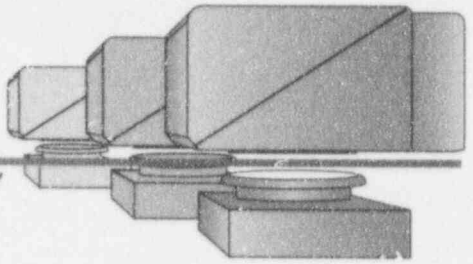
betacontrol of America, Inc.
PO Box 18 • 435 Route 202 • Towaco, NJ 07082 • Tel: 201-263-4243 • Fax: 201-263-0477



June 17, 1996

Michele Burgess
U.S. Nuclear Regulatory Commission
Mail Stop T8F5
Washington, DC 20555

Dear Ms. Burgess:

While checking on the status of *betacontrol's* pending license application for a general license, Stephen Courtemansche at King of Prussia, PA suggested I contact you about some additional questions I have.

1. John McGrath is out for the remainder of the week and I wondered if you could provide any additional information about when our license might be approved.
2. A discrepancy has come to my attention that has been on our specific license for some time. On our registry NR-122-D-101-S dated June 24, 1993 we are approved for 500 millicurie sources KAC.D1 and KAC.D3 however on our license 29-23394-01 the KAC.D1 source is designated not to exceed 60 millicuries. What do I need to do and how should I proceed to correct this error with as little delay as possible?
3. Please clear up a misunderstanding. Mr. Courtemansche suggested that once the general license is approved the specific license we now posses will still be needed. I was under the impression that the general license would replace the specific license we now have.
4. *betacontrol* intends to place an application to increase the allowable activities of the sources we now use along with adding additional sources. On the advise of our consultant we held off submitting this application until our general license was approved, hopefully avoiding any delays. After speaking with Mr. Courtemansche it seems that both applications (for general license and new/amended devices) should have been submitted at the same time. My dilemma at present is that we need to deliver to a customer two 10 millicurie Sr90 sources of model X117, SIF.D1 (Amersham) in place of the originally licensed VZ-337 (Amersham). This change was to be included in the above mentioned registration application. Is there a means to allow this delivery to proceed either by temporary letter or authorization?

Sincerely,

Ray Santoianni
Service Manager

betacontrol

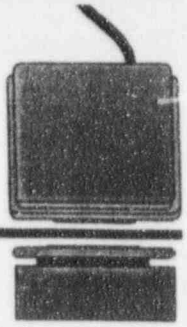
P.O. Box 18 • 435 Route 202 • Towaco, N.J. 07082

Michele Burgess
U.S. Nuclear Regulatory Commission
Mail Stop T8F5
Washington, DC 20555

recd 5/14/96

betacontrol

P.O. Box 235 • 435 Route 202 • Towaco, N.J. 07082 • Tel.: 201-263-GAGE, 201-263-0724 • Fax: 201-263-0477



May 1, 1996

Michele Burgess
U. S. Nuclear Regulatory Commission
Mail Stop T8F5
Washington, DC. 20555

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 March 28, 1996 for additional information for the amendment to the above referenced documents. Each item is addressed in the same order as your letter. Our response is as follows:

1. We verify that no design changes have been made between the specifically licensed (SL) devices and the generally licensed (GL) devices.

2. Attached is a text of the GL label (Attachment #1) that will be placed on the GL devices. The location is identified on the attached drawing. We verify that the GL label will not be placed on SL devices. These labels will be attached by rivets or screws.

3. We verify that the GL devices will have a label indicating the date of assay.

4. Betacontrol will perform all installation and removal of the GL devices. In addition, Betacontrol will perform all maintenance and testing of the GL devices.

5. The General Licensed User will be approved to perform the leak testing of the GL devices requiring this testing. The amendment (previously submitted) to the users operation manual has procedures for the GL user to follow. Also, the General Licensed User is approved for replacing the cover film in the event of damage. The procedure for replacing such a cover foil is contained in the operating manual provided by Betacontrol.

6. Enclosed is a copy of the Operations Manual for GL users which has the amendment to the operations manual for GL devices. We verify that the amendment to the manual will only be provided for GL devices.

