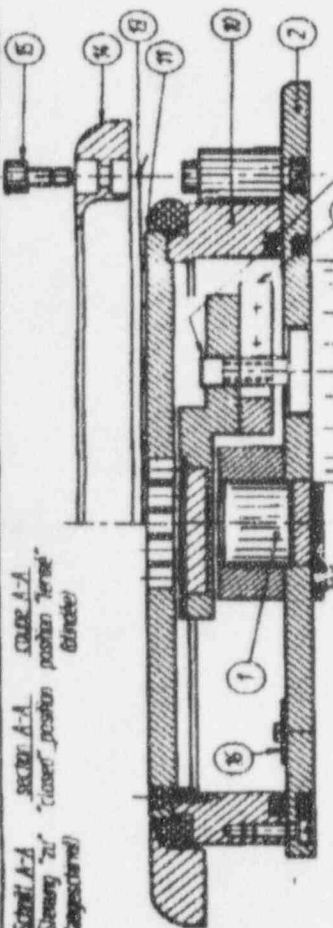
Special socket key with hole boring



- * special socket key with hole boring in short leg.
- * for stainless steel socket keys with hole boring see section 9

* L3 values according to manufacturers standard.

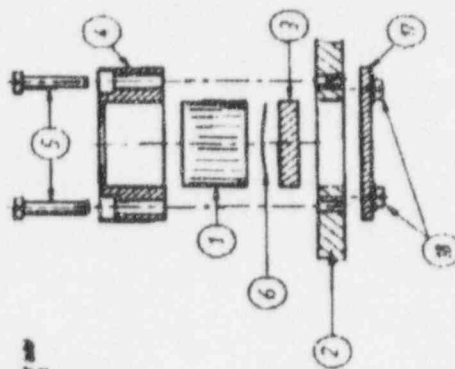
Schnitt A-A
Schnitt "Zu"
position "normal"
position "ouvert"



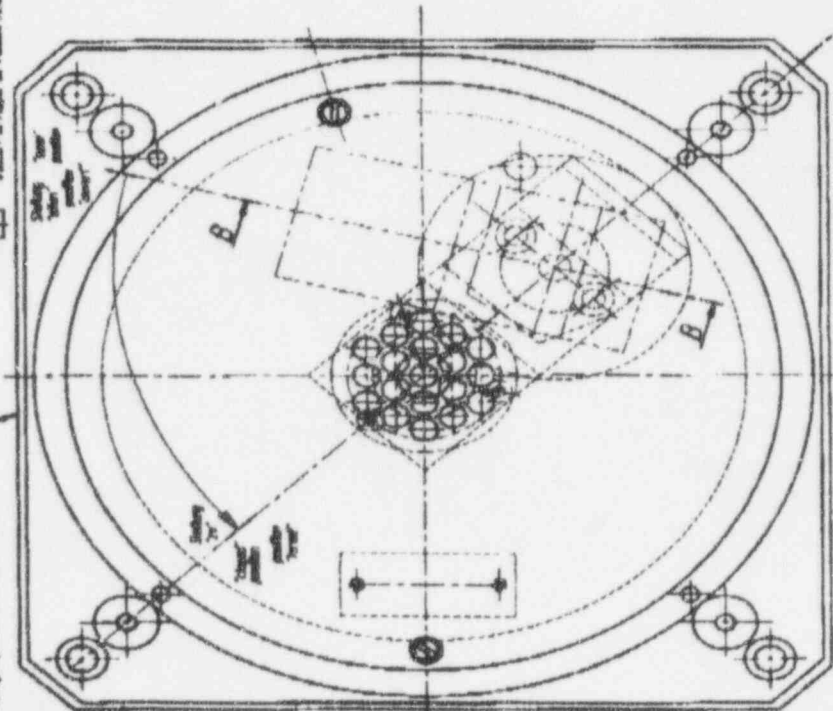
(Drehmotor elektrisch angeschlossen)
(Turning motor electrically connected)
(Moteur rotatif excité par le courant)

1. Gehäuse (Housing)
2. Gehäuse (Housing)
3. Gehäuse (Housing)
4. Gehäuse (Housing)
5. Gehäuse (Housing)
6. Gehäuse (Housing)
7. Gehäuse (Housing)
8. Gehäuse (Housing)
9. Gehäuse (Housing)
10. Gehäuse (Housing)
11. Gehäuse (Housing)

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1. Gehäuse (Housing)
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7. Gehäuse (Housing)
8. Gehäuse (Housing)
9. Gehäuse (Housing)
10. Gehäuse (Housing)
11. Gehäuse (Housing)

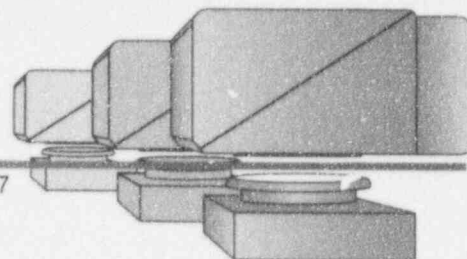


betacontrol

Geräte Nr. 76 09 994
Schnitt A-A
Schnitt "Zu"

