TRINITY MEMORIAL HOSPITAL

5900 SOUTH LAKE DRIVE • CUDAHY, WISCONSIN 53110 • 414/769-9000

August 28, 1985

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60132

Dear Sirs:

I am leaving Trinity Memorial Hospital and retiring my position as Radiation Safety Officer. During my stay here as Radiation Safety Officer, Mr. Joseph Allen has been the consulting physcist and has carried out the majority of the functions of Radiation Safety Officer under my guise. Dr. Werner Kordas has been selected as my replacement for Radiation Safety Officer. He has been with the imaging department at Trinity Memorial Hospital for 3 years and has been a member of the Radiation Safety Committee for the past one year. He has worked with me and Mr. Allen very closely in regard to compliance with Nuclear Regulatory regulations and the other functions of the committee. He is the best qualified candidate for replacement for me as Radiation Safety Officer. Mr. Allen will continue as consulting physicist.

Sincerely,

Robert M. Boex, M.D.

Robert M. Boex, M.D.
Radiation Safety Officer

RB:vh

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Werner Kordaş, M.D.	Wisconsin

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Joseph's Hospital Milwaukee, Wisconsin 1-2-79 - 6-30-82	160	50
b. RADIATION PROTECTION	Same as above 1-2-79 - 6-30-82	28	2
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Same as above 6-1-80 - 6-30-82	22	0
d. RADIATION BIOLOGY	Same as above 1-2-79 - 6-30-82	25	0
e. RADIOPHARMACEUTICAL CHEMISTRY	St. Joseph's Hospital Milwaukee, Wisconsin 9-1-80 thru 12-31-80	16	16

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
99mTc	20 mCi/pt.	Same as above	4 months	imaging
32 P	4 mCi/pt.	" " "	4 months	therapy
131-I	1000 uCi/pt.	" " "	4 months	imaging/therapy
169 Yb	2 mCi/pt.	" " "	4 months	imaging
201 Tl	2 mCi/pt.	" " "	4 months	"
111 In	500 uCi/pt.	" " "	4 months	"

FORM NRC-313M-SUPPLEMENT B
(8-78)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

WERNER KORDAS

STREET ADDRESS

3125 N. MENOMONEE RIVER PKWY

CITY | STATE | ZIP CODE

WAUWATOSA WI 53222

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	54	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	0	
	LIVER FUNCTION STUDIES	0	
	FAT ABSORPTION STUDIES	0	
	KIDNEY FUNCTION STUDIES	16	
	IN VITRO STUDIES	0	
OTHER			
I-125	DETECTION OF THROMBOSIS	0	
I-131	THYROID IMAGING	86	
P-32	EYE TUMOR LOCALIZATION	0	
Se-75	PANCREAS IMAGING	0	
Yb-169	CISTERNOGRAPHY	5	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	0	
OTHER			
Tc-99m	BRAIN IMAGING	81	
	CARDIAC IMAGING	135	
	THYROID IMAGING	4	
	SALIVARY GLAND IMAGING	2	
	BLOOD POOL IMAGING	2	
	PLACENTA LOCALIZATION	0	
	LIVER AND SPLEEN IMAGING	329	
	LUNG IMAGING	119	
	BONE IMAGING	237	
OTHER			

Item 4

CONTROL NO. 79689

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	1	
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT	0	
I-131	TREATMENT OF THYROID CARCINOMA	1	
	TREATMENT OF HYPERTHYROIDISM	6	
Au-198	INTRACAVITARY TREATMENT	0	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	0	
	INTRACAVITARY TREATMENT	0	
I-125 or Ir-192	INTERSTITIAL TREATMENT	0	
Co-60 or Cs-137	TELETHERAPY TREATMENT	0	
Sr-90	TREATMENT OF EYE DISEASE	0	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	2	
Sn-113/ In-113m	GENERATOR	0	
Tc-99m	REAGENT KITS	5	
Other			
TL-201	MYOCARDIAL SCAN	256	
GALLIUM67	GALLIUM SCAN	14	
Tc-99m	GI. BLOOD FLOW	6	
Tc-99m	BILIARY SCAN	5	
In-111	CSF LEAKAGE STUDY	2	
~~Tc-99m~~	~~SALIVA~~		

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

9-1-80 THRU 12-31-80 720 HOURS

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
JOHN P. MATSIS, MD.

b. NAME OF INSTITUTION
ST. JOSEPH'S HOSPITAL

c. MAILING ADDRESS
5000 W. CHAMBERS ST.

