



Re: Environics USA, Inc. License # 19-23974-01E Renewal

Appendix 5-copy of EUSA Rad SOP



Standard Operating Procedure **(SOP)** **For Licensed Radioactive Materials**

(Version 3.2 May , 2012)

Initial Approval: _____ Date: _____

<i>Approved by:</i>	<i>Date:</i>
Timo Jaakkola	June 14th 2012

Environics USA, INC
1308 Continental Drive, Suite J
Abingdon, Maryland 21009



Revision history

Version	Date	Action	Accepted by
3.2 -current	May 29th 2012	Training logs and records added, Pregnant worker section added, safety audits section added, license copies updated.	

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Standard Operating Procedures (SOP) for
Licensed Radioactive Materials(s)
Version 3.2, June 2011

1. Intent

This document constitutes Environics USA, Inc. Standard operating procedure (SOP) for Licensed Radioactive Materials at its operating facility at 1308 Continental Drive, Suite J Abingdon, Maryland 21009 and any ancillary site indicated and approved in the respective licenses or any approved temporary job site.

The intent of the SOP is to define procedures which will enable Environics USA to operate in a safe and regulatory compliant manner in order to appropriately protect its employees, visitors, customers, shipping agents and the general public.

This SOP is specific to the current intent of use of the Radioactive Materials License, which is to handle, maintain, repair and distribute the Environics product line.

2. Responsibilities:

Every employee of the company will be made aware of Radioactive Materials license and this SOP; and will receive specific training, as appropriate to his /her job requirements. The procedures herein are fully supported by the company's officers and management, and every employee will be instructed to adhere to them. In addition all employees are positively encouraged to identify any safety or practical concerns or discrepancies to the RSO, their supervisor, or a manager as soon as practical.

The Radiation Safety Officer (RSO) has primary responsibility for ensuring compliance with Environics' USA's SOPs, US State Codes or regulations where work is done, State and Federal regulations, conditions of the NRC License, DOT Transportation Regulations under 49 CFR, and any other applicable regulations in regards to working with the Licensed Materials.

3. Radiation Safety Officer, Specific Responsibilities:

Specific duties and responsibilities of the RSO include but are not limited to the following:

A. Ensure that all terms and conditions of the Licenses for the US State location of operations, the Federal NRC code are complied with; and to identify any potential issues, reporting these to Management, and resolving them.

B. Ensure that all hardware received by Environics USA, which contain the Licensed Radioactive Material is leak tested in accordance with the License and incorporated into the required documentation and tracking system in a timely manner.



C. Ensure that the licensed Radioactive Material is serviced or distributed only by individuals who are authorized by the License.

D. Ensure that full records are maintained for seven years to include the following; Leak Test Records, Training Records, 'Exemption Distribution' Records, and Transfer and Disposal Records.

E. Ensure that all Radioactive Materials which have not been 'Exempt Distributed', transferred or disposed of are properly secured against unauthorized access and/or removal.

F. Serve as a point of contact with the Federal Nuclear Regulatory Commission, (NRC) State of Maryland, and any other regulatory bodies or individuals for reporting and discussion of License related issues, including loss, theft or damage of Radioactive Materials.

G. Ensure that all users read and understand Envionics USA Inc.'s Emergency, Operating and Radiation Safety Procedures.

H. Ensure that all required documentation, procedures, records, postings and other required documentation are appropriately displayed / maintained.

I. Maintain RSO certification and approval through mandatory refresher training and and study as required by Federal and State level regulations.

4. Normal Procedures:

The Normal Procedures define the usual operation of this facility

4.a Receipt:

Only Designated Shipping / Receiving Employee(s), who have received specific training for these tasks, are authorized to open incoming packages which contain, or are believed to contain, the Licensed Radioactive Materials. Typically these packages will be clearly identifiable through either the Shipper's identity or the attached Packing list.

Prior to opening any package containing the Licensed Radioactive Materials, and preferably before the carrier has left, the Receiving employee is required to perform a thorough visual / physical external inspection of the packaging. If any damage is noted that is considered to be potentially damaging to the integrity or safety of the regulated devices, the RSO must be notified immediately. If the RSO considers that a safety issue has occurred which affects the customer or shipper, he must immediately report the discrepancy in accordance with F.A.C. procedures, and proceed with surveying / securing the package.



4. b Unpacking /Identification:

It is necessary to identify and discriminate between customer's units (which have already been "Exempt Distributed", or sold), and new units and subassemblies arriving from Envionics OY, Finland. All new items, sensor units or any item containing a Rad source that lacks a recorded radiation wipe data must be wipe tested. See the appropriate appendixes at end of this document for specific wipe procedures.) No items containing a rad source may be sold or shipped without approved wipe results recorded in the RAD item database.

All units which have already been 'Exempt Distributed', and have existing wipe result data will be logged in, identifying the Serial Number, the customer and the reason for its return. The units will be logged into the facility's possession in the Radioactive Materials database, and subsequently logged out of the building when shipped back to the client. These units do not require wipe tests unless there has been work/ repair of the unit that has resulted in the replacement of the sensor module that contained the sealed source. If the replacement sensor module has already been wipe tested and there has been no damage to or work on the sealed source that may have compromised the sealed source then the standing wipe result for the replacement sensor module is acceptable for the repaired unit. The change of the sensor module will be noted in the company database and the new wipe data updated for the unit in question.

Licensed Radioactive materials which have not yet been 'Exempt Distributed' will be logged into the facility's Radioactive Materials Database, as soon as they are unpacked and wipe tests will be performed. The Radioactive Materials Database will be updated as they are repackaged for shipment after the RSO has released the units for distribution.

Licensed Radioactive Materials will be thoroughly inspected as they are unpacked to identify any possible damage which could pose a possible radiological threat. The receiving employee must inform the RSO immediately of any concerns. If the RSO considers that a safety issue has occurred which could affect a employ, customer or the shipper, he must immediately report the discrepancy in accordance with F.A.C. procedures and proceed with surveying / securing the package.

The receiving employee is also required to compare package contents with the Packing list; **ANY** discrepancies in respect to Licensed Materials must be reported to the RSO immediately. The RSO is responsible for contacting the customer/shipper and resolving the issue. All discrepancies or variations in regards to Licensed materials must be resolved to the RSO's satisfaction.



4. c Storage:

Environics USA, Inc's entire facility is considered a 'secure' site. Requiring both a key and access badge to obtain entry into the facility, this provides adequate protection for the Licensed Radioactive Materials. However materials or devices which are not going straight to the lab / Production areas or are not "work in progress" will be stored in the 'Radioactive Materials Storage Room' which is kept locked when not being accessed.

Special storage considerations are done for the ChemPro100 sensor boards that are based on a Ni-63 source material. These Ni-63 boards are licensed and approved for sale **ONLY in Canada.** Envionics is licensed to possess these Ni-63 boards in the US but they are not approved for sale/distribution in the US.

To ensure 100% control of these Ni-63 based boards they are stored in a locked yellow case that is connected to the shelving in the Rad Storage room. This case is to be locked at all times unless being accessed. To obtain access contact the RSO who will open the case and record specific serial numbers/use of the removed boards.

There is a limited number of Demo/Engineering units that have been converted to the Ni-63 sensor boards. All these units that have been converted have been relabeled with the Canadian Specified Ni-63 Radiation warning label. All Ni-63 demo/eng units not currently in use will be stored in the above mentioned yellow storage case located in the Rad Storage room.

4. d Work-in-Progress:

For "work-in-progress" items, the licensed Radioactive Materials may be stored in the Lab. / Production areas. Access to these areas will be limited to staff who have received the appropriate training and certification or under the supervision with the required training.

4. e Packing & Shipping:

Packing and Shipping will only be performed by employees having received the specific training required for these tasks.

Items must be packaged and shipped in accordance with the State of Maryland Radioactive materials possession license, the Federal NRC regulations regarding Exempt distributable devices, international air and cargo transportation regulations (IATA and ICAO), DOT (US Department of Transportation) Regulations and others.

For the Licensed Radioactive Materials for distribution by Envionics it is acceptable to package them in Standard Commercial Packaging, they must also be labeled in accordance with the specific License and DOT Regulations. All boxes must have the following statement placed inside: (see next page for example of inserts.)



The following are the required shipment inserts that must be placed inside the box in such a way that they are readily visible once the outer box is opened. The first two inserts are for the ChemPro or M-90 products or variants. In the majority of the time the insert for Americium-241 will be the insert used since this covers the M-90 and ChemPro and the majority of the variants of the ChemPro. (FX, UAV, or DM module.)

**Radioactive Material,
Limited Quantity
Excepted Package**

Class 7, UN 2911 Instruments or Articles

Radioactive, Americium-241 (AM-241)

160 microCuries

Class 7, UN2911

Limited Quantity; DO NOT OPEN

**THIS PACKAGE CONFORMS TO THE CONDITIONS AND
LIMITATIONS IN 49CFR 172.422 FOR RADIOACTIVE MATERIALS,
EXCEPTED PACKAGE-LIMITED QUANTITY OF MATERIALS,
UN2911**



The Nickel-63 sheet is for a ChemPro variant that uses a Nickel-63 source and is for distribution in Canada only at this time.

**Radioactive Material,
Limited Quantity
Excepted Package
Class 7, UN 2911 Instruments or Articles**

Radioactive, Nickel -63 (Ni-63)

370 mBq

Class 7, UN2911

Limited Quantity; DO NOT OPEN

**THIS PACKAGE CONFORMS TO THE CONDITIONS AND
LIMITATIONS IN 49CFR 172.422 FOR RADIOACTIVE MATERIALS,
EXCEPTED PACKAGE-LIMITED QUANTITY OF MATERIALS,
UN2911**

The last insert is for use with the ENVI series of industrial monitors/detectors that utilizes a Tritium source as the ionization material.

**Radioactive Material,
Limited Quantity
Excepted Package
Class 7, UN 2911 Instrument or Article**

Radioactive, Tritium (H-3)

8.1 mCi or (300 mBq)

Class 7, UN2911

Limited Quantity

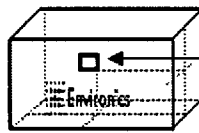
DO NOT OPEN

**THIS PACKAGE CONFORMS TO THE CONDITIONS AND
LIMITATIONS IN 49CFR 172.422 FOR RADIOACTIVE MATERIALS,
EXCEPTED PACKAGE-LIMITED QUANTITY OF MATERIALS,
UN2911**



The inner shipping box may have the “radioactive materials location” label applied to the outside of the white Envionics box if applicable. Note that this label is not required to be on the actual outer box.

Am-241, 160 μ Ci. THIS DETECTOR IS AUTHORIZED FOR DISTRIBUTION TO PERSONS EXEMPT FROM LICENSE UNDER NRC LICENSE NR-1160-D-101-E. THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH USNRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.



THE LOCATION OF
THE RADIATION
SOURCE IN THE
PACKAGE

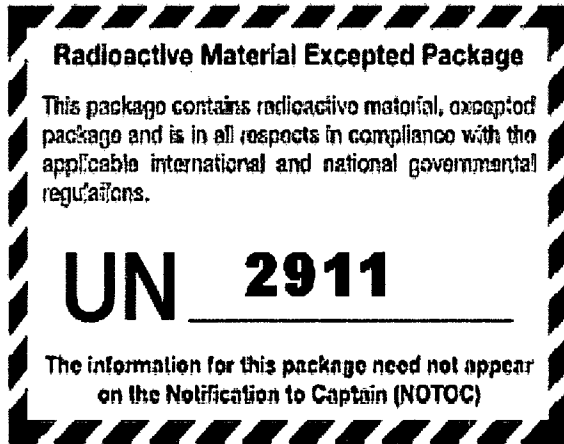


Per US Department of Transportation (DOT), (49 CFR 173.421); the International Civil Aviation Organization (ICAO) “Technical Instructions for the safe transport of Dangerous Goods by Air”, (“TI”) (table 3-1, Dangerous Goods List, column 5), and the International Air Transport Association, (IATA) requirements which are found in the “Dangerous Goods Regulations”, (“DGR”) section 10.5.9.2.2, there are no specific package labeling requirements for excepted packages. However the 2005 editions of the ICAO TI and IATA DGR imposed a new labeling requirement for excepted packages that they ‘recommend’ be used from that point in time, and became mandatory on Jan. 1, 2007. The label is a rectangle bordered by red hatchings with the heading “Radioactive Material-Excepted Package” and the following statement: “This package contains radioactive material, excepted package and is in all respects in compliance with the applicable international and national government regulations.” Below this statement are the letters “UN” followed by a space for the writing in of the appropriate UN number. A copy of the general label is enclosed on the following page. This label must be placed on the outside of the outer shipping container and is the only required external label bearing the word ‘radioactive’ required for shipping of product by air.

Per US Department of Transport (DOT), 49 CFR 173.422(a) all packages that contain exempt classed radioactive materials as a minimum require the UN 2911 classification label or wording on the outside of the package. Since Envionics USA currently labels all packages that have radioactive items with the above mentioned IATA/ICAO label this will cover the requirements of 49 CFR 173.422.

To ensure compliance all packages must have the UN2911 air transport label affixed.

This label will be affixed on all packages that have Rad containing devices within to ensure compliance if the box is routed via air.





5. Radiation Training:

Environics' Radiation Training Program is intended to provide employees with a working knowledge of radiation and its effects, such that they can conduct normal operations in the safest possible manner, and to make them aware of issues that may affect the general public, visitors, customers, shipping agents, and any other persons who might come into contact with the Licensed Material.

Radiation Training will be carried out for all employees who will be handling the Licensed Material. At this time it is the RSO's responsibility to provide the Radiation Training. Initial training with new personnel will be performed within 90 days of hire, before this training the new person must be supervised by fully trained personnel.)

Annual refresher Radiation Safety Training will be done for all needed personnel as part of the Radiation program review and hard counts which is done in December of each year and must be completed by the end of January.

The following topics are required to be covered in detail:

- i. Principles and fundamentals of radiation protection and safety practices related to the use of Radioactive materials, including ALARA principles including (20 Minutes)
 1. Health effects.
 2. Types of Radiation.
 3. Am-241 specific hazards.
 4. Typical Precautions and Protection.
 5. For any applicable personnel explain the procedures for Pregnant worker Declarations and the relevant procedures, (see Appendix 10 of this document.)
- ii. Radioactivity measurements, and the required Wipe Test per the NRC License (10 minutes)
- iii. Transportation Requirements, per 49 CFR to cover the following (20 minutes)
 - General awareness/familiarization with the general provisions of 49 CFR: 172 as well as materials specific requirements
 - Materials Safety and Security requirements specific to the materials
 - Emergency response, self protection and accident prevention
- iv. Practical experience with the use of Radioactive Materials (10 minutes)
- v. Normal and emergency procedures (20 minutes)



The RSO is also required to maintain on record a Resume of appropriate training and experience in order to be able to train the above subjects.

There will be an individual oral test at the completion of the training. The test standard is that each student will be required to satisfactorily demonstrate to the RSO that he/she has the knowledge and common sense required to safely operate in accordance with the SOP. The pass/fail status of each worker will be recorded on the training record in the appropriate column and signed by the RSO.

6. Hazardous Materials Training:

Every employee involved in any aspect of handling the licensed Radioactive Materials must receive Hazardous Materials Training per 49 CFR, Subpart H. New employees can work for 90 days without the training provided they are directly supervised by a trained employee.

Refresher training must be completed at least once every three years as specified by DOT regulations in 49 CFR: part 172 for the RSO and this is done as an addendum to the RSO certification and approval through mandatory refresher training and done every three years. For other employees the RSO is responsible for the initial and refresher training.

