

From: Mary Ann Neel
To: John Jankovich
Date: Tue, Aug 31, 1999 10:34 AM
Subject: STANDARDS

John,

I have placed ANSI N 540-1975 on the Reference Desk for you to pick up at your convenience. ANSI N 540-1975, "Classification of Radioactive Self-Luminous Light Sources," was Reaffirmed and Redesignated in 1989 as : ANSI N 43.4-1975 (R1989). (It is also NBS Handbook # 116) in the NBS series.

I can't find that we purchased a copy of the Reaffirmed and Redesignated ANSI N 43.4. If we did, it must be lost. Anyhow, the full text of both the N540 and N43.4 standards is exactly the same. If you prefer that I mail it to you, let me know.

Have a good one!!!!

Mary Ann

Mail Envelope Properties (37CBE7ED.93F : 8 : 37876)

Subject: STANDARDS
Creation Date: Tue, Aug 31, 1999 10:34 AM
From: Mary Ann Neel

Created By: TWFN_DO.TWF2_PO:MAN

Recipients

Post Office TWFN_DO.twf4_po
JPJ2 (John Jankovich)

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

August 31, 1999

Mr. Lawrence Keating, President
mb-microtec (USA)
P.O. Box 1174
North Tonawanda, NY 14120-9174

Dear Mr. Keating:

This letter is in response to your application dated July 1, 1999, requesting to add Model Nos. 100/4 and 100/5 timepieces to your registration certificate (R-446-D-103-E). We are in the process of evaluating your request. In order to continue our evaluation, we need additional information on the following issues:

1. Please submit a technical description of and engineering drawings for the Model 100/5 timepiece. The description and the drawings should be similar to those which you have provided for the Model 100/4 in your application.
2. Please provide overview drawings, with major dimensions, for both Model 100/4 and 100/5. The overview drawings should be similar to those in Attachments 1-4 of the registration certificate regarding the other models of your timepieces.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-7904 or Ms. Michele Burgess at (301) 415-5868.

Sincerely,

A handwritten signature in cursive script, reading "John P. Jankovich".

John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards



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Sincerely,

original signed by J. Jankovich
John P. Jankovich, Ph.D., Sr. Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Distribution:

IMNS r/f

SSD-99-46

NE01

NR-446-D103-E

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OFFICE	IMNS	<i>PP</i>	<i>E</i>					
NAME	JJankovich							
DATE	08/31	1999						

OFFICIAL RECORD COPY

Safety review
8/13/99
J. Jankovich

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: Lawrence Keating President mb-Microtech (USA) P.O. Box 1174 Tonawanda NY 14120		Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Lawrence Keating President 716 694-2695	
The Applicant is (check one): <input type="checkbox"/> Custom User <input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Distributor <input type="checkbox"/> Manufacturer and Distributor		If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: mb-microtec ag Freiburgstrasse CH-3172 Niederwangen Switzerland	
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: /		Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: /	
Model Number: 100/4 100/5		Principal Use Code (see Appendix F): W	
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):		For Use by: <input type="checkbox"/> Specific Licensees Only <input type="checkbox"/> General Licensees Only <input type="checkbox"/> Both Specific and General Licensees <input checked="" type="checkbox"/> Persons Exempt from Licensing	
Leak-Test Frequency: N/A		Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 32.22	
<input type="checkbox"/> Periodic Leak-Testing is Not Required <input type="checkbox"/> 6 Months <input type="checkbox"/> Attached is justification for a leak test frequency of greater than 6 months		Radionuclides and Maximum Activities (including loading tolerance): H-3	

CERTIFICATION:

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

Certifying Officer — Typed Name and Title

Signature:

Date:

CHECKLIST

Registration Certificate Holder: *NR-446-D-103-E*

Model: *100/4 100/5*

DESCRIPTION	OK/DEF	COMMENTS	
DESCRIPTION/CONSTRUCTION			
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	✓		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	✓		
Assembly methods (screw, welds, etc.); verify integrity		} <i>see previous approvals</i>	
Source mounting (size and integrity) and security			
Is source ANSI classification sufficient (from ANSI N542-1977):		<i>ANSI N450; T2GC122222</i>	
Radiography - Unprotected	43515		
Radiography - In Device	43313		
Medical - Radiography	32312		
Medical - γ Teletherapy	53524		
γ Gauges - Unprotected	43333		
γ Gauges - In Device	43232		
β Gauges, Low Energy γ Gauges, or X-ray fluorescence	33222		
Oil Well Logging	56522		
Portable Moist/Density	43333		
Neutron Applications	43323		
γ Irradiators (II, III, IV)	43424		
γ Irradiators (I)	43323		
Static Eliminators	22222		
Smoke Detectors	32222		
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	<i>N/A</i>	}	
On-Off indicators (description, qty., location)	<i>N/A</i>		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	<i>NA</i>		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	✓		
Shielding efficiency and integrity	✓		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	<i>NA</i>		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	<i>NA</i>		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	✓		<i>←</i>

APPENDIX C

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
LABELING		
Copy of label	}	<i>same as previous models</i>
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	NA	
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	✓	
Actions to be taken when product reaches end of its working life.	NA	
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	✓	
How the device will be used	✓	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	NA	
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)	✓	
Tests results	✓	
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.		
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	NA	
Conditions: including environments, scatter (product in beam), and use of guards and shields		
Distance from source/surface (per ANSI 538-1979)		
Shutter Open and Closed/Source Shielded		
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.		

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION	OK/DEF	COMMENTS
QUALITY ASSURANCE		
Materials, subassemblies, services	}	<i>see previous reviews</i>
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing	}	<i>NA</i>
Inherent shielding, inaccessibility		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers		
Mounting integrity		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	<i>NA</i>	
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys	}	<i>NA</i>
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations		

APPENDIX C

CHECKLIST

Registration Certificate Holder:

Model:

DESCRIPTION				OK/DEF	COMMENTS
SERVICING					
The following activities may be performed by the persons indicated:					
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant	} NA	
Installation					
Relocation					
Maintenance					
Repair					
Source Exchange					
Calibration					
Leak Testing					
Radiation Survey					
Training					
FOREIGN VENDORS					
Drop ship				} see section "Lot Testing of Finished Timepieces"	
Who and where is source installed					
Leak test and radiation surveys					
QA in the U.S.					