d. CITY
MILWAUKEE, WI. 53210

5. MATERIALS LICENSE NUMBER(S)
48-00537-03

6. PRECEPTOR'S SIGNATURE
John P Matsis M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
JOHN P. MATSIS, M.D.

8. DATE
12/10/82

FORM NRC-313M-SUPPLEMENT 8
(8-78)

Item 4

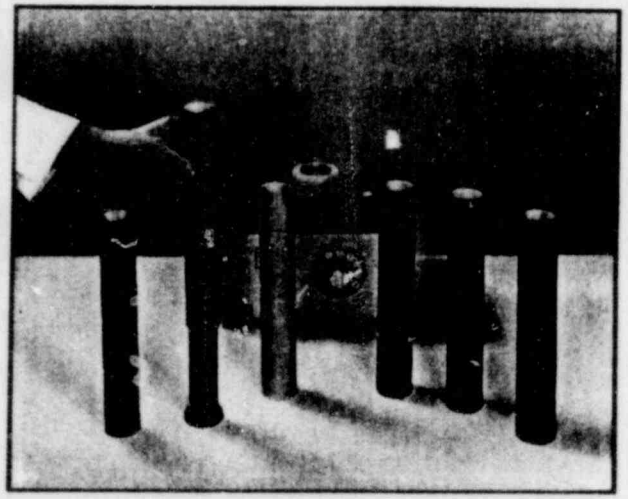
CONTROL NO. 79689

INSTRUCTION MANUAL

CALICHECK™

Dose Calibrator Linearity Test Kit

34-210



NUCLEAR ASSOCIATES

VICTOREEN

A Division of VICTOREEN, INC.
100 VOICE ROAD
CARLE PLACE, NY 11514-1593

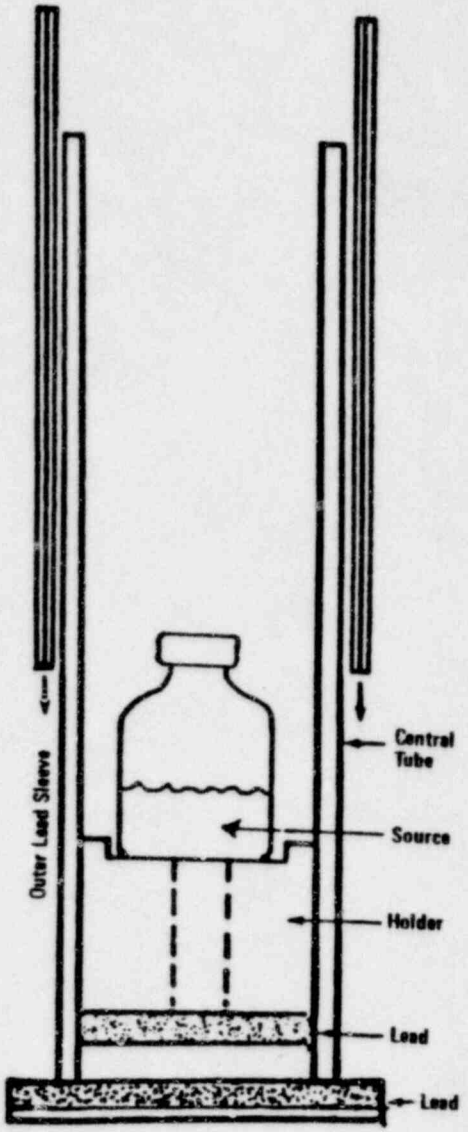
A Subsidiary of Sheller-Globe SG

Repairs (516) 741-2842 • Sales (516) 741-6360

TABLE of CONTENTS

Product Description

Calicheck is a kit designed to perform the activity linearity test on a dose calibrator quickly and accurately. The kit consists of seven tubes, six of which are lead-lined to attenuate gamma radiation from radioactive sources, and a seventh, unlined tube. Each lead-lined tube varies in the thickness of lead so as to simulate various stages of radioactive decay. These tubes are sequentially placed over a source of radioactivity in the dose calibrator and, within minutes, seven successive measurements are acquired representing values that would have been obtained at approximately 0, 6, 12, 20, 30, 40 and 50 hours after the initial assay of Tc-99m. The need for determining linearity by fractionating eluants, or decaying the elution for several days while data is being collected, is eliminated — and at greatly reduced radiation exposures to personnel.



