

November 28, 1978

U.S. Nuclear Regulatory Commission  
Region V  
Suite 202, Walnut Creek Plaza  
Walnut Creek, CA 94596

Re: License No. 04-17679-OIE

Gentlemen:

This letter is in response to two letters received from the Nuclear Regulatory Commission regards to subject matters as follows:

1. A letter hand delivered to myself and Dave Lieberman of Suncrux, dated November 1, 1978.
2. A notice of violations received through the mail on November 6, 1978.

The letter of November 1 required two items of action from Suncrux.

Item number 1 was to limit watches distributed to items authorized by our license.

Regards this item we have after investigation to determine what has been distributed arrived at a decision to curtail sales of all watches and modules containing tritium until all situations now in question are fully resolved.

Item number 2 required a recall of some items which were distributed.

To accomplish this we contacted our customers and drafted a letter which was sent to them, a copy of which is attached. The letter basically spells out our situation and requests return of certain watches to the factory for retesting before re-distribution. As of the time of this writing we have received some items back from two customers where questionable watches were sent. These items will not be re-distributed until they meet all requirements as stated in our license.

#### SUMMARY OF ABOVE TO DATE

As stated above it is Suncrux's intention to curtail tritium watch sales until all items in question have been resolved. The reason for this decision is based on a situation which exist between Suncrux and American Atomics who supply the tritium light sources for use in our watch modules. Breifly, this situation is as follows: When Suncrux originally started to use light sources from American Atomics the tritium tube assemblies were constructed using two small

781226 0059

sealed tubes per watch module. This type of construction was identified as American Atomics model number 60297. It was this type of tritium tube watch module combination which initially was tested and approved for Suncrux's Nuclear Regulatory Commission materials license. Currently American Atomics is phasing out production of this type of construction and replacing the two tube assembly with one single tube. This of course is being done for a series of manufacturing reasons and undoubtedly cost saving factors from American Atomics manufacturing standpoint. Unfortunately the use of a single tube instead of two tubes by American Atomics presents a new model number which when associated with Suncrux's module is not completely identical to the initial proto-types, there in the problem lies. In order to guarantee continuing supplies of tritium assemblies from American Atomics, Suncrux will be forced to use the single tube design tritium assembly. In preparation for this we have constructed modules using the latest type tube assembly from American Atomics and contracted with Viking Test Laboratory a series of proto-type tests. A copy of the purchase order is attached.

The modules currently under test utilize American Atomics sources 60307 and 10276. Suncrux's intent is to re-verify the watch models utilizing the latest American Atomics sealed sources and apply to the Nuclear Regulatory Commission in Washington for either correction to or amendment of our license. This will allow us to use an either or situation regards sealed sources from American Atomics. At the present moment the exact amount of time required to accomplish complete testing and receive approval and license amendment is somewhat unknown, consequently, our decision to curtail sales in regards to stating firm deliveries to our customers. What we will do is accept orders and confirm deliveries only after it appears that we are close to having our nuclear license amended and can put definated delivery dates on any orders that may be outstanding at that time.

Regards orders for tritium watches in our sales backlog, as of this writing three customers have orders for model 41001 type watch. This is an item that was authorized on our original license. Suncrux's intent is to fill these orders adhearing to the requirments established by the license regards to testing and quality assurance procedures etc.

We have received back from some of our customers, watches that appear at the moment not to follow conditions of our materials license. These watches will not be redistributed until they are rebuilt with approved tritium tube assemblies and re-tested to conform to our materials license or we receive ammendments from the Nuclear Regulatory Commission to our original license authorizing distribution of the watches with different tubes.

The following is in response to the November 6, 1978 letter received from the Nuclear Regulatory Commission containing a notice of violation. There were six violations cited as follows:

Violation #1. Watches were distributed using tritium light sources which differed from sources approved in our material license.

