

November 21, 1986

Mr. Thomas T. Martin, Director  
United States Nuclear Regulatory Commission  
Region I  
Division of Radiation Safety and Safeguards  
631 Park Avenue  
King of Prussia, PA 19406

Dear Mr. Martin:

SUBJECT: Docket Nos. 030-20570  
030-12704

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

The following data is in response to the June 17, 1986, safety inspection of our facilities in Lancaster, Pennsylvania. The inspection is relevant to activities authorized by NRC License Nos. 37-03572-08E and 37-03572-06.

Please review the information that is listed by items of your Appendix A - Notice of Violation of the above-mentioned safety inspection (Attachment #1).

Item 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.

Response - The license to possess (#37-03572-06) and the license to distribute (#37-03572-08E) have been amended to be able to possess and distribute watches that contain by-product materials. A new administration has been designated by Corporate Management to eliminate the possibility of any license expiring or not be properly updated. The new Radiation Safety Officer is Thomas E. Deitzler with an Assistant of Joseph C. Sabol.

These two gentlemen head a committee of seven management members which meet monthly to discuss pertinent information regarding both licenses. Minutes are published and follow-up committees are formed to ensure against further violation (Attachment #2).

Both licenses have been amended per the discussion we held with Mr. John Miller. I have enclosed the following two copies which are:

Attachment #3 - License #37-03527-08E (Distribution)

Attachment #4 - License #37-03572-06 (Possession)

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Item B - 10 CFR 30.34(C) requires that each licensee confirms 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.

Response - Possession and distribution amendments have been amended in both licenses to cover the 1817 William Penn Way facility. I have highlighted this amendment on Attachment #3 and Attachment #4 under Item A mentioned earlier.

Item C - 10 CFR 32.16 requires that each person licensed under 32.14 submit a report to the Commission within 30 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.

Response - I have made arrangements with Mr. B. Carrico of the Washington, DC, office to have a year-end summary of all brands distributed from 1984 to the end of 1986, by model, sent to his attention by the end of January, 1987.

This summary will include:

1. Hamilton - January, 1984 through December, 1986
2. Certina - May, 1984 through December, 1986
3. SWATCH - June, 1984 through December, 1986
4. Omega - January, 1986 through December, 1986

This report will be issued at year-end to Mr. B. Carrico's division of the NRC in Washington, DC. NOTE: Many hours were spent by our management team to develop an on-line system to give accurate and timely information regarding units containing by-product material.

Item 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.

Response - I have enclosed copies of invoices, memos, and tests results over the past two months which will verify we have asserted efforts with the bioassays and swipe tests (Attachment #5). These tests are performed by the following firm (see Page 3):

Mr. Thomas T. Martin, Director  
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Page 3

Radiation Physics, Inc.  
10133 Bacon Drive  
Beltsville, MD 20705  
Atten: Mr. Louis M. Rubin, President

We have responded by testing on a monthly basis for the remainder of 1986. For 1987, since all of our results are within regulation guidelines, we will have quarterly testing. These tests are performed by D. R. Klein, Supervisor-Assembly Operations, and T. E. Deitzler, Radiation Safety Officer.

Item E - Condition 8 of License No. 37-03572-08E requires that each lot of timepieces, 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.

I have enclosed invoices which state the SWATCH watches imported have been in accordance with the European Nuclear Energy Agency standards (Attachment #6).

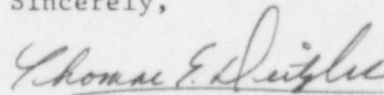
NOTE: Mr. Paul D. Karpouzis is no longer with our company. All correspondence should be sent to:

SMH, Inc.  
Mr. T. E. Deitzler  
Radiation Safety Officer  
941 Wheatland Avenue  
Lancaster, PA 17604

Please call me at 717-394-7161, Ext. 2133 if you have any further questions regarding the responses in this letter.

I would like to thank all of the individuals in the Commission who gave us assistance in updating our licenses and directing us with steps of corrective action. Special thanks goes to Mr. John Miller, Health Physicist of the Region I office, who inspected us in June and kept in close touch to ensure we could resolve any problem or question.