SECTION II

General Information

Several important points must be understood prior to using Calicheck. The points are as follows:

1. Thorough quality control is performed on all kits. However, we suggest that the kit be checked to assure that it hasn't been damaged in shipment.
2. The components of the kit and/or the dose calibrator can be damaged if misused. It is especially important that damage does not occur to the ends of the tubes.
3. Should tubes become damaged or lost, replacement parts can be ordered.
4. Calicheck confirms activity linearity. It will not make your dose calibrator linear.
5. The dose calibrator must exhibit activity linearity prior to utilizing the Calicheck kit. This must be accomplished by performing an activity linearity test using standard techniques such as described in your license application. For NRC license holders, this test should be at a minimum equivalent to Appendix D of Regulatory Guide 10.8, October, 1980. If nonlinearity is demonstrated, the instrument should be repaired.
6. Calicheck must be specifically calibrated for each dose calibrator in the facility since variations between manufacturers (and sometimes, models) are known to exist. Similarly, kits should not be interchanged without first confirming calibration factors. Each tube in the Calicheck kit must be calibrated and each time a tube is replaced in the kit, the new tube must be calibrated. A procedure is enclosed that describes the calibration technique.
7. Readings obtained from Calicheck are not to be used for assay purposes.
8. The radionuclide used for testing must be Tc-99m, and it must be relatively free of Mo-99 contamination. The concentration of Mo-99 in the sample should be less than .15 uCi Mo-99/mCi Tc-99m. If a central radiopharmacy is used as the source of Tc-99m, ask the radiopharmacist for his assay results.

9. Do not use the tubes as shielding devices. The black center tube offers absolutely no radiation protection since it is plastic with no lead in its side wall. The other tubes do contain varying amounts of lead, but should never be regarded as a protective shield.
10. The entire kit should be stored in the mailing container in an upright position when not in use. The black center tube should be inserted upside down to avoid damage to the tubes.
11. Typically, regulatory agencies, such as the Nuclear Regulatory Commission or state licensing agencies, require that methods for activity linearity evaluations be filed with them in the form of a license amendment application.
12. If you have questions regarding the kit, the directions for its use, or the data generated, call (516) 741-2842 for assistance.

CAUTION

Calicheck should be used only by qualified personnel. Place the tube carefully into the dose calibrator to avoid damage to the tube and/or the chamber itself.

SECTION III

Calibration of Calicheck

OBJECTIVE:
To generate calibration factors for each tube in the Calicheck Kit, thereby expressing the amount of attenuation by each tube.

PREPARATION:
All radiation sources in the vicinity of the dose calibrator should be shielded to avoid erroneous readings. Further, the instrument may be sensitive to dosed patients in the vicinity. Move the patients to another location before you start. Both the "Kit Calibration" and the "Activity Linearity Procedure" must be performed in an environmentally stable background.

Syringe hangers and vial holder assemblies supplied with Capintec, Nuclear Associates, and some Picker dose calibrators must be removed. Molded chamber liners as supplied by RadX and some Picker dose calibrators must be lifted out. Calicheck will not fit the Mediac dose calibrators because the chamber diameter is too small.

The calibration source that is used should be the largest activity measured in the dose calibrator. This would normally be the Monday morning elution in the case of the generator, or the largest dose obtained from your radiopharmacy.

In order to use Calicheck, a source of Tc-99m must be placed into the central black tube. If the source is in a top loading lead elution shield, use extension tongs to transfer the source. If the source is in a bottom loading elution shield, remove the base cover, put the open end of the black tube to the bottom of the lead shield and allow the source to slide down into the black tube by tilting the tube at an angle. The center tube accommodates vial sizes up to 20 ml. and syringes up to 10 ml. Proper technique dictates that when using a syringe, a clean needle be used and it should be no longer than 1-1/2" in length. When the black tube is inserted into the dose calibrator, it should be done carefully with the open end in the upward position. The black tube must remain in the dose calibrator throughout all steps in the calibration cycle. Once the source is placed in the dose calibrator, the source must be kept in exactly the same position throughout the test to insure consistent geometry.

If the unit has a manual range adjust, adjust the range as necessary to acquire three significant figures for each reading.

When the activities displayed are at the uCi level (e.g., when the purple and possibly blue tubes are in place), dose calibrator displays may "float" or vary on successive measurements. Be sure to record an average figure on your data sheets. Record all values on the data sheets in mCi units.