General awareness / familiarization, function specific, and safety training must also be covered. Training records must be maintained for the duration of employment plus 90 days. The RSO will give this training at the same time as the Radiation Training. Annual refresher training will be done for all personnel as needed as part of the Radiation program review and hard counts which is done in December of each year and must be completed by the end of January.

7. Emergency Procedures:

For the purpose of this document an emergency is any situation in which a potential Radiological threat exists, or may exist. It is every employee's responsibility to monitor for, identify or report potential Emergencies. The intent of these Emergency Procedures is to;

- A: Limit personnel and environmental exposures to potential radiation.
- B: Contact the appropriate personnel and authorities.
- C: Contain the emergency.

Due to their nature, emergencies are unexpected and unpredictable, and therefore each emergency may call for handling in a different way. With safety being the overriding criteria, use common sense to deal with each emergency appropriately; however typical procedure might be as follows:

- i. In the case of fire or Facility damage (e.g. from a storm or other natural event) call 911 if needed.
- ii. Contact the RSO or his deputy.
- iii. Move all employees from the suspected radiological hazard zone.



- iv. Limit access to the suspected hazard zone to those who are not actively involved in responding.
- v. In the case of localized damage to Licensed Material (for example if a damaged detector is received in a shipment) the device should be sealed, labeled and securely stored until survey results are available.
- vi. Ensure that all responders are aware of the potential radiological hazards.
- vii. As necessary, arrange for appropriate radiological surveys of the emergency.
- viii. In the event that the emergency is unrelated to the Licensed Materials, ensure the responders are aware of the location and type of the Licensed Materials, should the extent of the emergency conditions change.
- ix. Report as necessary to the Maryland Department of the Environment and Federal NRC and any other authorities as needed.

For any Emergency involving the Licensed Material the RSO must generate a report to include the following information. This report will given to the President of EUSA and any appropriate regulatory agencies as necessary and a copy will be placed in the Rad files.

- a. Type of Emergency
- b. Response to the Emergency
- c. Licensed Materials affected
- d. Details of the Emergency
- e. Personnel involved & Exposure Risks
- f. Date / time / location
- g. Resolution
- h. Recommendations

Natural disaster or storm preparation

In the preparation for a possible storm or other natural disaster the standard procedure regarding Rad Sources is that all Rad sources or devices with a Rad source will be moved into the Rad storage closet for safety as part of the building preparation for the event. The RSO will ensure that all Rad items in any stage of production or testing are located and placed in the Rad storage closet. A copy of the Rad item database will be made and taken offsite by the RSO to ensure record continuity.

There is a possibility that the Fed NRC or State Radiation control Department might contact Environics USA before the storm to ensure that the facility is being prepared for the approaching storm and that the Rad Sources are being safeguarded.

After the storm has passed the RSO or his designate will visit the Environics facility as soon as possible to check on the facility and the security of the Rad storage. If the building and/or Rad closet has taken any damage the RSO will take whatever steps are necessary to contain and limit any damages. If any damages to the Rad closet or the devices contained within has occurred, then the RSO will report this and the actions taken to resolve the issue to the president of EUSA and to the Fed NRC and specific State Department of Radiation Control as necessary. If there has been no damage or impact to the facility that affects the Radiation sources, this information will also be relayed to the president of EUSA. Federal NRC and specific State Department of Radiation Control may be notified also if necessary.



8. Survey Laboratory:

Environics USA uses accredited laboratories for all Radiological testing. The primary lab and consultant in regards to Radiation issues and wipe tests is Radiation Safety Services Inc. (RSSI).

Radiation Testing Laboratory

Radiation Safety Services, Inc. (RSSI)
6312 West Oakton Street
Morton Grove, IL. 60053-2723
Phone 1-847-965-1999
Fax 1-847-965-1991

Radioactive Materials License # IL-01429-01

A copy of RSSI's complete license and permit is on file in the Open Radiation files located in the file room. The RSO also has a copy in his records

9. Safety Audits:

At this time Environics USA, uses the services of International Radiation Safety Consulting, Inc. to perform periodic Radiation program audits and other consulting and assistance in applications and license work.

Radiation audits are performed as desired by the CEO of Environics USA. The audit reports and the actions done based on them may be found in Appendix 13 of this SOP. Official copies of the audit reports are on file in the public section of the Radiation records found in the front file room at Environics USA, Inc.

International Radiation Safety Consulting, Inc.
17 Norfolk Road, Holbrook, MA 02343, USA
Phone : 877-266-0794 (US)
 : 781-767-2176 (Outside US)
Fax: 781-207-0453
www.irsc-inc.com



10. Survey Meter and other tools:

At this time there is no direct requirement by the Federal NRC or the State of Maryland for Environics USA to possess a hand held survey meter (aka Geiger counter.) However it was noted in the last Radiation program audit that Environics did not possess one.

Environics USA is currently investigating the requirements and cost of obtaining a survey meter.



Appendix 1 to Environics USA Radiation Standard Operating Procedure (SOP)

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Appendix 1 to Envionics USA Radiation Standard Operation Procedures (SOP) for ChemPro 100 and variants: (ChemRAE, Draeger Multi IMS, ChemPro-DM module, ChemPro-PD and ChemPro-FX)

Receiving Inspection Procedures conducted EUSA

The ChemPro 100 and “marketing” named variants, (the Multi-IMS and the ChemRAE are CP100s that have been relabeled for sale through a marketing agreement with the respective distributors,) in the following sections the general name of ChemPro100 will be used to indicate all types of units unless there are specific instructions or procedures needed for a branded unit.

The other variants on the ChemPro100; the ChemPro-FX, DM, and PD are all family variations of the ChemPro100 where the form or external case has been redesigned to meet specific requirements of customers or applications. However all of these variants use the ChemPro100 sealed source design that has been reviewed and approved for exempt distribution by the US NRC. All of these family variants are considered as ChemPro100s by the US NRC and are held to the same level of labeling and requirements as specified in Envionics USA's federal license.

Units are shipped directly from Finland (EOY) to the Envionics USA (EUSA) facility in shipping packages. The EUSA personnel will perform contamination surveys (wipe tests) and visual inspections as well as startup tests and fill out the NRC Exemption Compliance/Quality Checklist, (see attachment 1) ***100% of units received to EUSA will have the NRC Exemption Compliance/Quality Checklist completed.*** The radiation wipe test is preformed using the same procedure as is used in Finland by Envionics OY or their representative. **No device may be shipped from the EUSA office without the Radiation wipe test and the Compliance/Quality checklist being completed and the RSO or his designate approving the shipment.**

NRC requirement: 100% of the ChemPro and Multi-IMSS distributed by Envionics USA will be leak (wipe) tested.

Contamination Survey (Wipe Test)

Overview

The wipe test is a two-phase operation. The first phase is conducted in Finland where the unit is tested for contamination as part of the build process or as preparation for shipping. Phase two of the test is preformed in the United States where all SSD containing units are wipe tested as part of the receiving process. The wipe tests are conducted as contamination surveys on all the received ChemPro 100 or other named detectors that contain a Rad source. The detectors are wiped after delivery to the EUSA office in the United States as part of the device receiving procedures. The contamination survey data from both sets of wipes is then compared. Any result above the action level of 0.005 micro Curie (uCi) or (5x10⁻³ uCi) requires immediate notification to the RSO and immediate stoppage of shipment. This information will be maintained by the RSO of Both EUSA and EOY. 100% of Rad source containing devices will be wipe tested by EUSA.



The Finnish wipe test results are recorded on a RAD1 form and or a copy of the actual results and the RAD1 forms are on file with the RSO of Environics OY

Environics USA is required to perform an identical wipe test of all detectors on their initial receipt by EUSA. An independent lab reads the US wipes. (See appendix 5 for Lab information and location.) The information provided by the lab will include the actual laboratory readings of the wipe tests, information on the detection instrument background counts, measuring time, calibration of the instrument efficiency and detection limit of the instrument, as well as the name and signature of the instrument operator. This information will be retained by EUSA in both the original copy received from the lab and the resultant data will be entered into the Radiation Device Database.

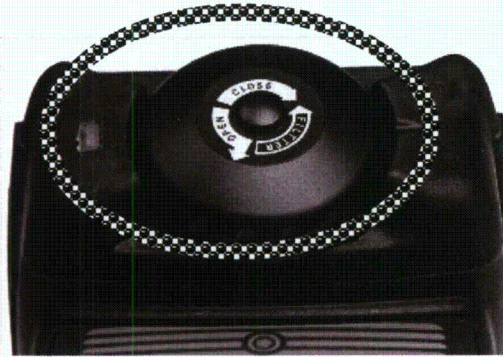
The US wipe test results are recorded on a Radiation Wipe Survey form (see appendix 6) next to the Finnish results, a copy of the completed Radiation Wipe Survey form is then sent to EOY in care of the EOY RSO or his designate. Both Environics and Environics USA are required to keep the results for seven years.

Procedures for conducting ChemPro 100 detector wipe test.

EUSA will perform contamination survey (wipe test) upon receipt of a new or repaired detector upon arrival into the facility or office from EOY.

1. The following equipment is needed:
 - a. Wipes/swabs
 - b. Gloves – Provided as part of the wipe kit.
 - c. Containers/envelops
 - d. RSSI Rad Wipe request form
2. The tester is required to wear gloves while performing wipe sampling, these gloves are provided as part of the wipe test kit from the testing Lab and are to be returned to the test Lab as part of the wipe test kit.
3. The locations, where the wipe sample is to be performed are along the air inlet\outlet and along the edges of the top and bottom assembly. (See drawings below.)
4. A maximum of five devices may be wiped with one wipe.
5. The wipe or swab is then placed in an envelope or the swab container, which is then sealed. The appropriate wipe test paperwork will be completed and checked and then forwarded to the EUSA RSO or his designate. The RSO will check the paperwork and then ship the wipe kit using an overnight mailer to the test Lab for analysis.
6. The minimum information required on the Wipe results is the name of the person recording the information, date, serial number of the detector(s) and the laboratory results. Measurements can be in microCuries, megabecquerels or disintegration per min (dpm)

Areas required to be wiped are within the dotted area



Wipe Area for the Top of the ChemPro



Wipe Area for the Left and Right side of the ChemPro

7. Upon receipt of the lab results the data will be compared with the data provided from EOY. The results will be compared based upon the unit serial number (or other unique indicator for each device tested,) to ensure that each individual device is tracked and tested. If any detector exceed the limit of greater than 0.005 micro Curie (uCi) or (5x10⁻³ micro Curie) the RSO will take immediate action to safely isolate the units(s) to ensure that they are not shipped and confirm the results. The RSO will inform the President of EUSA and the RSO and President of EOY or designates therein of the situation and take whatever actions are dictated by the situation. **Any unit with a contamination result above the acceptance threshold will not ship!**

8. The lab results will also be entered into the Detector database and compared with the wipe results provided by EOY. **Any error or discrepancy MUST be resolved.**
9. After all wipe test readings are recorded on the Radiation Wipe Survey form for that lot of devices received a copy of the completed form will be sent to EOY care of the RSO.
10. The Radiation Wipe Survey form along with a copy of the lab results are filed together in the RAD files and kept for a minimum of seven years.

Additional inspections required

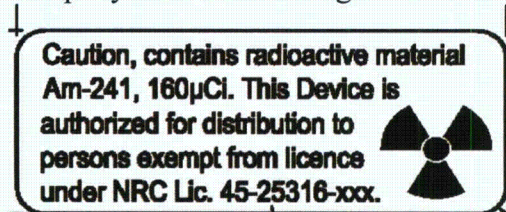
A visual inspection is also conducted to ensure that:

All detector labels are in place and readable
 Detectors are manufactured in accordance with the drawings and specifications submitted to the NRC and in compliance with the applicable regulations pertaining to the EUSA's licenses.

Radiation Label

Below is the example of the radiation label and the location on the detector. The sticker is located on the backside of the detector next to the belt clip. During incoming inspections EUSA personnel will insure that the sticker is correctly placed and readable.

If the device license label is missing the unit can not be shipped, notify the company RSO or his designate.



Radiation Label and Location





Start up procedure

Every ChemPro will be started and have the simulant check conducted. If any unit fails to pass the stimulant test that unit will not be shipped, it will be returned to the factory for further tests and repair.

See operator's manual for correct startup procedures and simulant checks.



Attachment 1: NRC Compliance/Quality Checklist for the ChemPro100 or Branded device

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NRC Exemption Compliance / Quality Checklist

ChemPro 100 ☐ / Multi-IMS ☐ / ChemRAE unit ☐ / Other Unit ☐ / ChemPro-DM ☐
ChemPro-PD ☐ / Other ☐

NOTES:

- This document is to be completed for all new ChemPro 100 or Multi-IMS units received from Environics OY, Finland.
- This document must be completed before any unit can be shipped to a customer.

Confirm White Environics Box has Radiation source location sticker attached if applicable:

Detector Serial Number:	#: _____
Case / Packaging External Inspection:	PASS ☐ FAIL ☐
Check SAK and all on-board spares incl. manual:	PASS ☐ FAIL ☐ N/A ☐
Confirm unit has correct NRC Exemption Label:	PASS ☐ FAIL ☐
Confirm unit is assembled with four tamper-proof screws on back of case:	PASS ☐ FAIL ☐
Perform external inspection if applicable:	PASS ☐ FAIL ☐ N/A ☐
Turn on and start-up check if applicable:	PASS ☐ FAIL ☐ N/A ☐
Validate correct Software & Library Versions / Splash Screen Check the TIC & CWA libraries:	PASS ☐ FAIL ☐ N/A ☐
Confirm detector is enters normal sampling mode in less than 5 minutes if applicable:	PASS ☐ FAIL ☐ N/A ☐
No Error Messages (Functional Exceptions) if applicable:	PASS ☐ FAIL ☐ N/A ☐
After 10 minutes perform a "Sensor Test" if applicable:	PASS ☐ FAIL ☐ N/A ☐
Run the unit for 1 hour and observe for any anomalies (e.g. random faults) if applicable:	PASS ☐ FAIL ☐ N/A ☐
Perform the Radiation Wipe Test:	Date: _____

NOTES:

INSPECTOR STAMP / SIGNATURE: _____ DATE: _____



Appendix 2: M-90 and MGD-1 Receiving inspection procedures

M-90 and MGD Receiving Inspection Procedures conducted at EUSA

The M-90 and MGD units are shipped directly from Finland (EOY) to the Environics USA (EUSA) facility in shipping packages. The Environics USA (EUSA) personnel will perform contamination surveys (wipe tests) and visual inspections as well as startup tests and fill out the NRC Exemption Compliance/Quality Checklist, (see attachment 2) ***100% of units initially received to EUSA will have the NRC Exemption Compliance/Quality Checklist completed.*** The radiation wipe test is preformed using the same procedures as used in Finland by Environics OY or their representative. **No device may be shipped from the EUSA office without the Radiation wipe test and the Compliance/Quality checklist being completed and the RSO or his designate approving the shipment. .**

NRC requirement: 100% of the M-90s or MGDs distributed by Environics USA will be leak (wipe) tested.

Contamination Survey (Wipe Test)

Overview

The wipe test process is a two-phase operation. The first phase is conducted in Finland where the unit is tested for contamination as part of the build process or as preparation for shipping. Phase two of the test is preformed in the United States where all SSD containing units are wipe tested as part of the receiving process. The wipe tests are conducted as contamination surveys on all the received M-90 or MGD detectors. The detectors are wiped after delivery to EUSA in the United States. The contamination survey data from both tests is then compared. Any result above the action level of 0.005 micro Curie (uCi) or $(5 \times 10^{-3} \text{ uCi})$ requires immediate notification to the RSO and immediate stoppage of the shipment. This information will be maintained by the RSO of both EUSA and EOY. 100% of Rad source containing devices will be wipe tested by EUSA.

