

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-188-S-101-S

DATE: SEP 23 1983

PAGE 1 OF 4

SOURCE TYPE: Whole Body Counter Calibration Sources

MODEL: BNMI-P0, P1, P2, P3, P4 or P5 (see Description for further explanation).

MANUFACTURER/DISTRIBUTOR:

Bio-Nuclear Measurements, Inc.
P.O. Box 445
Ipswich, MA 01438

MANUFACTURER/DISTRIBUTOR:

<u>ISOTOPE:</u>	<u>MAXIMUM ACTIVITY:</u>
Cobalt-60	1 microcurie
Cesium-137	10 microcuries
Iodine-125	1 microcurie
Iodine-131	1 microcurie
Chromium-51	1000 microcuries
Cadmium-109	10 microcuries
Zinc-65	10 microcuries
Barium-133	10 microcuries
Manganese-54	10 microcuries

LEAK TEST FREQUENCY: 6 months or not required (see Limitations and/or Other Considerations of Use for further explanation).

PRINCIPAL USE: (T) Calibration Sources

CUSTOM DEVICE: _____ YES _____ X NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-188-S-101-S

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PAGE 2 OF 4

SOURCE TYPE: Whole Body Counting Calibration Source

DESCRIPTION:

The sources are constructed, with the exception of the simulated lung source, by uniformly mixing the radioactive material into a polyester resin matrix. The spiked matrix is then poured into a plastic container. Each plastic container is appropriately sized and held in an appropriate position by a masonite jig. Thus, simulating the principal organs of man. The simulated lungs are constructed by absorbing the radioactive material into shaped cellular foam. The foam is then sealed by wrapping in fiberglass cloth and covered with several coats of polyester resin. These sources are used to standardize a chair type whole body counting system. The assigned source model designation are as follows:

<u>Model No.</u>	<u>Description</u>
BNMI-P0	Entire phantom set including inserts
BNMI-P1	Neck phantom with thyroid insert
BNMI-P2	Chest phantom with lung inserts (2)
BNMI-P3	Trunk phantom with kidney inserts (2), liver insert (1), and GI insert (1)
BNMI-P4	Thigh phantom with muscle/bone inserts (2)
BNMI-P5	Whole body phantom (2) consist of 2-20 liter nalgene jugs filled with spiked polyester resin.

The replacements of individual sources may be ordered by the user. These are designated as follows:

<u>Model No.</u>	<u>Description</u>
BNMI-P1-1	Thyroid Insert (1) - 300 cc volume
BNMI-P2-1	Lung inserts (2) - 1800 cc volume each
BNMI-P3-1	Kidney inserts (2) - 150 cc volume each
BNMI-P3-2	Liver insert (1) - 1500 cc volume
BNMI-P3-3	GI tract insert (1) - 1000 cc volume
BNMI-P4-1	Thigh muscle/bone insert (2) - 800 cc volume each

The manufacturer reserves the flexibility to vary or combine isotopes and activities in each source to suite the unique needs of a customer. However, the manufacturer clearly states that no single activity will exceed the activity limits addressed on the front page of this registration sheet.

LABELING:

Each source/phantom is labeled in accordance with Section 20.203, 10 CFR Part 20.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-188-S-101-S

DATE: SEP 22 1993

PAGE 3 OF 4

SOURCE TYPE: Whole Body Counting Calibration Sources

DIAGRAM:

See attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The sources will be used in whole body counters and by personnel trained to handle the equipment and the sources. Examples of users of these sources would be, power companies, universities, hospitals, all of whom are specifically licensed.

PROTOTYPE TESTING:

The manufacturer indicated that the sources they produce are larger in size but are very similar in construction to calibration sources manufactured by New England Nuclear (NEN). NEN uses a similar resin solidification method to make some calibration standards.

Each source is tested to ensure proper solidification of the polyester resin and for uniform distribution of the radioactive material. The manufacturer cut open a source and performed a removable contamination test, the test yielded, on several occasions, a removable activity of less than 0.001 microcurie.

