

MATERIALS LICENSE

Amendment No. 04

ORC

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. mb-microtec, Inc. (USA)

2. P.O. Box 1174

North Tonawanda, New York 14120-9174

In accordance with letter dated
January 11, 1996,3. License Number 31-23712-01E is amended in
its entirety to read as follows:

4. Expiration Date April 30, 2003

5. Docket or
Reference No. 030-304336. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This License

A. Hydrogen-3

A. Sealed light sources
mb-microtec
Models: 400/1, 400/2,
and 400/3A. Not applicable
(See Condition 10)

9. Authorized Use

Pursuant to Section 32.22, 10 CFR Part 32, the licensee is authorized to distribute wrist watches containing gaseous tritium light sources as specified in Condition 10 of this license to persons exempt from the requirements for a license pursuant to Section 30.19, 10 CFR Part 30, or equivalent provisions of the regulations of any Agreement State.

CONDITIONS

10. Luminous wrist watches may be distributed pursuant to Condition 14 F. of this license provided the amount of hydrogen-3 contained in each device does not exceed the amount specified in the following table:

Device ModelMaximum Activity per Device

100/1

100 millicuries in 1 to 20 sources

100/2

100 millicuries in 1 to 20 sources

100/3

100 millicuries in 1 to 20 sources

010112

11. This license does not authorize possession or use of licensed material.

12. The licensee may distribute only from its facility located at 908 Niagara Falls Boulevard, North Tonawanda, NY.

o/i
MLDD
cytoRI

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

31-23712-01E

Docket or Reference Number

030-30433

Amendment No. 04

CONDITIONS

(Continued)

13. The licensee shall file periodic reports as specified in Section 32.25(c), 10 CFR Part 32.
14. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated February 11, 1988;
 - B. Letter dated June 27, 1991;
 - C. Letter dated August 30, 1991;
 - D. Application with letter dated March 23, 1993;
 - E. Letter dated November 10, 1994; and
 - F. Registration Certificate NR-0446-D-103-E.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DATE: December 18, 1996

BY:

ORIGINAL SIGNED BY

Susan L. Greene
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards
Washington, DC 20555

L. Keating

-2-

5. Submit a complete renewal application (with proper fee) or termination request (no fee required) at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 90 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

If you have any questions, please feel free to contact me at (301) 415-7843.

Sincerely,

ORIGINAL SIGNED BY

Susan L. Greene
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Docket No. 030-30433

Enclosure: Amendment No. 04

cc: Rita Aldrich, Principal Radiophysicist
Radiological Health Unit
Division of Safety and Health
New York State Department of Labor
New York State Office Campus
Building 12, Room 457
Albany, NY 12240

DISTRIBUTION:
License File 31-23712-01E
IMAB r/f
SBaggett

DOCUMENT NAME: G:\MBMICRO.CJB

To receive a copy of this document, indicate in the box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

OFFICE	IMAB:NMSS								
NAME	SLGreene:cjb								
DATE	12/18/96								

OFFICIAL RECORD COPY

December 18, 1996

mb-microtec, Inc. (USA)
ATTN: Lawrence Keating
President
P.O. Box 1174
North Tonawanda, New York 14120-9174

Dear Mr. Keating:

Enclosed is Amendment No. 04 amending NRC License No. 31-23712-01E in its entirety.

Please review the enclosed license carefully and be sure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections and answers can be provided.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, to include the following:

1. Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

2. Distribute only those products containing radioactive material which are specifically authorized in your license.
3. Notify NRC in writing within 30 days of any change in mailing address (no fee is required if the location of radioactive material remains the same).
4. Request and obtain appropriate amendments if you plan to change control or ownership of your organization, change locations of distribution of products containing radioactive material, or make any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with NRC. A license fee may be charged for the amendments if you are not in a fee-exempt category.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 17, 1996

MEMORANDUM TO: Susan Greene, Health Physicist
Commercial Section

FROM: Chris L. Brown, General Engineer
Sealed Source Safety Section

SUBJECT: SSD TECHNICAL ASSISTANCE REQUEST:
MB-MICROTEC
CONTROL NO. - N/A
LICENSE NO. - 31-23712-01E

In response to a technical assistance request from the Commercial Section dated January 18, 1996 for the need of a SSD review associated with mb-microtec's license application, we have completed the SSD review. Please find attached a copy of registration certificate NR-446-D-103-E.

If you have any questions, please contact me at 415-5787 or Mr. Douglas Broaddus at 415-5847.

Attachment: As stated

cc: Skimberley, LFDCB
C. Boyle

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 1 OF 6

DEVICE TYPE: Wrist Watch

MODEL: 100/1, 100/2, 100/3 (formerly P375, P550, P600, P650)

DISTRIBUTOR: mb-microtec (USA)
P.O. Box 1174
North Tonawanda, NY 14120

MANUFACTURER: mb-microtec ag
Freiburgstrasse
CH-3172 Niederwangen
SWITZERLAND

SEALED SOURCE MODEL DESIGNATION: Mb-Microtec Model: 400/1
400/2
400/3

ISOTOPE:

Hydrogen-3

MAXIMUM ACTIVITY:

100 mCi (3.7 GBq) in 1 to 20 sources

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (W) Self-Luminous Applications

CUSTOM DEVICE: _____ YES _____ X _____ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 2 OF 6

DEVICE TYPE: Wrist Watch

DESCRIPTION:

Models 100/1, 100/2, and 100/3 wrist watches use gaseous tritium light sources to enable the wearer to read the watch dial in low or no light situations. These devices incorporate design and construction features of the former Models P375, P550, P600, P650, and have been redesignated as the Models 100/1, 100/2, and 100/3 to distinguish between the watch type for simplicity purposes. Model 100/1 watches are analog timepieces with mechanical or quartz movement. Model 100/2 watches are digital timepieces with liquid crystal display (LCD). Model 100/3 watches are timepieces with analog reading and LCD display.

Previously, the watches were approved for up to 78 mCi (2.9 GBq) tritium in 15 mb-microtec Model 400/1 gas sources (12 sources in the hour positions, one source in each of the hands) or 83 mCi (3.1 GBq) tritium in 16 sources (one additional in a rotating bezel). The Models 100/1, 100/2, and 100/3 may contain up to 100 mCi (3.7 GBq) tritium in 1 to 20 mb-microtec Model 400/1, 400/2, or 400/3 sources. Digital LCD watches may only need one source for illumination where additional sources may be needed to illuminate additional functions of newer watch styles. However, only Model 400/1 sources will be used for illumination of the watch hands (analog reading). The design and construction of specific watches within each Model designation may vary, but will be in accordance with the designs of the former Models P375, P550, P600, P650, including:

- Materials for the case and bottom plate may include one or more of the following: brass, stainless steel, titanium, gold, platinum, injection molded plastic and polymers. Case bottoms may be snap-on, screw-on, or attached by screws.
- Acrylic, sapphire, and mineral glass crystals, secured by a press-fit stainless steel ring. Removal of the crystal requires a special tool normally available only in watch factories or repair shops.
- Unless the watch is destroyed or the crystal removed, there is no access to the sources. Although the case bottom may be removed, the design and construction is such that access to the sources on the hands and dial is not possible without destruction of the watch. For quartz analog modules, a hatch is used in the case bottom to change batteries.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 3 OF 6

DEVICE TYPE: Wrist Watch

DESCRIPTION: (Cont'd)

- Watch hands are specially designed to permit attaching a source from below by a non-hardening adhesive.
- Sources are attached to the dial by either placing them into milled slots and securing them with a silicone adhesive, or by a source retaining ring that, when bonded to the watch dial, secures the sources in place.
- Watches may contain a rotating bezel, with or without a light source. Light sources mounted external to the case and crystal (such as in a bezel) will be secured and protected from damage by a metal housing and crystal, as described above.

