NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(5-1997)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

# APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 7/31/1998

Estimated burden per response to comply with this information collection request: 7 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Forward comments regarding burden estimate to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0120), Office of Management and Budget, Washington, DC 20503. NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

**INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.**

*APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:*

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

*ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:*

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23T85
ATLANTA, GEORGIA 30303-3415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*
   - [X] A. NEW LICENSE
   - [ ] B. AMENDMENT TO LICENSE NUMBER _____
   - [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

**Refer to Accompanying Supplemental Information**

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

TELEPHONE NUMBER

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE

5. RADIOACTIVE MATERIAL.
   a. Element and mass number; b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
    FEE CATEGORY | AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* 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, 32, 33, 34, 35, 36, 39 AND 40, 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/PRINTED NAME AND TITLE | SIGNATURE | DATE |
|---|---|---|
| Richard J. Timbo, Principal | Richard J. Timbo | 12-2-04 |

## FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|---|---|---|---|---|---|
| | | | $ | | |
| APPROVED BY | | | | DATE | |

# SUPPLEMENTAL INFORMATION

## RICHARD BARRY MARKETING GROUP
## APPLICATION FOR EXEMPT DISTRIBUTION LICENSE

ITEM 1. THIS IS AN APPLICATION FOR

A new exempt distribution license in accordance with 10 CFR 30, §30.15 and 10 CFR 32, §32.14.

ITEM 2. NAME AND ADDRESS OF APPLICANT

Richard Barry Marketing Group
81 Ruckman Road
Closter, NJ 07624-2102

ITEM 3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

81 Ruckman Road
Closter, NJ 07624-2102

ITEM 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

- Michael Shane Brightwell, Applicant Radiation Safety Officer, Business Phone: (631) 278-0610
- Richard J. Timbo, Applicant Certifying Official, Business Phone: (201) 750-8000

# SUPPLEMENTAL INFORMATION

ITEM 5. RADIOACTIVE MATERIAL

| A. ELEMENT AND MASS NUMBER | B. CHEMICAL OR PHYSICAL FORM | C. MAXIMUM AMOUNT THAT WILL BE POSSESSED AT ANY ONE TIME |
|---|---|---|
| Hydrogen-3 (Tritium). | Sealed Gaseous Tritium Light Sources (GTLS); (mb-microtec Models X00/A, X00/B, and X00/C); (123 Manufacturing Company Models Y00/A, Y00/B, and Y00/C) | N/A – This is covered in the possession/use license application |

ITEM 6. PURPOSES FOR WHICH RADIOACTIVE MATERIALS WILL BE USED

This license is intended to facilitate the distribution of devices listed in Item 5 to persons exempt from licensing in accordance with an Exempt Distribution License issued pursuant to §30.15 and §32.14.

Each lot of devices listed in Item 5 containing tritium for distribution pursuant to §30.15 will be accompanied by a certificate that attests to the following:

A. The devices have been manufactured in accordance with the International Atomic Energy Agency, International Standards Organization, OECD Nuclear Energy Agency, American National Standards Institute or equivalent; and

B. The amount of tritium on the devices is not in excess of of the maximum permissible amount authorized in §30.15(a).

Periodic reports will be filed as specified in §32.25(c).

**Attachment 1** contains components of the Quality Control Program.

ITEM 7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

Richard J. Timbo, Applicant Radiation Safety Officer (RSO) – Mr. Timbo will be qualified as the RSO as submitted in the associated radioactive materials possession/use license application.

# SUPPLEMENTAL INFORMATION

ITEM 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

N/A – This is covered in the possession/use license application.

ITEM 9. FACILITIES AND EQUIPMENT

N/A – This is covered in the possession/use license application.

ITEM 10. RADIATION SAFETY PROGRAM

**Operational**

N/A – This is covered in the possession/use license application.

**General**

This application refers to the radiological assessments of such timepieces performed in NUREG -1717, Section 2.3 as the bases for exemption.

ITEM 11. WASTE MANAGEMENT

N/A – This is covered in the possession/use license application.

