

American Scitec, Incorporated
3505 Cadillac Avenue, Building J
Costa Mesa, California 92626
(714) 549-8680
Telex No. 295648 Scitec



24 June, 1988

U.S. Nuclear Regulatory Commission
Division of Material Licensing
Washington, DC. 20548

Reference: License Number 04-21357-01E

American Scitec Inc. wishes to renew USNRC Distribution license number 04-21357-01E with amendments 01 through 04, per section 30.27, 10 CFR Part 30.

The current license has been reviewed. Our current and anticipated program dictates no changes be made regarding radionuclide, chemical or physical form of radionuclide, possession limit or uses of the radionuclide.

Submitted documents dated 15 April 1983 and letters dated 24 June 1983, 1 July 1983, 6 July 1983, and 29 July 1983 accurately reflect manufacture, quality control procedures, labeling, storage, external radiation profile, access to 241-Am foil and conditions of handling.

The license was amended in its entirety with amendment 2. This reflected a change in methodology for the listing of model numbers and additional listings.

Amendment 3 involved a minor design change to reflect Underwriters Laboratories Inc. listing requirements. Condition 14 was the only affected change in the license.

Amendment 4 reflected an additional listing to Condition 10.

American Scitec Inc. is operating under representations and conditions listed in License # 04-21357-01E Amendment 2, and incorporating condition 14 in Amendment 3 and condition 10 in Amendment 4.

Documents supporting these representations are attached.

In compliance with Section 32.12, 10 CFR Part 32, a record of transfer of smoke detectors is included with the renewal

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USNRC License Renewal, 24 June 1988

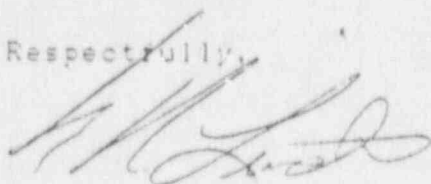
Page 2

application. Period of transfer is from last report dated 2 September 1983 to the present.

Point of contact regarding this renewal is R.R. "Dutch" Ludt II, (714) 549-8680.

A check, number 6576, to cover the license fee of \$390.00, is attached.

Respectfully,



R.R. "Dutch" Ludt II
American Scitac Inc.

AMERICAN SCITEC, INC.
 3505 CADILLAC AVE., BLDG. J
 COSTA MESA, CA 92626

INVOICE	AMOUNT	INVOICE	AMOUNT
LICENSE RENEWAL			310.00
LICENSE NO. 04-21357-CIE			

90-3851/12

6576

390 DOLS 00 CTS

PAY

DOLLARS

DATE	TO THE ORDER OF	CHECK NO	GROSS PAYABLE	GROSS DIRECT	DISCOUNT	CHECK AMOUNT
6/24/88	U.S. NUCLEAR REGULATORY Commission	6576				390.00

GENERAL ACCOUNT

MARINE NATIONAL BANK
 SANTA ANA, CALIFORNIA

Kwan-Jin Chen

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 1 C 2

DEVICE TYPE: Smoke Detector

MODEL: 168101-series
168102-series
168103-series
168104-series
168106-series
168111-series
168112-series

FORMERLY: SDI2002

(all models sold under various brand names some with different plastic housings.)

MANUFACTURER/DISTRIBUTOR: American Scitec, Inc.
Building J-5
3505 Cadillac Avenue
Costa Mesa, CA 92626
(714) 549-8680

MANUFACTURER: Wing Wah Chong Investment Company, Ltd.
40 Lee Chung Street
Chai Wan, Hong Kong
Telex 66325 WWC HX

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation Foil
Model AMM 1001H

ISOTOPE: Americium-241
MAXIMUM ACTIVITY: 0.9 ± .09 µCi/unit

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (P) Ion Generators, Smoke Detectors

CUSTOM DEVICE: _____ YES _____ X _____ NO

B/1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 2 OF 6

DEVICE TYPE: Smoke Detector

All models of this detector contain a single foil source of Americium-241 having an activity of 0.9 μ Ci. The Americium-241 oxide is dispersed in a gold matrix which is covered by 0.001 mm gold layer and then backed by a 0.2 mm silver layer. This foil source is mounted on a stainless steel carrier and then swaged into an electrode by the source manufacturer. The source carrier-electrode are sent to the manufacturer for attachment to a plastic reference chamber. This reference chamber is then attached to the printed circuit board. The metal leads (electrodes) coming from the reference chamber are secured to the circuit board by soldering. The entire reference chamber is then covered with a perforated metal cap which is screwed to a plastic insulator which captures a wire which is soldered to the circuit board. The completed circuit board is then mounted within a decorative plastic housing. Screws, anchors, etc., are provided by the manufacturer to mount the unit to the ceiling, wall, or doors, etc. The source-carrier-electrode or chamber is the same for all models. The American Scitex, Inc. (ASI) model numbering system is as follows:

- 168101-(*) Basic battery operated ion smoke detector. Photo "Fig. 1" is a partial sampling of the covers now "tooled" with many more in process and soon to follow. Note the covers are all about 7" or 5" in diameter ("Large" or "Small" illustrated in photo Fig. 2), and all are round. The printed circuit board, which contained the Ion Chamber, is universally interchangeable in all housings.
- 168102-(*) Battery operated ion smoke detector designed for use on Christmas trees. This model employs the same chamber, electronics, and materials as 168101 model except that housing is designed to be "hung" mounted from objects such as Christmas trees, mantels, etc. In most cases the plastic housing for this model will be spherical in design.
- 168103-(*) Portable battery operated ion smoke detector with clock/alarm. Travel design for use in hotels and motels. Can be self-standing or hung on door. Formally licensed as "Sleep Safe" Model SDI2002.