7. Enclosed is the QA/QC procedures that will be implemented at the time of installation by Betacontrol technicians. The parent company in Germany will have similar procedures to ensure the proper labeling of the devices and operations manuals are provided. The attached QA/QC procedures are used as a double check by the technician at the time of installation and/or changing from a specifically licensed device to a generally licensed device. Documentation of the QA/QC sheets will be maintained in each customer's file.

Thank you for your assistance in this registration. If you have any questions, please contact me at (201) 263-4243.

Sincerely,

George R. Stoddard
National Sales Manager

ATTACHMENT #1

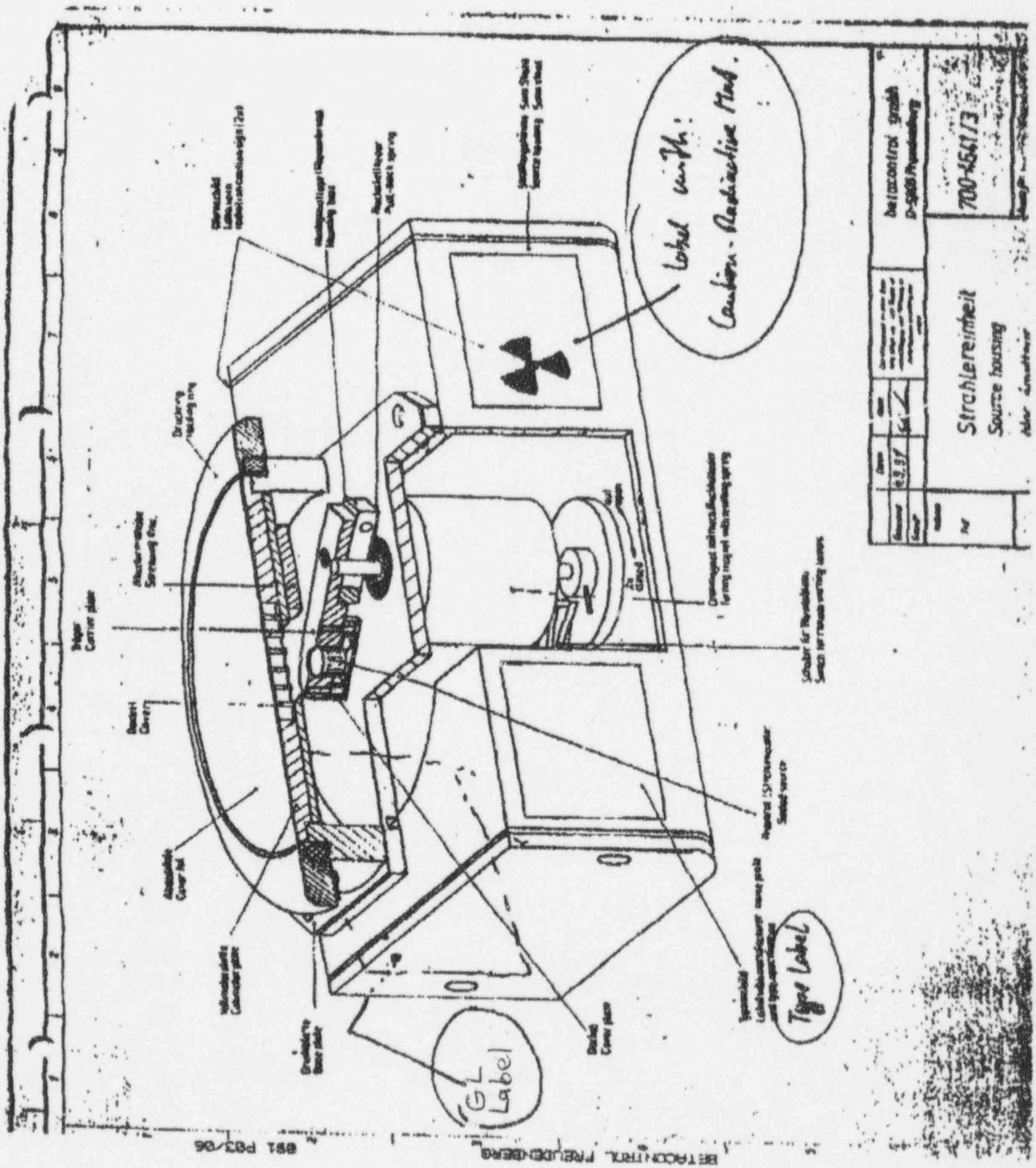
Label for General Licensed Gauges

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.