The items as stated in the violation, were American Atomics model numbers 60307, 60320 and 10726. Investigation revealed the following: Model number 60307 had been distributed in some mens watches. This item is a direct replacement of an original American Atomics model number 60297. There is a difference in construction regarding the fact that there is now only one sealed tube per tritium assembly versus originally two sealed tubes per tritium assembly. Based on the fact that it is now labeled as a different model number and there is theoretically a change in American Atomics assembly procedures, Suncrux has taken the approach that it is a new item and in order to use source number 60307 we are currently retesting our modules and watches using this new source. There will be no distribution of watches with this source until it has received proper approval and Suncrux's material license has been ammended. Customers who may have received source No. 60307 have been sent a letter of recall.

American Atomics sealed sources model number 60320 and 10726 were purchased for use in a program to design a ladies watch module for use in tritium watches for women. As of the time of this writing, Suncrux's ladies watches are being tested by Viking Labs and Suncrux's intent is to apply for a license ammendment after receiving test results. Consequently, the above mentioned tritium light sources will not be used or distributed until we have received official approval to do so. There were some of the ladies watches with source number 10726 sent to one of our customers as proto-types for his use in market preparation. A letter of recall for these items has been sent to the customer. Source number 60320 has not been distributed to any customers.

Both source number 60320 and 10726 are offered by American Atomics for use in ladies watch modules. the sources are identical in physical size; they do differ slightly in manufacturing construction. Source number 60320 is produced using two tritium tubes, source number 10726 uses one tritium tube. It is Suncrux's intent to persue the use of source number 10726 based on the fact that it is currently the item that American Atomics will probably make one of their standard units.

Violation #2. Proto-type test were not made in regards to certain watches which were distributed.

This again refers to American Atomics sealed source model number 60307, which as stated above in violation number 1, was delivered to the feild. Suncrux will recall as many of that model as possible. We will discontinue use of that tritium source until Suncrux receives license ammendment which will allow its use.



Violation #3. Watches were distributed without complete identifying markings. Watches did not have the Suncrux name on the outside of the watch.

All watches distributed by Suncrux did have the symbol "3H" indentifying the item as having a tritium light source. But quite a few items manufactured and distributed by Suncrux did not have the name Suncrux on the outside of the watch. The watches were manufactured as private label items for other watch companies, consequently, the names Clinton or Hamilton appeared on the item and not Suncrux. All watches regardless of brand name, did have the internal module very clearly identified as being manufactured by Suncrux and containing a tritium light source. All markings on the watch back have been by engraving. We have purchased tooling for our engraving machine which will allow Suncrux in the future to include the name "Suncrux" along with "3H" when the watch backs are engraved. This should resolve any future descrepency regards to proper identification of tritium watches.

Violation #4. Quality assurance test results were not available for review at the time of inspection.

Suncrux's Q.A. test proceedures state that each lot (500 units) of watches will undergo vibration, shock and water emulsion test. The results of the water emulsion test then to be analyzed for tritium content to determine leakage or breakage of tritium tubes. The results of these tests determine acception or rejection of the lot of watches. All tests, with the exception of water analyzing, are conducted internally by Suncrux. Two outside labratories have been used for analyzing tritium content of water samples, since Suncrux does not have the equipment to do so itself.

There has been a series of personel changes and areas of manufacturing moved during the past year at Suncrux. As of the time of this writing we still have not been able to locate paperwork indicating internal test results of different lots produced by Suncrux. We were also unable to find copies of test results from outside test labratories in some cases. We have contacted and received from the outside test labratories copies of reports they sent to Suncrux's Q.A. department. Copies of these are attached.

It appears that there is a large problem internally with paperwork over the last year. We have revised our system and created a form for use in Q.A. testing of watches. This form was put into practice and will be used starting November 1, 1978 and thereafter.

Violation #5. No report for distribution of finished watches manufactured during the year ending June 30, 1978 was submitted to the Nuclear Regulatory Commission.

The report in question deals with distribution of tritium watches by model number and tritium content. The report has now been finalized and sent to the correct agencies. A copy is attached to this letter.

