

REGISTRY OF RADIOACTIVE SEALED SOURCE AND DEVICES
SAFETY EVALUATION OF DEVICES

NO: NY-1271-S-101-S
(Supercedes NR-446-S-102-S)

DATE: December 14, 2006

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SOURCE TYPE: Gaseous Light Source

MODEL: 400/1, 400/2, 400/3, 400/4, 400/5, 400/6

DISTRIBUTOR: mb-microtec USA, Inc.
908 Niagara Falls Boulevard
PO Box 1174
North Tonawanda, NY 14120

MANUFACTURER: mb-microtec ag
Freiburgstasse 634
3172 Niederwangen
Switzerland

ISOTOPE:

MAXIMUM ACTIVITY

Hydrogen-3

1.85 TBq (50 Ci)

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (W) Self Luminous Light Source

CUSTOM DEVICE: _____ YES ___X___ NO

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SOURCE TYPE: Gaseous Light Source

<u>MODEL #</u>	<u>DESCRIPTION</u>
400/4	<u>Disk Sources</u> (D) Diameter (Min) 10 mm (D) Diameter (Max) 70 mm (H) Height (Min) 1.4 x D (H) Height (Max) ½ x D (T) Thickness of the Wall 0.2 x H → 0.3 x H
400/5	<u>Spherical Sources</u> (D) Diameter (Min) 10 mm (D) Diameter (Max) 70 mm (T) Thickness of the Wall 0.1 x D → 0.3 x D
400/6	<u>ARC Sources*</u> (A) Arc (Min) 15° (A) Arc (Max) 330° (Rr) Radius (Min) = 3 x (H) Height (Rr) Radius (Max) = 100 x (H) Height

*These sources are constructed by bending a Model 400/1 → 4 source design to the required arc. Therefore the wall thickness is commensurate with the requested source design model number.

LABELING:

Labeling of the individual glass source is impractical. The sources are always used within a device/source holder. These components will bear labeling that is required by the regulatory authority authorizing distribution of the product. The licensees are informed on all data of interest to them such as activity, ANSI N540 classifications, and dimensional configuration with tolerances.

DIAGRAM:

See attachments 1, 2, 3, 4, 5, 6, and 7

CONDITIONS OF NORMAL USE:

The GTLS are used in device/source holders in a wide range of conditions. Refer to the appropriate device registration document for the specific conditions of use

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PROTOTYPE TESTING:

For Model numbers 400/1 → 6 the manufacturer reported an ANSI 540 classification of TAGC1444X44. "A" may be any of the digits 1 → 6 depending on source activity and intended usage determined by the following table.

<u>Tritium Source Activity</u>	<u>Intended Usage</u>	<u>Classification A</u>
< 50 mCi	Any	1
≥ 50 mCi but < 500 mCi	Any	2
≥ 500 mCi but < 5Ci	Fixed	3
	Mobile	4
≥ 5 Ci to 50 Ci	Fixed	5
	Mobile	6

It must be noted that the test level for temperature, thermal shock, reduced pressure, vibration, and emersion is achieved only when the source is suitably mounted on a substrate, which is not deformed under the test conditions. If installed on a device, the performance test level must be determined by actual tests on the device. In particular, the test level for impact (denoted "X") depends wholly on the device parameters, as a drop test cannot be performed on the bare glass source.

EXTERNAL RADIATION LEVELS:

Intact sources cause a dose commitment that is negligible in normal use of a device containing a GTLS.

QUALITY ASSURANCE AND CONTROL:

Mb-microtec inspects all incoming glass vessels, radioactive gas is certified by the shipper to have an isotopic purity of 94% and a maximum oxide content of 0.5%.

The manufacturer controls the content of radioactive materials by determination of internal volume and filling pressure. And using the specific activity provided by the gas supplier.

Finished sources are tested for:

- Proper dimensions
- Brightness
- Temperature and thermal shock
- Reduced pressure (prototype test)
- Discolorations (prototype test)
- Immersion (prototype test)
- Leakage test

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LIMITATIONS AND/OR CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- mb-microtec's U.S. consultant and U.S. representative is Mr. Lawrence Keating at (716) 694-2695.
- Products containing these light sources must be properly evaluated and licensed prior to the distribution of the product to the commercial market.
- This registration sheet and the information contained within the references shall not be changed without written consent of the New York State Department of Health, Bureau of Environmental Radiation Protection.

SAFETY ANALYSIS SUMMARY:

The United States Nuclear Regulatory Commission has previously reviewed and approved these sources for distribution to specific licensees under SS&D registry sheet number NR-446-S-102-S. Furthermore, thousands of these and similar GTLS have been distributed in various consumer products for more than three decades with no documented cases of adverse health effects to the users or members of the general public. In those recorded instances where devices containing GTLS have been severely damaged, doses to individuals in the vicinity or even to those actually handling the broken tubes have ranged from trivial to nonexistent.