Label with Text:
Caution - Radioactive Mat.
Strahlereinheit
Source housing
700-4541/3
GL Label
Type Label

QA/QC PROCEDURES FOR GENERALLY LICENSED DEVICES

The following procedure shall be complete for each generally licensed device or specifically licensed device being changed to a generally licensed device prior to installation.

PROCEDURE:

1. Prior to installation, choose the proper Quality Control checklist as identified below. These checklists are to ensure all devices are properly labeled and all required information is provided to the customer.

    a. Checklist for Generally licensed device.
    b. Checklist for changing a Specific licensed device to a Generally licensed device.

2. Checklist for Generally Licensed Devices:

    a. Complete the customer information.
    b. Complete the device information.
    c. Are all labels for generally licensed devices attached to the device?
    d. Is the operations manual for the generally licensed device provided?
    e. Date and sign.
    f. This document must be placed in the customer's file.

3. Checklist for changing a Specific Licensed Device:

    a. Complete the customer information.
    b. Complete the device information.
    c. Have all labels been changed to the general licensed device as required?
    d. Has the customer been provided the amendment to the operations manual for generally licensed devices?
    e. Date and sign.
    f. This document must be placed in the customer's file.

CHECKLIST FOR GENERALLY LICENSED DEVICES

Date of 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 "Caution Radioactive Material" label with isotope, activity, date of assay is attached.
(Check one) _____ Yes _____ No

   If no, explain corrective action: _____

   _____

   _____

2. The general licensed label is attached? _____ Yes _____ No

   If no, explain corrective action: _____

   _____

   _____

OPERATIONS MANUAL:

The operations manual for this general licensed device has been provided to the customer. (Check one) _____ Yes _____ No If no, explain corrective action: _____