DIAGRAM:

See attachments 1-4.

LABELING:

The dial face is marked with a "T" (for tritium) as recommended in "Radiation Protection Standards for Gaseous Tritium Light Devices" Section 7 - Marking and Labeling (Nuclear Energy Agency, OECD, 1973). The bottom is marked by etching with "3H" for the contained tritium and with "mbm" for the manufacturer's logo.

CONDITIONS OF NORMAL USE:

The expected useful life of the watch is 10 years. The watch will be subjected to environs allowing human occupancy.

PROTOTYPE TESTING:

The manufacturer has subjected prototype timepieces to the requirements of ANSI N540. The prototype timepieces passed the requirement for classification T2GC122222.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NQ: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 4 OF 6

DEVICE TYPE: Wrist Watch

EXTERNAL RADIATION LEVELS:

External radiation dose rates are minimal and need not be considered. Primary tritium beta rays do not penetrate the GTLS glass enclosure. Traces of very soft (a few keV) secondary Bremsstrahlung are absorbed by the watch case.

Potential doses for LCD watches with GTLS backlighting of the display have been estimated and are reported in NUREG/CR-0215, ORNL/NUREG/TM-255 "Estimates of Potential Radiation Doses from Wristwatches Containing Tritium Gas" by McDowell-Bayer and O'Donnell.

QUALITY ASSURANCE AND CONTROL

mb-microtec has specified the following quality control test on production lots of wrist watches.

SOURCE TESTING

All (100%) of the sources used are tested for tritium leakage and must pass the soaking test per ANSI N540, section 8.3.2. Lots of 1 to 20 sources are accepted when total leakage is less than 50 nCi (1.85 kBq) in 24 hours.

LOT TESTING OF FINISHED WATCHES

All finished watches are subjected to a 100% visual inspection for missing, dislodged, dim, or black light sources. In addition, a random sample of each finished lot is subjected to the following: a visual inspection for the "H-3" and "mbm" on the watch; a drop test from 3.28 feet (1 m) to a steel plate, then a visual inspection for missing, dislodged, dim, or black light sources; and a soak test per section 8.3.2. of ANSI N540 to a maximum of 50 nCi (1.85 kBq) in 24 hours. Any failure will trigger a 100% inspection of the lot for the defect.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The import of the device is subject to the provisions of Section 110.27, 10 CFR Part 110.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 5 OF 6

DEVICE TYPE: Wrist Watch

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (Cont'd)

- These devices may be distributed to persons exempt from the requirements for a license as defined in Section 30.19 if manufactured and initially transferred in accordance with a specific license issued pursuant to 10 CFR, section 32.22. This license shall only be issued by the NRC.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information submitted, we conclude that Model 100/1, 100/2, and 100/3 (formerly P375, P550, P600, P650) wrist watch designs are acceptable for licensing purposes. Furthermore, we conclude that these watch models would be expected to maintain their integrity under the conditions associated with their intended use.

REFERENCES:

The following supporting documents for the Models 100/1, 100/2, and 100/3 (formerly P375, P550, P600, P650) wrist watch designs are hereby incorporated by reference and are made a part of this registry document.

- mb-microtec's letters dated June 19, 1987, July 23, 1987, June 27, 1991, August 30, 1991, October 20, 1993, January 13, 1994, November 10, 1994, December 21, 1994, July 18, 1995, January 11, 1996, and September 5, 1996, with enclosures thereto.
- mb-microtec's faxes dated February 14, 1995 and September 17, 1996, with enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

PAGE 6 OF 6

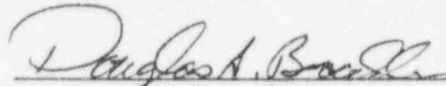
DEVICE TYPE: Wrist Watch

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: October 1, 1996

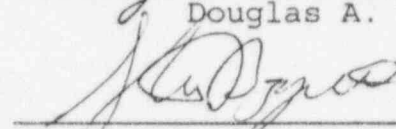
Reviewer:



Douglas A. Broadus

Date: October 1, 1996

Reviewer:



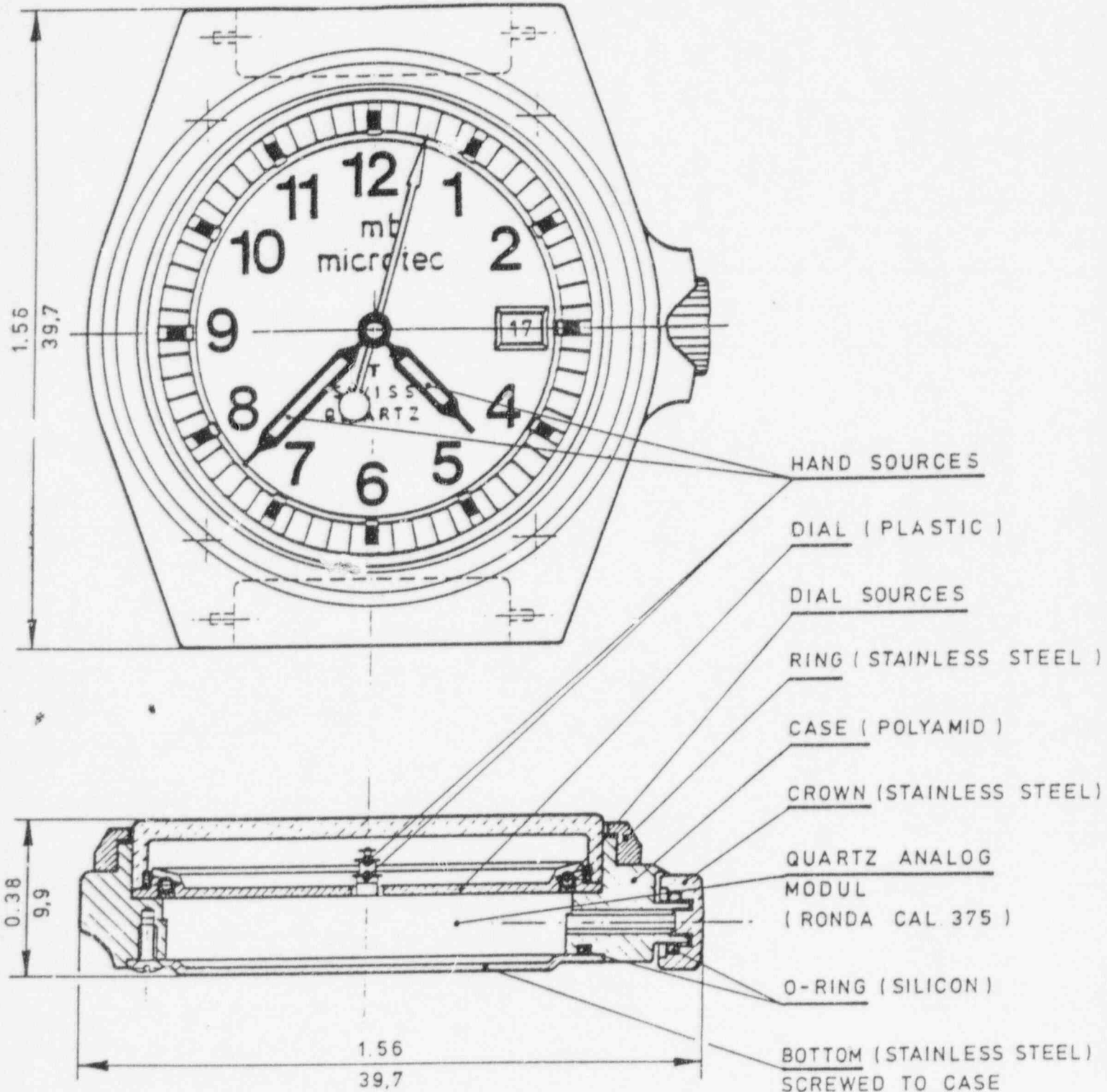
Steven L. Baggett

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

ATTACHMENT 1



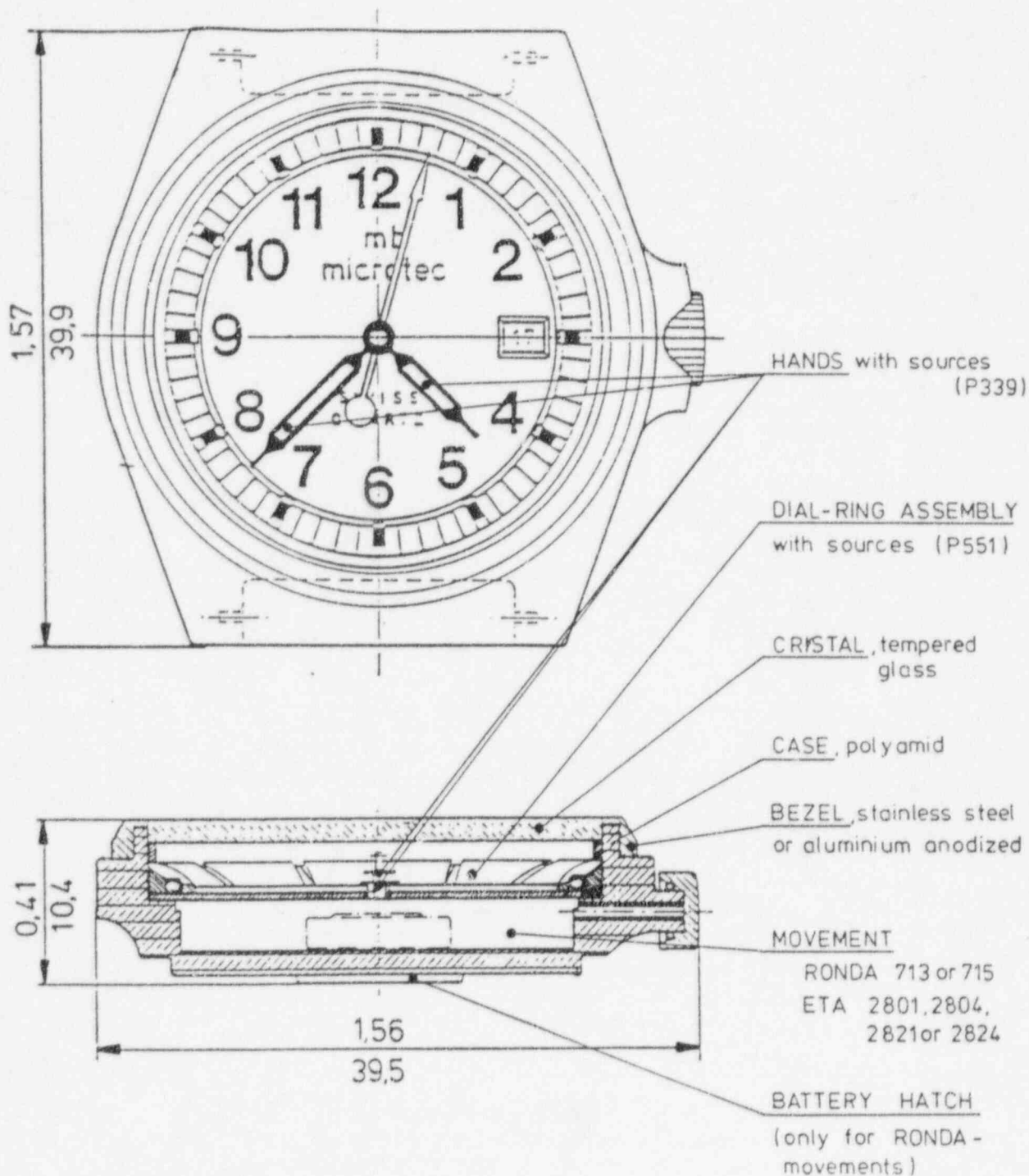
Former Model 375 Wrist Watch

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

ATTACHMENT 2



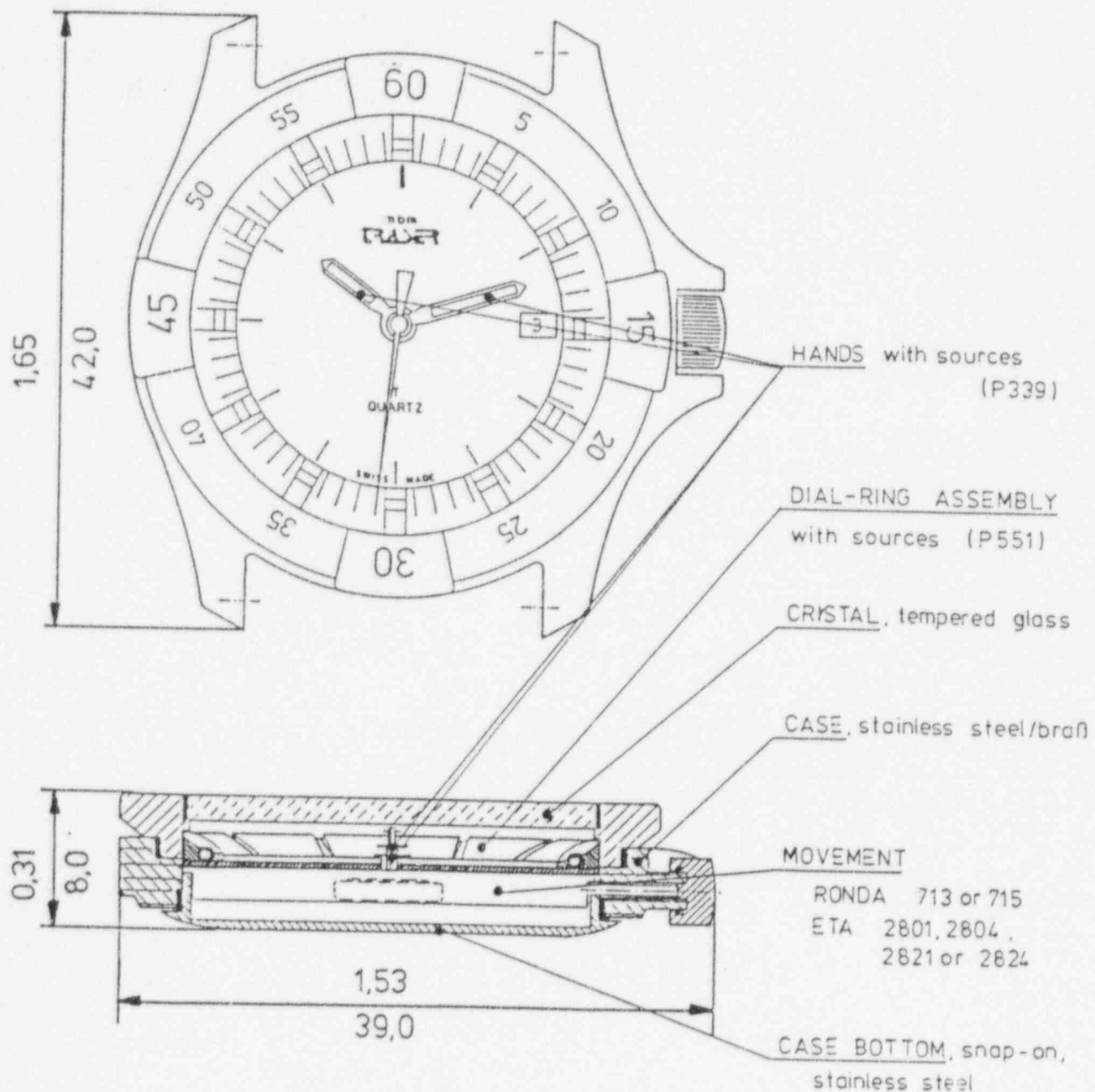
Former Model 550 Wrist Watch

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

ATTACHMENT 3



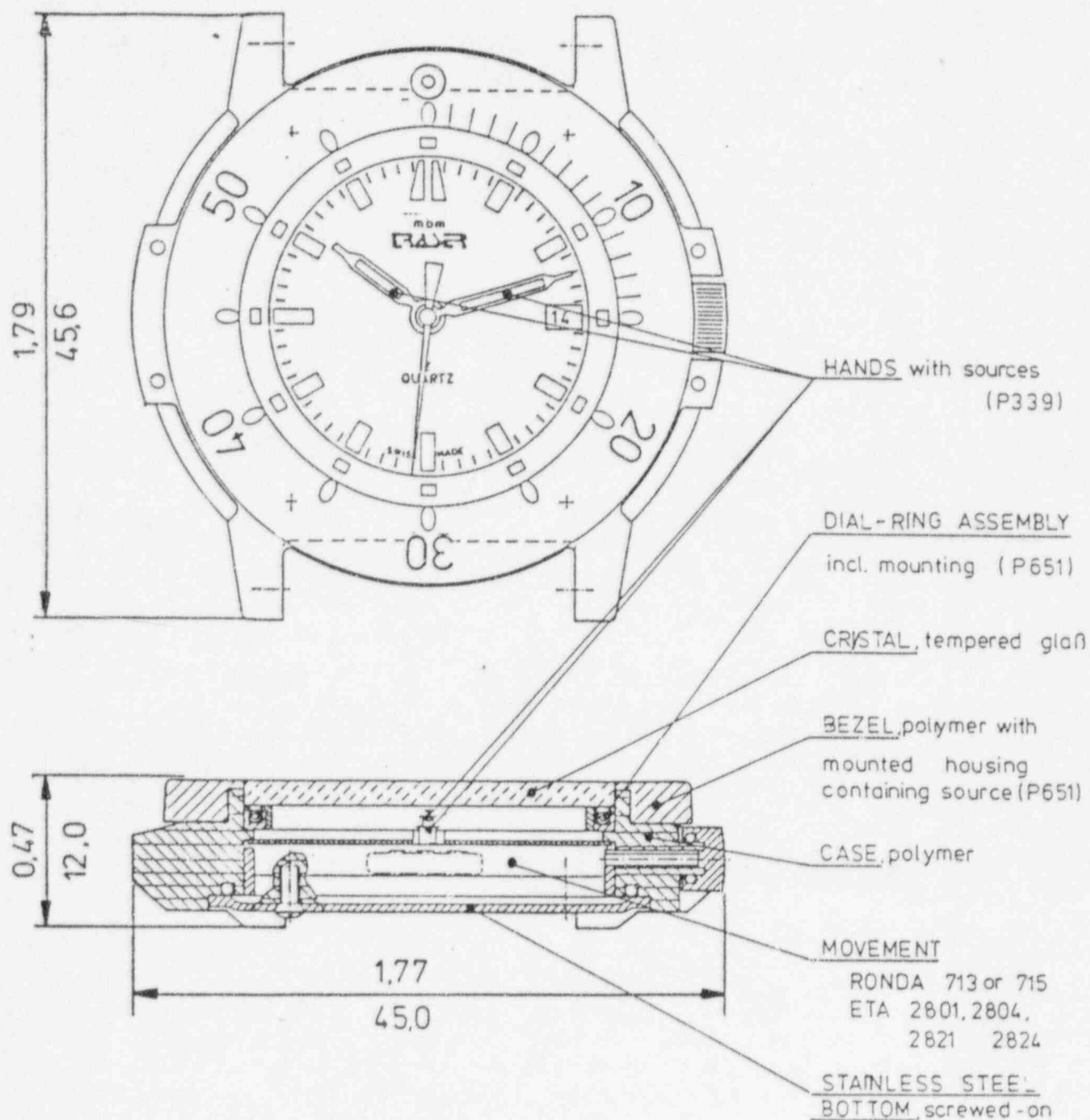
Former Model 600 Wrist Watch

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
 SAFETY EVALUATION OF DEVICE
 (RENDERED IN ITS ENTIRETY)

NO: NR-0446-D-103-E

DATE: October 1, 1996

ATTACHMENT 4



Former Model 650 Wrist Watch

mb-microtec

mb-microtec (USA)
P.O. Box 1174
North Tonawanda, New York 14120-9174
(716) 694-2695

February 29, 1996

United States Nuclear
Regulatory Commission
Washington, DC 20555

Att: Carolyn Boyle, Licensing Assistant
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

Re: Control No. 021506 / Docket No. 030-30433

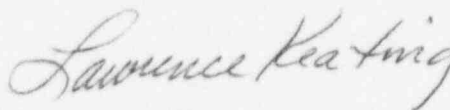
Distribution of product under License No. 31-23712-01E
from January 1, 1995 through December 31, 1995.

<u>WATCH MODEL</u>	<u>TTL UNITS</u>	<u>ACTIVITY/UNIT</u>	<u>TOTAL ACTIVITY</u>
P550	955	.078 Ci	74.49 Ci
P600	6	.078 Ci	.48 Ci
P650	9631	.083 Ci	799.37 Ci

TOTAL UNITS: 10592

TOTAL ACTIVITY TRITIUM: 874.33

Sincerely,



Lawrence Keating
President

LK:kjw

LICENSE FEE REQUIREMENTS

ATTN: S. Kimberley, MST-GE10
LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

301 415 6096

MB - Microtec (USA)

ATTN: Lawrence Keating
President

P.O. Box 1174

North Danamanda, NY 14120-9174

TYPE OF ACTION

NEW LICENSE

RENEWAL OF LICENSE

☒ AMENDMENT TO LICENSE

REQUESTED DATE

1/11/96

LICENSE NUMBER

31-23712-01E

CONTROL NUMBER

021810

