

07 NOV 1986

Docket Nos. 030-20570
030-12704

License Nos. 37-03572-08E
37-03572-06

Hamilton Watch Company, Inc.
ATTN: Paul D. Karpouzis
Vice President of Operations
and Director of Purchasing
941 Wheatland Avenue
Lancaster, Pennsylvania 17604

Gentlemen:

Subject: Inspection Nos. 030-20570/86-01 and 030-12704/86-01

This refers to the special safety inspection conducted by John J. Miller of this office on June 17, 1986 at 941 Wheatland Avenue, Lancaster, Pennsylvania, and on June 24, 1986 in the Region I Office in King of Prussia, Pennsylvania, of activities authorized by NRC License Nos. 37-03572-08E and 37-03572-06. This also refers to the discussions of our findings held by Mr. Miller with yourself and Thomas Dietzler, Joe Sabol, and Donald Cargas at the conclusion of the inspection.

The inspection was an examination of activities conducted under your licenses as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your licenses. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

Our inspector also verified the steps you have taken to correct the violations brought to your attention in the enclosure to our letter dated January 31, 1984. We have no further questions regarding the steps you took to correct items A, B.1, B.2 and C. With regard to item B.3, this item has recurred. In addition, the violation cited in our letter dated March 22, 1985, was not fully corrected until May 3, 1986.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. These violations have been categorized by severity level in accordance with the revised NRC Enforcement Policy (10 CFR 2, Appendix C) published in the Federal Register Notice (49 FR 8583) dated March 8, 1984. You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A. In addition to the need for corrective action regarding these

Also

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specific violations, we are concerned about the implementation of your management control systems that permitted them to occur. Consequently, in your reply, you should describe in particular, those actions taken or planned to improve the effectiveness of your management control systems.

Item D in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities on December 8, 1983, and was documented in the enclosure to our letter dated January 31, 1984. Your letter to this office dated January 31, 1984, stated that bioassays will be performed on employees who work in the tritium area. From our June 17, 1986, inspection it appears that the stated corrective actions were not effective since this item has recurred.

Also, Item A in the Notice of Violation enclosed with this letter was identified during a telephone inquiry on January 28, 1985 and documented in a Notice of Violation dated March 22, 1985. From our June 17, 1986 inspection, it appears that your corrective actions were not effective since this item was not fully corrected until May 3, 1986.

Recurrent and uncorrected violations are considered in the selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur. In addition to supplying information on the corrective action required by the Notice of Violation, you are required, pursuant to 42 U.S.C. 2232a, to provide an explanation of the circumstances surrounding your decision to continue to order, receive and distribute radioactive materials following your receipt of the Notice of Violation dated March 22, 1985 and before your authorization to possess these materials under License No. 37-03572-06 by amendment dated October 24, 1985 and your authorization to distribute these materials under License No. 37-03572-08E by amendment dated May 3, 1986. This information is required to enable the Commission to determine if further enforcement action is needed to assure complete and long term corrective action. These actions could include modification, suspension or revocation of your licenses.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter, the enclosures to this letter, and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

07 NOV 1986

Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:
James H. Joyner

Thomas T. Martin, Director
Division of Radiation Safety
and Safeguards

Enclosure:

- 1. Appendix A, Notice of Violation
- 2. NRC Region I Combined Inspection Report Nos. 030-20570/86-01 and 030-12704/86-01

cc:

Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

bcc:

Region I Docket Room (w/concurrences)
Management Assistant, DRMA

RI:DRSS
J. Miller/klm

JAG
RI:DRSS
J. Glenn

RI:DRSS
J. Joyner

JAG
RI:DRSS
T. Martin

RI:DRSS
J. Gutierrez

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OFFICIAL RECORD COPY

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APPENDIX A

NOTICE OF VIOLATION

Hamilton Watch Company, Inc.
Lancaster, Pennsylvania 17604

Docket Nos. 030-20570
030-12704
License Nos. 37-03572-08E
37-03572-06

As a result of the inspection conducted on June 17 and 24, 1986, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 30.3 requires that no person possess, transfer, or use by-product material except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

Contrary to the above, on April 1, 1984, Hamilton Watch Company, Inc. possessed watches and watch parts containing material which requires a specific NRC license and continued to import and possess additional watches containing by-product material during the time interval from April 1, 1984 to October 23, 1985, without a valid license. In addition, Hamilton Watch Company, Inc. distributed (transferred) watches containing hydrogen-3 and promethium-147 paint during the interval of April 1, 1984 to May 2, 1986, without a valid license authorizing distribution.

