

偉仁實業有限公司
GREATON INDUSTRIES LIMITED

香港柴灣利眾街40號亨誠工業大廈二樓A1 A2室
Flat A1 & A2, 2/F., Fortune Factory Bldg.,
40, Lee Chung Street.

Chai Wan, Hong Kong

TEL: (852) 8072146
FAX: (852) 8072146

June 22, 1990

U.S. Nuclear Regulatory Commission
Medical, Academic, & Commercial Use Safety Branch
Washington, D.C. 20555

Ref: American Scitec Inc.
USNRC License 04-21357-01E

Dear Mr. Sirs:

A winding up petition was filed in Hong Kong, against Wing Wah Chong Inv. Co. Ltd, forcing it into liquidation proceedings. Wing Wah Chong was the manufacturer of the smoke detectors distributed by American Scitec Inc.


Greaton Industries Limited has acquired those assets of Wing Wah Chong which deal with Smoke Detector manufacturing, and hired a substantial portion of the employees of Wing Wah Chong involved with the manufacture of those detectors. Operations will continue in the same Wing Wah Chong facility without change until Greaton obtains new facilities.

All of the Wing Wah Chong Radiologic Health, Quality Control, Quality Assurance, Manufacturing, Underwriters Laboratories, and Personnel Policies are to continue unchanged. The product manufactured for American Scitec Inc. is unchanged in materials and process from that manufactured by Wing Wah Chong, and will remain the same until further notice. Dr. F.H. Kendall Phd, has agreed to be the Radiologic Health consultant to Greaton, just as he was to Wing Wah Chong. Dr. Kendall has supervised our transition from Wing Wah Chong to Greaton and prepared the reports for the application and license with the Hong Kong Radiation Board. A copy of that License is attached.

9102080285 901210
PDR FDIA
GOMEZ

PDR

Sincerely,


Kwanwei Chen
Managing Director
for and on behalf of
Greaton Industries Limited

JUL 12 1990

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RECEIVED 29 DEC 1989

RADIATION ORDINANCE

Licence No. 1464

(Chapter 303)

Fee \$ 1200.

RADIOACTIVE SUBSTANCES LICENCE

Under the provisions of the RADIATION ORDINANCE (CAP. 303)

Greator Industries Ltd.

(Name in full)

12, 3/4, Fortune Factory Building, 40 Lee Chung Street, Chaiwan, Hong Kong

is hereby licensed to import, transport, store and assemble sealed sources

containing Americium-241 into smoke detectors

12, 3/4, Fortune Factory Building, 40 Lee Chung Street, Chaiwan, Hong Kong

(Approved Purposes)

for the purpose of

export for sale outside Hong Kong

Subject to the provisions of the RADIATION ORDINANCE (Cap. 303)

(a) The provisions of the RADIATION (CONTROL OF RADIOACTIVE SUBSTANCES)

REGULATIONS and

(b) The CONDITIONS attached hereto

This licence is valid until 26th December 1990

Handwritten signature

K.H. CHENG

for RADIATION BOARD

Dated this 27th day of December 1989

REMARKS (if any)

Interpretation

In these conditions:

"Regulations" means the Radiation (Control of Radioactive Substances) Regulations (Cap.303, Section 13), "Consultant's Report" means the Report by Dr.F.H.Kendall for Greacon Industries Ltd. and titled The Radiological Protection Requirements for the manufacturing of smoke detectors containing Americium-241 submitted to the Radiation Board by Greacon Industries Ltd.

Conditions

1. This licence permits the import, transport, possession, storage, use and re-export sale of the following radioactive substances in quantities not exceeding the stated levels at any time :-

Radionuclide	Description of substance	Maximum amount of radioactivity
Americium-241	Unsealed sources with Am-241 as AmO2 sandwiched between a gold foil and silver backing, with radioactive content of 33.3kBq per source	Not more than 5GBq in store at any time

2. The following persons will be responsible for all activities concerning the radioactive substances covered by this licence:-

Mr.SIA Khiam-beng
Mr.NG Wai-kyok
Mr.HO Wai-kyong

The Radiation Board must be notified in writing of any change of the above personnel within 7 days.