*A suffix letter follows the dash mark in the model number to indicate the type of plastic outer housing used with the basic detector mechanism as denoted by the seven digit numbers before the dash. With regard to their multiple listees, the ASI distribution license number appears on both the smoke detector and retail box, regardless of name and model.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 3 OF 6

DEVICE TYPE: Smoke Detector

- 168104-(*) Basic smoke detector with heat detector option added. Photo Fig. 3 shows the heat detector option added to the -B, -C, and -D covers, as typical examples.
- 168106-(*) Basic smoke detector with escape light option added.
- 168111-(*) Basic 120 V.A.C. operated smoke detector. Uses mechanical horn instead of piezo.
- 168112-(*) A.C. Detector with "Multiple Station" option added. (Not pictured, same as 168111 with a fourth wire brought out of unit.) Allows interconnection of up to 10 units. When any one unit detects smoke all interconnected units sound alarm.

Referring to photo figure 4, the changes in the detector, from a radiological health standpoint, are negligible. The changes in the smoke detector models are not significant and do nothing to change the containment integrity of the source. These changes are principally electronic and/or cosmetic in nature.

LABELING:

Each detector and point-of-sale package are labeled in accordance with Section 32.29(b), 10 CFR Part 32.

DIAGRAM:

See attachment(s)

DEVICE TYPE: Smoke Detector

CONDITIONS (F NORMAL USE:

These units are designed for use in residential environments to protect life or property from fires.

PROTOTYPE TESTING:

The foil sources used in the smoke detector have been deemed acceptable for licensing purposes by the NRC or an Agreement State. To obtain additional information on the foil sources, consult registration document Nos. NR-136-S-174-U.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 4 OF 6

DEVICE TYPE: Smoke Detector

ASI contracted the services of Janet A. Johnson and James E. Johnson, certified health physicist, to conduct special studies on their devices.

These studies included:

- Drop test - from a height of 8 feet with random orientation onto a concrete surface
- Swipe test - from the source and ion chamber showed less than 1 pCi of activity
- Fire test - units were placed in an oven at 600°C for 1 hour in an oxidizing atmosphere
- Radiation dose rate measurement
- Accessibility to the source
- Vibration
- Impact
- Puncture

The consultants concluded that the smoke alarm satisfactorily passes the requirements of 10 CFR 32.26 and 32.27 and is considered acceptable for distribution to person exempt from NRC regulations.

External Radiation Levels:

The manufacturer reported exposure rates in micro-Roentgens per hour at the surface, 5 cm, and 25 cm from the unit. These exposure rates were obtained by the use of a scintillation type detector, GE (LI) detector with a multi-channel analyzer system, that was calibrated for dose rates using a 0.00795 uCi-241 Am standard. No exposure rate exceeded 7.0 micro-Roentgens per hour.

QUALITY ASSURANCE AND CONTROL:

The manufacturer inspects all incoming parts and supplies, all in-process steps, performs final assembly inspection and/or functional test, and then a final inspection prior to shipment of the unit. They maintain a master file of

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 5 OF 6

DEVICE TYPE: Smoke Detector

records for inspections and for the repairs, sampling plan rejection reports, and swipe test results. The Quality Control Manual for ASI is on file with the Material Certification and Procedures Branch, U.S. NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The devices are used as residential smoke detectors and may be distributed to persons who are exempt from the requirements for a license pursuant to Section 30.20, 10 CFR Part 30.
- The manufacturer states that the devices have been designed, manufactured, and tested to meet the requirements of Section 32.26, 10 CFR Part 32.
- This registration sheet and the information contained within the reference shall not be changed or transferred without written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The manufacturer has demonstrated that the sources are secured within the detector unit in such a manner that extraordinary efforts and special tools are required to remove it.

From the dose calculations submitted by the manufacturer, it is unlikely that in normal use, disposal, handling, storage, of a single unit that an individual would receive a dose in excess of those specified in Column I of the table in Section 32.28, 10 CFR Part 32.

In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in Section 32.38 and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in Section 32.28, 10 CFR Part 32.

Finally, based on our review of the information and test data contained in the references listed below, we conclude that the smoke detector Models 168101, 168102, 168103, 168104, 168106, 168111, and 168112 series are acceptable for

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: NR-134-D-101-E

DATE:

PAGE 6 OF 6

DEVICE TYPE: Smoke Detector

licensing purposes for distribution to persons who are exempt from the requirements of a license pursuant to Section 30.20, 10 CFR 30. The smoke detectors are expected to maintain their containment integrity during conditions of use as specified.

REFERENCES:

The following supporting documents for the Models 168101, 168102, 168103, 168104, 168106, 168111, and 168112 series smoke detector devices are hereby incorporated by reference into and are made a part of this registry document:

- ASI application dated April 15, 1983, with enclosures thereto.
- ASI letter dated June 24, 1983, with enclosures thereto.
- ASI letter dated July 1, 1983, with enclosures thereto.
- ASI letter dated July 6, 1983.
- ASI letter dated July 29, 1983.
- ASI letter dated September 19, 1983.
- ASI amendment application dated October 6, 1983, with enclosures thereto.
- ASI letter dated March 15, 1984, with enclosures thereto.
- ASI letter dated March 20, 1984.
- ASI amendment application dated March 28, 1984, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

DATE: 7 September

DATE: 9-10-84

REVIEWER: Stacy Bell

CONCURRENCE: James Singer

AMERICAN SCITEC INC.