Aufbauplan Strahlerabschirmung Sr 90
Construction plan of source shielding
Plan de construction du blindage de source

700-5652/3



Key to "Lubbles" on drawing 700-5652/3

bubble number	description
1	radiation source
2	base plate steel 5mm
3	distance ring 3.5mm
4	cover plate steel
5	fixing screws M2.5x12
6	spring
7	turning magnet with built-in recoil spring
8	mounting base (terminal on the turning magnet axis)
9	allen screw M4x6
10	distance ring steel 11.5mm
11	collimator plate compl. brass 5mm
12	shielding bracket with 4mm lead
13	cover foil polyester 0.05mm (70 g/m ²)
14	holding ring
15	allen screw
16	label for source data
17	cover plate
18	fixing screws M2.5x6

ATTACHMENT #5

Removal of Gauges

The following procedures are used by Betacontrol technicians when removing the gauge at the customer site:

1. The following personnel monitoring devices shall be worn by individuals removing gauges:
 - a. Whole Body Badge
 - b. Extremity Badge
2. Turn the keyed lock-out device to the closed (OFF) position.
3. Confirm that the shutter is closed by using a survey meter.
4. Remove the gauge from its permanent mounting. Survey the gauges to ensure the shutter is closed.
5. If the gauge is to be shipped to Betacontrol, Germany for repairs or disposal place the gauge in the crate and prepare the necessary shipping papers and labeling of the crate in accordance with the 49 CFR (DOT regulations) and 10 Fx 71 (NRC Regulations).

Servicing of Gauges

1. The customer is only allowed to perform the following services on the gauge:
 - a. Leak testing (wiping) of the gauge using an approved licensed firm's kit. They are not allowed to analyze the wipes unless they have a specific license for such services from the NRC or Agreement State.
 - ~~b. Replace the cover film in the event of damage, following proper lock-out procedures and following the procedure for replacing such a cover foil contained in the operating manual.~~