Given this above data and the quantity of radioactive material involved, the manufacturer reports no probability of a release that would cause significant radiation exposures.

EXTERNAL RADIATION LEVELS:

The manufacturer submitted dose rates for a source containing 1 microcurie of Cesium-137 and 0.9 microcurie of Cobalt-60.

<u>Distance</u>	<u>Dose rate in mrem/hr</u>
Contact	0.2
5 centimeters	0.1
30 centimeters	<0.01
100 centimeters	<0.01

QUALITY ASSURANCE AND CONTROL:

The manufacturers quality control program consists of the following:

- o 100% check of all materials used in the construction of the source.
- o 100% check on the activity of radioactive material used in each source.
- o 100% check of complete solidification of the spike resin.
- o 100% check on uniform distribution of the radioactive material within the resin matrix.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-188-S-101-S

DATE:

SEP 23 1983

PAGE 4 OF 4

SOURCE TYPE: Whole Body Counting Calibration Sources

QUALITY ASSURANCE AND CONTROL (Cont'd):

- o 100% removable contamination survey.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- o The sources shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- o Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- o The source is exempt from the six month leak test interval when the source contains a 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- o This registration sheet and the information contained within the references shall not be changed or transferred without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information cited below, that similar products are presently distributed and that source activities are within the exempt quantities specified in schedule B Section 30.71, 10 CFR 30, we conclude that the source designs are acceptable for licensing purposes.

Furthermore, we conclude that the source would be expected to maintain their containment integrity for normal conditions of use and that in accidental conditions such as a fire, it is unlikely that an individual would receive an exposure in excess of the maximum permissible body burden limits.

REFERENCES:

The following supporting documents for the calibration sources are hereby incorporated by reference and are made a part of this registry document:

- o Bio-Nuclear Measurements, Inc. application dated June 29, 1983, and letter dated August 23, 1983, with enclosures thereto.

ISSUING AGENCY: U.S. Nuclear Regulatory Commission

SEP 23 1983

Date:

Reviewer:

[Signature]

Date:

SEP 23 1983

Concurrence:

[Signature]

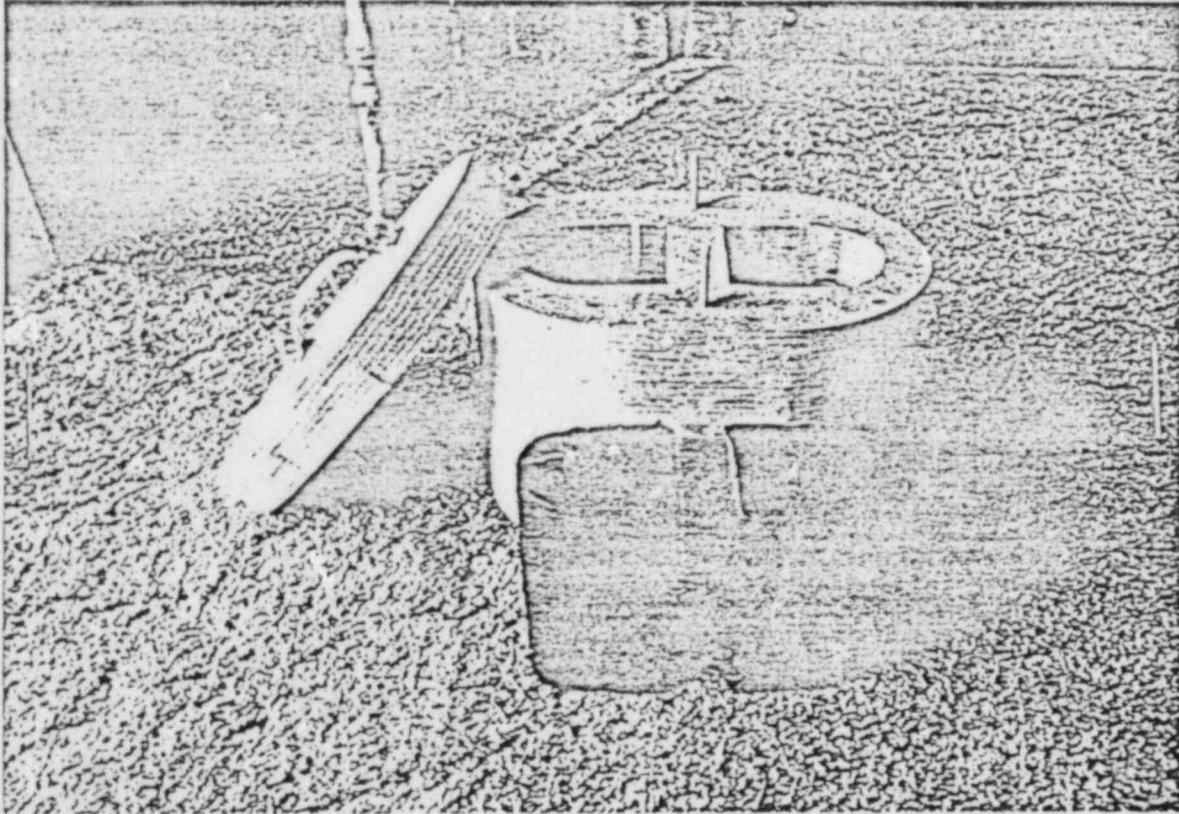
BIO-NUCLEAR MEASUREMENTS, INC.