3. The above-named supervisors shall, in accordance with Regulation 32 have received basic training in radiological protection.
4. In accordance with Regulation 11, a register shall be maintained of all workers involved in the radiation sensitive operations. These operations shall include :-
 - (a) transportation and handling of incoming/outgoing sources and finished/semi-finished products ;



- (b) source mounting and ion chamber assembly;
 - (c) reworking of faulty chambers;
 - (d) transportation and storage of ion chambers;
 - (e) assembly of ion chambers into smoke detector body.
5. The names of workers on the register shall be forwarded (with due updating) to the Secretary, Radiation Board. All persons engaged in the handling, transport, storage and use of the radioactive substances are subject to the safeguards specified in Regulations 10, 12, 13, 14, 17, 27, 29, 30, 31, 32, 33 & 34 and the following :-
- Members of staff known to be pregnant shall not engage in any radiation work.
6. Copies of Regulation 30 Section (1) and (2) (a) and (b) together with the Code of Practice for personnel protection (Section 4.2 in the Consultant's Report) shall be reproduced as notices (in Chinese and English) and shall be displayed in suitable areas where they can be clearly seen by the staff to which they refer.
7. All imports of radioactive substances or finished/semi-finished smoke detectors containing radioactive substances shall be covered by an Import Licence issued under the Import (Prohibition) (Radiation) Regulations, by the Trade Licensing Section of the Department of Trade, Ocean Centre, Canton Road, Kowloon. Applications for such licences shall show the nature, quantity and total radioactivity of the material being imported. The Import Licence shall be presented when applying for the removal permit required by Regulation 7.
8. Transportation of the radioactive substances shall be subject to Regulations 6 & 7 and the following :-
- (a) The radioactive substances shall be transported direct from the place of entry into Hong Kong to the approved premises of the Licensee for storage.
 - (b) At least one of the persons named at (2) above shall be trained to handle the damage or loss, etc of radioactive substances, in the event of an accident occurring during transportation etc.
 - (c) Packaged finished goods shall be labelled in accordance with IATA or international shipping requirements.
 - (d) A removal permit as required in Regulation 7(1) shall be applied for and obtained from the Department of Health at 4th floor, Sunning Plaza, 10, Hysan Avenue, Causeway Bay, Hong Kong (Tel. No. 5-8980722).

RH106(2)



- (e) In case of a vehicle break down during transportation of radioactive substances, the vehicle shall not be left unattended.
9. The storage of the radioactive substances shall be subject to the provisions of Regulations 6, 8 and 24 and the following :-
- (a) All finished products containing Americium-241 shall be stored in a separate unoccupied locked store which shall not contain anything other than the smoke detector units. The store shall be kept locked and be of fire resistant construction.
 - (b) The Fire Services Department shall be notified of the locations of stores containing radioactive materials.
 - (c) Not more than 2 smoke detectors (finished products) of each distinct type shall be kept in the licensee's offices for demonstration purposes, these being kept in a securely locked storeroom when not in use.
10. Wipe tests shall be undertaken on 10 sample sources, taken at random, at intervals not exceeding 3 months and on the work-bench area at intervals not exceeding one month in the interests of worker protection. These records shall be submitted to the Radiation Board quarterly.
11. Warning notices shall be exhibited in accordance with Regulation 33, with the further condition that the number and form of warning signs shall conform with the specifications in attachment in Section 8 of the Consultant's Report.
12. Strict accounting shall be kept of all Americium-241 on the premises. In the event of damage or loss of Americium-241, Regulation 34 shall apply. Should a loss be noted, an immediate search shall be accounted for an radiation safety restored in accordance with the requirements of the radiation Board.
13. A radiation monitor (in proper working order) with detectors sensitive to alpha particles and 60 keV gamma rays shall be available at all times.
14. The premises used for radioactive work shall be cleaned in accordance with Regulation 26, with the further condition that decontamination procedures shall conform with Section 4.6 of the Consultant's Report.
15. Radioactive waste including damaged or defective sources and ion chambers, contaminated tissues or other cleaning materials, tools, etc shall be stored on the premises in accordance with Section 4.7 of the Consultant's Report. Final disposal from the premises shall be

RIU106(3)



effected by return of all Americium-241 waste to the original supplier, in accordance with conditions to be stipulated by the Radiation Board on application.