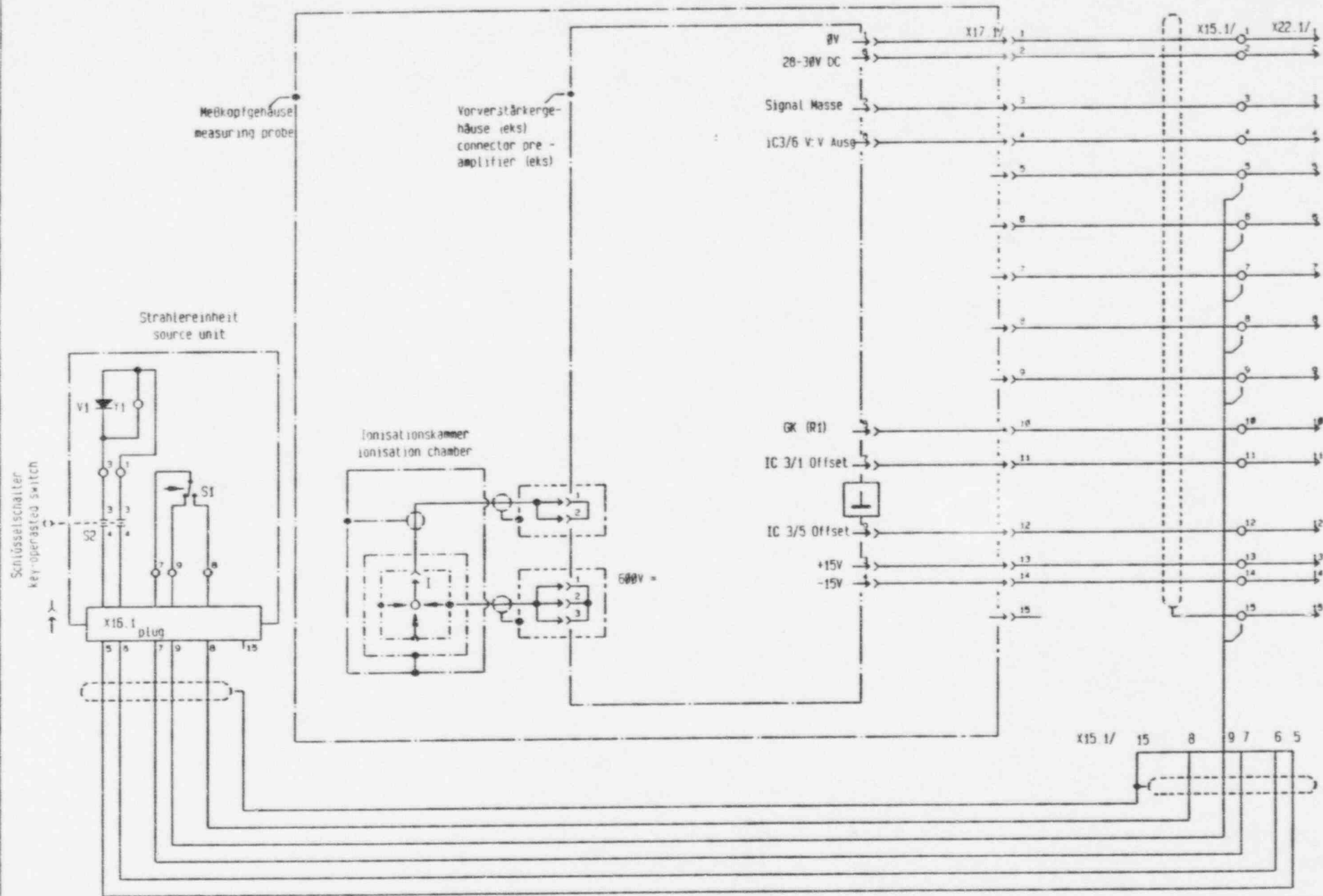
**Also Available on
Aperture Card**

ATTACHMENT #6

9611220110-01

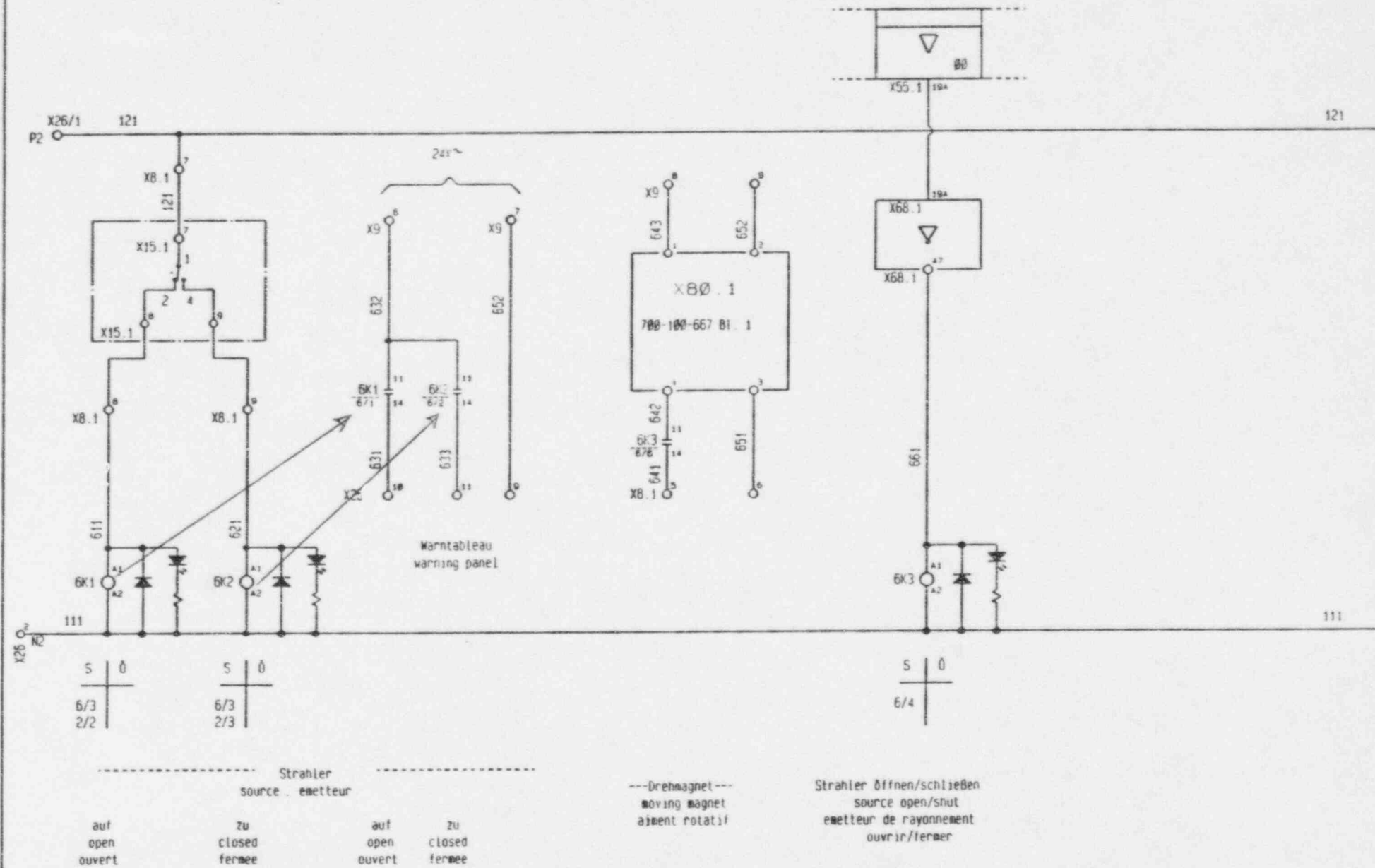
ATTACHMENT R7

12 0213



1	2	3	4	5	6	7	8
Zeich.-Nr.: 700-100-798 Bl. 34	Kom.-Nr.:	Erstellt 05.02.96	Geprüft	Geändert	betacontrol gmbh		Gruppe 0
Meßfühler: measuring probe	Name Schl.				Meß- und Regeltechnik		E798
							Bl. 34