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
34	\$	\$	\$ 990
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(S) DUE \$ 990
PAYMENT RECEIVED \$
AMOUNT DUE \$ 990

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____

☐ Your request was combined, prior to review, with your _____ request, Control No. _____

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

☐ INSUFFICIENT FUNDS☐ ACCOUNT CLOSED☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

SIGNATURE -- LICENSE FEE ANALYST

Sandra Kimberley

DATE

2/5/96

mb-microtec

C. Boyle
FVI
Paul 1/18/46
my seal license
mb-microtec (USA)
P.O. Box 1174
North Tonawanda, New York 14120-9174
(716) 694-2695

030-30433

January 11, 1996

Mr. Steven Baggett
United States Nuclear Regulatory Commission
Washington, D. C. 20555

RE: NR-446-D-103-E / LICENSE #31-23712-01E

Dear Mr. Baggett:

The above registration and license cover watches with gaseous tritium light sources (GTLS) for distribution exempt from certain regulatory requirements. The first watch model was registered in 1987. Further models were added by amending the registration and license so that now a total of some eight models including variations thereof are covered.

Accumulated experience suggests that a further amendment is indicated which classifies the timepieces in general and extends the scope of the licensed products. By way of an example, it is of no particular interest from the radiological point of view how a watch case is designed, what its size and configurations are and what materials are used. Neither is it relevant what movement is used, be it a mechanical or electronic one, of brand A or B. It is rather the criteria as defined by the required prototype testing and quality control which determine the safety of the device in use and maintenance of source integrity.