16. Emergency Action

(a) In case of FIRE or HUMAN CASUALTY, call Fire Services (999).

(b) In case of ACCIDENT or LOSS OF RADIOACTIVE SUBSTANCE :-

During office hours (9:00 a.m. to 5:00 p.m.),
notify 5-8988721, 5-8988722 or 5-8988725

After office hours (5:00 - 9:00 a.m.) and on Saturday
Afternoons, Sundays and Public Holidays, notify Telephone
Operator (QEH) 3-7182111.

In all cases, the Secretary of Radiation Board shall be notified in writing within 48 hours.

17. This licence is valid provided that procedures are strictly followed as given in the conditions of this licence together with a strict compliance with those safety precautions specifically laid down in the Consultant's Report and accepted by the Licensing Committee of the Radiation Board. Alteration of procedures will require a re-application to the Radiation Board.
18. This licence refers only to the product as described in the application and the accompanying documents. It is not transferable to products, procedures or premises other than those specified therein.
19. Smoke detectors containing Americium-241 may not be sold or leased for use in Hong Kong without the prior approval of the Radiation Board and suitable amendment to this licence.
20. These conditions may be varied, added to or revoked by the Radiation Board (Radiation Ordinance 1970 - Section 12). Requests for amendment in all cases must therefore be directed to the Board for its prior approval before any changes to the above conditions can be effected.
21. A current copy of the Radiation Ordinance (Cap 383) and the Radiation (Control of Radioactive Substances) Regulations shall be kept at the approved premises for reference.
22. The Radiation Board reserves the right to revise this licence without prior warning or agreement.

RHJ186(E)



Our Ref. : RHU 1304/2

Sunning Plaza, 4th floor,
10 Hysan Avenue,
Causeway Bay,
Hong Kong.

Your Ref. :

Tel. No. : 5- 8900722

The Manager,
Greaton Industries Ltd.,
Flat A2, 1/F., Fortune Bldg.,
40 Lee Chung Street,
Chai Wan,
Hong Kong.

29 DEC 1989

Dear Sir(s),

Issue of Radioactive Substances Licence and
Register of Radiation Workers

Further to my letter dated 19.12.89 , I forward herewith
-- licence No. 1464 together with a receipt for the licence fee.

In compliance with Regulation 11 of the Radiation (Control of Radioactive Substances) Regulations, you are now required to keep a record of all the workers engaged in radiation work in your company. This record should include the name, age, sex, address and date of last medical examination (if applicable) etc. A copy of this record should be provided to this Board, in order that medical examinations can be arranged by this Board for these workers at the appropriate time.

The Radiation Board must also be notified in writing within two weeks of any changes of personnel engaged in Radiation work.

Please note that metric units have been adopted in the licence. For your ease of reference, I table below the metric equivalent of the non-metric units of radiation dose and radioactivity.

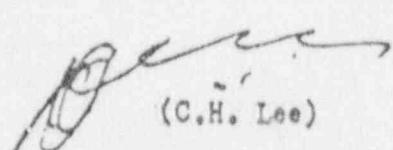
Metric Units

1 gray (Gy)	= 100 rad
1 sievert (Sv)	= 100 rem
1 coulomb per kilogram (C kg ⁻¹)	= 3876 or about 4000 roentgen
1 becquerel (Bq)	= 2.7 x 10 ¹¹ curie

As the units of "curies" had been most commonly used, I also
.....enclose herewith a conversion table which will help you to relate the curie activity to that in becquerels.

Please note that your licence only applied to the particulars as stated on the licence. Any changes in the particulars require an amendment to the existing licence or an application for a new licence. Please therefore give the Radiation Board prior notice in writing of any change in any of the particulars stated on your licence.

Yours faithfully,


(C.H. Lee)

for Secretary, Radiation Board

JUL 12 1990

RS/5

RADIATION BOARD
HONG KONG

Our Ref. : RHU 1304/Z
Your Ref. :
Tel. No. : 5-8900723
The Manager,
Greaton Industries Ltd.,
A2, 3/F., Fortune Factory Bldg.,
40 Lee Chung Street,
Chaiwan,
Hong Kong.