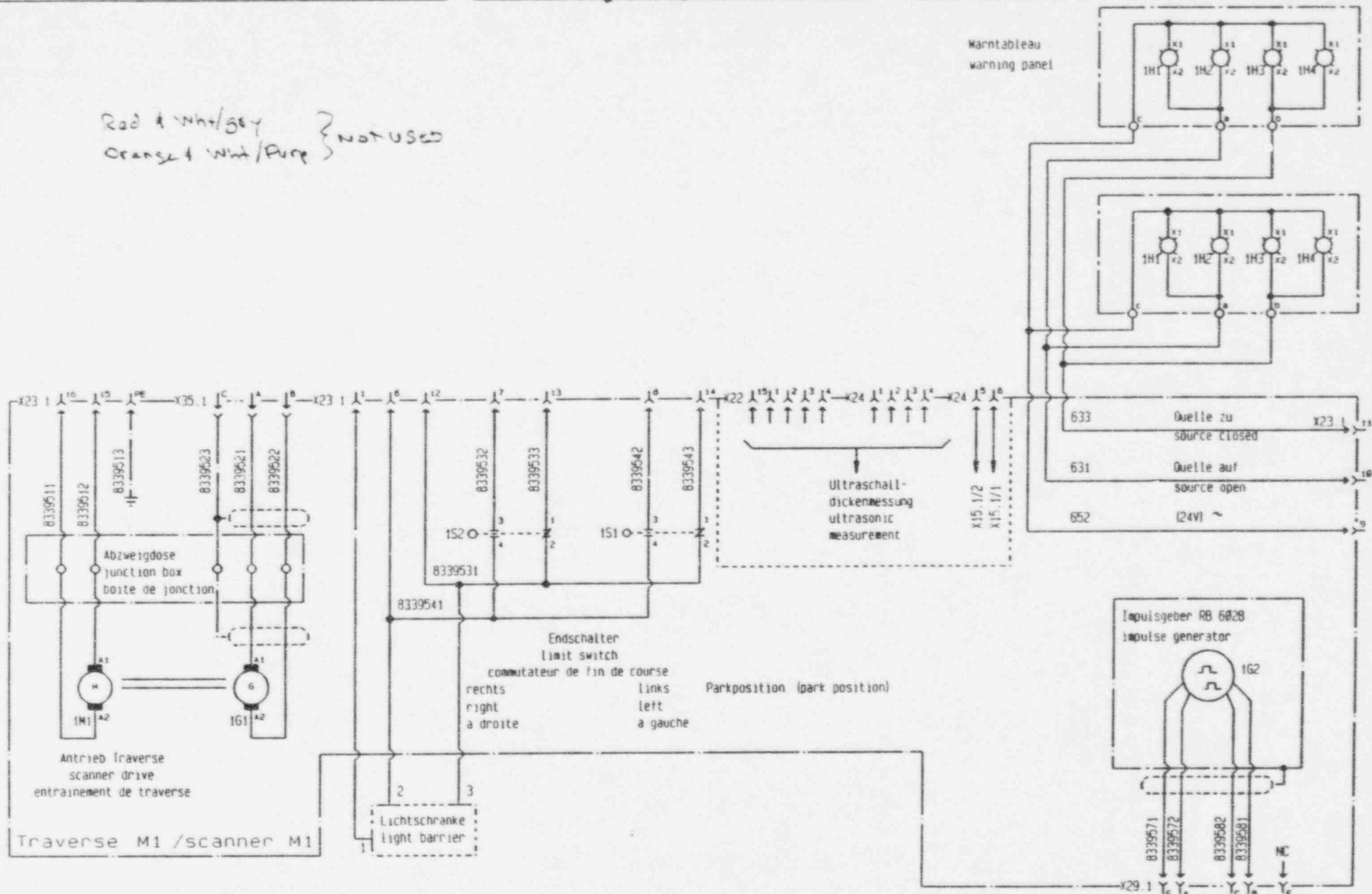
ATTACHMENT A8



1	2	3	4	5	6	7	8
Zeich.-Nr.: 700-100-1211 Bl. 6	Kom.-Nr.: 18/0683	Erstellt 30.1.96	Geprüft	Geändert	betacontrol gmbh	Gruppe 2	E1211
Systemverdrahtung / system wiring	Name pio				Meß- und Regeltechnik		Bl. 6