ITEM 12. LICENSE FEES

| | | |
|---|---|---|
| Fee Gategory | ≡ | 3.I. |
| Amount Enclosed = | | $4,300 |

# SUPPLEMENTAL INFORMATION

## ATTACHMENT 1

## Quality Control Program

The following describes components of the RBMG Quality Control (QC) Program, which is basically an adaptation of the current manufacturer's QC Program. This program includes a list of manufacturers, SSD design conformity requirements, regulatory QC requirements, and examples of manufacturer and distributor QC documentation.

### I. Manufacturers

The following two manufacturers are currently authorized as SSD manufacturers on the Sealed Source Device Registration (SSDR) listed below for the same model timepieces with higher $^{3}H$ activities not exempt from registration under §30.15 and §32.14.

*A. Manufacturers*

traser systems® mb-microtec
Freiburgstrasse 624rb
CH-3172
Niederwangen, Bern
Switzerland
Phone: 011-41-31-980-2020
Fax: 011-41-31-980-2021

Horoswiss S.A.
Avenue Charles-Naine 34
2304 La Chaux-de-Fonds
Switzerland
Phone: 011-41-32-925-3600
Fax: 011-41-32-927-3632

*B. Related SSDR*

US NRC Registry No.NR 446-D-103-E
US NRC License No. NR 31-23712-01E of mb-microtec (USA) Inc.

### II. Design Conformity

*A. mb-microtec*

The design conformity requirements for timepieces manufactured by mb-microtec will meet the same requirements specified in their current QC program, including markings "3-H MBM" on each timepiece.

# SUPPLEMENTAL INFORMATION

*B. RBMG*

The design conformity requirements for timepieces manufactured by Horoswiss will meet the same requirements specified in the current QC program implemented by mb-microtec, except that the markings "3-H MBM" on each timepiece will be replaced by "3-H RBMG."

## III. NRC QC Program Requirements

*A. Manufacturer*

Each manufacturer uses the QC program implemented by mb-microtec. Included at the end of this attachment are examples of the QC testing certificates that will be generated by either manufacturer for each lot of timepieces manufactured under this program.

*B. Distributor*

The distributor checks design conformity as specified in 10 CFR 32 Subpart A, *Exempt Concentrations and Items,* §32.25 – Conditions of licenses issued under §32.22: Quality control, labeling, and reports transfer; and Subpart C, *QC Sampling Procedures,* §32.110 – Acceptance sampling procedures under certain specific licenses. Included at the end of this attachment is an example of the QC testing certificate that will be generated by the distributor for each lot of timepieces manufactured under this program.

Device Inspection

The devices will be inspected in approximately 5% of the bulk packages received prior to placing the shipment in standard storage status. The actual number of devices inspected will be commensurate with the lot testing requirements specified in the following table, which shows the minimum sample sizes required for 5% Lot Tolerance Percent Defective (5% LTPD) as specified in 10 CFR 32.110, Table 6.

| Lot Size | Sample Size |
|---|---|
| 1 - 30 | All |
| 31 - 50 | 30 |
| 51 - 100 | 37 |
| 101 - 200 | 40 |
| 201 - 300 | 43 |
| 301 - 400 | 44 |
| 401 - 2,000 | 45 |
| 2001 - 100,000 | 75 |

# SUPPLEMENTAL INFORMATION

The NRC QC Program requires

i. visual inspection, under lighted conditions, of device labeling (design conformity), and
ii. visual inspection, under darkened conditions, of individual GTLSs in each device sample for adequate brightness (leak indication).

The random device inspection will consist of a visual inspection, in an adequately lighted space, of each individual device and packaging to assure they are intact and all inserts are present. If any device packaging does not meet the inspection criteria, the inspection frequency for the lot and/or shipment may be increased to 50% at the licensee's discretion. Identification of more than one (1) failure to this point should warrant 100% inspection of the lot and/or shipment. Any individual device packaging that does not meet these criteria should be placed in segregated storage status for further evaluation.