The Finnish wipe test results are recorded on a RAD1 form and a copy of the actual results and/or the RAD1 form is sent to the Environics USA (EUSA) location care of the RSO or his designate. The copies of this information should arrive before the detectors arrive in the United States.

Environics USA is required to perform an identical wipe test of all detectors on their initial receipt by EUSA. An independent lab reads the US wipes, (see appendix 5 for lab information and location). The information provided by the testing laboratory will include the actual laboratory readings of the wipe tests, information on the detection instrument background counts, measuring time, calibration of the instrument efficiency, detection limit of the instrument as well as the name and signature of the instrument operator. This information



will be retained by EUSA both as the original copy received from the test lab and the result data will be entered into the Radiation Device Database.

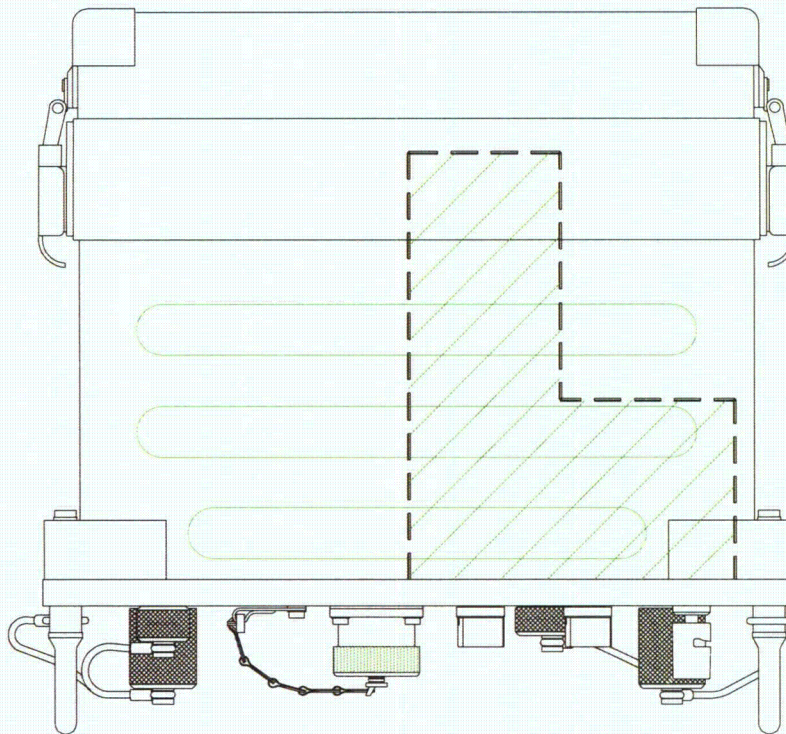
The US wipe test results are recorded on a Radiation wipe survey form (see appendix 6) next to the Finnish results, a copy of the completed Radiation wipe survey form is then sent to EOY in care of the RSO or his designate. Both Environics OY and Environics USA are required to keep the results for seven years.

Procedures for conducting M-90 and MGD detector wipe test.

EUSA will perform contamination survey (wipe test) upon receipt of a new or repaired detector upon arrival into the facility or location from EOY.

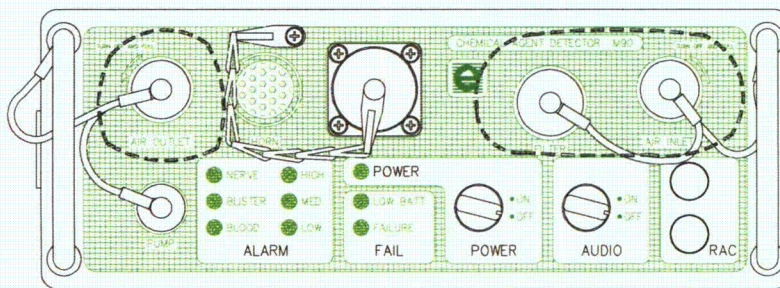
1. The following equipment is needed:
 - a. Wipes/swabs
 - b. Gloves-provided as part of the wipe kit.
 - c. Containers\envelops
 - d. RSSI Rad Wipe request form
2. The tester is required to wear gloves while performing wipe sampling, these gloves are provided as part of the wipe test kit from the testing lab and are to be returned to the test lab as part of the wipe test.
3. The locations, where the wipe samples are taken are along the air inlet\outlet and along the sensor assembly. (See drawings below)
4. A maximum of one wipe per five M-90 or MGD may be used.
5. The wipe or swab is then placed in an envelope or the swab container, which is then sealed. The appropriate wipe test paperwork will be completed and checked and then forwarded to the EUSA RSO or his designate. The RSO will check the paperwork and then ship the wipe test kit using an overnight mailer to the test lab for analysis.
6. The minimum information required on the Wipe results is the name of the person recording the information, date, serial number of the detector(s) and the laboratory results. Measurements can be in micro curies, megabecquerels or disintegration per min (dpm)
7. Upon receipt of the lab results the data will be compared with the data on the RAD1 or wipe test report form from Finland. The results will be compared based upon the unit serial number (or other unique indicator,) to ensure that each individual device is tracked and tested. If any detector exceeds the limit of greater than 0.005 micro Curie (uCi) or (5x10⁻³ micro Curie) the RSO will take immediate action to isolate that unit(s) to ensure that they are not shipped and confirm the results. The RSO will inform the President of EUSA and the RSO and President of EOY or designates therein of the situation, and take whatever actions are dictated by the situation. ***Any unit with a contamination result above the acceptance threshold will not ship.***
8. The lab results will be entered into the Detector database and compared with the wipe results from EOY. **Any error or discrepancy must be resolved.**

9. After all wipe test readings are recorded on the Radiation wipe survey form for that shipment a copy of the completed form will be sent to EOY care of the RSO.
10. The Radiation wipe survey form along with the copy of the lab results are filed together and kept for seven years at both Environics OY and Environics USA.



TOP VIEW OF THE WIPING AREAS OF THE M90-D1 DETECTOR

 = WIPING AREAS



FRONT VIEW OF THE WIPING AREAS OF THE M90-D1 DETECTOR

 = WIPING AREAS

The L shaped Sensor Module indicated in the upper diagram is wiped with the units outer shell removed.

Additional inspections required

A visual inspection is also conducted to ensure that:

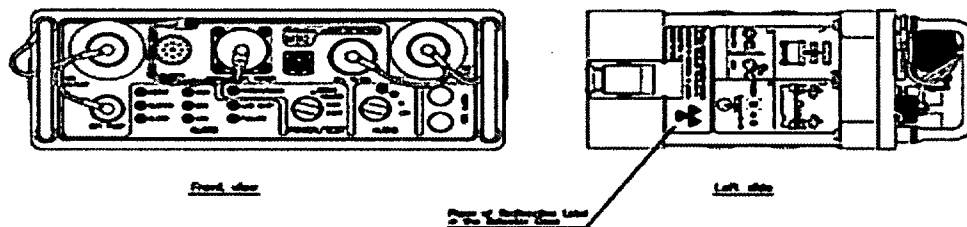
All detector labels are in place and readable.

Detectors are manufactured in accordance with the drawing submitted to the NRC.

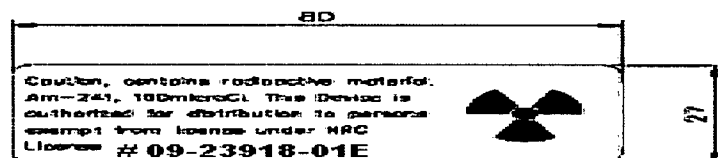
Radiation Label

Below is the example of the radiation label and the location on the detector. The sticker is located on side of the unit below the pictorial user instructions. During incoming inspections EUSA personnel will insure that the sticker is correctly placed and readable.

If the sticker is missing the detector unit cannot be shipped. Notify the company RSO.



Location of the External Radiation warning label.



**Start up procedure**

Every M-90 or MGD will be started and have the simulant check conducted. If any unit fails to pass the stimulant test that unit will not be shipped, it will be returned to the factory for further tests and repair.

See operator's manual for correct startup procedures and stimulant checks.

Attachment 2: M-90/ MDG-1 NRC Exemption Compliance / Quality Checklist

See Next Page



NRC Exemption Compliance / Quality Checklist

M-90 ☐ / MGD ☐ / Other ☐

NOTES:

- *This document is to be completed for all new M-90s or MGD units received from Environics OY, Finland.*
- *This document must be completed before any unit can be shipped to a customer.*

Detector Serial Number:	#:
Case / Packaging External Inspection:	PASS ☐ FAIL ☐
Check SAK and all on-board spares incl. manual if applicable:	PASS ☐ FAIL ☐ N/A ☐
Confirm unit has correct NRC Exemption Label:	PASS ☐ FAIL ☐
Perform external inspection:	PASS ☐ FAIL ☐
Turn on and start-up check if applicable:	PASS ☐ FAIL ☐ N/A ☐
Confirm detector enters normal sampling mode in less than 10 minutes if applicable:	PASS ☐ FAIL ☐ N/A ☐
No Error Messages or Functional Exceptions if applicable:	PASS ☐ FAIL ☐ N/A ☐
After 10 minutes perform the "Sensor Test" if applicable:	PASS ☐ FAIL ☐ N/A ☐
Run the unit for 1 hour and observe for any anomalies (e.g. random faults) if applicable:	PASS ☐ FAIL ☐ N/A ☐
Perform the Radiation Wipe Test:	Date:

Confirm White Environics Box has Radiation Source location sticker attached if applicable:

NOTES:

INSPECTOR STAMP / SIGNATURE: _____ DATE: _____



Appendix 3 to Environics USA Radiation Standard Operation Procedures (SOP) for FX Receiving Inspection Procedures conducted EUSA

The FX fixed site detector systems modules are shipped directly from Finland (EOY) to the Environics USA (EUSA) location in shipping packages. The EUSA personnel will perform contamination surveys (wipe tests) and visual inspections as well as startup tests and fill out the NRC Exemption Compliance/Quality Checklist, (see attachment 3) ***100% of units received to EUSA will have the NRC Exemption Compliance/Quality Checklist completed.*** The radiation wipe test is performed using the same procedure as is used in Finland by Environics OY or their representative. **No device may be shipped from the EUSA office without the Radiation wipe test and the Compliance/Quality checklist being completed and the RSO or his designate approving the shipment.**

NRC requirement: 100% of the FX fixed site detector modules distributed by Environics USA will be leak (wipe) tested.

Contamination Survey (Wipe Test)

Overview

The wipe test is a two-phase operation. The first phase is conducted in Finland where the unit is tested for contamination as part of the build process or as preparation for shipping. Phase two of the test is performed in the United States where all SSD containing units are wipe tested as part of the receiving process. The wipe tests are conducted as contamination surveys on all the received FX detectors or the FX sensor module. The detectors are wiped after delivery to the EUSA office in the United States. The contamination survey data from both sets of wipes is then compared. Any result above the action level of 0.005 micro Curie (uCi) or (5x10⁻³ uCi) requires immediate notification to the RSO and immediate stoppage of shipment. This information will be maintained by the RSO of Both EUSA and EOY. 100% of Rad source containing devices will be wipe tested by EUSA.

The Finnish wipe test results are recorded on a RAD1 form and or a copy of the actual results and the RAD1 form are sent to the Environics USA location. The copies of this information should arrive before or with the detectors arrival in the United States.

Environics USA is required to perform an identical wipe test of all detectors on their initial receipt by EUSA. An independent lab reads the US wipes. (See appendix 5 for Lab information and location.) The information provided by the lab will include the actual laboratory readings of the wipe tests, information on the detection instrument background counts, measuring time, calibration of the instrument efficiency and detection limit of the instrument, as well as the name and signature of the instrument operator. This information will



be retained by EUSA in both the original copy received from the lab and the resultant data will be entered into the Radiation Device Database.

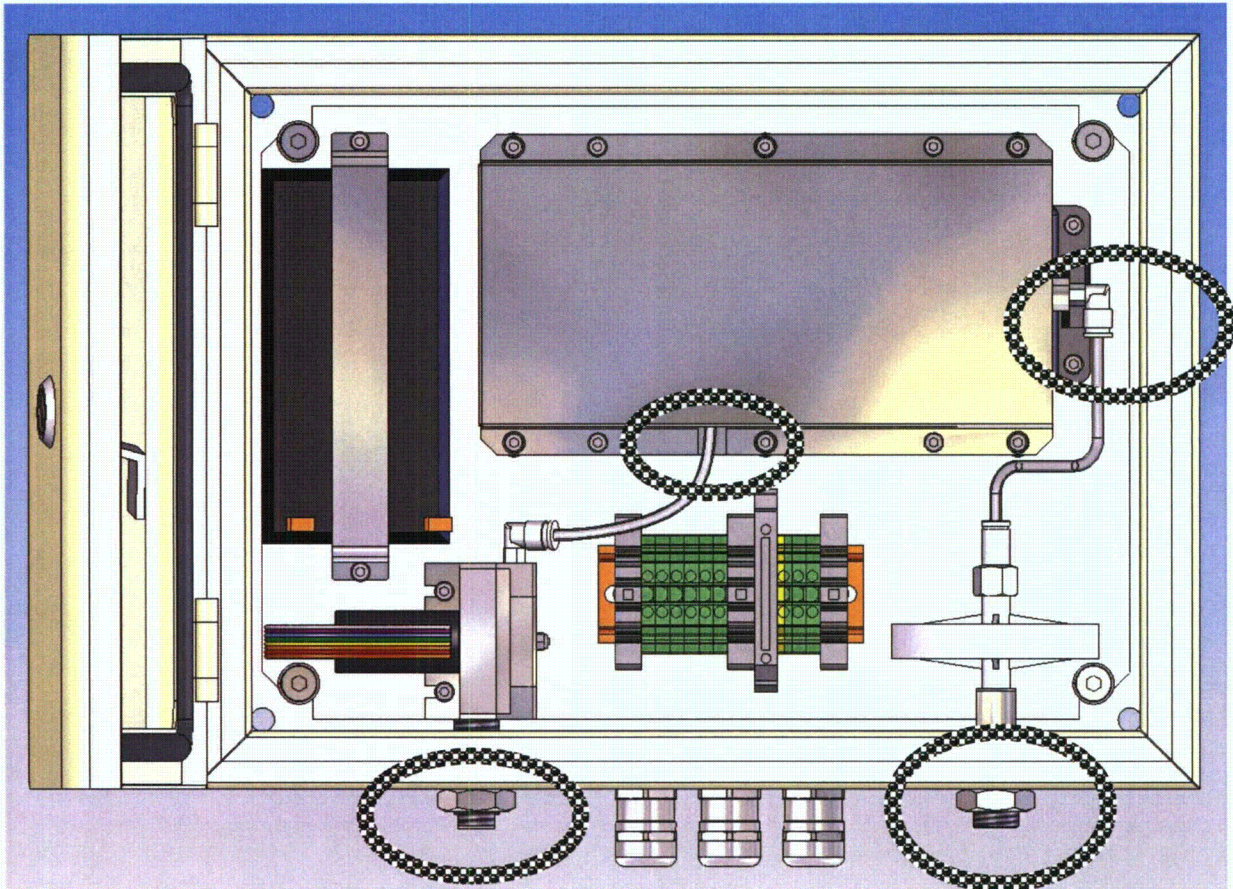
The US wipe test results are recorded on a Radiation Wipe Survey form (see appendix 6,) next to the Finnish results, a copy of the completed Radiation Wipe Survey form is then sent to EOY in care of the EOY RSO or his designate. Both Environics and Environics USA are required to keep the results for seven years.