ATTACHMENT # 10

Red & White/Grey } NOT USED
Orange & White/Purple }



1	2	3	4	5	6	7	8	
Zeich.-Nr.: 700-100-933 Bl. 95	Kom.-Nr.: 18/0683	Erstellt 16.4.96	Geprüft	Geändert	betacontrol gmbh mes- und regeltechnik	Gruppe 3	E833	Bl. 95
Traversenverdrahtung; scanner wiring		Name pio						

CHECKLIST FOR CHANGING A SPECIFIC LICENSED DEVICE TO A GENERALLY LICENSED DEVICE

Date of Change/Installation: _____

CUSTOMER INFORMATION: _____

Name: _____

Address: _____

City, State _____

Contact Person: _____ Telephone No.: _____

DEVICE INFORMATION:

Isotope: _____ Activity _____ mCi

Device Model #: _____ Device Serial #: _____

Date of Assay: _____

LABELS:

1. The following label(s) are attached to the general licensed device as required:

- a. The "Caution-Radioactive Material" label with isotope, activity, date of assay is attached and legible. The specific licensed device label is adequate. _____ Yes _____ No

If no, explain corrective actions: _____

- b. The general licensed label has been attached to the device.
_____ Yes _____ No.

If no, explain corrective actions: _____

OPERATIONS MANUAL:

The customer was provided a copy of the amendment to the operations manual for generally licensed devices. ☐ Yes ☐ No

If no, explain corrective action: _____

SERVICE MANUAL:

All original specific license service manuals were collected and destroyed and new general license service manuals provided. ☐ Yes ☐ No

If no, explain corrective action: _____

Signature of Technician

Date



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D. C. 20555-0001

September 17, 1996

Ray Santoianni
Service Manager
Betacontrol
P.O. Box 235
435 Route 202
Towaco, NJ 07082

Dear Mr. Santoianni:

This letter is in response to your letter dated August 12, 1996, regarding registration of the Model MK 1.0 transmission gauge. We have evaluated your response. However, in order to continue our review, the following information is necessary:

1. The TORX head screws indicated in your letter are too commonly available to be considered a tamper-resistant screw for use in devices distributed to persons using the device under a general license (GL user). As per your suggestion, the screw heads can be filled with a material to prevent a user from unscrewing it. Please either specify a less commonly available tamper-resistant screw or specify the screw and filling material. Please demonstrate that any fill material used will withstand the environmental and use conditions that the device will encounter.
2. Your letter indicates that, for devices that will be distributed to GL users, the tamper-resistant screws will be used on the top of the collimator to prevent access to the shutter mechanism when changing the cover film. Please be aware that since the dose rates for the device are given for the outside of the cover, tamper-resistant screws would also be required to prevent the user from removing the cover.
3. Please provide a description or drawing that clearly indicates the position of the "on/off" indicator lamps, and that demonstrates that they are readily visible in the mounted position.
4. Please verify that the GL user will not be required to remove any tamper-resistant screws in order to perform any service.
5. Please provide complete instructions that a person using the device under a general license (GL user) will follow to perform the on/off test. The procedure listed in your letter appears to test whether the lights are in working order but it is not clearly apparent that it tests the function of the shutter itself. Please provide additional information to clarify this apparent deficiency. In addition, please explain how the on/off lights function. For example, are the lights triggered by the switch independent of the shutter movement or triggered by the shutter movement? The method used to check whether the shutter is actually functioning correctly may be checked against expected readings from the console that demonstrates that the shutter is opened or closed.

7609180081 6pp

6. The text listing the part descriptions on the drawing submitted in your letter is unreadable. Please resubmit a clear drawing.
7. Section 1.1 in the GL user's operations manual and section 1.1.3 in the service manual states that "... persons working at the control area must wear a radiation dosimeter. The type of radiation dosimeter to be worn is prescribed by the supervisory authority...".

Please be aware that GL users are not required by the regulations to wear dosimeters. You may only recommend that the users wear dosimeters. Please provide revised wording that does not imply that the use of dosimeters by the GL user is required by regulation. For specifically licensed users (SL users), it is not necessarily true that they must wear dosimeters. Please provide revised wording that directs the user to consult any applicable requirements in the regulations.

8. The dose rate diagram in the service manual and the GL user's operation manual is given for a 18.5 GBq (500 mCi) Am-241 source. The application requests and the current registration certificate authorizes a maximum of only 11.1 GBq (300 mCi) of Am-241. Please explain this apparent discrepancy. Also please explain why there are no diagrams for the other isotopes included (some of the dose rates around the device for the Kr-85 and Sr-90 are higher). In addition, section 2.2 of the service manual also lists 18.5 GBq Am-241, and doesn't list any other isotopes.
9. In the case of a SL user changing to a GL user, we understand that the user would receive an amendment to the operations manual. This is the same as the first part of the GL user's operations manual. Please verify that the SL user's operations manual is the same as the last part of the GL user's operations manual, or supply a copy of the SL user's operations manual.
10. Is the service manual given to GL users the same manual as given to the SL users?
11. Section 1.1.3 in service manual and section 1.1 in the GL users operation manual states that "should the radiation shutter become damaged, the radiation exit port can also be closed by covering it with a ... plate...". GL users should not be directed to perform this procedure. If there is any problem with the shutter, the GL user should be directed only to secure the area and obtain assistance.
12. Written procedures are required for all of the services that the GL user is requested to be able to perform. These procedures should be presented to the GL user in a manner that would not encourage them or lead them into performing services that they are not authorized to perform. It should be clear what the GL user can and can not perform. There are some discrepancies within your application and manuals that appear to be in conflict with this.

