



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

EDUARDO J. SANCHEZ, M.D., M.P.H.
COMMISSIONER

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1-888-963-7111 • <http://www.dshs.state.tx.us>

July 10, 2006

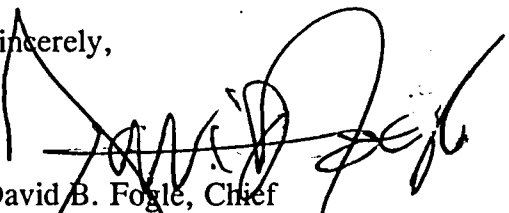
SOURCE CONTAINMENT AND DEVICES BRANCH
OFFICE OF NUCLEAR MATERIAL SAFETY
AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
ATTN TRACI KIME
DOCUMENT CONTROL DESK P1-37
WASHINGTON DC 20555

Dear Ms. ~~Kime~~:
TRACI

Enclosed is the device sheet, TX-634-D-858-B for Thermo MeasureTech Model 9388 ("Alloy Pro") x-ray fluorescence analyzer. This device sheet has been transferred to inactive status at the request of the manufacturer. We would appreciate you distributing copies of this sheet to the other State Programs and NRC Regions, as appropriate.

Thank you for your cooperation and efforts.

Sincerely,



David B. Fogle, Chief
Advanced Technology Licensing Program
Radioactive Material Licensing Group
Radiation Safety Licensing Branch

Enclosure

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX-634-D-858-B
(Supercedes TX-634-D-175-B)

DATE: July 10, 2006

PAGE 1 OF 4

DEVICE TYPE: X-Ray Fluorescence Analyzer

MODEL: 9388 ("Alloy Pro")

MANUFACTURER/DISTRIBUTOR:

Thermo MeasureTech
(formally TN Technologies, Inc.)
2525 North IH 35
Round Rock, TX 78664

Thermo Niton Analyzers LLC
1130 Ten Rod Road
North Kingston, RI 02852

SEALED SOURCE MODEL DESIGNATION:

Thermo MeasureTech Model 696957
(Fe-55 A/S Model IEC.D3; IPL Model XFB6)
(Cd-109 A/S Model CUC.D5; IPL Model XFB-6)

Thermo MeasureTech Model 696280
(Am-241 A/S Model AMC.D4)

ISOTOPE:

Fe-55
Cd-109
Am-241

MAXIMUM ACTIVITY:

20 mCi (740 MBq)
5.0 mCi (166.5 Mbq)
4 mCi (148 MBq)

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(U) X-Ray Fluorescence

CUSTOM DEVICE:

_____ YES ___X___ NO

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DEVICE TYPE: X-Ray Fluorescence Analyzer

DESCRIPTION:

The Model 9388 analyzer (also known as "Alloy Pro") is a portable instrument intended for general purpose analysis of wide variety of materials. The analyzer consists of a hand held probe connected by a cable to a portable battery powered electronic package and displays the analysis results. The system is intended for use either at field measurement sites or in a laboratory environment.

The analyzer is housed in an injection molded case. The body is roughly 12.1 inches (307 mm) long by 3.7 inches (94 mm) in width by 11.1 inches (282 mm) in height. The approximate weight of the probe is 6 pounds (2.7 kg). The measurement end of the analyzer is covered with a one inch (2.5 cm) lead safety cover and contains a 20 mCi (740 MBq) Fe-55 source, a 5.0 mCi (185 MBq) Cd-109 source and a 4 mCi (148 MBq) Am-241 source. The sources are located in a rotating stainless steel turret. Thus each source may be rotated into position by the source drive mechanism as required.

The radioactive sources in the probe provide x-ray excitation of the sample and the resultant fluorescent x-rays are detected by the probe. The information is received by the electronics package, which analyzes information and displays the analysis results. The device may be used in the field or in a laboratory environment.

As of April 25, 2006, 182 Model 9388 devices were sold prior to the discontinuance of manufacture. According to the manufacturer's records, eight Model 9388 devices have been disposed, leaving 174 units still in use including 25 units in manufacturer's storage. The manufacturer has provided confirmation that no changes were made to the Model 9388 since the previous amendment to this safety evaluation of device. The manufacturer has also provided a commitment to no longer commercially distribute the Model 9388 following depletion of fully assembled units in stock.

LABELING:

The device is labeled in accordance with 10 CFR 20.1901. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the distributor, and the words "CAUTION - RADIOACTIVE MATERIAL".

When distributed to persons generally licensed under 10 CFR 31.5, the device is additionally labeled in accordance with 10 CFR 32.51 and 32.51a.

The labels are made of metallized polyester, rectangular in shape and are permanently attached to the device. A copy of labeling is shown in Attachment 2.

DIAGRAM:

Attachment 1 contains multiple views of Model 9388 with labeling
Attachment 2 contains label examples.
Attachment 3 contains an example of the general license tag.