Once the procedure is started, do not stop. All readings should be recorded within a matter of minutes. Otherwise, the short half life of Tc-99m will introduce unacceptable error.

Calibration Procedure: (To be performed only once)*

1. Remove any syringe hanger or chamber liner, if necessary, from dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges, to add or subtract from final results when those ranges are used.
4. Place calibration source into black tube and insert black tube into dose calibrator **CAREFULLY** with the open end in the upward position. Read displayed activity.
5. Record reading in appropriate positions on Data Sheet #1 "Kit Calibration". (8 entries. See example on page 8.)

Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record reading as the appropriate denominator on Data Sheet #1, Kit Calibration Form.
7. Replace red tube with orange tube. Record.
8. Replace orange tube with yellow tube. Record.

* Or following repair of dose calibrator or Calicheck.

9. Replace yellow tube with green tube. Record.
10. Replace green tube with blue tube. Record.
11. Replace blue tube with purple tube. Record.
12. Remove the Calicheck assembly and place source in a shielded container. Place Calicheck in storage container provided.

DATA TREATMENT OF DATA SHEET #1:

1. Divide the numerator by the denominator in Column B to determine the Calibration Factor, and record in Column C. **Retain these values for future reference.** These factors will be used for all future activity linearity tests provided **all** conditions of the test are met (i.e., **same** dose calibrator, **same** kit, **same** radionuclide, **same** source configuration). Recalculation will be required following repair of dose calibrator or Calicheck.
2. Compare results to chart of "Typical Calibration Factors" on page 9. Differing values may be due to variations in geometry, in the response of the dose calibrator and/or in the kit manufacturing process itself.
3. Transfer determined Calibration Factors from Data Sheet #1 to appropriate place in Column C of Data Sheet #2. (See example on page 13.) To confirm the accuracy of the determined factors, complete Data Sheet #2. If no error has been made, all values in Column D (product of B x C) should be the same. If values differ, repeat the determination.

Kit Calibration

All readings must be taken at the lowest available range setting and converted to mCi units.

TUBES A		DISPLAYED ACTIVITY B		CALIBRATION FACTORS C
Black Only / Black Only	=	____ mCi / mCi	=	1.00
Black Only / Black & Red	=	____ mCi / mCi	=	____
Black Only / Black & Orange	=	____ mCi / mCi	=	____
Black Only / Black & Yellow	=	____ mCi / mCi	=	____
Black Only / Black & Green	=	____ mCi / mCi	=	____
Black Only / Black & Blue	=	____ mCi / mCi	=	____
Black Only / Black & Purple	=	____ mCi / mCi	=	____

SOURCE CONFIGURATION

_____ Syringe

_____ Vial

*Or following repair of dose calibrator or Calicheck Kit. In all instances these factors can only be determined following proof of activity linearity by standard techniques. **KEEP THIS FORM FOR FUTURE REFERENCE!**

Example

To determine the calibration factors for a Brand X dose calibrator, a source of Tc-99m was prepared. The source read 34.2 mCi in the black tube and generated the following data.

All readings were taken at the lowest possible range setting and converted to mCi units.

TUBES A		READINGS B		CALIBRATION FACTOR C
Black Only / Black Only	=	34.2 mCi / 34.2 mCi	=	1.00
Black Only / Black & Red	=	34.2 mCi / 19.9 mCi	=	1.72
Black Only / Black & Orange	=	34.2 mCi / 10.6 mCi	=	3.23
Black Only / Black & Yellow	=	34.2 mCi / 3.59 mCi	=	9.53
Black Only / Black & Green	=	34.2 mCi / 1.16 mCi	=	29.5
Black Only / Black & Blue	=	34.2 mCi / .354 mCi*	=	96.6
Black Only / Black & Purple	=	34.2 mCi / .112 mCi	=	305

*Read as 354 uCi and converted to .354 mCi. Similarly 112 uCi has been converted to .112 mCi and 92 uCi would be converted to .092 mCi.

Typical Calibration Factors

	CAPINTEC		RADX		PICKER	
	VIAL	SYRINGE	VIAL	SYRINGE	VIAL	SYRINGE
Black	1.00	1.00	1.00	1.00	1.00	1.00
Red	1.83	1.74	2.27	2.16	1.73	1.90
Orange	3.59	3.32	4.58	4.24	3.31	3.49
Yellow	10.9	9.74	14.4	12.9	9.71	9.96
Green	34.9	30.4	48.6	42.3	31.1	30.7
Blue	121	103	164	140	105	104
Purple	399	334	565	473	342	326

These factors were determined using Tc-99m in a 10 ml vial and a 3 ml syringe. They represent an average of several determinations using the same kit in different dose calibrators of the same type as well as different kits in the same dose calibrator. These factors are not to be used as a substitute for determined calibration factors. They are listed here for comparison purposes only.