With this in mind we have drafted the enclosed registry and wish to comment some of the guiding ideas.

1. Classification of time-measuring instruments: All concerned devices, worn or stationary, do not differ in the hazards they may present in view of identical prototype and QC testing. Each class as defined in the registry is assigned a model number.
2. Sealed sources specified: Sources used are registered under NR-446-S-102-S. The range of sources specified as yet is Model 400/1. It is extended to also use Model 400/2 and 400/3. The models differ only in the shape of the cross section (round, square, rectangular). Their manufacture and radiological characteristics are otherwise identical. Design options however, are extended.
3. Maximum tritium activity per time-measuring instrument: It is proposed to increase the limit from 83 mCiT (present maximum for Model P650) to 100mCiT for all newly classified models. In addition, the number of sources per device is left open and may range from one to twenty.

021810

One source may suffice, if time is read by a liquid crystal display (LCD), larger number of sources may be necessary to read modern multi-functional timepieces.

Please note, that all other characteristics determining safety and radiological containment remain unchanged, e.g.:

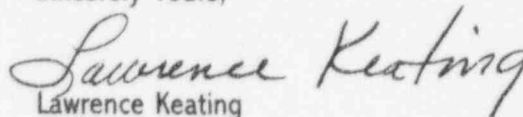
- installation of sources on timepiece components as dials, hands and bezels
- prototype and QC testing requirements
- access to the sources
- marking

We believe, that the requested amendment does not impact negatively any radiological safety aspect of the registered products, but would accelerate the substitution of the presently used products with tritium luminous paint which indisputably cause a higher effective dose commitment for the user and the general population.

Not least of all, it would relieve the regulatory burden on your commission.

We are glad to supply any additional information you may want.

Sincerely Yours,



Lawrence Keating
President

! K:kjw
Enclosures

31-23712-01E



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

September 2, 1995

Mr. Lawrence Keating
mb-microtec
P.O. Box 1174
North Tonawanda, New York 14120-9174

Dear Mr. Keating:

Based on your letter dated July 18, 1995, we have made the appropriate changes to your registration certificate NR-446-D-103-E to include modifications to watch Model P600.

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your registration certificate. As stated a general rule, you must request and obtain an amendment to the certificate before you make changes or modification to the information submitted to obtain the certificate.

Please read over the enclosed registration certificate in its entirety and notify us immediately of any errors or omissions.

You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing and inspection fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Debt Collection Branch at (301) 415-7544.

If you have any questions, please contact me at (301) 415-7857 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

Kim Randall

Kim Randall, Sealed Source Device Assistant
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: SKimberley, LFCDB
SGreene, IMAB ✓

Enclosure: As stated

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

PAGE 1 OF 6

DEVICE TYPE: Wrist Watch

MODEL: P375, P550, P600, P650

DISTRIBUTOR: mb-microtec (USA)
P.O. Box 1174
North Tonowanda, NY 14120

MANUFACTURER: mb-microtec ag
Freiburgstrasse
CH-3172 Niederwangen
SWITZERLAND

SEALED SOURCE MODEL DESIGNATION: mb-microtec Model 400/1

ISOTOPE:

MAXIMUM ACTIVITY:

Hydrogen-3

78 millicuries (2.886 GBq) for Models
P375, P550, and P600

1 source @ 7 mCi (259 MBq)

1 source @ 1 mCi (37 MBq)

1 source @ 4.5 mCi (166.5 MBq)

and 12 sources @ 5.5 mCi (203.5 MBq)

83 millicuries (3.071 GBq) for Model
P650

as above with additional source
at 5.5 mCi (203.5 MBq)

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (W) Self-Luminous Applications

CUSTOM DEVICE: _____ YES _____ X _____ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

PAGE 2 OF 6

DEVICE TYPE: Wrist Watch

DESCRIPTION:

All models are equipped with twelve gaseous tritium light sources at the hour positions of the dial and one on each hour, minute and second hands. The watches are assigned model numbers as follows:

Model P375 has a plastic case, a bottom of stainless steel fastened to the case by four screws, and an acrylic crystal mounted by means of a press-fitted stainless steel ring. The watch meets the standardized Swiss requirements for "water resistant at three atmospheres".

Model P550 has a one-piece polymer case including case bottom.

Model P600 has a stainless steel/brass case and a snap-on stainless steel bottom.

The Model P600 design has been modified to include a rotatable bezel which does not contain any light sources. The twelve sources used on the dial remain the same as those used in the previous design, however, they are mounted differently. They are glued with Rhone Poulenc Rhodorsil CAF 4 silicone adhesive into twelve milled slots at the hour positions of the 0.4mm (0.02") thick brass dial. The slots are 2.55mm (0.10") long, 0.8mm (0.03") wide, and 0.3mm (0.01") deep.

The dials for P375, P550, P600 consists of two injection mold plastic parts, which when positioned, take up a source at each hour position. The hands are specially designed to permit attaching a source to each of them from below by a non-hardening adhesive.

Model P650 is a diver's watch with a polymer case with screwed-on stainless steel bottom. It features a rotatable bezel containing an assembly with one additional source. The assembly consists of a metal housing with a press-fitted single crystal sapphire window. The ring with the sources marking the hour positions is a two-part polymer assembly attached to the interior wall of the watch case.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

PAGE 3 OF 6

DEVICE TYPE: Wrist Watch

DESCRIPTION(con't):

Unless the watch is destroyed or the crystal removed, there is no access to the sources. Removal of the crystal requires a special tool normally available only in watch factories or repair shops.

For quartz analog modules, a hatch is used in the case bottom to change batteries.

DIAGRAM:

Drawings of the Model P375, Model P550, Model P600, and Model P650 are in attachments 1-4.

LABELING:

The dial face is marked with a "T" (for tritium) as recommended in "Radiation Protection Standards for Gaseous Tritium Light Devices" Section 7 - Marking and Labeling (Nuclear Energy Agency, OECD, 1973). The bottom is marked by etching with "3H" for the contained tritium and with "mbm" standing for the manufacturer's logo.

CONDITIONS OF NORMAL USE:

The expected useful life of the watch is 10 years. The watch will be subjected to environs allowing human occupancy.

PROTOTYPE TESTING:

The manufacturer has subjected prototype watches to the requirements of ANSI N540. The prototype watches passed the requirement for classification T2GC122222.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO. NR-446-D-103-E

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PAGE 4 OF 6

DEVICE TYPE: Wrist Watch

EXTERNAL RADIATION LEVELS:

External radiation dose rates are minimal and need not be considered. Primary tritium beta rays do not penetrate the GTLS glass enclosure. Traces of very soft (a few keV) secondary Bremsstrahlung are absorbed by the watch case.

Potential doses for LCD watches with tritium light source backlighting of the display have been estimated and are reported in NUREG/CR-0215, ORNL/NUREG/TM-255 "Estimates of Potential Radiation Doses from Wristwatches Containing Tritium Gas" by McDowell-Bayer and O'Donnell.

QUALITY ASSURANCE AND CONTROL

mb-microtec has specified the following quality control test on production lots of wrist watches.

SOURCE TESTING

All (100%) of the sources used are tested for tritium leakage and have passed ANSI N540 when submitted to soaking per 8.3.2. Lots of greater than 13 sources are accepted when total leakage is less than 50 nanocuries (1.85 Bq) in 24 hours.