Violation #6. Certain documents as required by 10-CFR-19.11.  
Should be posted for employee observation.  
None were posted at time of inspection.

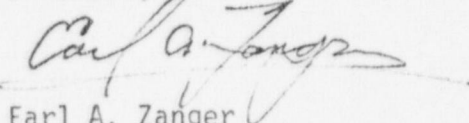
Some of the documents in question were not in Suncrux's possession. These items were received from the Nuclear Regulatory Commission personnel. Copies of all pertinent documents have now been posted in the tritium room, on the outside of the door to the tritium room and in the passage leading to this area of the building.

As the above would indicate, the material license for tritium use has not been followed completely in the last year. Discrepancies and violations of the license as outlined above, have at the time of this writing been corrected. Items currently in process, specifically, test results which will allow amendments to Suncrux's license to be applied for, are not completely finished. They will be pursued and the proper paperwork will be submitted.

I do believe that this investigation and subsequent work to correct the violations have been seriously undertaken by the Suncrux personnel involved. Similar situations should not occur in the future.

I thank you in advance.

I remain,

  
Earl A. Zanger  
President

EAZ: lv  
enclosure

1. Copy of recall letter
2. Copy of test purchase order
3. Copy of test results
4. Copy of distribution report

November 3, 1978

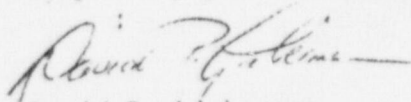
Mr. Aron Benshraga  
Dataking Incorporated  
291 S. La Cienega Blvd.  
Suite 310  
Beverly Hills, CA 90211

Dear Mr. Benshraga:

We have recently been inspected by the U.S. Nuclear Regulatory Commission. In reviewing our records they found that the model number assigned by American Atomics to the tritium product which was originally approved in our license was changed by American Atomics when we converted from two tubes to a one tube product. We are in the process of correcting this technically and hope to have approval shortly.

The U.S. Nuclear Regulatory Commission has requested that any customer with watches containing tritium purchased from us and currently in your inventory be returned to us for re-inspection and upon approval will be reshipped to you.

Very truly yours



David P. Lieberman  
Marketing Manager and Treasurer

DPL: lv



# SUNCRUX

INTERNATIONAL CORPORATION

10440 North Tantau Avenue  
Cupertino, California 95014  
Phone: (408) 257-9750  
Cable: SUNCRUXIN  
Telex: 35-7476

November 3, 1978

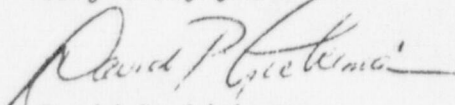
Mr. Yoon K. Lee  
President  
Y.H. Trading Co.  
1930 Wilshire Blvd. Suite 1202  
Los Angeles, CA 90057

Dear Mr. Lee:

We have recently been inspected by the U.S. Nuclear Regulatory Commission. In reviewing our records they found that the model number assigned by American Atomics to the tritium product which was originally approved in our license was changed by American Atomics when we converted from two tubes to a one tube product. We are in the process of correcting this technically and hope to have approval shortly.

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David P. Lieberman  
Marketing Manager and Treasurer

DPL: 1v

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10440 North Tantau Avenue  
Cupertino, California 95014  
Phone: (408) 257-9750  
Cable: SUNCRUXIN  
Telex: 35-7476

November 3, 1978

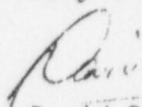
Mr. R.A. Dupree  
Electronic Readout Systems, Inc.  
4701 Eisenhower Blvd.  
Tampa, Florida, U.S.A. 33615

Dear Dick:

We have recently been inspected by the U.S. Nuclear Regulatory Commission. In reviewing our records they found that the model number assigned by American Atomics to the tritium product which was originally approved in our license was changed by American Atomics when we converted from two tubes to a one tube product. We are in the process of correcting this technically and hope to have approval shortly.