This is a Severity Level IV violation (Supplement VI)

- B. 10 CFR 30.34(c) requires that each licensee confine his possession and use of by-product materials to the locations and purposes authorized by the license. Condition 10 of License No. 37-03572-06 requires that licensed material be used only at 941 Wheatland Avenue, Lancaster, Pennsylvania.

Contrary to the above, on June 17, 1986, Swatch brand watches containing hydrogen-3 paint were possessed at 1817 William Penn Way, Lancaster, Pennsylvania, a location not authorized by the license.

This is a Severity Level IV violation. (Supplement VI)

- C. 10 CFR 32.16 requires that each person licensed under 32.14 submit a report to the Commission within thirty days after:

- (1) Five years after filing the preceding report; or
- (2) Filing an application for renewal of the license. The report must include the total quantity of the radionuclide in each type of product and the number of units of each type of product transferred during the reporting period.

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Contrary to the above, a report sent to the Commission dated March 21, 1985 intended to meet the requirements of 10 CFR 32.16 did not include the required data for all the watches containing by-product material that were transferred by the licensee during the reporting period. Specifically, no information was included in the report concerning the transfers of Certina, Omega, and Swatch brand watches that contained by-product material.

This is a Severity Level IV violation. (Supplement VI)

- D. Condition 14 of License No. 37-03572-06 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated October 2, 1985.

Item 3 of the letter dated October 2, 1985 requires that bioassays be performed on operators quarterly.

Contrary to the above, as of June 17, 1986, no bioassay was performed on any of the operators during the first quarter of 1986.

This is a Severity Level IV violation. (Supplement VI)

- E. Condition 8 of License No. 37-03572-085 requires that each lot of time-pieces, hands, and dials received by the licensee containing tritium or promethium-147 must be accompanied by a certificate which attests to the fact that the watches have been subjected to a specified quality control program.

Contrary to the above, as of June 17, 1986, each lot of Swatch brand watches was not accompanied by the required certificate.

This is a Severity Level IV violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Hamilton Watch Company, Inc. is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-20570/86-01
030-12704/86-01

Docket Nos. 030-20570
030-12704

License Nos. 37-03572-08E Priority 3 Category E
37-03572-06 3 E

Licensee: Hamilton Watch Company, Inc.
941 Wheatland Avenue
Lancaster, Pennsylvania 17604

Facility Name: Hamilton Watch Company, Inc.

Inspection At: Hamilton Watch Company, Inc., Lancaster, Pennsylvania and
631 Park Avenue, King of Prussia, Pennsylvania 19406

Inspection Conducted: June 17 and 24, 1986

Inspector: John Miller 10-6-86
John Miller, Health Physicist date

Approved by: John E. Glenn 10/6/86
John Glenn, Chief, Nuclear Materials date
Safety Section B

Inspection Summary: Special Safety Inspection Conducted June 17 and 24, 1986
(Report Nos. 030-20570/86-01 and 030-12704/86-01)

Areas Inspected: Licensee action on previous findings, receipt and transfer of materials, quality assurance, personnel protection - internal, training and instructions to employees, and posting of notices.

Results: Possessing and distributing watches containing by-product material without a valid license (paragraph 5); storing watches containing by-product material at a location not authorized on license (paragraph 5); failure to assure that each lot of watches was accompanied by quality assurance certificate (paragraph 6); failure to include in product transfer reports all watches that were distributed (paragraph 6); and failure to perform quarterly bioassay on personnel assembling watches (paragraph 7).

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DETAILS

1. Persons Contacted

- +*Paul D. Karpouzis, Vice President of Operations and Director of Purchasing
- *Donald Cargas, Jr., Vice President - Administration
- +*Thomas E. Deitzler, Director of Operations
- +*Joseph Sabol, Manager of Material Sales Department and Radiation Safety Officer

*Denotes those persons present at exit meeting at Hamilton Watch Company, Inc. on June 17, 1986.

+Denotes those persons present at meeting in Region I Office, King of Prussia, Pennsylvania on June 24, 1986.

2. Scope of Operations

Hamilton Watch Company, Inc. is authorized by NRC License No. 37-03572-06 to possess hydrogen-3 sealed sources for assembly into watchcases and storage incident to distribution of watches. License No. 37-03572-06 also authorizes the licensee to possess and use timepieces, hands, and dials to which Radium Chemie PS 362 tritiated luminous paint and W. Maier promethium oxalate luminous paint has been applied, for assembly into sealed watch cases and storage incident to distribution.

License No. 37-03572-08E authorizes the distribution of watches containing American Atomic Model 60307 sealed hydrogen-3 sources and also authorizes the distribution of timepieces, hands, and dials to which Radium Chemie PS 362 tritiated (hydrogen-3) luminous paint or W. Maier promethium-147 luminous paint has been applied.