LOT TESTING OF FINISHED WATCHES

All finished watches are subjected to a 100% visual inspection for missing, dislodged, dim, or black light sources. In addition, a random sample (per MIL-STD-105D, Special Inspection Level S4, AQL 1%) of each finished lot is subjected to the following: a visual inspection for the "H-3" and "mbm" on the watch; a drop test from 1 meter to a steel plate, then a visual inspection for missing, dislodged, dim or black light sources; and a soak test (8.3.2. ANSI N540) to a maximum of 154 nCi (5.698 kBq) in 24 hours.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

PAGE 5 OF 6

DEVICE TYPE: Wrist Watch

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The import of the device is subject to the provisions of Section 110.27, 10 CFR Part 110.
- The device shall only be distributed to persons exempt from the requirements for a license as defined in 10 CFR Section 30.19. The device is initially transferred by a specific license issued pursuant to Section 32.22. This license shall only be issued by the NRC.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information submitted, we continue to conclude that Models P375, P550, P600, and P650 wrist watch designs are acceptable for licensing purposes. Furthermore, we continue to conclude that these watch models would be expected to maintain their integrity under the conditions associated with its intended use.

REFERENCES:

The following supporting documents for the Models P375, P550, P600, and P650 are hereby incorporated by reference and are made a part of this registry document.

- mb-microtec's letters dated June 19, 1987, July 23, 1987, June 27, 1991, August 30, 1991, October 20, 1993, January 13, 1994, November 10, 1994, December 21, 1994, and July 18, 1995, with enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

PAGE 6 OF 6

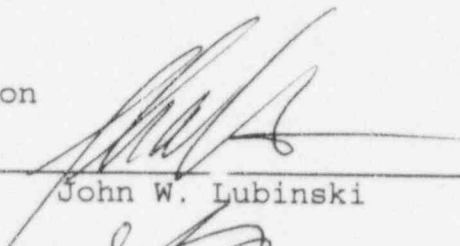
DEVICE TYPE: Wrist Watch

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission


Date: August 31, 1995

Reviewer:


John W. Lubinski

Date: August 31, 1995

Concurrence:


Steven L. Baggett

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

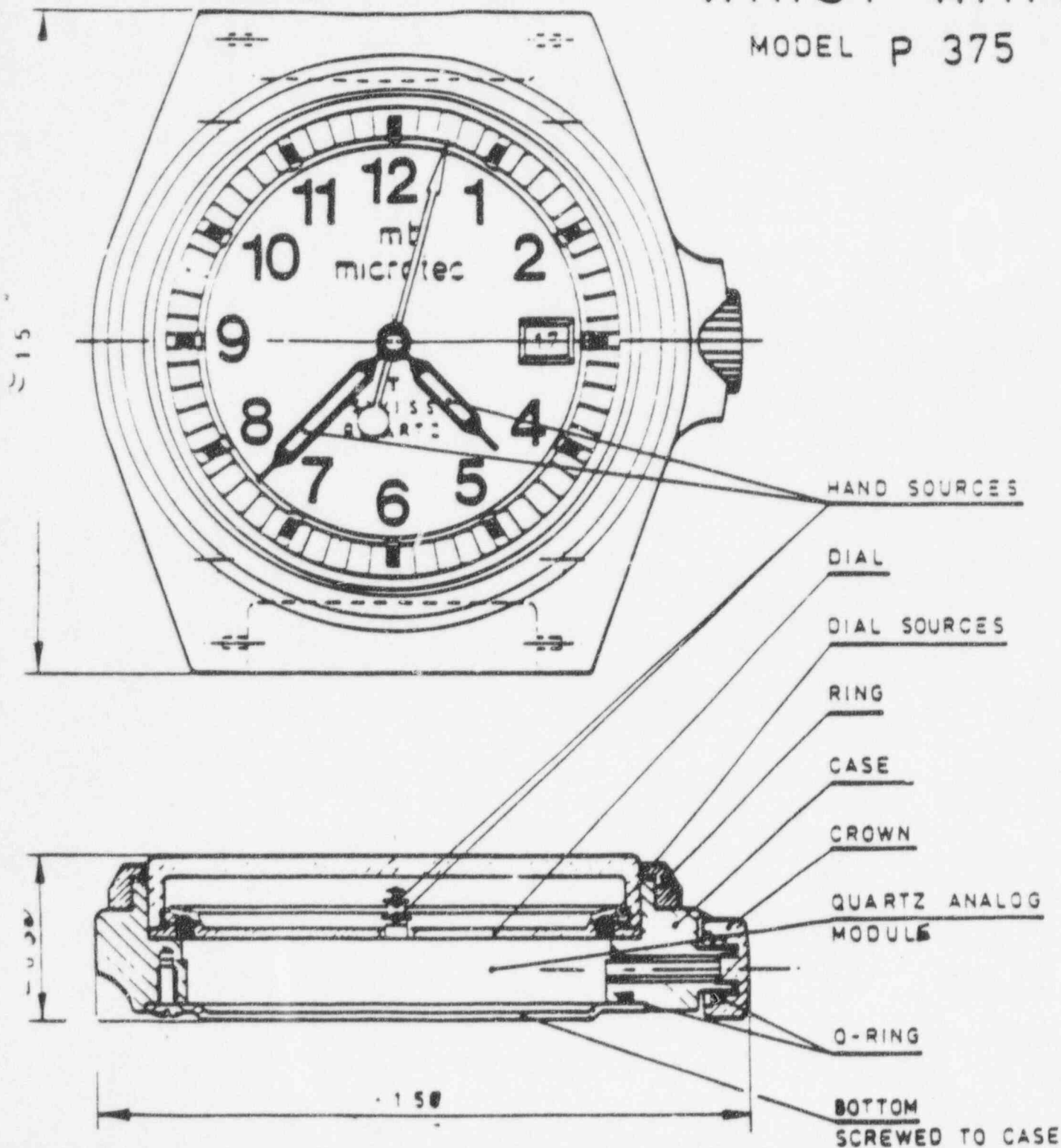
DATE: August 31, 1995

ATTACHMENT 1

DEVICE TYPE: Wrist Watch

WRIST WATCH

MODEL P 375



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

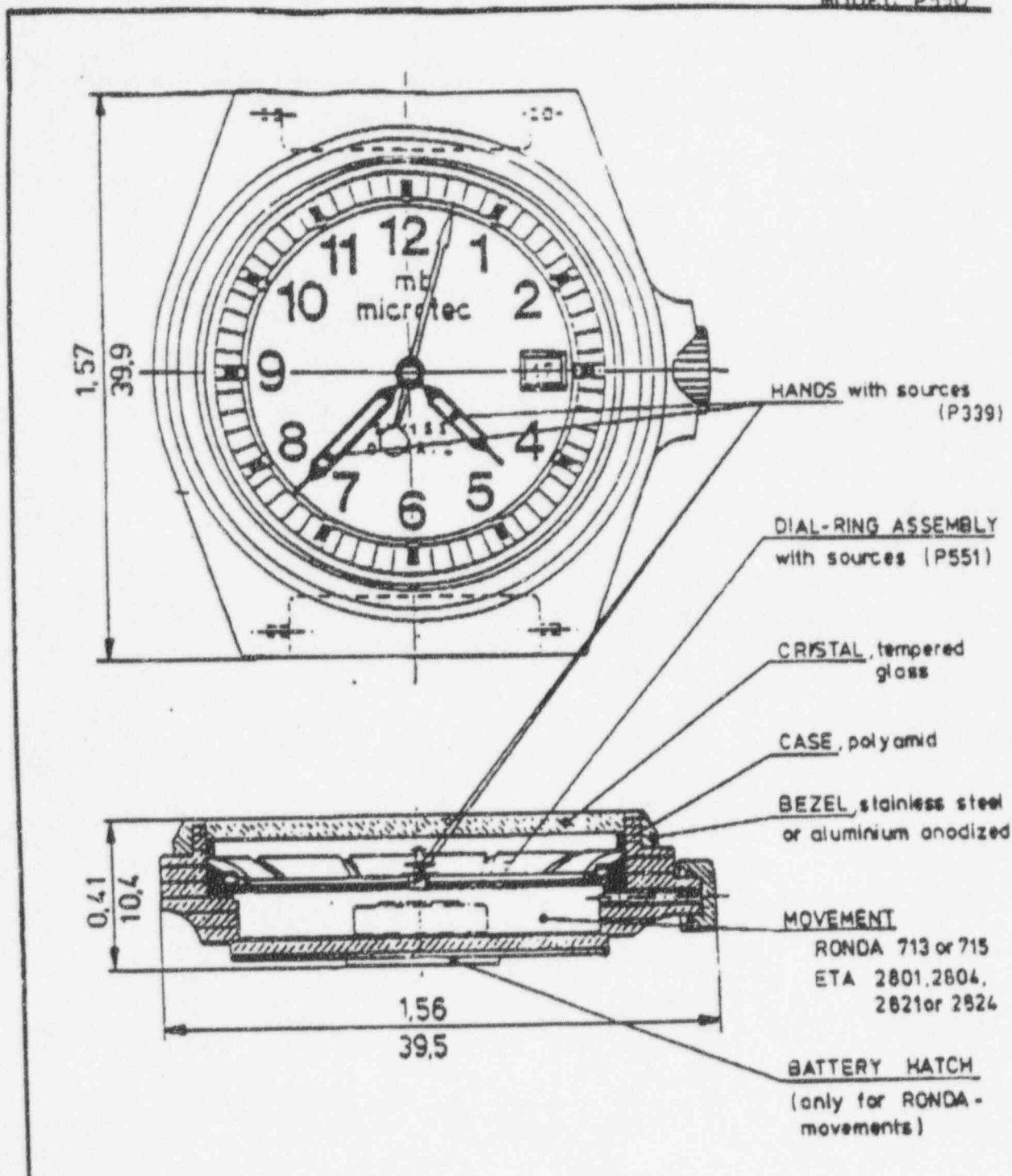
DATE: August 31, 1995

ATTACHMENT 2

DEVICE TYPE: Wrist Watch

WRIST WATCH

MODEL P550



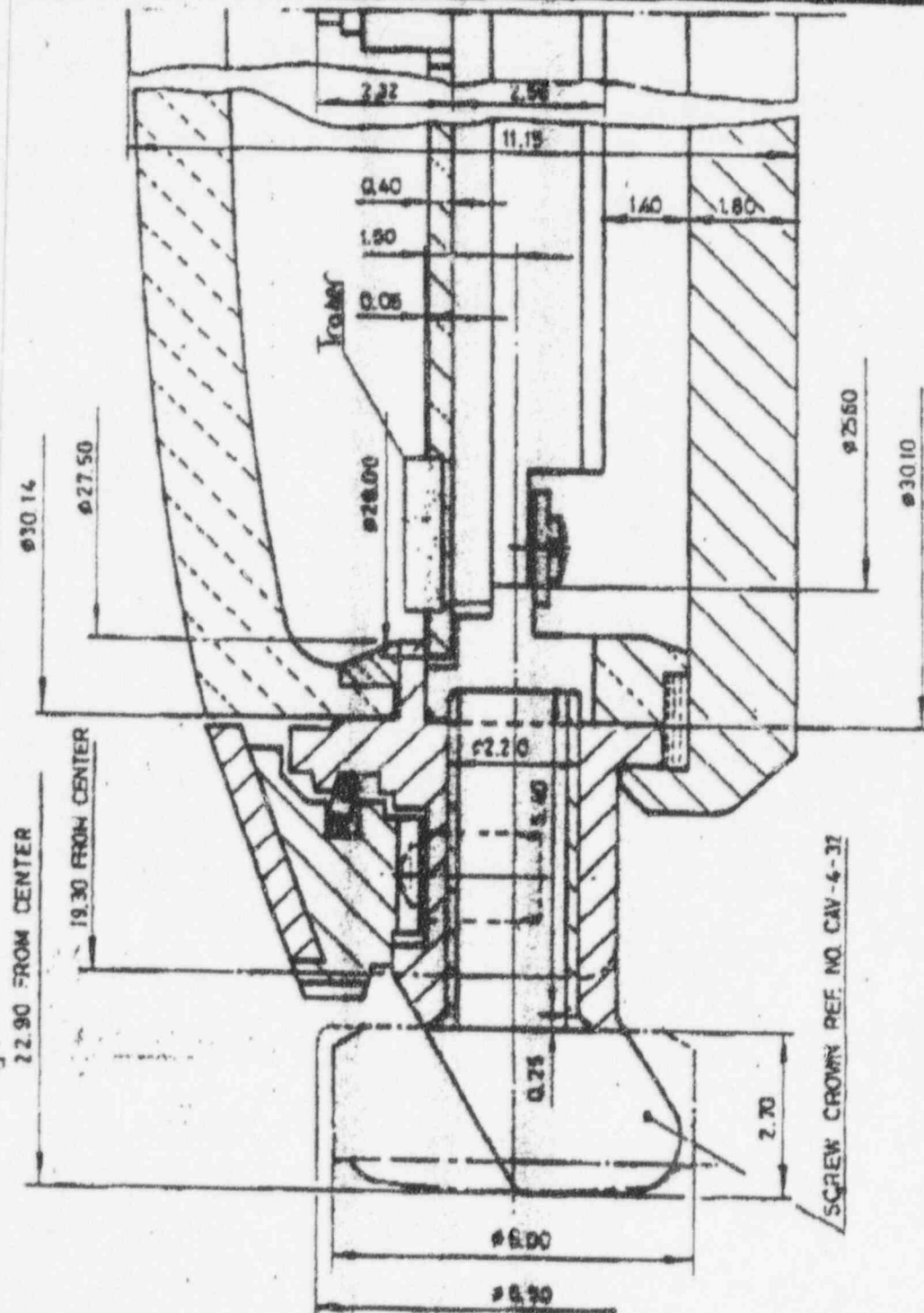
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