The GL user's operation manual states that the GL user is not authorized to service the device. Some of the services that you have requested that the GL user perform, are only in the service manual. The concern is that if you send them into the service manual

for one procedure, then they may have a tendency to attempt other procedures that they may not be authorized to perform. For example, your application requests that the GL can change the light bulb, but then they have to go to the service manual to get the instructions. It is suggested that the procedures for services that you are requesting the GL user be authorized to perform be put in the GL user's operations manual. The GL user's operations manual and/or the service manual would then state that the GL user can only perform those services listed in the GL user's operations manual. An alternative would be to mark all services/procedures in the service manual to state that the GL user can not perform that service and to obtain assistance.

Please explain how you will clarify this. As you make any changes, please also ensure that the manual(s) provide written instructions for all services that the GL user is requested to perform.

13. The dose calculations should address all services that the GL user is requested to be able to perform. There were some services listed that were not addressed in the dose calculations. For example, the dose calculations in your response did not mention adjust safety friction clutch, exchange of lamps, leak test, or on/off test. Please ensure that dose calculations have been provided for all services that the GL user is requested to perform.

14. I have enclosed updated copies of the Agreement State contacts for your reference.

Please provide the requested information within thirty (30) days of the date of this letter. If you have any questions, please contact me at (301) 415-5868 or Mr. John Lubinski at (301) 415-7868.

Sincerely,

LA/

Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Distribution:

SSSS Staff

NMSS r/f

SSD-95-95

NE01

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NAME	MBurgess/mb <i>mb</i>		JLubinski						
DATE	09/17/96		09/17/96						

OFFICIAL RECORD COPY

Ray Santoianni
Service Manager
Betacontrol
P O. Box 235
Towaco, NJ 07082

September 17, 1996

Dear Mr. Santoianni:

As requested in your August 7, 1996 letter and in order to expedite the request of one of your customers, we have amended your registration certificate (NR-0122-D-101-S) to include the Amersham SIF D1 source capsule. A copy of the certificate is enclosed. We are continuing to work on the remainder of your request.

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your registration certificate. As a general rule, you must request and obtain an amendment to the certificate before you make changes or modifications to the information submitted to obtain the certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions.

You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Debt Collection Branch at (301) 415-7544.

If you have any questions, please contact me at (301) 415-5868 or Mr. John Lubinski at (301) 415-7868.

Sincerely,

/s/

Michele L. Burgess, Mechanical Engineer
Sealed Source Safety Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

9610160237 IP.
Enclosure: As stated

cc w/encl: SKimberley, LFDCB

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NAME	MBurgess/mb	SBaggett						
DATE	09/16/96	09/17/96						

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended page 1 - September 16, 1996)

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

DATE: January 29, 1993

PAGE 1 OF 7

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)

ISOTOPE:

Strontium-90

Krypton-85

Krypton-85

Americium-241

Promethium-147

MAXIMUM ACTIVITY:

50 millicuries (1.9 GBq)

60 millicuries (2.2 GBq)

(700-052.002/4)

500 millicuries (18.5 GBq)

(KAC.D1, KAC.D3)

300 millicuries (11.1 GBq)

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

9610160940 10pp.

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

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

DATE: January 29, 1993 PAGE 2 OF 7

DEVICE TYPE: Transmission Gauge

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" (9.5 mm) to 1.97" (50 mm). However, in some applications the air gap may be as large as 13.2" (335 mm). 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 Amersham Buchler model VZ-337 strontium-90 source incorporates radioactive material contained in a sealed silverfoil into a sealed welded stainless steel capsule. The source models VZ-337 & 700-052.002/4 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 and americium-241 sources contain radioactive material incorporated in a ceramic enamel which is sealed in a welded 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.

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DEVICE TYPE: Transmission Gauge

DIAGRAM:

See attachments 1-3.

LABELING:

The manufacturer claims that the devices are labeled in accordance with Section 20.203, 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 of construction and contains the trifoil symbol. The labels are made of stainless steel or aluminum and are permanently attached by rivets or screws 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:

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.

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

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DEVICE TYPE: Transmission Gauge

PROTOTYPE TESTING: (Cont'd)

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 have been distributed under an NRC specific license by Baumer of America, Inc., since 1985. Baumer of America, Inc., states that no incidents of failure of the device causing a radiological hazard have been reported to date.

EXTERNAL RADIATION LEVELS:

The following are the dose rates reported by the manufacture 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

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DEVICE TYPE: Transmission Gauge

EXTERNAL RADIATION LEVELS: (Cont'd)

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

QUALITY ASSURANCE AND CONTROL:

Betacontrol 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.