SECTION IV

Activity Linearity Procedure

OBJECTIVE:
To determine if a dose calibrator can respond linearly to a variety of levels of radioactivity via the Calicheck Technique.

PREPARATION:

Same as described under "Calibration of Calicheck". See page 4. Use the same source configuration as used in that calibration procedure.

PROCEDURE:

1. Remove any syringe hanger or chamber liner, if necessary, from dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges to add or subtract from final results when those ranges are used.
4. Place source to be used for the activity linearity procedure into the black tube and insert tube into the dose calibrator **CAREFULLY** with the open end in the upward position.
5. Record "displayed activity" on "Black Only" on Data Sheet #2 "Dose Calibrator Activity Linearity Check", (see page 13).

Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record "displayed activity" on "Black & Red" blank on Data Sheet #2.
7. Replace red tube with orange tube. Record on "Black & Orange" blank.
8. Replace orange tube with yellow tube. Record on "Black & Yellow" blank.
9. Replace yellow tube with green tube. Record on "Black & Green" blank.

10. Replace green tube with blue tube. Record on "Black & Blue" blank.
11. Replace blue tube with purple tube. Record on "Black & Purple" blank.
12. Remove Calicheck assembly and place source in shielded container.

DATA TREATMENT OF DATA SHEET #2: (To be completed each calendar quarter or at a frequency required by your license conditions.)

1. Enter appropriate Calibration Factors from Data Sheet #1 for your dose calibrator in Column C.
2. Multiply the value in Column B by the corresponding value in Column C to determine product of each entry for Column D. Record values. (Ideally, these values will all be the same.)
3. Add all products in Column D and divide by 7 to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of ±5% variation.

If all values in column D fall between these two limits, your dose calibrator has acceptable activity linearity. The test is complete, unless additional readings are required to check the microcurie range. If so, continue the determination by withdrawing an aliquot containing 2-3 mCi more activity than the displayed activity in the last measurement. The test is then repeated (Data Sheet #2 only), using the same source configuration as that used in determining the calibration factor on Data Sheet #1.

If any values in Column D fall outside the limits, repeat the study to rule out possible variations in the initial data. Consistent results that are outside the limits indicate that the instrument is exhibiting non-linearity. Corrective action is indicated.

LIMITED WARRANTY

This instrument and its accessories, excluding those listed below, are warranted by VICTOREEN, INC. against defects in materials and workmanship for a period of one year from the date of original shipment. During the warranty period, VICTOREEN will repair or, at its option, replace, at no charge, an instrument containing such defect provided it is returned, transportation prepaid, to the VICTOREEN repair facility listed below. Instruments repaired in warranty will be returned transportation prepaid.

THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS, WHICH EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF. THIS EXPRESS WARRANTY EXCLUDES COVERAGE OF, AND DOES NOT PROVIDE RELIEF FOR, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND OR NATURE, INCLUDING BUT NOT LIMITED TO LOSS OF USE, LOSS OF SALES OR INCONVENIENCE. THE EXCLUSIVE REMEDY OF THE PURCHASER IS LIMITED TO REPAIR, RECALIBRATION OR REPLACEMENT OF THE INSTRUMENT AT VICTOREEN'S OPTION.

This warranty does not apply if the product, as determined by VICTOREEN, is defective because of normal wear, accident, misuse, or as a result of service or modification by other than an authorized VICTOREEN repair facility. This warranty is void if the unit is subjected to temperatures above 55° C.

NON-WARRANTY SERVICE

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with the repair or replacement.

REPAIR SERVICE: Return the product, prepaid, to:
Nuclear Associates, Division of Victoreen, Inc.
100 Voice Road • Carle Place, N.Y. 11514-1593

IMPORTANT: To expedite your repair, please supply the following: (1) Complete detailed description of problem. (2) Purchase Date. (3) Name of Vendor. (4) Order Number. Also indicate which, if any, accessory items (batteries, carrying case, check source, voltage converter, etc.) are included in the return.

.1-484 34-210

CONTROL NO. 7 9689