Hamilton Watch Company receives, stores, and ships Swatch watches for Swatch Watch U.S.A. Inc. Hamilton Watch Company and Swatch Watch U.S.A., Inc. are affiliated companies in the same parent company, SMH U.S. Hamilton Watch Company also imports, possesses, and distributes Omega and Certina brand watches. None of the Swatch, Certina, and Omega watches are assembled at the facility in Lancaster and only some of the Hamilton watches are assembled there.

3. Background Information

Hamilton Watch Company, Inc. was formerly authorized by License No. 37-03572-02E to possess and distribute timepieces, hands, and dials to which hydrogen-3 or promethium-147 luminous paint had been applied. The company allowed the license to expire on March 31, 1984. On March 22, 1985, the NRC Region I Office issued a Notice of Violation of 10 CFR Section 30.3 for possessing material without a valid specific license. The Notice of Violation further directed Hamilton Watch Company to place the radioactive material on hand in secure storage and no other use of the

material or purchase of additional material was authorized until a valid license was issued.

In a letter dated April 10, 1985, Hamilton Watch Co., Inc., applied to amend License No. 37-03572-06 to include possession and distribution of timepieces, hands, and dials to which Radium Chemie PS 362 and/or Brandhurst Co. Triluco tritiated luminous paint or W. Maier promethium-147 luminous paint has been applied. Amendment No. 3 to License No. 37-03572-06 was issued on October 24, 1985, authorizing Hamilton Watch Co., Inc. to possess and use timepieces, hands, and dials to which Radium Chemie PS 362 and/or Brandhurst Company, Ltd. tritium paint had been applied. This license was amended again on May 20, 1986 to include authorization to possess and use time-pieces, etc. with W. Maier promethium 147 paint.

On May 3, 1986, Amendment No. 1 to License No. 37-03572-08E was issued authorizing the distribution of timepieces, hands, and dials to which Radium Chemie PS 362 tritiated (hydrogen-3) luminous paint or W. Maier promethium paint has been applied.

4. Licensee Actions on Previous Findings

(Closed) Inspection 83-01: failure to instruct individuals in a restricted area in the subjects covered in 10 CFR 19.12. Licensee drafted safety precautions to be followed while frequenting the restricted area. Operators handling tritium painted watch parts were required to read these precautions.

(Closed) Inspection 83-01: failure to check tritium air monitor for operability daily and to calibrate tritium air monitor monthly. The Radiation Safety Officer is responsible for calibrating and maintaining the licensee's tritium air monitor. He checked the instrument for operability daily and calibrated the instrument on a monthly basis. Records of these tests were maintained.

(Closed) Inspection 83-01: failure to post current copies of 10 CFR 19 and 20 and Form NRC-3. The licensee had posted a current copy of Form NRC-3 and made available to their employees copies of 10 CFR 19 and 20.

(Open) Inspection 83-01: failure to perform bioassays on individuals working in the tritium area. Licensee corrective action not effective because the violation has recurred. A bioassay program was implemented since the last inspection, but no bioassays were performed from November, 1985 to June 17, 1986 on any of the operators.

(Open) Inquiry 85-01: possessing and distributing watches containing by-product material without a valid license. After Notice Of Violation dated March 22, 1985 was issued, licensee continued to order, possess, and distribute watches containing by-product material without a valid license (see paragraph 5).

5. Receipt and Transfer of Materials

The inspector reviewed the inventory records for the watches authorized by the licenses and he also reviewed records of receipt and distribution for the same watches. Based on the records, it appeared that Hamilton Watch had continued to purchase and distribute Certina, Hamilton, and Swatch brand watches after their license expired on March 31, 1984 and after the Notice of Violation dated March 22, 1985. The inspector interviewed the Vice President - Administration who supervised the distribution of the Swatch brand watches. He stated that Swatch brand watches had been purchased and distributed continuously by Hamilton for approximately two years. The inspector also interviewed the Radiation Safety Officer and the Director of Operations and they both indicated that the Hamilton brand watches had been continuously purchased, assembled, and distributed from March 31, 1984 to the time when Amendment No. 3 to License No. 37-03572-06 was issued on October 24, 1985 and Amendment No. 1 to License No. 37-03572-08E was issued on May 3, 1986. In addition, during the time period prior to May 20, 1986 when Amendment No. 4 was issued to authorize possession of timepieces with W. Maier promethium-147 paint, the licensee did possess timepieces with W. Maier promethium-147 paint. 10 CFR 30.3 requires that no person possess or use by-product except as authorized by a specific or general license issued pursuant to Title 10, Chapter 1, Code of Federal Regulations.