Additionally, if the end user receives the device directly from Betacontrol, then the end user is responsible for performing an initial quality check of the device upon receipt, as well as assuring 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.

Baumer of America, Inc., 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.

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DEVICE TYPE: Transmission Gauge

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device is to be distributed only to persons specifically licensed by the NRC or an Agreement State
- The device shall be serviced only by Baumer of America, Inc., or persons specifically licensed to do so by the NRC or an Agreement State.
- REVIEWER NOTE: 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.
- 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.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- 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. 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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DEVICE TYPE: Transmission Gauge

REFERENCES:

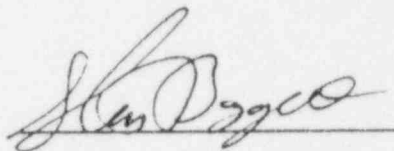
The following supporting documents for the Model MK 1.0 are hereby incorporated by reference and are made a part of this registry document.

- 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, June 25, 1992, and September 23, 1992, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 29, 1993

Reviewer: 

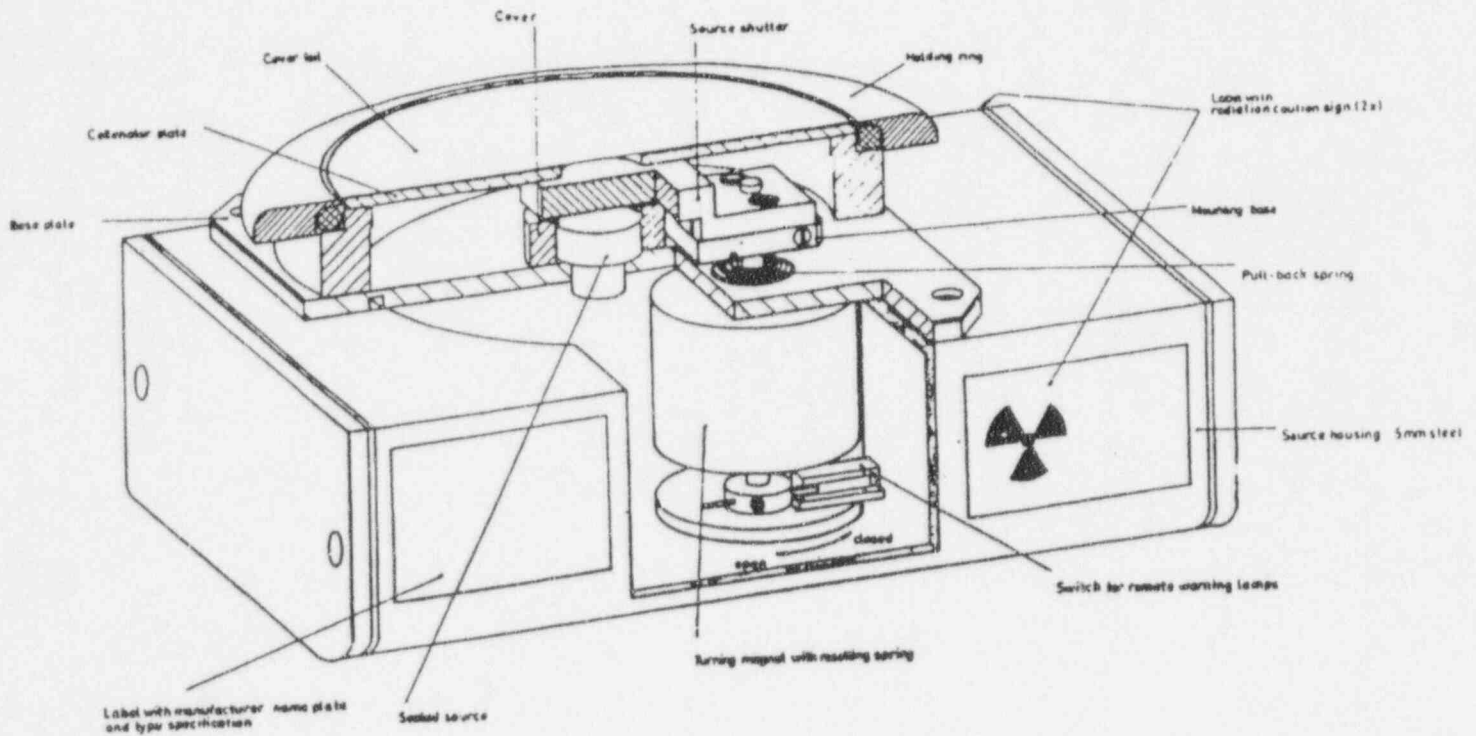
Date: January 29, 1993

Concurrence: 

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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NO.: NR-122-D-101-S