Sunning Plaza, 4th Floor,
10 Hysan Avenue,
Causeway Bay,
Hong Kong.

23 DEC 1989

Dear Sir(s)/Madam,

Radioactive Substances Licence No. 146-
- Register of Radiation Workers


Regulation 11 of the Radiation (Control of Radioactive Substances) Regulations states, amongst other things, that :

- (i) A register of all radiation workers shall be kept.
- (ii) A copy of this register, together with any subsequent amendments, shall be provided to the Radiation Board.
- (iii) Failure to comply with this Regulation is an offence and liable on conviction to a fine of HK\$5,000.

The purpose of this register is to ensure that full records of radiation workers are kept in order that medical examinations can be arranged by the Radiation Board at the appropriate time.

I should be grateful therefore if you would now provide me with a copy of this register which should include the name, age, sex and date of last medical examination (if applicable) of the workers. Please also ensure that a copy of all subsequent amendments will be provided to the Radiation Board as and when they occur.

Yours faithfully,


(C.H. Lee)
Secretary, Radiation Board

RS/6

RHUF28 (E)

Radiologic Health Branch
744 P Street
Sacramento, California 95811

STATEMENT OF TRAINING AND EXPERIENCE

(Use additional sheets as necessary)

Instruction: Every individual proposing to use radioactive material is required to submit a Statement of Training and Experience in duplicate to the address given above. Physicians should request Form RH 2000 A when applying for human use authorizations.

1. Name of proposed user: Laurence K. Chen Position title: Eng. Mgr
Address: 3505 Cadillac Ave. Bldg J City: Costa Mesa, CA. Zip: 92626
To be included on Lic. No. 4230-30 in name of American Scitec Inc.

2. Description of proposed use
241 AM is used in Ionization Chamber Smoke Detectors. Detectors are manufactured by Greacon Industries Limited of Hong Kong, imported by American Scitec Inc and warehoused by American Scitec Inc.

3. Training:
 - a. High School Graduate: Yes No
 - b. College or University: Name and location Univ. of Cincinnati, Ohio
Years completed 8 Degree Ph D Course of study Mechanical Engineering
 - c. Education specifically applicable to use of radioactive material
College Atomic Physics

4. Experience:
 - a. List experience with radioactivity beginning with most recent
 - (1) Dates: From 1977 to 1989
Title and duties: President, CFD: company manufacturing Ionization Smoke Detectors.
Employer: Wing Wah Chong Inv. Co. Ltd. Address: 40 Lee Chung St, Chai Wan, Hong Kong.
 - (2) Dates: From 1989 to Present
Title and duties: Eng. Mgr; Mrktg Mgr; company importing and warehousing Ionization Smoke Detectors.
Employer: American Scitec Inc. Address: 3505 Cadillac Bldg J, Costa Mesa, CA.
 - (3) Dates: From _____ to _____
Title and duties: _____
Employer: _____ Address: _____

- b. Radioactive materials previously used. Cite typical radioisotopes in appropriate box and key to Part 4.a above:

Quantities Handled

	Microcuries	Millicuries	Curies	Kilocuries
Sealed sources		60 mCi ^{241}Am		
Unsealed alpha emitters				
Unsealed beta-gamma emitters				
Neutron sources				

- c. Describe procedures similar to those proposed in Part 2 with which you have had experience. Indicate months or years for each and key to Part 4.a above.

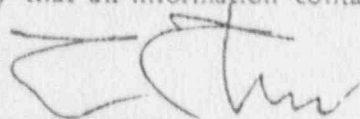
Incorporation of ^{241}Am foils into Ionization Chambers for Smoke Detectors. 1977 to present

- d. Indicate which types of facilities you have used and key to Part 4.a.

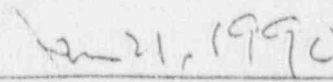
- Ordinary Chemical laboratories
- "Controlled Area" (Type B) laboratories
- Glove boxes
- Shielded glove boxes
- Caves with remote manipulators
- Field operations with portable equipment

5. Certificate:

I hereby certify that all information contained in this Statement is true and correct.



Signature of proposed user



Date