Procedures for conducting FX and FX sensor module wipe test.

EUSA will perform contamination survey (wipe test) upon receipt of a new or repaired detector upon arrival into the facility or office from EOY.

1. The following equipment is needed:
 - a. Wipes/swabs
 - b. Gloves – Provided as part of the wipe kit.
 - c. Containers\envelops
 - d. RSSI Rad Wipe request form
2. The tester is required to wear gloves while performing wipe sampling, these gloves are provided as part of the wipe test kit from the testing Lab and are to be returned to the test Lab as part of the wipe test kit.
3. The locations, where the wipe sample is to be preformed are along the air inlet\outlet and along the edges of the intake fitting to the FX Sensor Module. (See drawings below.)
4. A maximum of five devices may be wiped with one wipe.
5. The wipe or swab is then placed in an envelope or the swab container, which is then sealed. The appropriate wipe test paperwork will be completed and checked and then forwarded to the EUSA RSO or his designate. The RSO will check the paperwork and then ship the wipe kit using an overnight mailer to the test Lab for analysis.
6. The minimum information required on the Wipe results is the name of the person recording the information, date, serial number of the detector(s) and the laboratory results. Measurements can be in MicroCuries, megabecquerels or disintegration per min (dpm.)

Areas required to be wiped are within the dotted area



Wipe Areas from the top of the FX

7. Upon receipt of the lab results the data will be compared with the data provided from EOY. The results will be compared based upon the unit serial number (or other unique indicator for each device tested,) to ensure that each individual device is tracked and tested. If any detector exceed the limit of greater than 0.005uCI (or 5×10^{-3} micro Curie) the RSO will take immediate action to safely isolate the unit(s) to ensure that they are not shipped and confirm the results. The RSO will inform the President of EUSA and the RSO and President of EOY or designates therein of the situation and take whatever actions are dictated by the situation. **Any unit with a contamination result above the acceptance threshold will not ship!**

8. The lab results will also be entered into the Detector database and compared with the wipe results provided by EOY. **Any error or discrepancy MUST be resolved.**
9. After all wipe test readings are recorded on the Radiation Wipe Survey form for that lot of devices received a copy of the completed form will be sent to EOY care of the RSO.
10. The Radiation Wipe Survey form along with a copy of the lab results are filed together in the RAD files and kept for a minimum of seven years.

Additional inspections required

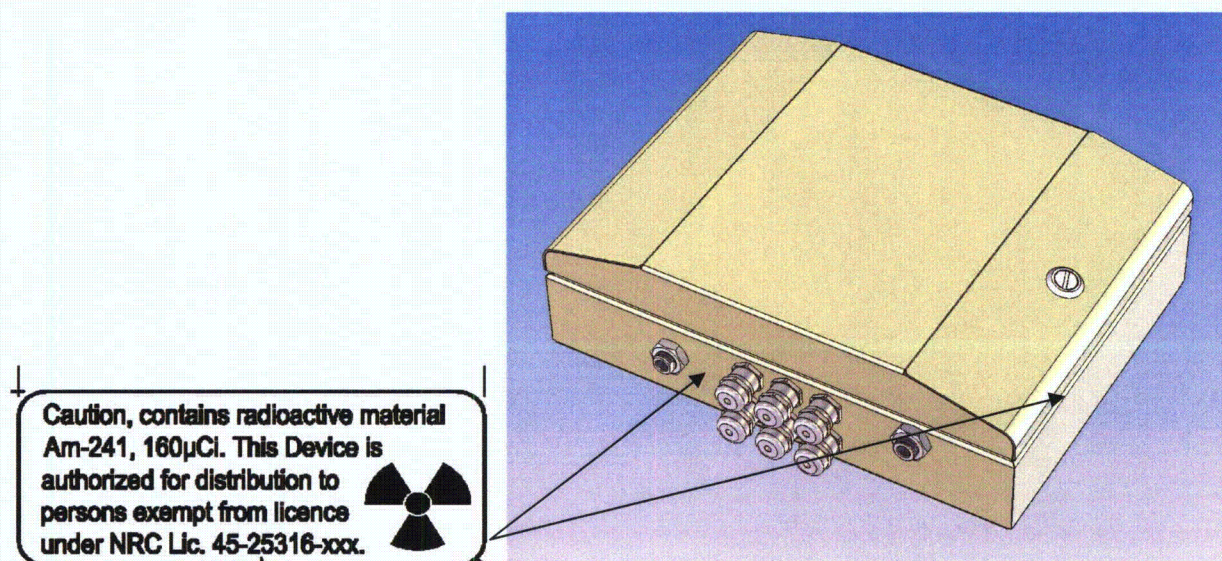
A visual inspection is also conducted to ensure that:

- All detector labels are in place and readable
- Detectors are manufactured in accordance with the drawing submitted to the NRC.

Radiation Label

Below is the example of the radiation label and the location on the detector. The sticker is located on the backside of the detector next to the belt clip. During incoming inspections EUSA personnel will insure that the sticker is correctly placed and readable.

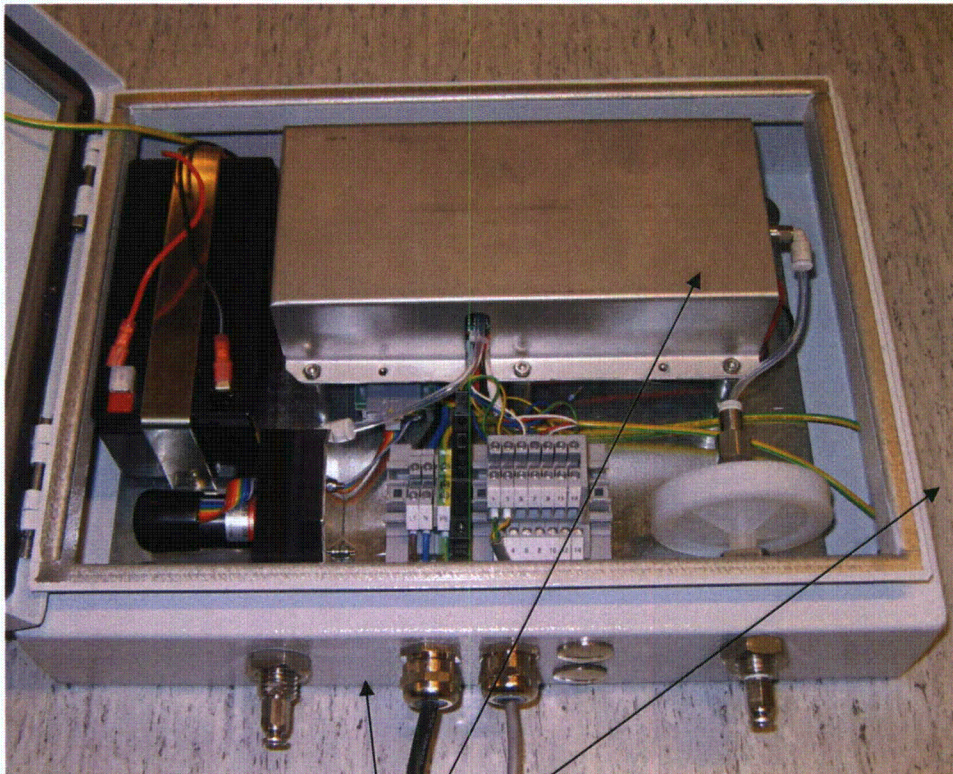
If the sticker is missing the detector unit cannot be shipped. Notify the company radiation officer.



Radiation Label and Location

Serial number Labels

The serial number of the FX unit is placed on the outside of the FX as well as on a label on the outer Sensor Module protective shell. It is necessary that the serial number on **all** labels is checked to ensure that they are all correct.



Serial number label locations

Start up procedure

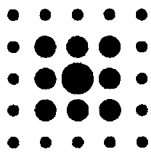
Every FX unit will be started and have the simulant check conducted if applicable. If any unit fails to pass the stimulant test that unit will not be shipped, it will be returned to the factory for further tests and repair.

See operator's manual for correct startup procedures and simulant checks.



Attachment 3: FX NRC Exemption Compliance / Quality Checklist

See Next Page



NRC Exemption Compliance / Quality Checklist

FX ☐ / Sensor unit ☐ / Other ☐

NOTES:

- *This document is to be completed for all new FX Modules or other device units received from Envionics OY, Finland.*
- *This document must be completed before any unit can be shipped to a customer.*

Detector Serial Number: Ensure all labels are correct	#:
Case / Packaging External Inspection:	PASS ☐ FAIL ☐
Check SAK and all on-board spares incl. manual if applicable:	PASS ☐ FAIL ☐ N/A ☐
Confirm unit has correct NRC Exemption Label:	PASS ☐ FAIL ☐
Perform external inspection:	PASS ☐ FAIL ☐
Turn on and start-up check if applicable:	PASS ☐ FAIL ☐ N/A ☐
Confirm detector enters normal sampling mode in less than 10 minutes if applicable:	PASS ☐ FAIL ☐ N/A ☐
No Error Messages or Functional Exceptions if applicable:	PASS ☐ FAIL ☐ N/A ☐
After 10 minutes perform the "Sensor Test" if applicable:	PASS ☐ FAIL ☐ N/A ☐
Run the unit for 1 hour and observe for any anomalies (e.g. random faults) if applicable:	PASS ☐ FAIL ☐ N/A ☐
Perform the Radiation Wipe Test:	Date:

Confirm White Envionics Box has Radiation Source location sticker attached if applicable:

NOTES:

INSPECTOR STAMP / SIGNATURE: _____ DATE: _____



Appendix 4: Rad containing Sensor Modules; Receiving Inspection Procedures

Appendix 4 to Environics USA Radiation Standard Operation Procedures (SOP) for

Rad containing Sensor Modules; Receiving Inspection Procedures conducted EUSA

The M-90; ChemPro 100 and FX families of detection systems all have the radioactive material containing sealed source located in a “sensor unit” or module that can be received by EUSA separate from the outer case or other components of the complete sensor system in the case of device build or repair supplies. These sensor modules are shipped directly from Finland (EOY) to the Environics USA (EUSA) location or personnel only. The EUSA personnel will perform contamination surveys (wipe tests) and visual inspections on all sensor modules received. ***100% of units received to EUSA will have the NRC Exemption Compliance/Quality Checklist completed.*** The radiation wipe test is performed using the same procedure as is used in Finland by Environics OY or their representative. **No device may be shipped from the EUSA office without the Radiation wipe test and the Compliance/Quality checklist being completed and the RSO or his designate approving the shipment.**

NRC requirement: 100% of the sensor modules received by Environics USA will be leak (wipe) tested.

Contamination Survey (Wipe Test)

Overview

The wipe test is a two-phase operation. The first phase is conducted in Finland where the sensor unit is tested for contamination as part of the build process or as preparation for shipping. Phase two of the test is performed in the United States where all SSD containing units are wipe tested as part of the receiving process. The wipe tests are conducted as contamination surveys on all the sensor modules received by EUSA. The modules are wipe tested after receipt at the EUSA office in the United States. The contamination survey data from both sets of wipes is then compared. Any result above the action level of 0.005 micro Curie (uCi) or (5×10^{-3} uCi) requires immediate notification to the RSO and immediate stoppage of shipment. This information will be maintained by the RSO of Both EUSA and EOY. 100% of Rad source containing devices will be wipe tested.

The Finnish wipe test results are recorded on a RAD1 form and or a copy of the actual results and the RAD1 form are sent to the Environics USA location. The copies of this information should arrive before or with the detectors arrival in the United States.

Environics USA is required to perform an identical wipe test of all radioactive material containing items on their initial receipt by EUSA. An independent lab reads the US wipes. (See appendix 5 for Lab information and location.) The information provided by the lab will include the actual laboratory readings of the wipe tests, information on the detection instrument

background counts, measuring time, calibration of the instrument efficiency and detection limit of the instrument, as well as the name and signature of the instrument operator. This information will be retained by EUSA in both the original copy received from the lab and the resultant data will be entered into the Radiation Device Database.

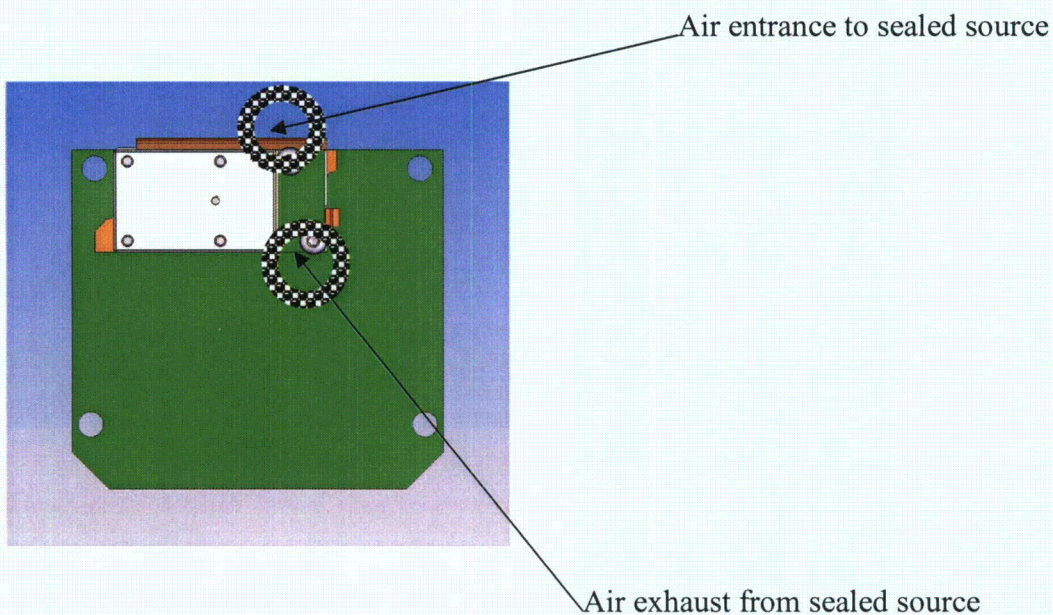
The US wipe test results are recorded on a Radiation Wipe Survey form (see appendix 6,) next to the Finnish results, a copy of the completed Radiation Wipe Survey form is then sent to EOY in care of the EOY RSO or his designate. Both Environics and Environics USA are required to keep the results for seven years.

Procedures for conducting sensor module wipe tests.