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DEVICE TYPE: X-Ray Fluorescence Analyzer

CONDITIONS OF NORMAL USE:

The Model 9388 analyzer is intended for general purpose analysis of a wide variety of materials. The device is portable and must be used in environments compatible with man. If severe conditions occur (explosion or fire), the analyzer will likely be destroyed. However, the sealed sources should remain intact under these adverse conditions. Construction criteria for each sealed source was provided to the manufacturer in which American National Standards Institute (ANSI) classifications were provided. The ANSI classification for Fe-55 was C44243, for Cd-109 was C54243 and for Am-241 the classification was C54344.

PROTOTYPE TESTING:

The source holder mechanism is similar in design to the Thermo MeasureTech Metallurgist and Metallurgist Pro models. These analyzers have operated in the field for over 20 years with great success.

EXTERNAL RADIATION LEVELS:

With the three sources at their maximum activity and the source in the shielded or closed position, the gamma and x-ray exposure rate is < 0.1 mR/hr ($1.0 \mu\text{Sv/hr}$). The maximum unshielded exposure rate was measured, for each source, using a thin-window NaI scintillation counter to measure the photon flux and then converting that flux into mR/hr using the mass-energy attenuation coefficient for air at the particular energy being measured. Dose rates when each source is in place are provided in the following table.

RADIONUCLIDE, MAXIMUM ACTIVITY	2 inches (5 cm) from source	12 inches (30 cm) from source	36 inches (91 cm) from source
Fe-55, 20 mCi (740 MBq)	220 mR/hr (2200 $\mu\text{Sv/h}$)	6 mR/hr (60 $\mu\text{Sv/h}$)	0.2 mR/hr (2 $\mu\text{Sv/h}$)
Cd-109, 4.5 mCi (166.5 MBq)	108 mR/hr (1080 $\mu\text{Sv/h}$)	3.8 mR/hr (38 $\mu\text{Sv/h}$)	0.5 mR/hr ($< 5 \mu\text{Sv/h}$)
Am-241, 4 mCi (148 MBq)	4 mR/hr (40 $\mu\text{Sv/h}$)	0.5 mR/hr (5 $\mu\text{Sv/h}$)	< 0.1 mR/hr ($< 1 \mu\text{Sv/h}$)

QUALITY ASSURANCE AND CONTROL:

The devices are checked against the strict adherence and applicable quality assurance procedures of the ISO 2001 program. Any deviation below those specifications or inadequate performance during testing will cause the device to be rejected.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The devices were distributed to specific or general licensees of NRC or an Agreement State.
- The device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 185 Bq ($0.005 \mu\text{Ci}$) of removable contamination.
- Repair, maintenance, disposal and source exchange, if necessary, will be provided by Thermo Niton Analyzers LLC.

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DEVICE TYPE: X-Ray Fluorescence Analyzer

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont'd):

- The customer is provided with a comprehensive instruction manual. For general licensees, the appropriate regulations are also included.
- The customer is advised that all repairs on the probe are to be performed only by **Thermo Niton Analyzers LLC**.
- Handling, storage, use, transfer and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- Work on the system near the source holder is prohibited when the shutter is in the OPEN position.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the **Texas Department of State Health Services**.

SAFETY ANALYSIS SUMMARY:

This device is designed to be safely used by an individual, who follows the manufacturer's instruction.

Although the device is no longer being manufactured or commercially distributed by the manufacturer, we continue to conclude that Model 9388 devices are acceptable for licensing purposes.

REFERENCES:

The following supporting documents from Thermo MeasureTech are hereby incorporated by reference and are made part of this registry document.

- letter dated July 8, 2002 with associated documents and drawings
- letter dated October 8, 2002
- letter dated October 11, 2002 with associated documents and drawings
- letters dated January 10, 2003
- letter dated January 23, 2003 with associated drawings and
- letter dated April 25, 2006

ISSUING AGENCY:

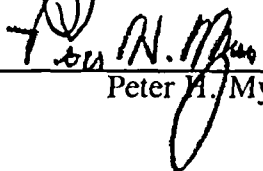
Texas Department of State Health Services
Radiation Safety Licensing Branch

Date: July 10, 2006

Reviewer: 

David B. Fogle

Date: July 10, 2006

Concurrence: 