Sincerely,



Thomas E. Deitzler  
Radiation Safety Officer &  
Director, Watch Manufacturing

TED:whd

Attachments

CC: John Miller, Region I  
Bruce Carrico, Washington, DC  
Thomas J. Middleton, Vice-President, Logistics/Operations  
Joseph C. Sabol, Assistant Radiation Safety Officer



APPENDIX ANOTICE 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. 37-03572-08E 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  
37-03572-06

Priority 3  
3

Category E  
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  
John Miller, Health Physicist

10-6-86  
date

Approved by:

John E. Glenn  
John Glenn, Chief, Nuclear Materials  
Safety Section B

10/6/86  
date

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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INTERNAL CORRESPONDENCE

TO: R. C. Wyerman  
P. Haleman \*  
C. R. Keen \*  
W. D. Lamma  
R. C. Hoxworth \*  
J. C. Sabol \*  
D. R. Klein  
E. Steudel  
D. Hildebrand  
R. V. Pilukaitis  
B. Mahaffey \*

FROM: T. E. Deitzler \*

cc: P. D. Karpouzis  
J. F. Gelson  
D. G. Cargas

DATE: June 27, 1986

\* In Attendance

Subject: NRC REGULATIONS

Re: Minutes of Initial Meeting

I'd like to begin by mentioning the fact that we are in a critical period of time regarding our NRC license. Each of the individuals mentioned on this memo had better become more aware of the circumstances we, SMH, Inc. may face if compliance is not met immediately.

First, there could very well be a substantial fine. Secondly, possible stoppage of shipments of tritium/promethium substances in Swatch, Omega, Certina and Hamilton products.

I'm attaching a memo (attachment 1) which I wrote and had E. Steudel deliver personally to ensure everyone would have time to schedule attendance. Only one person, D. Hildebrand, sent a reply to have an alternate attend in his absence.

Over the past week, J. Sabol, P. Karpouzis and myself have spent the greatest percentage of our working hours on this project. This is not including Wendy DiGiacomo's efforts in coordinating the data and typing all responses to Washington, D.C. and King of Prussia.

Also, on June 24, 1986, Paul, Joe and myself spent a morning presenting our revised applications and compliance plan to the NRC inspector in King of Prussia. Efforts by all members on this committee had better become serious very soon! It's imperative when future meetings are called we arrange our schedule to attend or have an alternate in place to access requirements we will need from respective departments.

The following are a few topics we discussed today:

Inventory/Shipments - Within the first week of the new month, I will require total shipments of product containing promethium/tritium of the previous month. Also, inventory at month's end will be required. This is the identical information that was accumulated for our presentation of YTD figures over the past two weeks. We must continue to update and maintain accurate inventories!

(Attachment 2) Data Processing has almost completed this project for Keen and Hoxworth. They will face a problem loading necessary components and models into the system if it's not ready by shutdown. Ron will monitor with Bruce to insure we will have project completed by August!

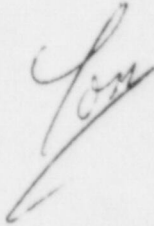
Swipe Tests/Bioassays - Joe Sabol will involve E. Steudel (swipe testing) and D. Klein (bioassays) in the procedure of testing and record keeping of the production areas. These tests will be performed on a monthly basis for the remainder of 1986.

Compliance of Shipments - Pat Haleman suggested M. Luckenbill attend future meetings since he will receive the compliance forms. We all agree he should represent Purchasing.



The next meeting will be on Monday, July 7 1986  
at 9:00 a.m. in the 4th Floor Conference Room. Please  
be advised to have an alternate at this meeting if you  
cannot attend!!

Thank you.

A handwritten signature in cursive script, appearing to read 'T. E. Deitzler', written in dark ink.

T. E. Deitzler

TED/jap

- ATTACHMENT #1 -

INTERNAL CORRESPONDENCE

TO: R. C. Wyerman  
P. Haleman -  
C. R. Keen -  
W. D. Lamma  
R. C. Hoxworth -  
J. C. Sabol -  
D. R. Klein -  
D. Hildebrand  
R. V. Pilukaitis

FROM: T. E. Deitzler

DATE: June 25, 1986

CC: P. D. Karpouzis  
D. G. Cargas

SUBJECT:

NRC REGULATIONS  
RE: COMPLIANCE REPORTING DATA

On Friday, June 27, 1986, at 9:00 a.m. in the new Fourth Floor Conference Room, we will meet to review requirements necessary to comply with our NRC license.

Please send an alternate in your absence to discuss issues which will involve your respective departments.

Thank you.

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TED:whd

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