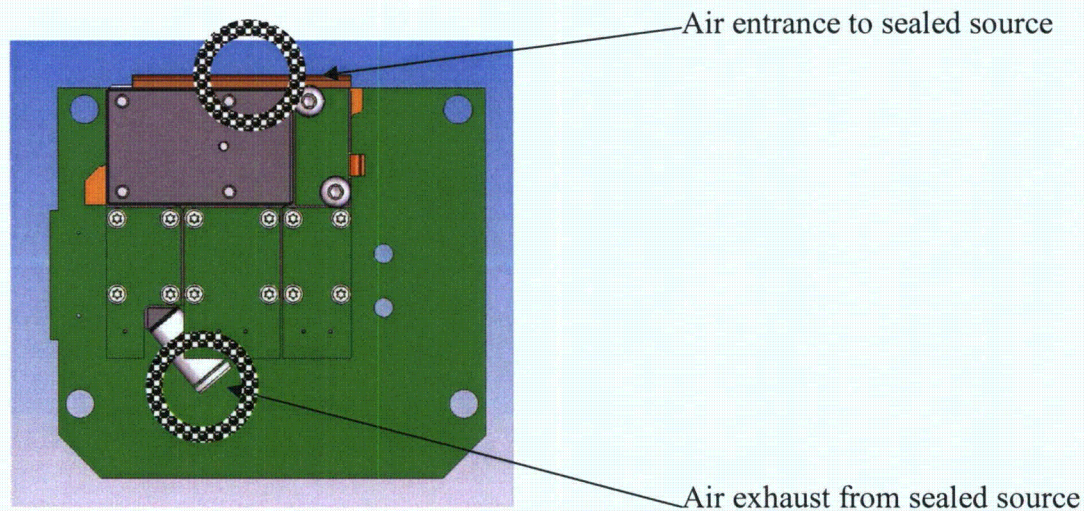
EUSA will perform contamination survey (wipe test) upon receipt of a new or repaired detector upon arrival into the facility or office from EOY.

1. The following equipment is needed:
 - a. Wipes/swabs
 - b. Gloves – Provided as part of the wipe kit.
 - c. Containers\envelops
 - d. RSSI Rad Wipe request form
2. The tester is required to wear gloves while performing wipe sampling, these gloves are provided as part of the wipe test kit from the testing Lab and are to be returned to the test Lab as part of the wipe test kit.
3. The locations, where the wipe sample is to be performed are along the air inlet\outlet ports of the sensor module and along the side and top of the sealed source. (See drawings below.)
4. A maximum of five devices may be wiped with one wipe.
5. The wipe or swab is then placed in an envelope or the swab container, which is then sealed. The appropriate wipe test paperwork will be completed and checked and then forwarded to the EUSA RSO or his designate. The RSO will check the paperwork and then ship the wipe kit using an overnight mailer to the test Lab for analysis.
6. The minimum information required on the Wipe results is the name of the person recording the information, date, serial number of the detector(s) and the laboratory results. Measurements can be in microCuries, megabecquerels or disintegration per min (dpm)

Areas required to be wiped are within the dotted area for each of the different styles of sealed source.

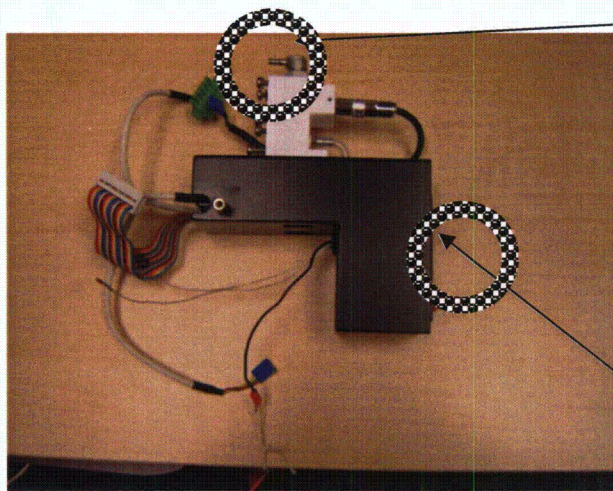


ChemPro 100 Version 1 and 2 Sensor Board



ChemPro 100 Version 3, or CP100i Sensor Board

M-90 Sealed Source

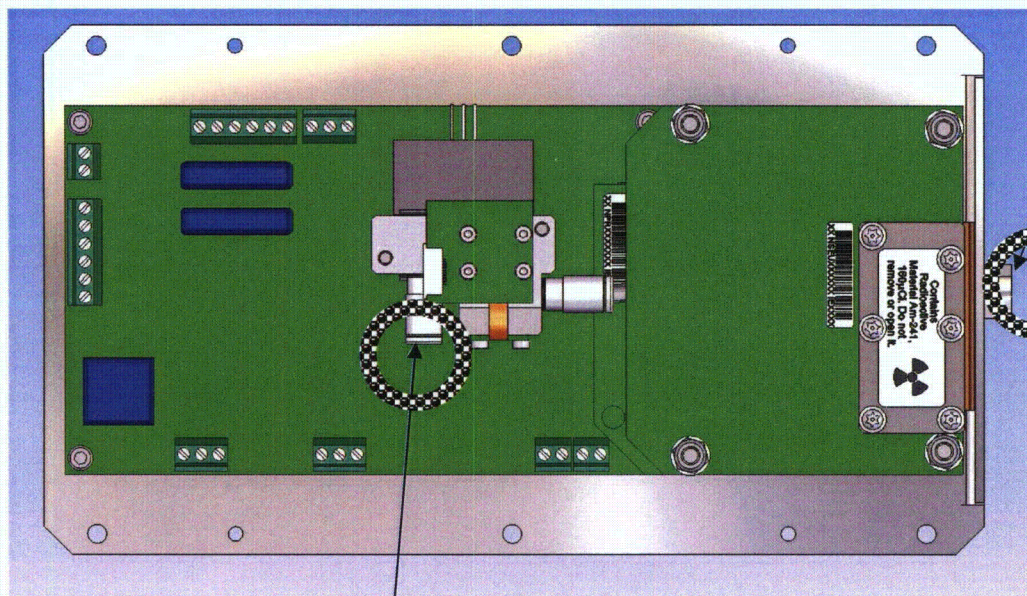


Air exhaust from sealed source

Air entrance to sealed source

M-90 Sensor Module

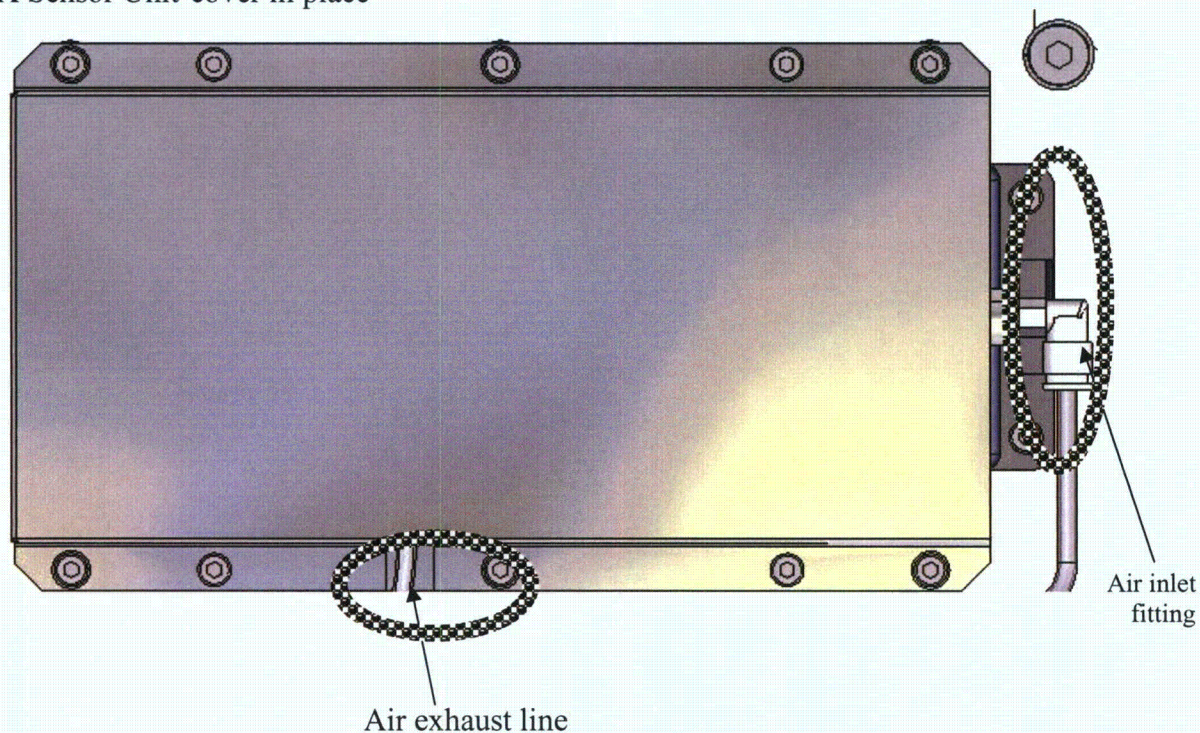
FX Sensor Unit-cover removed



Air inlet

Air exhaust

FX Sensor Unit-cover in place



7. Upon receipt of the lab results the data will be compared with the data provided from EOY. The results will be compared based upon the unit serial number (or other unique indicator for each device tested,) to ensure that each individual device is tracked and tested. If any detector exceed the limit of greater than 0.005uCi or (5×10^{-3} micro Curie) the RSO will take immediate action to safely isolate the unit(s) to ensure that they are not shipped and confirm the results. The RSO will inform the President of EUSA and the RSO and President of EOY or designates therein of the situation and take whatever actions are dictated by the situation. **Any unit with a contamination result above the acceptance threshold will not ship!**
8. The lab results will also be entered into the Detector database and compared with the wipe results provided by EOY. **Any error or discrepancy MUST be resolved.**
9. After all wipe test readings are recorded on the Radiation Wipe Survey form for that lot of devices received a copy of the completed form will be sent to EOY care of the RSO.
10. The Radiation Wipe Survey form along with a copy of the lab results are filed together in the RAD files and kept for a minimum of seven years.



Additional inspections required

A visual inspection is also conducted to ensure that:

All detector labels are in place and readable.

Detectors are manufactured in accordance with the drawings and specifications submitted to the NRC.

Confirm that security torx screws have been used to assemble the sealed source.

Appendix 5 to Environics USA Radiation Standard Operation Procedures (SOP) for

ENVI Series Industrial monitors, Receiving Inspection Procedures conducted EUSA

The ENVI series of industrial air and Process monitors (ENVI-AIR,- STACK and - PRO) are all based in the use of the Tritium (H-3), activity level of 8.1 mCi or 300 mBq source as supplied by the Envionics-IUT division of Envionics International based in Berlin Germany. The ENVI monitors are in two basic external forms, a standard 19 inch rack device and one with the same sensor components that have been mounted in a NEMA 4X rated enclosure. In this document the term "ENVI" series covers both unless there is a specific reference needed to the actual outer form of the detector. In that case there will be a specific reference to the outer form of the unit by indication of 'rack' or 'NEMA 4X'..

Units are shipped directly from Finland (EOY) or Berlin (IUT) to the Envionics USA (EUSA) facility in standard shipping packages. The EUSA personnel will perform contamination surveys (wipe tests) and visual inspections as well as startup tests and fill out the NRC Exemption Compliance/Quality Checklist, (see attachment 4.) ***100% of units received to EUSA will have the NRC Exemption Compliance/Quality Checklist completed.*** The radiation wipe test is preformed using the same procedure as is used in Finland by Envionics OY, IUT in Berlin or their representatives. **No device may be shipped from the EUSA office without the Radiation wipe test and the Compliance/Quality checklist being completed and the RSO or his designate approving the shipment.**

NRC requirement: 100% of the ChemPro and Multi-IMs distributed by Envionics USA will be leak (wipe) tested.

Contamination Survey (Wipe Test)

Overview

The wipe test is a two-phase operation. The first phase is conducted in Berlin or Finland where the unit is tested for contamination as part of the build process or as preparation for shipping. Phase Two of the test is preformed in the United States where all SSD containing units are wipe tested as part of the initial receiving process. The wipe tests are conducted as contamination surveys on all the initially received units that contain a Rad source. The detectors are wiped after delivery to the EUSA office in the United States. The contamination survey data from both sets of wipes is then compared. Any result above the action level of 0.005 micro Curie (uCi) or (5x10⁻³ uCi) requires immediate notification to the RSO and immediate stoppage of shipment. This information will be maintained by the RSO of Both EUSA and EOY. 100% of Rad source containing devices will be wipe tested.

The Finnish or Berlin wipe test results are recorded on a RAD1 form and or a copy of the actual results and the RAD1 form are sent to the Envionics USA location. The copies of this information should arrive before or with the detectors arrival in the United States.



Environics USA is required to perform an identical wipe test of all detectors on their initial receipt by EUSA. An independent lab reads the US wipes. (See appendix 6 for the test Lab information and location.) The information provided by the lab will include the actual laboratory readings of the wipe tests, information on the detection instrument background counts, measuring time, calibration of the instrument efficiency and detection limit of the instrument, as well as the name and signature of the instrument operator. This information will be retained by EUSA in both the original copy received from the lab and the resultant data will be entered into the Radiation Device Database.

The US wipe test results are recorded on a Radiation Wipe Survey form (see appendix 7) next to the Finnish results, a copy of the completed Radiation Wipe Survey form is then sent to EOY in care of the EOY RSO or his designate. Both Environics and Environics USA are required to keep the results for seven years.

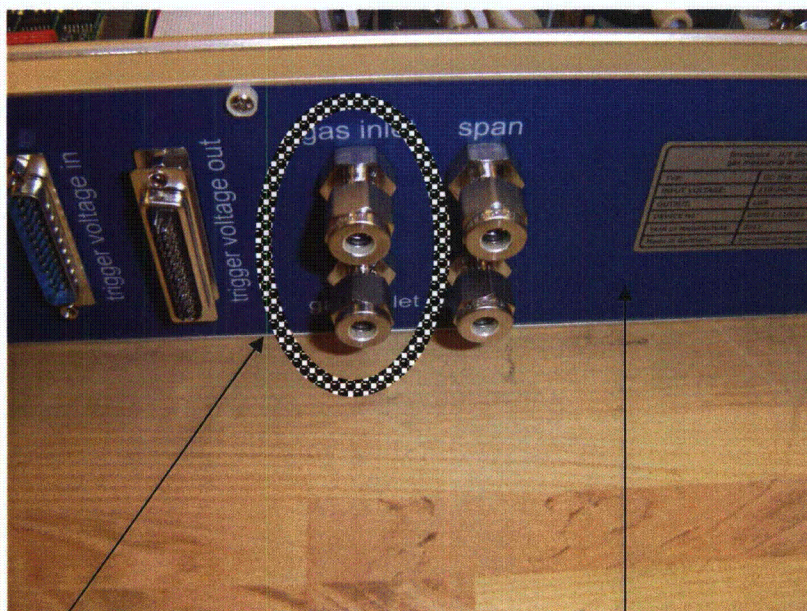
Procedures for conducting ENVI-series detector wipe test.

EUSA will perform contamination survey (wipe test) upon receipt of a new or repaired detector if the service has impacted the sealed source upon arrival into the facility or office from EOY or IUT.