The finding that the licensee imported, possessed, and distributed watches containing by-product material, without a valid license, is an apparent violation of 10 CFR 30.3.

The inspector accompanied the licensee to the facility where the Swatch brand watches were stored. The Swatch brand watches were stored and distributed from a facility located at 1817 William Penn Way, Lancaster, Pennsylvania. 10 CFR 30.34(c) requires that each licensee confine his possession and use of by-product materials to the locations and purposes authorized by the license. Condition 10. of License No. 37-03572-06 requires that licensed material be used only at 941 Wheatland Avenue, Lancaster, Pennsylvania.

The finding that the licensee was storing Swatch brand watches containing Radium Chemie PS 362 triated luminous paint at 1817 William Penn Way, Lancaster, Pennsylvania, is an apparent violation of License Condition 10.

The inspector reviewed the inventory records for the watch containing hydrogen-3 and promethium-147. The records indicated that the possession limits of 200 curies authorized on the license had not been exceeded.

The inspector asked the Radiation Safety Officer (RSO) what types of radioactive paint were used in the watches possessed and distributed by Hamilton Watch Company. The RSO stated the Purchasing Department in Lancaster had recently inquired to the Hamilton European Purchasing Department in Geneva, Switzerland concerning this issue and had been

informed that Hamilton had only two suppliers of radioactive luminous paint. The RSO stated that the two suppliers were Radium Chemie and W. Maier. He added that they had not received any watches containing Broadhurst Company, Ltd. tritium paint.

No additional violations were identified.

6. Quality Assurance

The inspector asked the licensee if each lot of timepieces, hands and dials they received containing hydrogen-3 or promethium-147 was accompanied by a certificate which attests that the timepieces have been manufactured in accordance with the European Nuclear Agency and International Atomic Energy Agency standards and that the timepieces do not contain more than the maximum quantity of by-product material authorized by NRC Regulations. The RSO and Director of Operations stated that they had not received the certificates for the Swatch brand watches.

The licensee's failure to assure that each lot of timepieces, hands and dials they receive containing hydrogen-3 or promethium-147 was accompanied by the required certificate is an apparent violation of Condition 8 of License No. 37-03572-08E.

The inspector asked the RSO if the licensee had filed the periodic reports required by 10 CFR 32.16 and 32.25. The RSO produced a letter dated March 21, 1986 in which he reported the number of watches containing hydrogen-3 or promethium-147 transferred during the reporting period. The inspector asked the RSO if this report contained information for all brands of watches imported by Hamilton Watch Co. including the Certina, Omega, and Swatch brands. The RSO stated that his report was strictly for the Hamilton watches and the other brands had not been included in his report.

The finding that the licensee distributed Omega, Certina, and Swatch brand watches and did not include these product transfers in their report dated March 21, 1986 is an apparent violation of 10 CFR 32.16.

7. Personnel Protection - Internal

The inspector reviewed the bioassays records for the operators assembling Hamilton watches. No bioassays had been performed since November 15, 1985. The RSO was asked if any Hamilton watches containing hands and dial faces painted with hydrogen-3 had been assembled since November, 1985. The RSO stated seven operators had worked intermittently since November, 1985 assembling watches with hydrogen-3. Condition 15 of License No. 37-03572-06 requires that bioassays be performed quarterly.

The failure of the licensee to perform bioassays during the first quarter of 1986 on the operators handling dials and hands painted with tritium paint is an apparent violation of License Condition 15.

The inspector visited the storage area where the licensee housed the

hydrogen-3 sealed sources. The room was properly posted and maintained locked. A continuous hydrogen-3 air monitor was operating in this storage room. The records indicated that this monitor had been calibrated monthly and tested for operability daily. The RSO and the Director of Operations stated that they were actively pursuing the disposal of the final sealed hydrogen-3 sources presently in storage.

8. Training and Instructions to Employees

The RSO had attended the Radiation Safety Course that is presented by Harvard University. The Director of Operations showed the inspector a memorandum that all of the operators are required to read prior to starting work. The contents adequately met the intent of 10 CFR 19.12.

No violations were identified.

9. Posting of Notices

An ample number of NRC Form-3 were conspicuously posted and current copies of 10 CFR 19 and 20 were available to employees.

No violations were identified.

10. Exit Interview

The inspector met with the licensee representatives denoted in paragraph 1 at the conclusion of the inspection at the Hamilton Watch Co. facility in Lancaster, Pennsylvania on June 17, 1986 and at the NRC Region I Office in King of Prussia on June 24, 1986. During the June 17 and June 24 exit interviews, the inspector discussed the scope and findings of the inspection and expressed concern with the management's apparent lack of control over the licensed program.