Moreover, since the GTLS are to be distributed to specific licensees for incorporation into other devices, it will be the responsibility of those licensees to demonstrate to the regulatory body having authority that the products containing GTLS will maintain the integrity of the sources for the conditions of use specified for the products.

We therefore continue to conclude that the mb-microtec Model 400/1→6 source designs are acceptable for licensing purposes.

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REFERENCES:

The following supporting documents for the Model 400/1 → 6 source designs are hereby incorporated by reference and are made a part of this registry document:

- A. mb-microtec application dated November 15, 2004, with enclosures thereto.

ISSUING AGENCY:

N.Y.S. Department of Health
Bureau of Environmental Radiation Protection

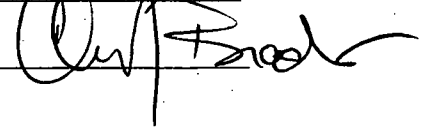
Date: 12/14/06

Date: 12/14/06

Reviewer:



Concurrence:



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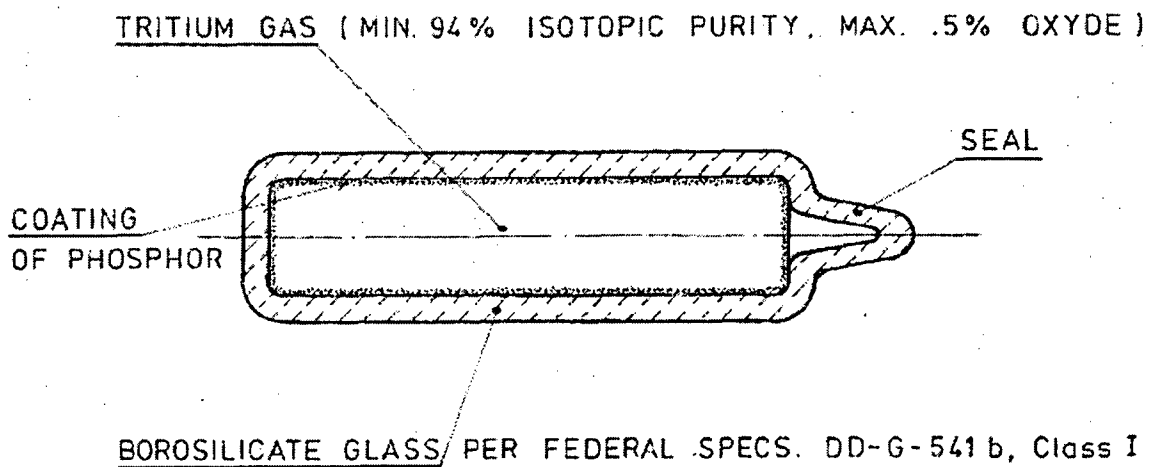
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ATTACHMENT: 1

CONCEPT AND MATERIALS SOURCES MODEL NR. 400



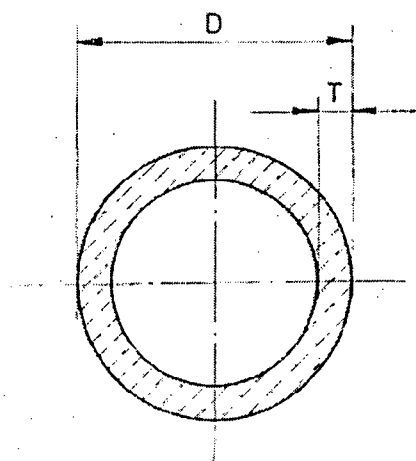
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ATTACHMENT: 2

ROUND SECTION CYLINDRICAL SOURCES MODEL NR. 400



LASER SEAL

$D_{\max.} = 7,5$

$D_{\min.} = 0,3$

$L_{\max.} = 95,0$

$L_{\min.} = 2,5 D$

$T = 0,1 D - 0,2 D$

HAND SEAL

$D_{\max.} = 25$

$L_{\max.} = 300$

DIMENSIONS : mm

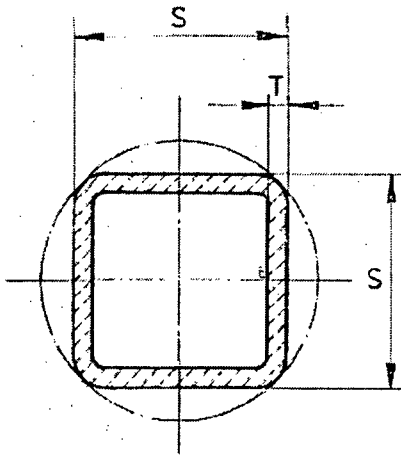
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ATTACHMENT: 3