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Very truly yours



David P. Lieberman  
Marketing Manager and Treasurer

DPL: 1v



TELEPHONE: (408) 257-9750  
TELEX: 35-7476  
CABLE: SUNCROXIN

PURCHASE ORDER NUMBER  
8-3095  
PREFIX DENOTES ORDERING LOCATION.  
SEE INSTRUCTIONS BELOW FOR ORIGIN.

SUNCRUX INCORPORATED  
10440 N. TANTAU AVENUE  
CUPERTINO, CA. 95014

TO: Viking Laboratories  
440 Bernardo Ave.  
Mt. View, CA 94043

969-5500

SHIP &amp; WRITE TO:

BIL  
TO

SUNCRUX INCORPORATED  
10440 N. TANTAU AVENUE  
CUPERTINO, CA. 95014

DATE OF ORDER 11/16/78	CONFIRMING <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES X TO Kristie	TERMS N-30	TAXABLE <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	CALC. RESALE # SRGH 26-119544	Q A REQ D YES
DELIVERY REQ D BY ASAP	SHIP VIA <input type="checkbox"/> PPD <input type="checkbox"/> COLL Will Call	F O B Mt. View	PRIORITY		VENDOR CODE NO

[illegible]

EST TOTAL \$

TOTAL 600.00

DATE WRITTEN	REQUESTOR'S NAME - EXT	REQUESTOR'S ORGANIZATION		ITEM	JOB NO.	GL JOB	DEPT / SECT	VER
11/16/78	Earl Zanger							
DELIVER TO IF OTHER THAN REQUESTOR		DATE NEEDED	YES XX	NO				
			INSPECT					
			RESALE	XX				

REMARKS SPECIAL INSTRUCTION, SUGGESTED VENDOR, PREVIOUS P.O. NUMBER, ETC.

BUYER		PHONE / EXT		PRESIDENT		TREASURER	
P.O. TYPE		<input type="checkbox"/> INFORMAL		REQUESTION NO		168913	
<input type="checkbox"/> FORMAL		<input type="checkbox"/> SHORT					
ORGANIZATION NAME	DATE	FACTORY NAME	DATE		DATE		DATE

## A. Test Procedures

At least five prototypes of each watch model will be subjected to the performance testing indicated below. Each watch shall undergo all the tests. The tests shall be conducted in the order indicated below. Upon completion of each test, each watch shall be visually inspected for failure. In the absence of failure, the watch shall be subjected to the succeeding test. If there appears to be failure in any test, the watch shall be subjected to the immersion test indicated in A.6 for a positive indication of leakage before proceeding with the next test. Such watches shall also be subjected to the immersion test after completion of vibration testing. Failure of one or more of the prototypes to pass the testing and inspection requirements is cause for rejection of the watch model. Prototypes of the defective model shall not be retested until the defect is corrected.

### 1. Temperature Test

- a. Equipment. The heating and cooling equipment shall have a test zone volume of at least five times the volume of the test watch. The temperature of the test chamber shall be determined by at least two recently calibrated temperature-measuring instruments, and the average of the readings shall be taken as the true temperature. If a gas or oil-fired furnace is used for the temperature test, an oxidizing atmosphere must be maintained at all times.

- b. Procedure. All temperature tests shall be performed in air. All test watches shall be held at or above 65 degrees Centigrade for at least one hour and at or below minus 30 degrees Centigrade for at least one hour. The test watches shall be allowed to remain in the test chamber until they return to ambient conditions. Watches shall be raised from ambient temperature to 65 degrees Centigrade within a five minute period. Watches shall be cooled from ambient temperatures to minus 30 degrees Centigrade within 45 minutes.

## 2. Thermal Shock Test

- a. Equipment. Same as A.1.a.-Temperature Test
- b. Procedure. Watches shall be heated to 65 degrees Centigrade or greater and held at this temperature for at least 15 minutes. The watch shall then be transferred in 15 seconds or less to the cold chamber held at or below minus 30 degrees Centigrade and remain there for at least 15 minutes.