These activities can be performed by any properly trained individual user.

traser® systems
mb-microtec

# CERTIFICATE

It is certified that the watches Model **100/1 (S 8000)** shipped to mb-microtec (USA) Inc. and invoiced per enclosure were taken from the production lot covered by the

- **"Certificate of Quality Control Testing No.: 10936/1" for 200 watches**
- **"Certificate of Quality Control Testing No.: --------" for ----- watches**
- **"Certificate of Quality Control Testing No.: --------" for ----- watches**
- **"Certificate of Quality Control Testing No.: --------" for ----- watches**

These certificates are on file at the consignee's office.

Certified: **October 6, 2004**

Jakob Bänziger

traser® systems
mb-microtec

# CERTIFICATE OF QUALITY CONTROL TESTING NO. 11231/1
# PRODUCTION LOT No. 216

## ANALOG WRISTWATCH MODEL 100/1

**Activity:** 41 mCi T as gaseous tritium light sources
**US NRC Registry No.:** NR 446-D-103-E
**US NRC License No.:** NR 31-23712-01E of mb-microtec (USA) Inc.
**NYS. DOL Radioactive Material License No.:** 2641-3912

1. **Requirements on sources used for 100/1 watch**

All sources used are taken from production lots exhibiting leakage of less than 50 nCi T / 24 hours per batch of min. 16 sources.
Results of 100% test per ANSI N43.4, section 8.3.2. are on file at mb-microtec Inc., Niederwangen, Switzerland.

2. **Requirements of Production Lots of Finished Watches**

2.1. 100 % visual inspection in dark room for absence of dislodged, dim or black sources.

2.2. Random samples testing per MIL- Std-105D, level S4, AQL 1% for

- visual control for marking on dial and case bottom
- drop from 1 m height to a steel plate followed by visual inspection for absence of dislodged, dim, dark and broken sources
- leakage test per 8.3.2. ANSI N43.4 to a max. of 50 nCi T per 24 hours

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mb-microtec

## RESULTS OF PRODUCTION LOT NO.: 216

Lot Size: 3000
Manufactured: June 04

**Results 100% Visual Inspection 2.1:** all passed

**Results Random Sample Test 2.2:**

Sample Size: 50 Acceptance No. 1

Markings: all passed
Drop test: all passed
Leakage: all passed

| | | |
|---|---|---|
| Watch 1: 0,3uG | Watch 19: 0,6uG | Watch 37: 0,6uG |
| Watch 2: 0,4uG | Watch 20: 0,4uG | Watch 38: 0,4uG |
| Watch 3 0,4uG | Watch 21: 0,4uG | Watch 39: 0,5uG |
| Watch 4: 0,2uG | Watch 22. 0,5uG | Watch 40: 0,6uG |
| Watch 5: 0,5uG | Watch 23: 0,5uG | Watch 41: 0,3uG |
| Watch 6: 0,4uG | Watch 24: 0,4uG | Watch 42: 0,4uG |
| Watch 7: 0,6uG | Watch 25: 0,4uG | Watch 43: 0,4uG |
| Watch 8: 0,4uG | Watch 26. 0,3uG | Watch 44: 0,5uG |
| Watch 9: 0,4uG | Watch 27: 0,4uG | Watch 45: 0,5uG |
| Watch 10: 0,6uG | Watch 28: 0,3uG | Watch 46: 0,6uG |
| Watch 11: 0,2uG | Watch 29: 0,6uG | Watch 47: 0,6uG |
| Watch 12: 0,4uG | Watch 30. 0,6uG | Watch 48 0,6uG |
| Watch 13: 0,6uG | Watch 31: 0,4uG | Watch 49: 0,4uG |
| Watch 14: 0,5uG | Watch 32: 0,6uG | Watch 50: 0,4uG |
| Watch 15: 0,5uG | Watch 33: 0,4uG | |
| Watch 16: 0,5uG | Watch 34: 0,5uG | |
| Watch 17: 0,5uG | Watch 35: 0,2uG | |
| Watch 18: 0,5uG | Watch 36: 0,6uG | |