DATE: January 29, 1993 ATTACHMENT 1

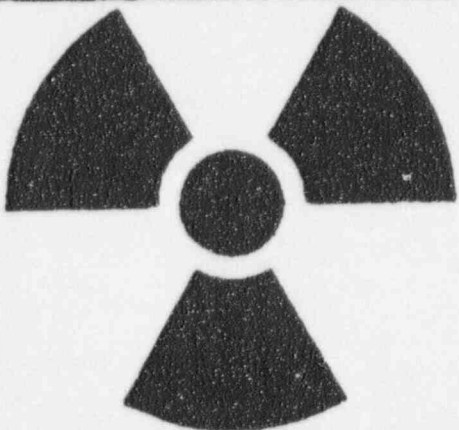


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DATE: January 29, 1993 ATTACHMENT 2

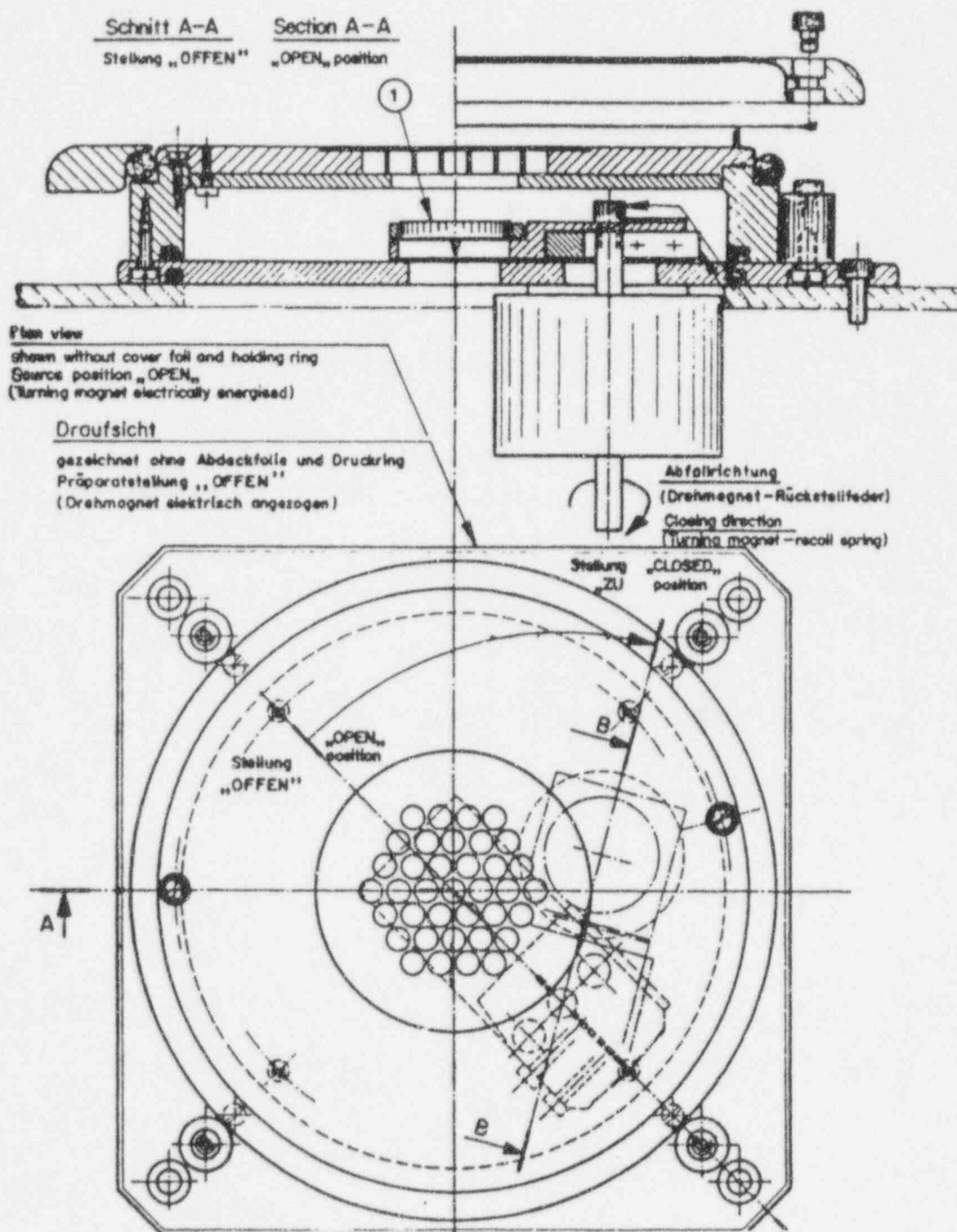
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D-5905 FREUDENBERG	
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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DATE: January 29, 1993 ATTACHMENT 3



betacontr I

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Michele Burgess
NRC Nuclear Regulatory Commision
11545 Rockville Pike
Mail Stop T-8F5
Rockville, MD 20852



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				DATE RECEIVED 9/20	ADDITIONAL TRACKING NUMBER(s) (if applicable)
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