## 3. Reduced Pressure Test

- a. Equipment. The apparatus used for the pressure test shall consist of of a vacuum pump vented to an exhaust system and a sealed chamber having means for visual observation of the watch under test. The pressure gauge shall be calibrated within six months preceeding the test and should have a range at least 10 percent greater than the test pressure.



- b. Procedure. The test watch shall be put into the chamber and exposed to a test pressure of 175 mm Hg (absolute) or less for four periods of 15 minutes each, the pressure being returned to atmospheric between each period.

#### 4. Impact Test

- a. Equipment. A rigid steel plate mounted on an unyielding surface and a support or shelf for watches.
- b. Procedure. The watch support shall be mounted one meter above the steel plate. The watch to be tested will be placed on a support and, using any device or means which will not have a tendency to orient the watch, pushed from the support and allowed to free fall and impact the steel plate in a random manner. The procedure shall be repeated 20 times. The support shall then be positioned two meters above the steel plate. The watch shall be placed on the support and then pushed from the support and allowed to impact the steel plate in a random manner. The procedure shall be repeated twice.

#### 5. Vibration Test

- a. Equipment. The equipment shall be capable of providing a simple harmonic motion having an amplitude of 0.075 centimeter (0.03") and a maximum total excursion of 0.15 centimeter (0.06"), the frequency being varied uniformly between the approximate limits of 10 (hertz) Hz and 55 Hz.

b. Procedure. Test watches shall be subjected to the above simple harmonic motion for 60 minutes. The entire frequency range, between 10 Hz and 55 Hz and return to 10 Hz, shall be traversed in approximately one minute.



COPY

3284 F EDWARD AVENUE • SANTA CLARA, CALIFORNIA 95050 • TELEPHONE (408) 988-1111

ASSAY REPORT

To: Suncrux Incorporated Date November 7, 1977  
10440 North Tantau Avenue Date Sample Received November 3, 1977  
Cupertino, California 95014 Customer P. O. No. 7-1814  
\_\_\_\_\_  
\_\_\_\_\_  
SSi Project No. 77170  
Attn: \_\_\_\_\_

<u>Sample Designation</u>		<u>Activity*</u>
<u>SSI No.</u>	<u>Client No.</u>	<u>Tritium</u> <u>pCi</u>
77170A	1	≤ 700
B	2	≤ 700
C	3	≤ 700
D	4	≤ 700
E	5	≤ 700
F	6	≤ 700
G	7	≤ 700
H	8	≤ 700
I	9	≤ 700
J	10	≤ 700
K	11	≤ 700
L	12	≤ 700
M	13	≤ 700
N	14	≤ 700
O	15	≤ 700
P	16	≤ 700
Q	17	≤ 700

(Continued)





3284 F EDWARD AVENUE • SANTA CLARA, CALIFORNIA 95050 • TELEPHONE (408) 988-1111

ASSAY REPORT (Continued)

To: Suncrux Incorporated Date November 7, 1977  
10440 North Tantau Avenue Date Sample Received November 3, 1977  
Cupertino, California 95014 Customer P. O. No. 7-1814  
\_\_\_\_\_  
SSI Project No. 77170  
Attn: \_\_\_\_\_

<u>Sample Designation</u>		<u>Activity*</u>
<u>SSI No.</u>	<u>Client No.</u>	<u>Tritium</u> <u>pCi</u>
77170R	18	$\leq 700$
S	19	$750 \pm 500$
T	20	$\leq 700$
U	21	$\leq 700$
V	22	$\leq 700$
W	23	$\leq 700$

Analyst: John V. Harrison, Jr.

Approved: M. P. Hughes, General Manager

\*The  $\pm$  values are the two sigma Poisson standard deviation of the counting error.  
The  $\leq$  values are equal to or less than three sigma of the counting error.