P. O. Box 445

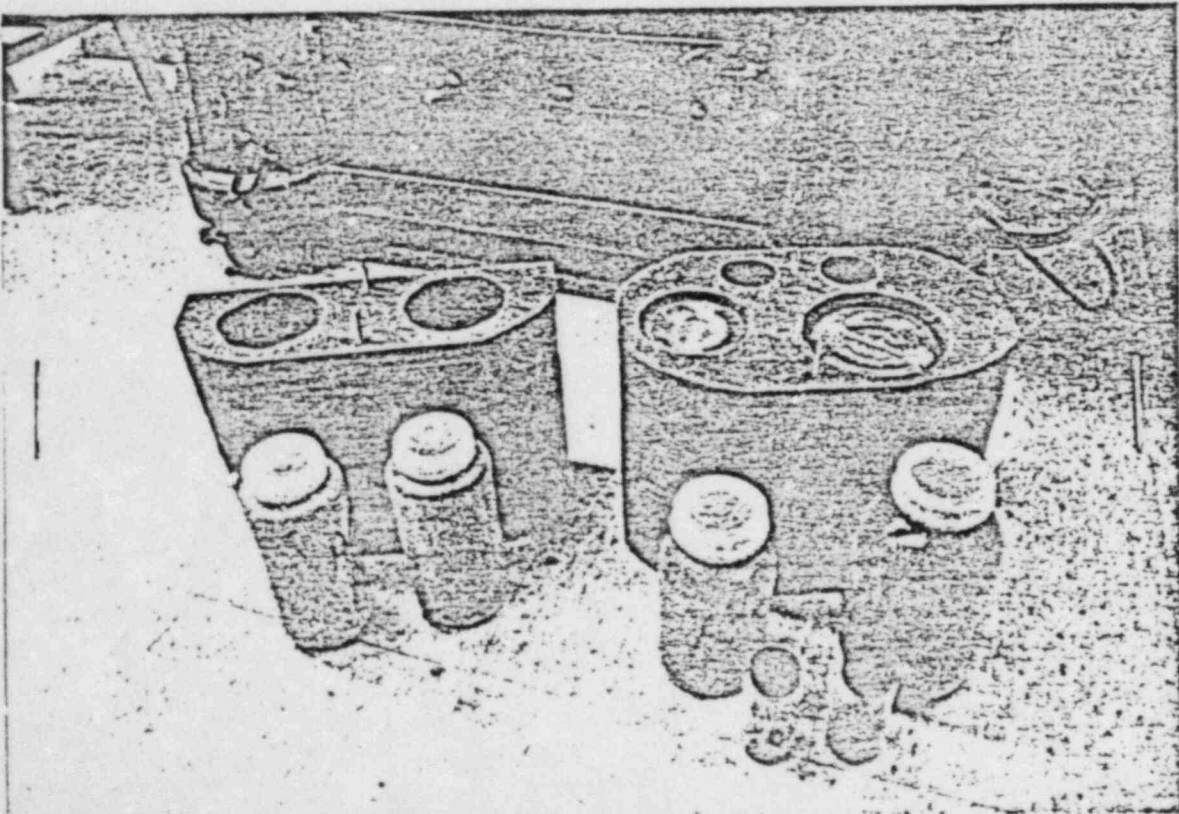
IPSWICH, MASSACHUSETTS 01938

F. X. MASSE
617-245-6600

M. M. BOLTON, JR.
617-356-3825



↑
SIMULATED LUNGS



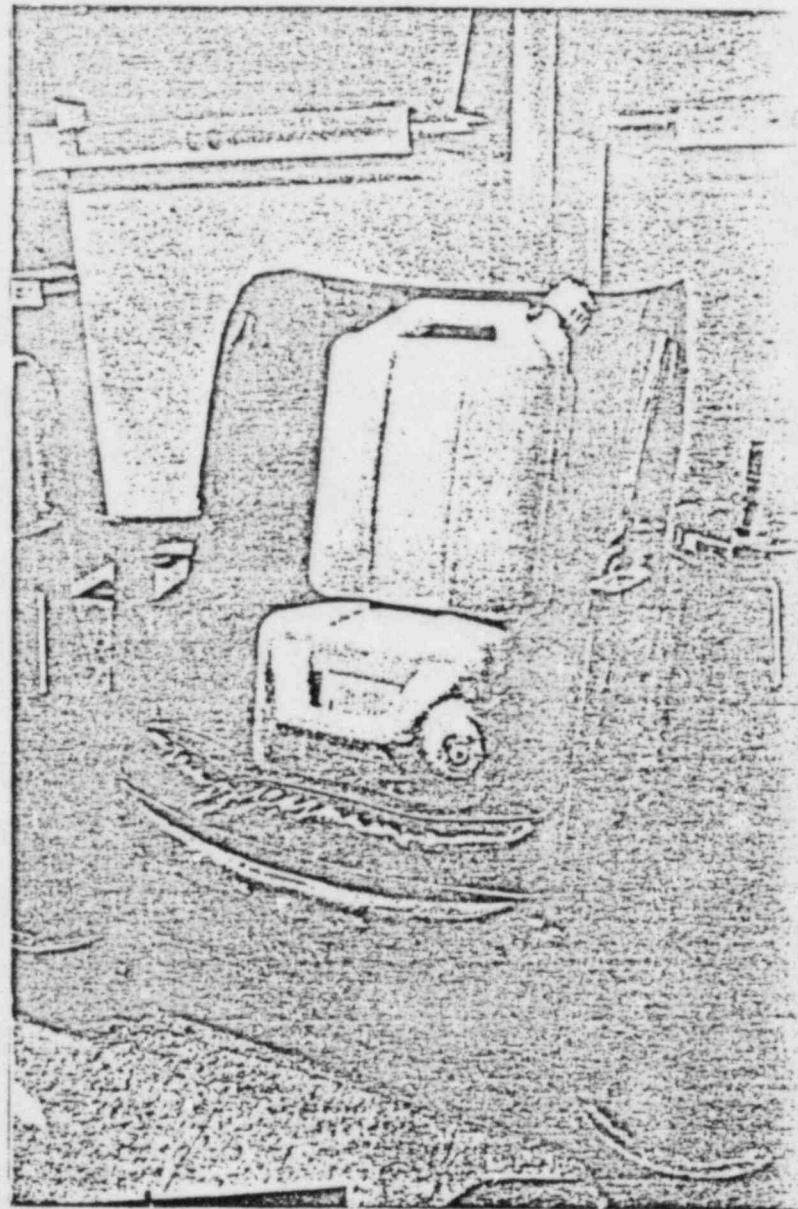
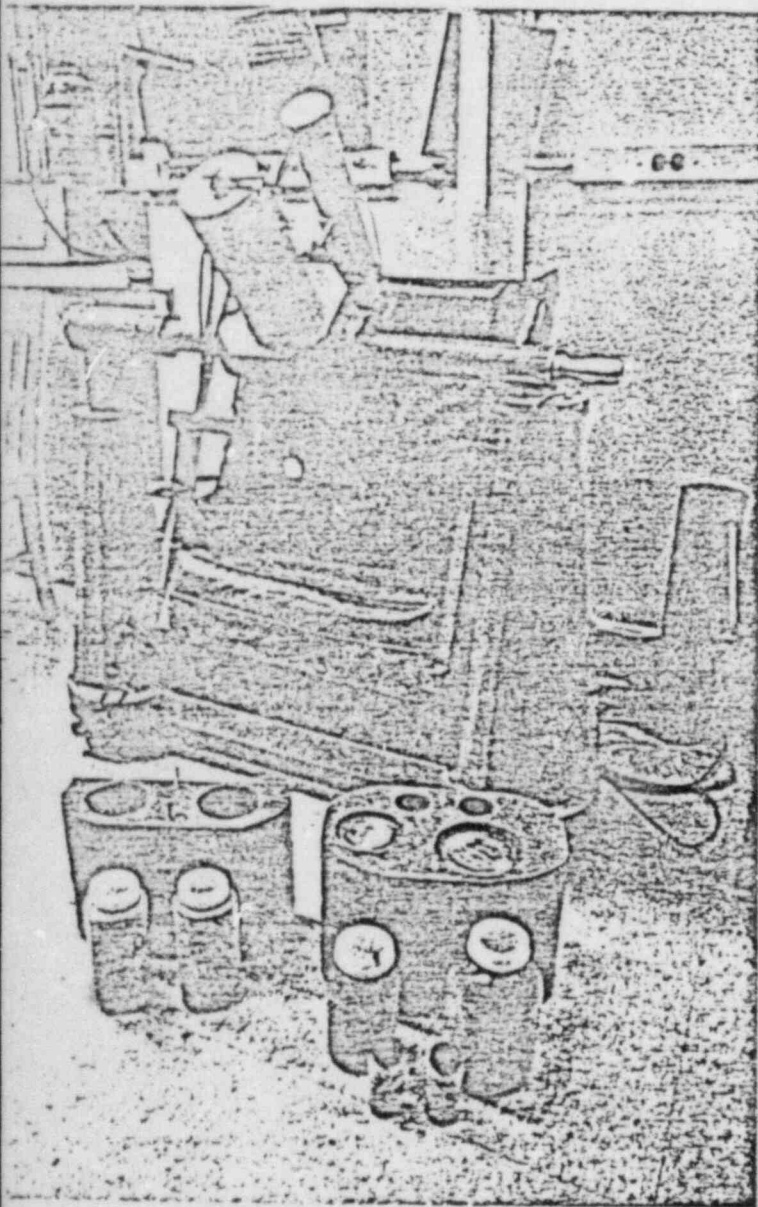
↓
SIMULATED THIGH SECTION

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SIMULATED GI TRACT, LIVER
KIDNEYS


BIO-NUCLEAR MEASUREMENTS, INC.

P. O. Box 445

IPSWICH, MASSACHUSETTS 01938

F. X. MASSE
617-245-6600M. M. BOLTON, JR.
617-356-3825

WHOLE ↑ BODY
SIMULATION

		CAUTION RADIOACTIVE MATERIAL	
Isotope _____		Date _____	
Activity _____		_____	
Physical Form _____		_____	
Radiation Level Outside Container			
_____ mrad/hr	_____ at	_____ cm	_____

← Example of Label
assigned to the products.