Production Lot. No. 216 is accepted

Certified : July 15, 2004

Chief, Quality Assurance:

Jakob Bänziger

# HOROSWISS S.A.

## CERTIFICATE

It is certified that the watches Model 100/1 (serie 1553) shipped to Richard Barry Marketing Group (USA) inc. and invoiced per enclosure were taken from the the production lot covered by the

- "Certificate of Quality Control Testing No : 850" for 520 watches
- "Certificate of Quality Control Testing No: " for watches

These certificates are on file at the consignee's office

Certified : October 3rd, 2003

Rachel Banderet

Av. Charles-Naine 34- 2300 La Chaux-de-Fonds Tel. +41 (0)32 925 36 00 - Fax +41 (0)32 927 96 92 - Email : info@horoswiss.com

# HOROSWISS S.A.

## CERTIFICATE OF QUALITY CONTROL TESTING NO. 850
## PRODUCTION LOT NO. 380

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## ANALOG WRISTWATCH MODEL 100/1

| | |
|---|---|
| Activity: | 83 mCi T as gaseous tritium light sources |
| US NRC Registry No: | NR 446-D-103-E |
| US NRC Licence No: | NR 31-23712-01E of mb-microtec (USA) Inc. |

1 Requirements on sources used for 100/1 watch

All sources used are taken from production lost exhibiting leakage of less than 50 nCi T / 24 hours per batch of min. 13 sources.
Results of 100% test per ANSI N540, 8.3.2. are on file at mb-microtec Inc., Niederwangen, Switzerland.

2 Requirement of Production Lots of Finished Watches

2.1 100% visual inspection in dark room for absence of dislodged, dim or black sources.

2.2 Random samples testing per MIL-Std-105D,Level S4, AQL 1% for

- visual control for marking on dial and case bottom
- drop from 1 m height to a steel plate followed by visual inspection for absence of dislodged, dim, dark and broken sources
- leakage test per 8.3.2. ANSI N540 to a max. of 50 nCi T per 24 hours

# HOROSWISS S.A.

## RESULTS OF PRODUCTION LOT NO. : 380

Lot size: 1,000
Manufactured September - October

Results 100% Visual Inspection 2.1: all passed

Results Random Sample Test 2.2:

Sample Size: 13 Acceptance No. 0

Markings: all passed
Drop test: all passed
Leakage: all passed

| Watch | | |
|---|---|---|
| | 1 | |
| | 2 | |
| | 3 | |
| | 4 | |
| | 5 | |
| | 6 | |
| | 7 | 0,4 - 0,7 |
| | 8 | |
| | 9 | |
| | 10 | |
| | 11 | |
| | 12 | |
| | 13 | |

Production Lot 380 is accepted

Certified : October 3rd, 2003

Chief, Quality Assurance :

Michael Vrolijk

# QC-3: U.S. Distributor Certificate of Quality Control Testing

## Sealed Source Device (SSD) – Richard Barry Marketing Group Timepieces Containing Gaseous Tritium Light Sources (GTLS)

**SSD Model:** _____

**SSD Production Lot Number:** _____

**SSD US NRC License Number:** XX-XXXXX-XX-E

**1. Manufacture Requirements for Production Lots of Assembled SSD**

All SSDs used are taken from production lots that have been accepted by the manufacturer as meeting all requirements set forth in the QC Program.

**2. Exempt Distribution Requirements of Production Lots of Assembled SSD**

Visual inspections of final packaged SSD in accordance with the LTPD requirements of the QC Program:

2.1 Visual inspection of timepiece for proper markings/labeling (design conformity).

2.2 Visual inspection of GTLSs in timepiece for proper brightness (leakage).

## Inspection Results

Lot Size = _____ units

Sample Size = _____ units  Acceptance Number = 0 units

**2.1 Visual inspection of timepieces for proper markings/labeling:** Pass / Fail

**2.2 Visual inspection of GTLSs in timepieces for proper brightness:** Pass / Fail

Comments: _____

_____

_____

Production Lot Number _____ is Accepted / Rejected

_____ _____

Licensee Representative Signature  Certification Date