1. The following equipment is needed:
 - a. Wipes/swabs
 - b. Gloves – Provided as part of the wipe kit.
 - c. Containers\envelops
 - d. RSSI Rad Wipe request form
2. The tester is required to wear film gloves while performing wipe sampling, these gloves are provided as part of the wipe test kit from the testing Lab and are to be returned to the test Lab as part of the wipe test kit.
3. The locations, where the wipe sample is to be preformed are along the air inlet\outlet and along the edges of the top and bottom assembly. (See drawings below.)
4. A maximum of five devices may be wiped with one wipe.
5. The wipe or swab is then placed in an envelope or the swab container, which is then sealed. The appropriate wipe test paperwork will be completed and checked and then forwarded to the EUSA RSO or his designate. The RSO will check the paperwork and then ship the wipe kit using an overnight mailer to the test Lab for analysis.
6. The minimum information required on the Wipe results is the name of the person recording the information, date, serial number of the detector(s) and the laboratory results. Measurements can be in microCuries, megabecquerels or disintegration per min (dpm)

Areas required to be wiped are within the indicated area

Wipe Area on the back of a 19" Rack unit assembly

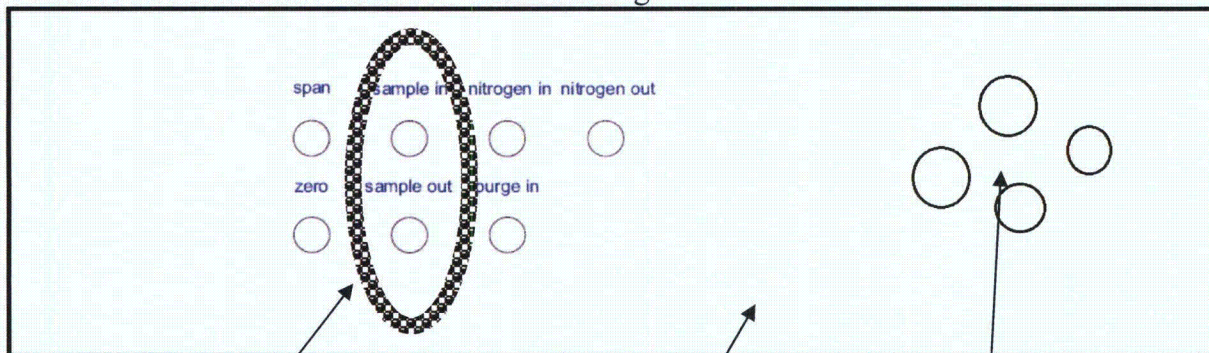


Sample Inlet/outlet
to be wiped

Location of Radiation
warning/license label

Wipe area for a NEMA 4X Enclosure assembly

Bottom of a NEMA 4X Enclosure - Line Drawing



Sample Inlet/outlet ports
to be wiped

Location of Radiation warning/License label

Cable brushings

7. Upon receipt of the lab results the data will be compared with the data provided from EOY. The results will be compared based upon the unit serial number (or other unique indicator for each device tested,) to ensure that each individual device is tracked and tested. If any detector exceed the limit of greater than 0.005 micro Curie (uCi) or (5×10^{-3} micro Curie) the RSO will take immediate action to safely isolate the units(s) to ensure that they are not shipped and confirm the results. The RSO will inform the President of EUSA and the RSO and President of EOY or designates therein of the situation and take whatever actions are dictated by the situation. **Any unit with a contamination result above the acceptance threshold will not ship!**
8. The lab results will also be entered into the Detector database and compared with the wipe results provided by EOY. **Any error or discrepancy MUST be resolved.**
9. After all wipe test readings are recorded on the Radiation Wipe Survey form for that lot of devices received a copy of the completed form will be sent to EOY care of the RSO.
10. The Radiation Wipe Survey form along with a copy of the lab results are filed together in the RAD files and kept for a minimum of seven years.

Additional inspections required

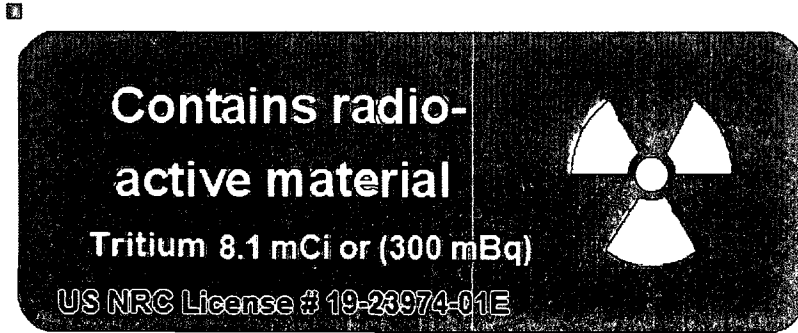
A visual inspection is also conducted to ensure that:

All detector labels are in place and readable
Detectors are manufactured in accordance with the drawings and specifications submitted to the NRC and in compliance with the applicable regulations pertaining to the EUSA's licenses.

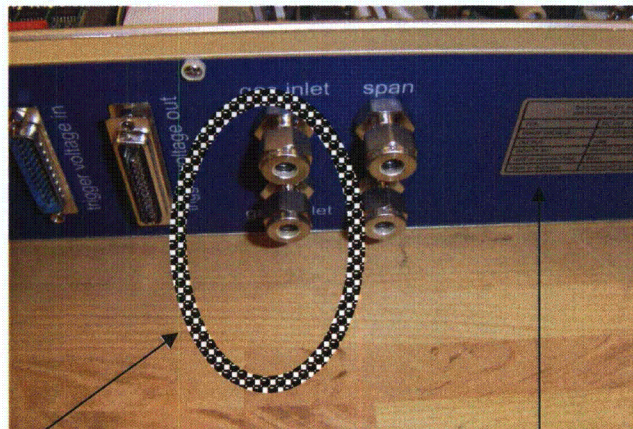
Radiation Label

Below is the example of the radiation label and the location on the detector. The radiation warning label is usually located on the back of the 19" Rack and on the side or bottom of the NEMA 4X form of the ENVI series detectors. A rad warning label is also located on the cell enclosure within the analyzer. During incoming inspections EUSA personnel will insure that the sticker is correctly placed and readable.

If the device license label is missing the unit cannot be shipped, notify the company RSO or his designate.



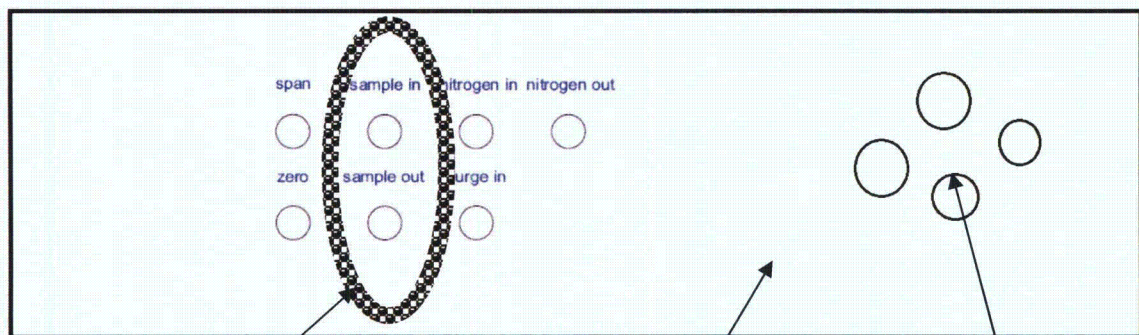
Radiation Label and Location on Rack Wipe Area on the back of a 19" Rack unit assembly



Sample Inlet/outlet
to be wiped

Location of Radiation
warning/license label

Radiation label location on NEMA 4X enclosure Bottom of a NEMA 4X Enclosure - Line Drawing



Sample Inlet/outlet ports
to be wiped

Location of Radiation warning/License label

Cable brushings

Start up procedure

All ENVI-series detectors will be started and checked for function as part of the receiving inspection process. See operator's manual for correct startup procedures and simulant checks.



Attachment 4: NRC Compliance/Quality Checklist for the ENVI-series detectors

Next Page



NRC Exemption Compliance / Quality Checklist

ENVI-series "Rack" ☐/ ENVI-series NEMA 4X ☐/TUT Mini IMS☐/Other ☐

NOTES:

- *This document is to be completed for all new ENVI-Series detector units received from Environics OY, or Environics-IUT.*
- *This document must be completed before any unit can be shipped to a customer.*

Detector Serial Number:	#: _____
Case / Packaging External Inspection:	PASS ☐ FAIL ☐ Comments: _____
Internal case/packing Inspection	PASS ☐ FAIL ☐ Comments: _____
Check SAK items:	PASS ☐ FAIL ☐ Comments: _____
Perform device inspection:	PASS ☐ FAIL ☐
Confirm unit has correct NRC Exemption Label: (#19-23974-01E)	PASS ☐ FAIL ☐
Turn on and start-up check if applicable:	PASS ☐ FAIL ☐ N/A ☐
Validate correct Software & Script Versions /	PASS ☐ FAIL ☐ N/A ☐
Confirm detector is enters normal sampling mode in less than 10 minutes if applicable:	PASS ☐ FAIL ☐ N/A ☐
No Error Messages (Functional Exceptions) if applicable:	PASS ☐ FAIL ☐ N/A ☐
Run the unit for 1 hour and observe for any anomalies (e.g. random faults) if applicable:	PASS ☐ FAIL ☐ N/A ☐
Perform the Radiation Wipe Test:	Date: _____

NOTES:

INSPECTOR STAMP / SIGNATURE: _____ **DATE:** _____



Appendix 6: Radiation Testing Laboratory

Radiation Safety Services, Inc. (RSSI)
6312 West Oakton Street
Morton Grove, IL. 60053-2723
Phone 1-847-965-1999
Fax 1-847-965-1991

Radioactive Materials License # IL-01429-01

A copy of RSSI's complete license and permit is on file in the Open Radiation files located in the file room. The RSO also has a copy in his records



Appendix 7: Radiation Wipe Survey Form

See next page



Radiation Survey Form

[illegible]

Appendix 8: Finnish Radiation Wipe form (RAD1)

See next page





Appendix 9: Getting and Maintaining Rad licenses

Overview

Fed license – Explanations, SSDR registry -exempt distribution

- Renewals, updates, amendments

State license - Explanations, renewals, updates, amendments

Canada licenses- Explanations, renewals, updates, amendments

Overview

Environics USA, Inc. (EUSA) holds several licenses regarding its radioactive sealed source devices, (The ChemPro100 and M-90 device product families and the ENVI-series industrial monitoring devices,) and their exempt distribution from the Federal US Nuclear Radiation Commission as well as materials possession license at the state level since Maryland is an Agreement state and maintains its own Radiation control division. The company is also licensed in Canada for the distribution of its products through the auspices of the Canadian Nuclear Safety Commission.

Federal licenses

Sealed Source Device Registry

The US Federal Nuclear Regulatory Commission is the sole authorizing agency regarding the licensing and registration of any Radioactive Sealed Source Device (SSD) in the United States and maintains the SSD registry at the federal level. All sealed source devices manufactured or distributed in the US must be reviewed, approved and have a sealed source device registry (SSDR) number granted before any further licensing actions can be taken.

To get a device approved by the SSDR division requires an application for the device or source in question must be written and submitted for review by the US NRC that contains all pertinent details of the materials and design of the proposed device as well as its proposed use and lifespan. This application must contain details regarding the actual design and materials used the manufacturing process, proposed lifespan and intended use and justification for the device. Detailed drawings are recommended. Specifics on the application process and requirements can be found in the collected documents in the NEREG collections on the US Federal database online.

Environics currently has Three sealed source devices approved and registered, one for the M-90 product line and the second for the ChemPro 100 product line, the third is for the Envi-Series Industrial monitoring devices. See attachment 4 for copies of current SSDR documents. (Note the term product line, the significance of this will be explained in a following paragraph.)

The only item that the NRC is directly concerned about is the sealed source and its integrity and use. Currently the device registry and exempt distribution license that Envionics holds are specific to the actual sensor modules or boards that contain the SSD itself. This



allows Environics to make changes to the outer case or labels provided certain specific items are maintained.

Those items that must remain constant are the design and manufacture of the actual sealed source its radioactive material contents shielding and security and labeling features stipulated by the details of the rad license and exempt distribution regulations that Environics has submitted the devices under and received approval.

This allows Environics to hold a license on the sealed source module and maintain the continuity of the sealed device while being able to make changes to the electronics and other hardware that are not directly a part of the sealed source without having to submit these changes to the NRC for review and approval. This allows Environics to make external changes or “rebranded” versions of the ChemPro 100 for sale as other named devices by companies that Environics has executed direct marketing agreements. The marketing and distribution agreements allow the ChemPro to be sold as a differently named device by the other company without having to have that company hold specific or general license for the device.

Specific details regarding the exact wording for the SSD and the Exempt Distribution license can be found in the relevant sections of the Code of Federal Regulations (CFR) in part 10 (Energy.) It is highly advised that the relevant sections of the CFR 10 part 2; 20; 21; 30; and part 32 be read before attempting any change to the existing license.

Exempt Distribution License

The Environics Products in the US have been granted the status of “Exempt Distributable” items by the US NRC due to the nature of the materials used and the design of the sealed source. This classification allows the named product to be sold to persons that are exempt from the need to have a radioactive materials or possession license. The “burden” of the regulations and requirements for conformance to the class requirements are on Environics OY as the manufacturer and Environics USA as the importer/primary distributor. The “burden” comes in the form of the exempt device initial check in and Compliance sheet as well as wipe tests and other records keeping.

Specific details regarding the exact wording for the SSD and the Exempt Distribution license can be found in the relevant sections of the Code of Federal Regulations (CFR) in part 10 (Energy.) It is highly advised that the relevant sections of the CFR 10 part 2; 20; 21; 30; and part 32 be read before attempting any change to the existing license. Current NRC regulations and guidance documents can be found on the NRC’s website www.NRC.gov, look under “Nuclear materials, Medical, academic and industrial uses of Nuclear Materials” as well as the section listing the Regulations, Guidance and Communications documents. Guidance documents are combinations of direct interpretations and outlines in layman terms of the actual NRC and government regulations for specific instances or applications and are often far more concise and helpful than the bulk reading of the NRC regulations and rules as found in section 10 of the CFR.



State license

Environics' Federal license allows the company to distribute, (sell) the company products in the US. The Company also is required to hold a "materials possession" license which permits the actual work and office facility and allows the company to hold the devices. This possession license is usually at the state level due to the fact that many of the states in the US are what are termed "agreement" states where the state itself operates the State Rad control division under the specifications and overall guidelines of the Federal NRC. Note that the State Radiation control divisions can not make regulations or laws that "trump" or exceed that of the Federal Mandates. What this mean in reality is that the states can not limit or deny something through their regulation activities if it is covered or approved by the Federal NRC or is specifically stated in the Federal CFR.

The State possession license must be obtained in addition to the Federal license for the company to be allowed to operate in the US. Environics currently holds a State possession license in Maryland (see attachment 6 for example,) that was applied for when the facility location was moved from Florida to the current location in Maryland.

Canada licenses

Environics currently holds two certificates granted by the Canadian Nuclear Safety Commission, (CNSC) pursuant to the *Canadian Nuclear Safety and Control Act* (NSC Act) and the *Nuclear Substances and Radiation Devices Regulations* (NSRD regs) of Canada. The certificates are the equivalent to the Sealed Source Device Registry documents granted the US NRC regarding the basic design, assembly and purpose for the named device.

Certificate # 185-0001-0-2017 which was granted in Dec 2002 covers the ChemPro and its related devices while the M-90 and related devices are under certificate 185-0002-0-2017, also granted in Dec 2002. These certificates were updated and renewed in 2011. See Attachment 7 for copies of the Canadian certificates.

See the Canadian Nuclear Safety Commission web site <http://www.nuclearsafety.gc.ca> for current regulations and application forms regarding the licensing or certification of devices in Canada. Be aware that any application for device certification will require completion of the Canadian application (see the current Canadian Radiation commission regulations for the relevant documentation,) as well as schematic drawings and materials lists as part of the initial request and may take up to six months or more for the addition of a device to the existing certificates.

Currently all Am-241 sealed sources have a exemption limit of 10kBq (ten times the activity limit for a normal piece of raw Am 241 (1kBq)) any device above this activity limit in Canada requires that the distributor has a "Demonstration license" or a general license to actually possess and show the device in Canada. In addition the end user or purchaser of the device is required to have a general Radiation license that lists the device in question in Canada before the device can be purchased or transferred.