DATE: August 31, 1995

ATTACHMENT 3

DEVICE TYPE: Wrist Watch



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-446-D-103-E

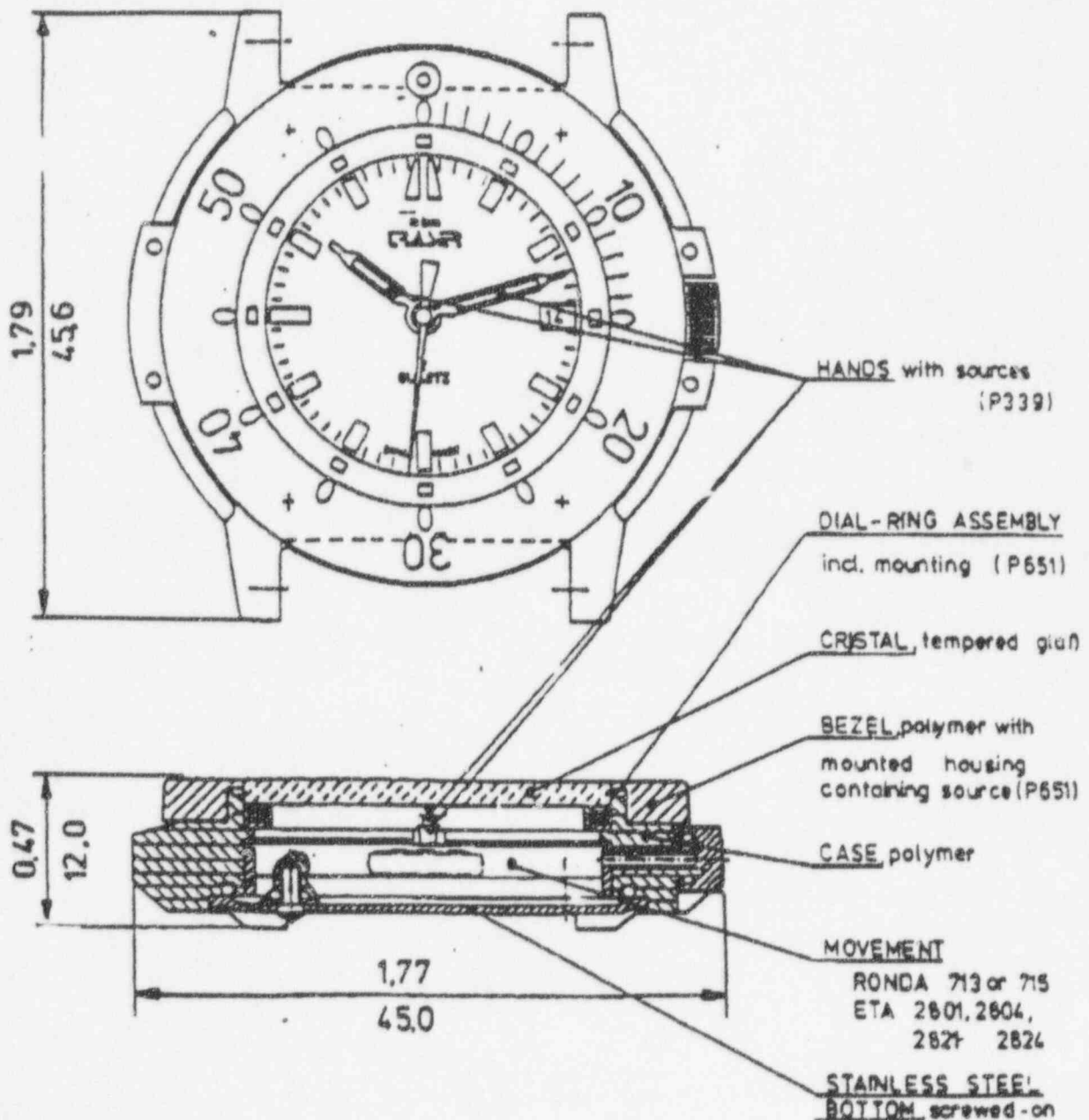
DATE: August 31, 1995

ATTACHMENT 4

DEVICE TYPE: Wrist Watch

WRIST WATCH

MODEL P650



R1201021

LICENSING TRACKING SYSTEM

DATE: 960122
PAGE: 1

LTS WORKSHEET

SLG

DOCKET NO : 03030433 LICENSE NO : 31-23712-01E STATUS: 0

MAIL CONTROL: 021810 RECEIPT DATE : 960119 ACTION TYPE: 4
DUE DATE : 960418

FED. GOVT : N INST. CODE : 23712 LICENSE REGION: 0

ISSUE DATE: ~~950322~~ ⁹⁶¹²¹⁸ ORIGINAL DATE: 880331 EXPIRATION DATE: ~~19980430~~ ²⁰⁰³⁰⁴³⁰

NAME : MB-MICROTEC, INC (USA) DECOM FIN ASSUR REQD: N
SUBM: -

DEPT/BUREAU: _____ CONT PLAN REQ: N APPRV: -

BUILDING : _____

STREET : P.O. BOX 1174

CITY : NORTH TONAWANDA STATE: NY ZIP: 141209174

CONTACT PERSON: LAWRENCE KEATING PHONE: 716-694-2695

PRIMARY PGM CODE : 03254 SECONDARY PGM CODES: _____

INSPECTION REGION: 1 PRIORITY CODE: 5 INSPECTION CATEGORY: E

RADIATION SAFETY OFFICER: _____

STATES WHERE USE IS AUTHORIZED: 1 0 - ALL LISTED STATES
1 - SAME AS STATE IN ADDRESS
2 - ALL STATES
3 - NON-AGREEMENT STATES

AUTHORIZED STATES: _____ (USE ONLY IF ABOVE IS ZERO)

REPORTING IDENTIFICATION SYMBOL: _____

APPROVAL FOR: REDISTRIBUTION: N STORAGE ONLY: N
TEMPORARY JOB SITES: N INCINERATION: N
BURIAL: N

EXEMPTIONS: (1) _____ (2) _____

POSSESSION LIMIT INFORMATION

PAGE: 2

MATERIAL TYPE : NPA FORM CODE: NPA AGGREGATE CODE: NPA
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : 0000000.000000000 UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

MATERIAL TYPE : _____ FORM CODE: _____ AGGREGATE CODE: _____
MODEL NUMBER : _____
DESCRIPTION : _____
TOTAL QUANTITY : _____ UNIT: _____
OTHER : _____ # SOURCES: _____

NAME

AUTHORIZATION

ADDRESS WHERE MATERIAL IS USED OR POSSESSED

BUILDING: MB-MICROTEC

ROOM:

STREET:

CITY:

STATE: 908 NIAGARA FALLS BLVD.
NORTH TONAWANDA
NY 14120

BUILDING:

ROOM:

STREET:

CITY:

STATE:

BUILDING:

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ROOM:

STREET:

CITY:

STATE:

DOCKET: 03030433 LIC: 31-23712-01E NAME: MB-MICROTEC

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : _
ADDR1 : MECH AMOUNT: _
ADDR2 : APPROVED? DATE: _
CITY : EXPIRES ? DATE: _
STATE: ZIP: _

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : _
ADDR1 : MECH AMOUNT: _
ADDR2 : APPROVED? DATE: _
CITY : EXPIRES ? DATE: _
STATE: ZIP: _

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
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CITY : EXPIRES ? DATE: _
STATE: ZIP: _

PARTY ISSUING MECHANISM: ASSUR TYPE : _ (C=CERT D=DFP)
NAME : MECH TYPE : _
ADDR1 : MECH AMOUNT: _
ADDR2 : APPROVED? DATE: _
CITY : EXPIRES ? DATE: _
STATE: ZIP: _

PAGE: 5

MEDICAL QUALITY MANAGEMENT PROGRAM REQUIRED: N RECEIVED: APPROVED:

DECOMMISSIONING FINANCIAL ASSURANCE REQUIRED: N SUBMITTED:

CONTINGENCY PLAN REQUIRED: N APPROVED: _____

DECAY-IN-STORAGE APPROVED: N HOLDING FOR < 10 HALF-LIVES APPROVED: _

T 1/2 > 65 DAYS, ISOTOPE(S): _____

INTERIM STORAGE UP TO 1996: N

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03254
Status Code: 0
Fee Category: 3H
Exp. Date: 19980430
Fee Comments: REQUIRES SS&D EVAL.
Decom Fin Assur Req'd: N
1996 JAN 22 PM 4:18

LICENSE FEE TRANSMITTAL

A. REGION 0

1. APPLICATION ATTACHED

Applicant/Licensee: MB-MICROTEC
Received Date: 960119
Docket No: 3030433
Control No.: 021810
License No.: 31-23712-01E
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.:

3. COMMENTS

Signed
Date

C. Boyle
1/22/96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

1. Fee Category and Amount: 3H \$990

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal _____
License _____

3. OTHER _____

Signed
Date

Sh
2/13/96

Log	726.1 HDS
Remitter	
Check No.	0694
Amount	\$990
Fee Category	3H
Type of Fee	AMD
Check Rec'd.	2/13/96
Date Completed	
By	Sh