SQUARE SECTION CYLINDRICAL SOURCES MODEL NR. 400



LASER SEAL

$$S_{\max.} = 5$$

$$S_{\min.} = 0,5$$

$$L_{\max.} = 95,0$$

$$L_{\min.} = 2,5 S$$

$$T = 0,1 S - 0,2 S$$

HAND SEAL

$$S_{\max.} = 15$$

$$L_{\max.} = 300$$

DIMENSIONS : mm

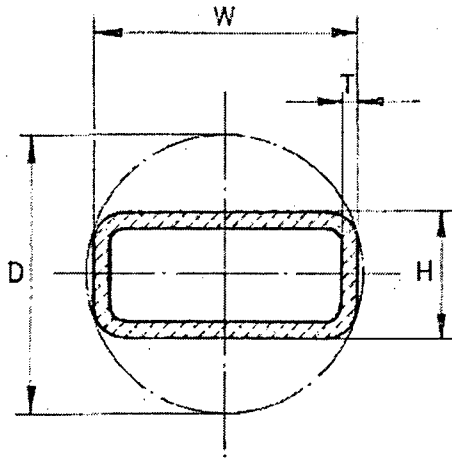
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ATTACHMENT: 4

RECTANGULAR SECTION CYLINDRICAL SOURCES MODEL NR. 400



LASER SEAL

HAND SEAL

$$D_{\max.} = 7,5$$

$$D_{\max.} = 25$$

$$D_{\min.} = 0,7$$

$$\frac{W}{H}_{\max.} = 5$$

$$L_{\max.} = 95,0$$

$$L_{\max.} = 300$$

$$L_{\min.} = 2,5 D$$

$$T = 0,1 D - 0,2 D$$

DIMENSIONS : mm

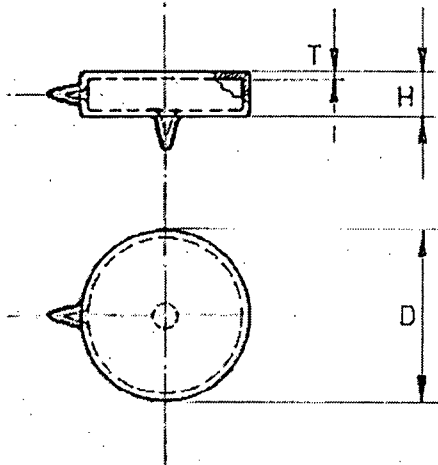
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ATTACHMENT: 5

DISC SOURCES MODEL NR. 400 (AXIAL OR RADIAL PIP)



$$D_{\max.} = 70$$

$$D_{\min.} = 10$$

$$H_{\max.} = \frac{1}{2} D$$

$$H_{\min.} = \frac{1}{4} D$$

$$T_{\max.} = 0,3 H$$

$$T_{\min.} = 0,2 H$$

DIMENSIONS : mm

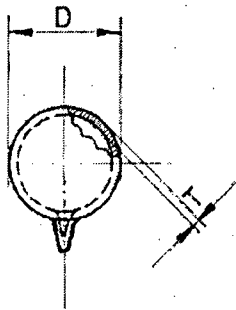
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ATTACHMENT: 6

SPHERICAL SOURCES MODEL NR. 400



$D_{\max.}$	=	20
$D_{\min.}$	=	6
$T_{\max.}$	=	0,3 D
$T_{\min.}$	=	0,1 D

DIMENSIONS : mm

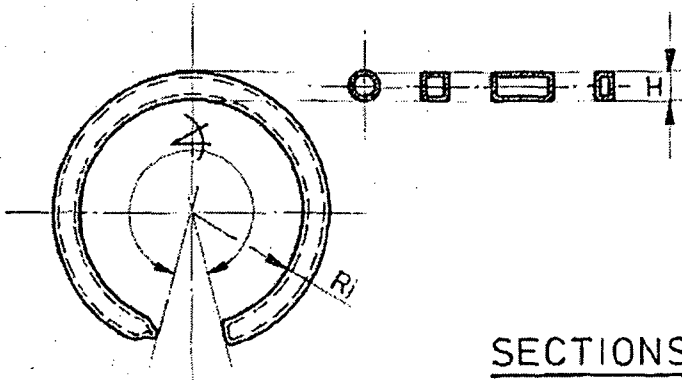
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ATTACHMENT: 7

ARC SOURCES MODEL NR. 400



$$\angle \text{ max.} = 330^\circ$$

$$\angle \text{ min.} = 15^\circ$$

$$Ri \text{ max.} = 100 H$$

$$Ri \text{ min.} = 3 H$$

SECTIONS : AS LASER AND HAND
SEALED CYLINDRICAL SOURCES