Environics USA is currently in the process of confirming this regulation and applying for a general radiation license in Canada to allow Environics personnel to possess demonstrate and use the company products legally in Canada.

Environics has also made a sealed source for the ChemPro100 product line that uses a Ni-63 source material with a activity level of 370 mBq that allows the item to be possessed in Canada without the need for a possession license. This is due to the activity level limits for Ni-63 being lower than the regulatory limit for Am-241.

The Ni-63 based sealed source has been approved by the Canadian Radiation Commission for distribution in Canada without the need for the end user to hold a device possession license. This Ni-63 source is NOT approved for sale or distribution within the United States by the Federal NRC. Environics USA however is allowed to posses the Ni-63 sources by specific item on Environics Maryland possession license.

Special storage considerations are done for the ChemPro100 sensor boards that are based on a Ni-63 source material. These Ni-63 boards are licensed and approved for sale **ONLY in Canada.** Environics is licensed to possess these Ni-63 boards in the US but they are not approved for sale/distribution in the US.

To ensure 100% control of these Ni-63 based boards they are stored in a locked yellow case that is connected to the shelving in the Rad Storage room. This case is to be locked at all times unless being accessed. To obtain access contact the RSO who will open the case and record specific serial numbers/use of the removed boards.

There is a limited number of Demo/Engineering units that have been converted to the Ni-63 sensor boards. All these units that have been converted have been relabeled with the Canadian Specified Ni-63 Radiation warning label. All Ni-63 demo/eng units not currently in use will be stored in the above mentioned yellow storage case located in the Rad Storage room.



Attachment 5 Environics Products Sealed Source Device Registry (SSDR) document

See Next Page



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-101-E DATE: January 30, 2009 PAGE 1 OF 5

DEVICE TYPE: Gas and Aerosol Detector

MODELS: ChemPro 100 V2
ChemPro 100 V3
Chempro FX

DISTRIBUTOR: Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, MD 21009

MANUFACTURER: Environics Oy
Graanintie 5
P.O. Box 349
50100 Mikkeli, Finland

SEALED SOURCE
MODEL DESIGNATION: Amersham: AMM
NRD: A-001

ISOTOPE: MAXIMUM ACTIVITY:
Americium-241 160 µCi (5.92 MBq)

LEAK TEST FREQUENCY: Not required

PRINCIPAL USE: (N) Ion Generator, Chromatography

CUSTOM DEVICE: ☐ YES ☒ NO



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-101-E DATE: January 30, 2009 PAGE 2 OF 5

DEVICE TYPE: Gas and Aerosol Detector

DESCRIPTION:

The ChemPro 100 is a chemical detector with the Sensor Unit using open loop ion mobility spectrometry technology and is manufactured in Finland by Environics Oy. The ChemPro 100 will be distributed in the United States to persons exempt from license by Environics USA, Inc. The ChemPro 100 is designed to detect harmful gases and vapors. Uses range from trained military and civilian personnel detecting chemical warfare agents to monitoring gas concentrations of the on-the-job hazardous toxic compounds. The Sensor Unit is designed such that the ionization chamber is integral part to the circuit card that has the associated electronics for generation of the signals used for detection of chemicals.

A Pump Unit draws sample air from the environment through the Sensor Unit which consists of a 160 μ Ci (5.92 MBq) Am-241 source, lead blocks, teflon cell block, teflon gaskets, six tamper resistance stainless steel screws, circuit boards made of fibreglass/epoxy resin composite, and various electronic components.

The Sensor Unit is 4.6 cm (1.81") long, 2.1 cm (0.83") wide, and 1.19 cm (0.47") high and is installed in the ChemPro 100 V2 with the heater and detector electrically connected to the analysis system. The Sensor Unit dimensions for the ChemPro 100 V3 and ChemPro FX are 4.6 cm (1.81") long, 2.2 cm (0.86") wide and 1.22 cm (0.48") high. The source in the Sensor Unit has no on-off mechanism, and radiation levels are constant during both use and storage. Radiation level is calculated to be 1.9 μ rem/hr (0.019 μ Sv/hr) at 5 cm (1.97") from the surface of ChemPro 100 case, which is secured with 4 screws and 4 tamper resistance stainless steel screws to prevent access to the inside of the device and the Sensor Unit.

The ChemPro 100 can be a portable or fixed device and weighs less than 2 lb. (0.9 kg) with battery pack and its overall dimension is 10.2 cm x 22.9 cm x 5.1 cm (4.01" x 9.02" x 2").

The manufacturer suggested a 10 year useful life for the ChemPro 100, which is labeled in accordance with 10 CFR 32.29(b).

07/08/11

10-03 0000-0000-0000



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1150-D-101-E DATE: January 30, 2009 PAGE 3 OF 5

DEVICE TYPE: Gas and Aerosol Detector

DESCRIPTION (Cont.):

The ChemPro 100 device is manufactured in two versions: Version 2 or V2, and Version 3 or V3. There are only minor differences between the ChemPro 100 V2 and the ChemPro 100 V3. The differences are related to the additional sensors in the ChemPro 100 V3 and do not affected the sealed source in regards to the source material, activity level, shielding or assembly process.

The ChemPro FX Module is designed as a fixed site detector for gases and vapors. It is designed for use by trained military to civilian personnel detecting chemical warfare agents, and individuals monitoring gas vapor concentrations of various on the job hazardous toxic chemical compounds. The FX module is designed to operate in temperature ranges from -30°C to 55°C at relative humidity ranging from 0 to 95% and storage temperature range from -40°C to 71°C. It can withstand corrosive environments, vibration, and shock incidents expected to be encountered during storage, installation, and use.

The ChemPro FX Detector Unit consists of the Sensor Unit and associated electronics on two other circuit board assemblies. The sensor unit containing the sealed source is fixed to a detector mounting plate made out of 2mm thick FeZnK grade galvanized steel using four Resistorex security torx screws. This detector unit mounting plate is then installed onto the main assembly plate using six Resistorex security torx screws. The FX detector unit is then covered with a 2mm thick FeZnK grade galvanized steel cover and secured with five more Resistorex torx screws. The sealed source is mounted and secured to the main FX Assembly plate which is made out of galvanized steel. The main assembly plate is then mounted to the enclosure using tamper proof screws. This way even with the door to the FX module open there is no direct access to the sealed source.

Each ChemPro has a unique serial number. The ChemPro 100 V2 serial number is displayed as 20CPXXXXXXXXXX, where the "20" represents the Version 2. The ChemPro 100 V3 serial number will

ST-001

10-07 0022-001-000



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-101-E DATE: January 30, 2009 PAGE 4 OF 5

DEVICE TYPE: Gas and Aerosol Detector

DESCRIPTION (Cont.):

be displayed as 30CPXXXXXXXX, where the "30" represents the Version 3. The ChemPro FX serial number is displayed as 20FXXXXXXXXX, where the "FX" represents the FX Version. The next four "X" provide information regarding the time of manufacture of the ChemPro models and the last six "X" are the unique portion of the serial number for the specific unit.

DIAGRAM:

See Attachments 1 and 2.

REFERENCES:

The following supporting documents for the Model ChemPro 100 are hereby incorporated by reference and are made a part of this registry document.

- Environics USA, Inc.'s application dated March 7, 2002, with enclosures thereto.
- Environics USA, Inc.'s letters dated April 8, 2002, and May 28, 2002, with enclosures thereto.
- Environics USA, Inc.'s facsimile dated April 16, 2002, with enclosure thereto.
- Environics USA, Inc.'s letter dated February 26, 2003, with enclosures thereto.



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-101-E DATE: January 30, 2009 PAGE 5 OF 5

DEVICE TYPE: Gas and Aerosol Detector

REFERENCES (Cont.):

- Environics USA, Inc's letters received on December 14, 2006, with enclosures thereto.
- Environics USA, Inc's letters dated January 29, 2007, and January 30, 2007, with enclosures thereto.
- Environics USA, Inc's letter dated January 27, 2009, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 30, 2009

Reviewer:


John P. Jankovich

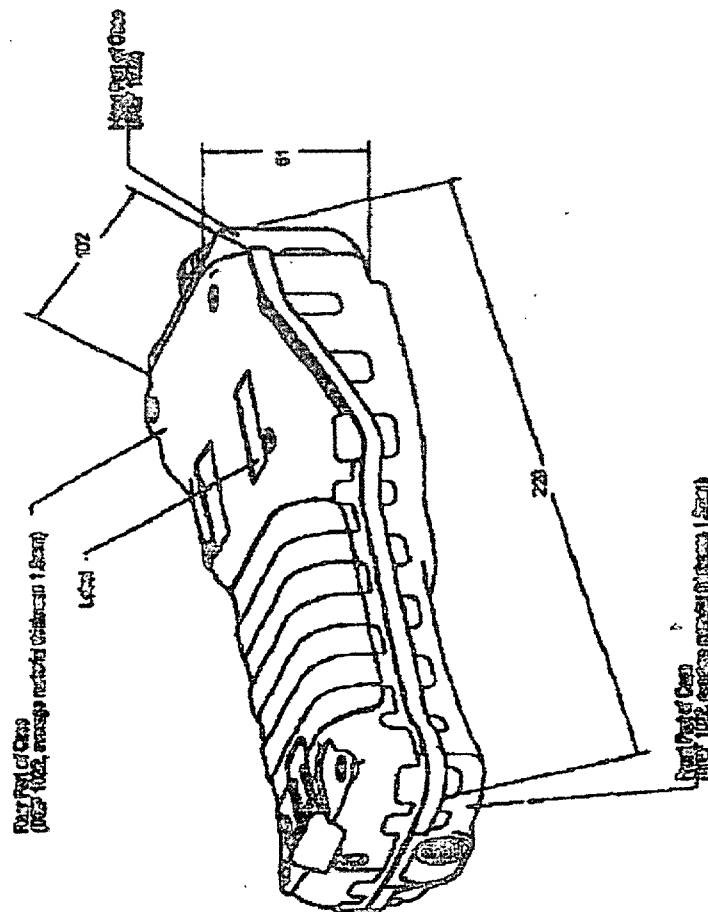
Date: January 30, 2009

Concurrence:


Ujagar S. Bhachu

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Enclosed in its Entirety)

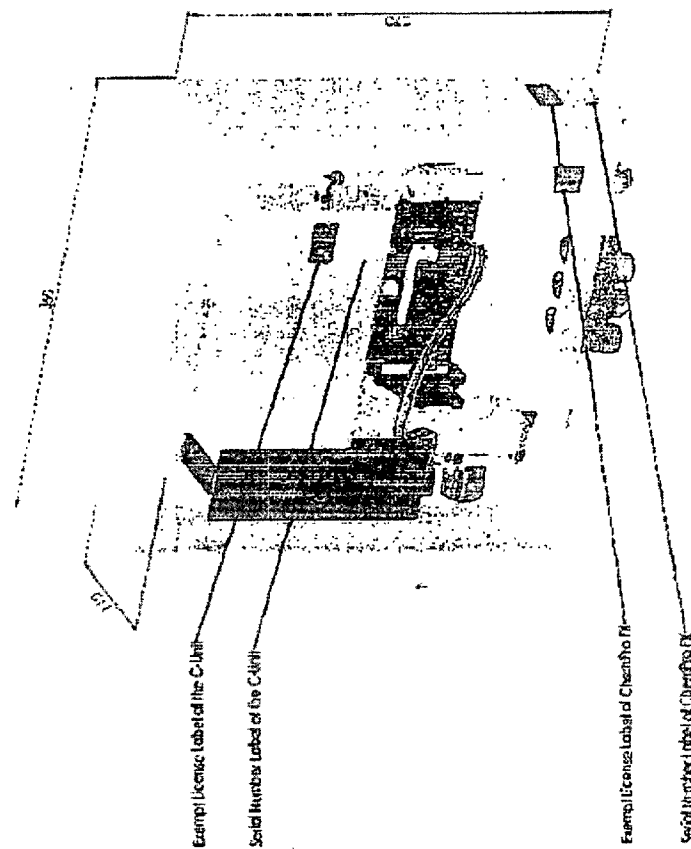
NO.: NR-1160-D-101-E DATE: January 30, 2009 ATTACHMENT 1 of 2



ChemPro 100 V2 and V3

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-101-B DATE: January 30, 2009 ATTACHMENT 2 of 2



The dimensions are in millimeters

ChemPro FX



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NQ.: NR-1160-D-102-E DATE: January 30, 2009 PAGE 1 OF 4

DEVICE TYPE: Gas and Aerosol Detector

MODEL: M90 Chemical Agent Detector
MGD-1 Multi Gas Detector

DISTRIBUTOR: Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, MD 21009

MANUFACTURER: Environics OY
Työmiehenkatu
50101 Mikkeli, Finland

SEALED SOURCE MODEL DESIGNATION: Amersham: AMM
MRD A-001

ISOTOPE: MAXIMUM ACTIVITY:
Americium-241 160 μ Ci (5.92 MBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (P) Ion Generator, Chemical Agent
Detector

CUSTOM DEVICE: ☐ YES ☒ NO



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-E DATE: January 30, 2009 PAGE 2 OF 4

DEVICE TYPE: Gas and Aerosol Detector

DESCRIPTION:

The M90 Chemical Detector and MGD-1 Gas Detector containing the Ion Mobility Sensor Unit is manufactured in Finland by Environics OY and will be distributed in the United States to persons exempt from license by Environics USA, Inc, previously Sensor Applications, Inc., and previously under registration certificate NR-0174-D-101-E. The Sensor Unit is a detector module incorporated in the M90 and MGD-1 systems to detect harmful and toxic gases and vapors. It has the ability to detect life and health threatening hazards which enables the taking of protective action. These hazards include common chemical warfare agents such as nerve and blister agents and on-the-job hazards such as waste anesthetic gases and products of combustion.

Air is drawn through the Sensor Unit by sampling pump in the M90 and MGD-1. Air is heated, flows through an ionization chamber containing a 160 μ Ci (5.92 MBq) Am-241 source in a source bed and into a detector chamber adjacent to the source bed. The current in the detector chamber is affected by ion capture by particles and gases passing through the ionization chamber. The analytical system in the M90 and MGD-1 incorporates software to perform analyses for selected gases and aerosols.

The primary difference between the M90 and MGD-1 is in the software and user interface, which in the case of the MGD-1 is optimized to show the gas names using an LCD display whereas the M90 is optimized to warn of Chemical Warfare Agents with specific LED displays. The M90 faceplate is green while the MGD-1 faceplate is blue.

The sensor unit is the component containing licensed material. The source is cut and shaped to fit in the ionization chamber in the source bed. A fiberglass/epoxy resin composite chamber cover is bolted to the source bed locking the source into position. The source bed assembly is partially shielded with 1 mm lead and fastened into the stainless steel Sensor Unit housing with tamper resistant Torx stainless steel screws. The Sensor Unit is 15 cm (5.91") long, 11 cm (4.33") wide, and 4.8 cm (1.89") high. The Sensor Unit is installed in the M90 Chemical Detector and MGD

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EN-01 4087-00-1010



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-E DATE: January 30, 2009 PAGE 3 OF 4

DEVICE TYPE: Gas and Aerosol Detector

DESCRIPTION (Cont.):

Gas Detector with the heater and detector electrically connected to the analysis system. The source in the Sensor Unit has no on-off mechanism, and radiation levels are constant during both use and storage. Radiation levels at 10 cm (3.9") from the Sensor Unit surface are less than or equal to 30 μ rem (0.30 μ Sv), and lower at 10 cm (3.9") from the surface of the M90 and MGD-1. The only openings into the ionization chamber are 3 mm (0.12") ports, too small for human access. The M90 and MGD-1 are labeled in accordance with 10 CFR 32.29(b).