Peter A. Myers

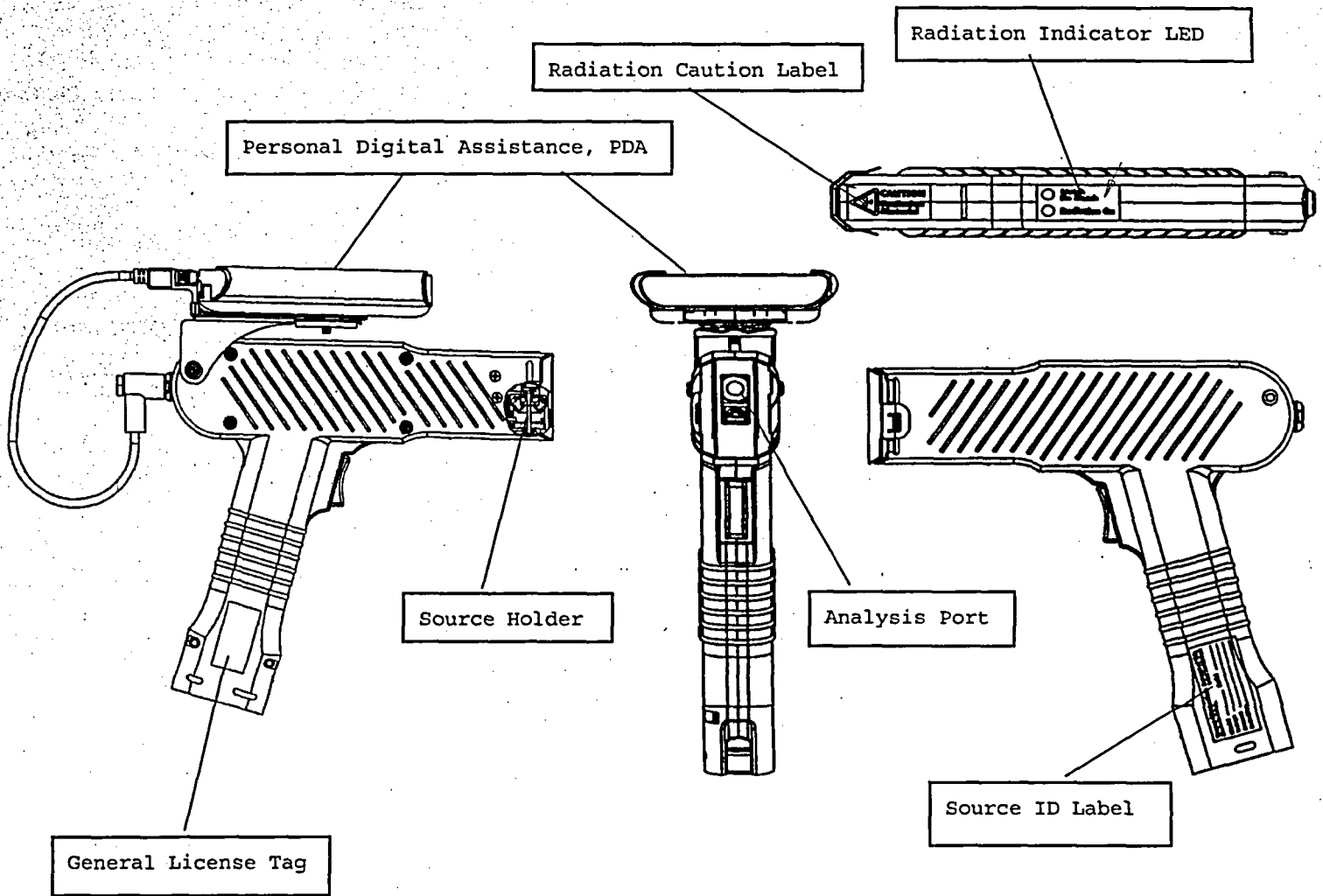
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ATTACHMENT 1 OF 3

DEVICE TYPE: X-Ray Fluorescence Analyzer



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SAFETY EVALUATION OF DEVICE

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ATTACHMENT 2 OF 3

DEVICE TYPE: X-Ray Fluorescence Analyzer

Thermo MeasureTech	Removal of This
Made in U.S.A.	Label Prohibited
Model _____	Serial _____
Isotope _____	_____
Amount _____	_____
Date Meas. _____	_____



<input type="radio"/>	Match
<input type="radio"/>	No Match
<input type="radio"/>	Radiation On

License Information
Can Be Retrieved
from PDA Display

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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ATTACHMENT 3 OF 3

DEVICE TYPE: X-Ray Fluorescence Analyzer

REMOVAL OF THIS LABEL IS PROHIBITED

1. The receipt, possession, use and transfer of this device is subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission (USNRC) or the regulations of a State with which the USNRC has entered into an agreement for the exercise of regulatory authority.
2. Abandonment or disposal is prohibited. Transfers must be in accordance with USNRC or State regulations.
3. Continued operation is prohibited if there is any indication of failure of the source containment or shielding, and TN Technologies should be notified.
4. Only persons specifically authorized by the USNRC or an Agreement State may install, relocate, dismantle or repair the source containment portion of this device.
5. This device shall be tested for leakage of radioactive material at intervals not to exceed six months, and records of the results maintained on file.
6. Additional information on the regulatory requirements and safe use of this device are contained in the operating manual and regulatory information furnished by TN Technologies.

General License Tag