_____

_____

_____ _____

Signature of Technician Date

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

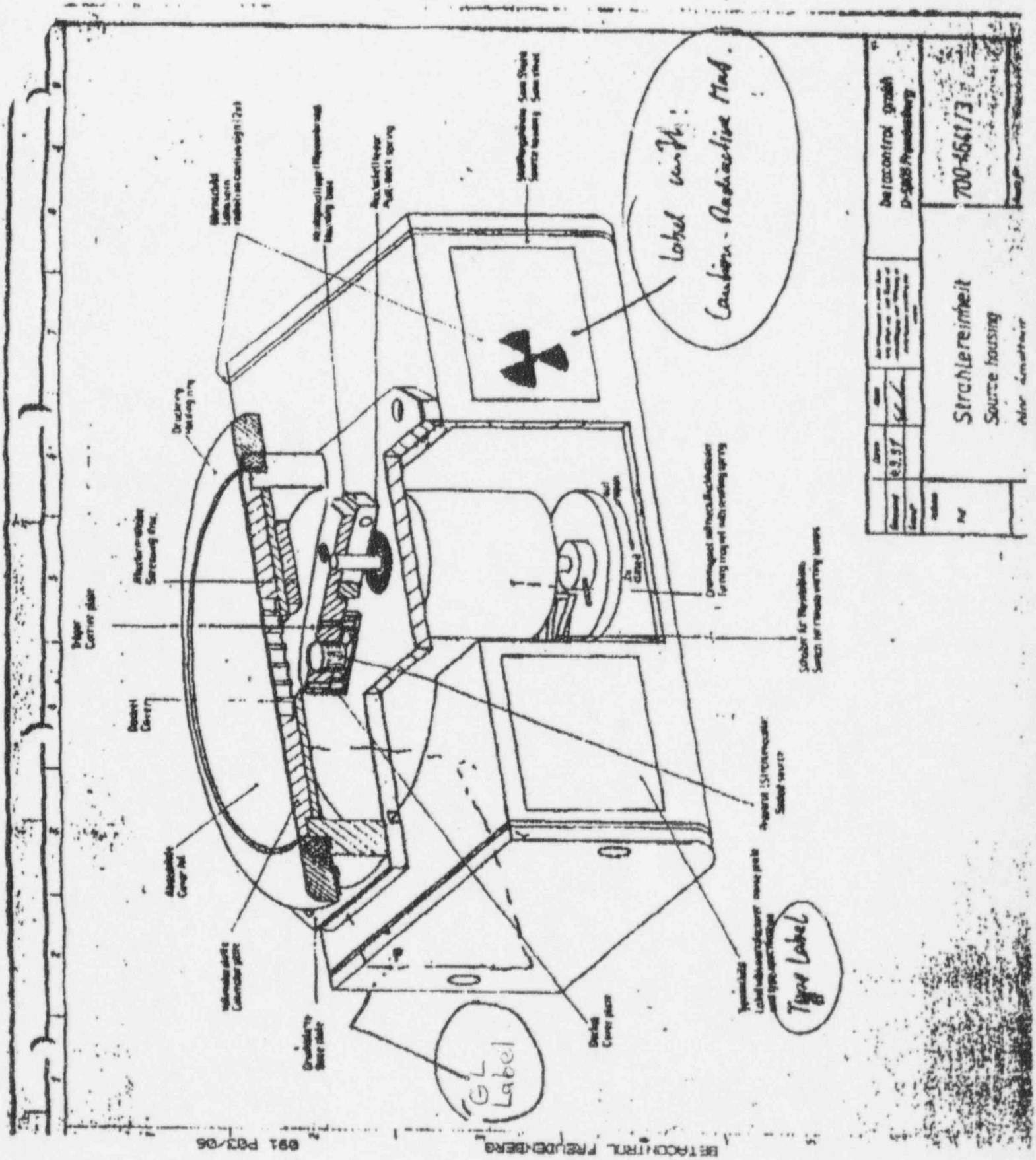
If no, explain corrective: _____

_____

_____

_____ _____

Signature of Technician Date


Label with Caution - Radioactive Mat.
Strahlereinheit
Source housing
700-4561/3
Type Label
ECL Label

The Honorable Paul E. Gillmor
Member, United States
House of Representatives
120 Jefferson St., 2nd Floor
Port Clinton, OH 43452

April 30, 1996

Dear Congressman Gillmor:

I am responding to your letter dated April 1, 1996, written on behalf of your constituent Mr. Ronald Abbott, of Sandusky Vinyl Products, requesting information on the status of an application for amendment to Betacontrol's registration certificate. The Nuclear Regulatory Commission is in the process of evaluating Betacontrol's request for safety review of its Model MK 1.0 transmission gauge, for distribution to generally licensed users, and is waiting for a reply, from Betacontrol, to NRC's letter dated March 28, 1996, requesting additional information necessary to complete the safety review. As of April 26, 1996, the NRC has not received a response. Upon receipt of their response, the NRC will continue the review.

Betacontrol has been informed that, in addition to requesting the safety review, it must apply for a distribution license, to distribute the newly approved devices to persons for use under a general license. Betacontrol has a license to distribute the currently registered models to persons for use under a specific license. Betacontrol indicated that they would apply to the NRC's Region I office for its specific license to distribute the gauges to persons for use under a general license. As of April 26, 1996, the Region I staff reports that it has not received the application, and that upon receipt, will begin the review.

Concerning Sandusky Vinyl's receipt and use of the devices, the device is currently registered for use under a specific license. As such, Sandusky Vinyl could apply to the NRC's Region III office for a specific license, and receive and use the devices under a specific license. We will contact Mr. Abbott to make all of these points clear and answer any questions he may have.

I trust this response addresses your concerns.

Sincerely,

Original Signed by:
James L. Milhoan for
James M. Taylor
Executive Director for Operations

Distribution: GT96250

SSSS r/f	IMNS Central Files	NMSS r/f	CEstep
CPoland	Hester Thompson	IMAB r/f	EDO r/f
DMorrison	NRC File Center	SECY (CRC No. 96-0370)	
PUBLIC	DRathbun, PA	HThompson	JTaylor
NEO-1	SSD 95-95	NR-0122-D-101-S	

*SEE PREVIOUS CONCURRENCES

DOCUMENT NAME: A:\BETA.CGS ce4/19/96 CO/PROOFED/APRIL 19, 1996

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Member, United States
House of Representatives
120 Jefferson St., 2nd Floor
Port Clinton, OH 43452

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I trust this response addresses your concerns.

Sincerely,

James M. Taylor
Executive Director for Operations

Distribution: GT96250

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