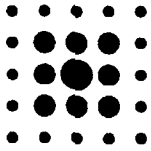
DIAGRAMS:

See Attachments 1, 2, and 3.

REFERENCES:

The following supporting documents for the Model M90 Gas and Aerosol Detector and the MGD-1 Multi Gas Detector are hereby incorporated by reference and are made part of this registry document.

- Temet USA Inc.'s application dated July 13, 1995, and June 5, 1995, with enclosures thereto.
- RSSI's letter on behalf of Temet USA date July 6, 1995, with enclosure thereto.
- Sensor Applications, Inc.'s letter dated January 10, 2002, January 28, 2002, February 26, 2002, and October 30, 2003 with enclosures thereto.
- Sensor Applications, Inc.'s e-mails dated March 25, 2002, and April 10, 2002, with enclosures thereto.
- Sensor Applications, Inc.'s facsimile dated April 15, 2002, with enclosure thereto.



Environics

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-E DATE: January 30, 2009 PAGE 4 of 4

DEVICE TYPE: Gas and Aerosol Detector

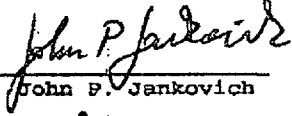
REFERENCES (Cont.):

- Environics USA letters dated May 1, 2002, January 29, 2004, and August 10, 2004, with enclosures thereto.
- Environics USA letters dated September 8, 2004 and September 30, 2004, with enclosures thereto.
- Environics USA Inc.'s letter dated January 27, 2009 with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: January 30, 2009

Reviewer: 
John P. Jankovich

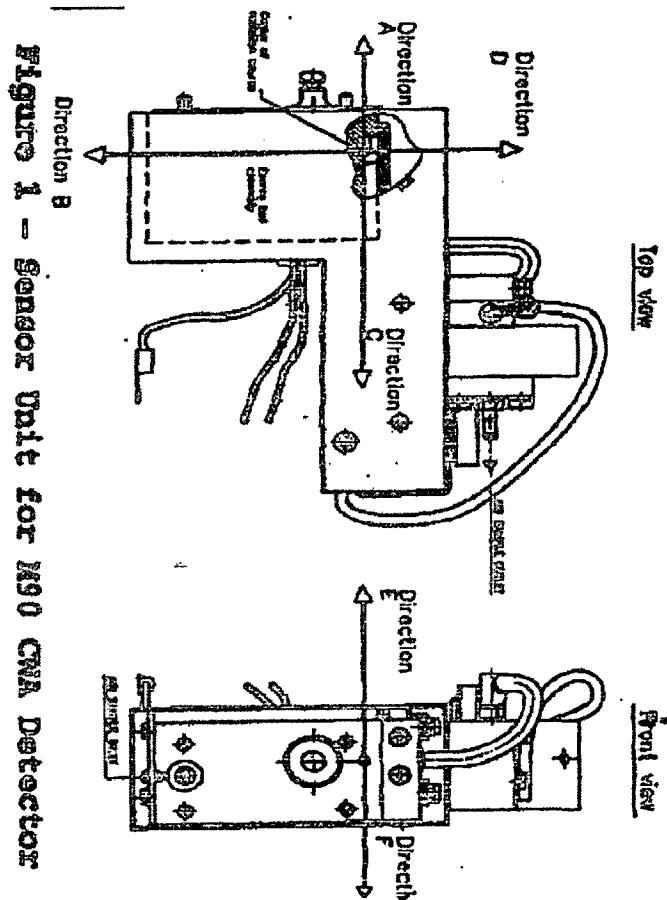
Date: January 30, 2009

Concurrence: 
Ujagar S. Bhachu

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-E DATE: January 30, 2009 ATTACHMENT 1 of 3

DEVICE TYPE: Gas and Aerosol Detector



P.14/19

DT-01 CRP-02-100

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-B DATE: January 30, 2009 ATTACHMENT 2 of 3

DEVICE TYPE: Gas and Aerosol Detector

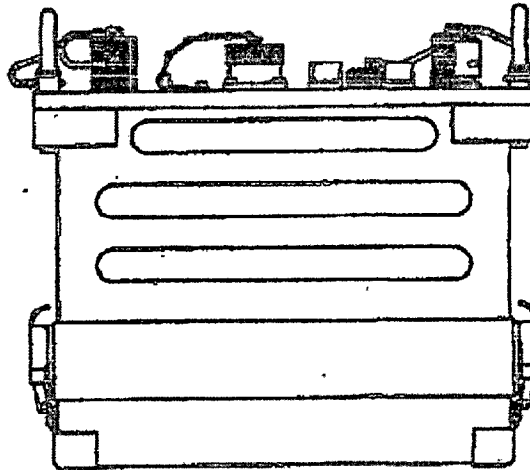
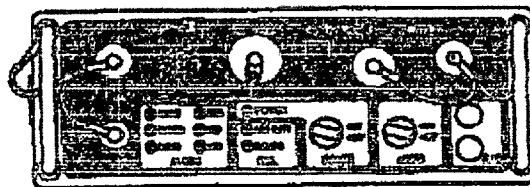
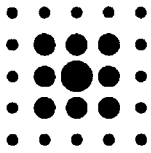


Figure 2 - X90 CMA Detector



BT/CT/1

NY-01 0007-01-1010



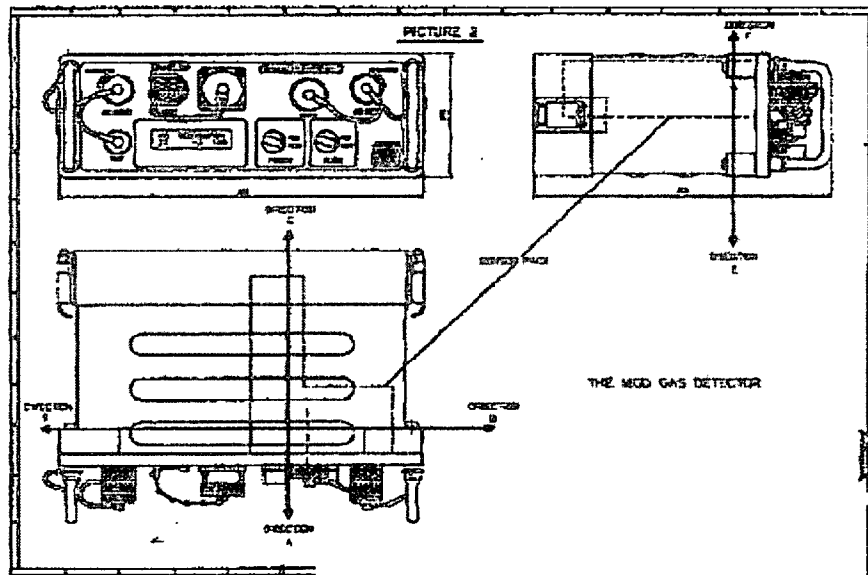
Environics

5178 8111

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(Amended in its Entirety)

NO.: NR-1160-D-102-E DATE: January 30, 2009 ATTACHMENT 3 of 3

DEVICE TYPE: Gas and Aerosol Detector



MOD-1, interface, external dimensions and sensor location

91/10/12

DT:BT 6020-00-00-00-00



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE

No.: NR 1160 D 103 E DATE: September 8, 2011 PAGE: 1 of 3
(Supersedes NR-6199-D-501-E)

DEVICE TYPE: Gas Detector

MODELS: ENVI Series

DISTRIBUTOR: Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, MD 21009

MANUFACTURER: Environics Oy
Työmiehenkatu
50101 Mikkeli, Finland

SEALED SOURCE DESIGNATION: Model BE 3.21

Ritverd GmbH
2-nd Murinsky Ave. 28, 194021
St. Petersburg, Russia

<u>ISOTOPE:</u>	<u>MAXIMUM ACTIVITY</u>
Hydrogen 3	6.1 mCi (300 MBq)

LEAK TEST FREQUENCY: Not Required

PRINCIPAL USE: (N) Ion Generators,
Chromatography

CUSTOM DEVICE: ☐ Yes ☒ No



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE

No.: NR-1160-D-103-E DATE: September 8, 2011 PAGE: 2 of 3
(Supersedes NR-8199-D-801-E)

DEVICE TYPE: Gas Detector

DESCRIPTION:

The ENVI Series consist of three models: ENVI Air, ENVI Stack, and ENVI Pro. The ENVI series uses a combined Ion Mobility Spectrometry (IMS) and Gas Chromatography (GC) system to determine the chemical makeup of gases sampled. The device is designed to be used by manufacturing and process facilities to determine levels of pollutants, contaminant in process air or gasses, and hazardous fumes/gasses. The medium to be sampled flows through the drift region by means of a shutter grid. In the drift region, an electric field is maintained and, due to their mobility, different ions arrive at a collector at the end of the drift cell at different times. These drift times are used for identification of the molecules that are to be identified. The difference between the models involves calibration settings and software configuration of the unit to meet the specified application.

The ENVI series comes in two configurations: rack mount system and industrial enclosure (NEMA 4X) model. The rack mount system and the industrial enclosure model differ in the way the components are assembled in the device. The overall dimensions of the rack mount system are 483 mm in length, 89 mm in height, and 358 mm in width. The overall dimensions of the industrial enclosure (NEMA 4X) model are 400 mm in length, 500 mm in height, and 157 mm width.

The detection unit contains a tritium source with a maximum activity of 8.1 mCi (300 MBq). The source consists of a stainless steel disc which is covered on one side with a layer of titanium, charged with tritium. The titanium layer is sealed with two protective top layers of silicone dioxide and aluminum/gold combination. The source is mounted in an IMS cell constructed of stainless steel. The dimensions of the IMS cell are 4.1 inches (105 mm) in length, 1.6 inches (40 mm) in width, and 1.5 inches (38 mm) in height.



SEP-08-2011 07:51

NRC

010 001 0200 1.000

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE

No.: NR-1160-D-103-E DATE: September 8, 2011 PAGE: 3 of 3
(Supersedes NR-8199-D-801-E)

DEVICE TYPE: Gas Detector

DIAGRAMS:

See Attachment 1

REFERENCES:

The following supporting documents for the Environics USA, Inc. gas detector are hereby incorporated by references and made a part of this registry document:

- Environics USA, Inc.'s application letter dated March 21, 2011, with enclosure thereto.
- Environics USA, Inc.'s letter dated July 28, 2011, with enclosure thereto.
- Environics USA, Inc.'s e-mails dated, September 1, 2011, and September 6, 2011, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: September 8, 2011

Reviewer: 
Eymari Sepulveda

Date: September 8, 2011

Concurrence: 
John P. Jankovich

TOTAL P.002



Attachment 6

Environics USA's US Federal Exempt Distribution License

The following license is enclosed with the cover letter and other communication from the NRC as an example of the nature of a Federal NRC communication document.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

September 16, 2011

Mr. Rolf Meinholtz
Eng Manager/Chemist/RSO
Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, Maryland 21009

SUBJECT:

Dear Mr. Meinholtz:

Please find enclosed a corrected copy of Amendment No. 1 to U. S. Nuclear Regulatory Commission (NRC) exempt distribution License No. 19-23974-01E, as well as Registration Certificate No. NR-1160-D-103-E, reflecting the addition of the ENVI Series Industrial detectors. The Reference No. in Item 5 was corrected to read: 030-36677, and the amendment number was added to pages 2 and 3.

Please review the enclosed document carefully and be sure that you understand all the conditions. If there are any errors or questions, please contact me so that appropriate corrections and answers can be provided.

Please be advised that you must conduct your program involving radioactive materials in accordance with the conditions specified in your NRC license, representations made in your license application, and other rules, regulations, and orders of the U.S. Nuclear Regulatory Commission, now or hereafter in effect, to include the following:

1. Comply with applicable NRC regulations in 10 CFR Part 30, "Rules of General Applicability to domestic Licensing of Byproduct Material"; 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; and other applicable regulations.

NOTE: Licensees authorized to distribute or initially transfer products containing byproduct material must also possess a valid possession license issued either by NRC or an Agreement State(s) which authorizes possession and use of byproduct material.

2. Distribute only those products containing radioactive material which are specifically authorized in your license.
3. Notify NRC in writing within 30 days of any change in mailing address.
4. Request and obtain appropriate amendments if you plan to change control or ownership of your organization, change locations of distribution of products containing radioactive material, or make any other changes in your program which are contrary to the license conditions or representations made in your license application and any supplemental correspondence with NRC.

R. Meinholz

- 2 -

5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 90 days before the expiration date. Continued distribution of products containing radioactive material after your license expires is a violation of NRC regulations.
6. In accordance with 10 CFR 30.36, request termination of your license if you plan to permanently discontinue activities involving distribution of products containing radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in compliance with NRC regulations, license conditions and representations made in your license application and supplemental correspondence with NRC may result in enforcement action(s) against you. This could include issuance of a notice of violation; proposed imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," (NUREG-1600).

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions concerning the license or the registration certificate, you may contact me at (301) 415-5477 or richard.struckmeyer@nrc.gov.

Sincerely,



Richard K. Struckmeyer
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
Washington, DC 20555

Docket No. 030-37898
Enclosures: License No. 19-23974-01E
Amendment No. 01
NR-1160-D-103-E

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 3 PAGES

CORRECTED COPY

Amendment No. 01

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Environics USA, Inc. 2. 1308 Continental Drive, Suite J Abingdon, MD 21009	In accordance with letter dated March 21, 2011 3. License number 19-23974-01E is amended in its entirety to read as follows: 4. Expiration date July 31, 2012 5. Docket No. 030-37898 Reference No. 030-36677
---	--

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Americium-241	A. Foil Sources (NRD Model A-001, Amersham Corp. Models AMM-1001 or AMM-1001D)	A. Not Applicable (See Condition 11)
B. Hydrogen-3	B. Foil Sources (Ritverc Model BH 3.21)	B. Not Applicable (See Condition 11)

9. Authorized use:

A. and B. Pursuant to Section 32.26, 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," the licensee is authorized to distribute smoke detector devices specified in Condition 10 and gas analyzer devices specified in Condition 11 to persons exempt from the requirements for a license pursuant to Section 30.20, 10 CFR Part 30, or equivalent provisions of the regulations of any Agreement State.

NRC FORM 374A COMMISSION	U.S. NUCLEAR REGULATORY	PAGE 2 of 3 PAGES
MATERIALS LICENSE SUPPLEMENTARY SHEET		License Number 19-23974-01E
		Docket or Reference Number 030-37898
		Amendment No. 01

CONDITIONS

10. The following smoke detector devices may be distributed pursuant to this license provided the amount of americium-241 contained in the device does not exceed the amount specified in the following table:

<u>Device Model</u>	<u>Maximum Quantity per Device</u>
ChemPro 100 (V2)	160 microcuries (5.92 MBq)
ChemPro 100 (V3)	160 microcuries (5.92 MBq)
ChemPro FX	160 microcuries (5.92 MBq)
M90 Chemical Agent Detector 1	160 microcuries (5.92 MBq)
MGD-1 Multi Gas Detector	160 microcuries (5.92 MBq)

11. The following gas and aerosol detector devices may be distributed pursuant to this license provided the amount of hydrogen-3 contained in the devices does not exceed the amounts specified in the following table:

<u>Device Model</u>	<u>Maximum Quantity per Device</u>
ENVI-Air	8.1 millicuries (300 MBq)
ENVI-Pro	8.1 millicuries (300 MBq)
ENVI-Stack	8.1 millicuries (300 MBq)

12. This license does not authorize possession or use of licensed material.

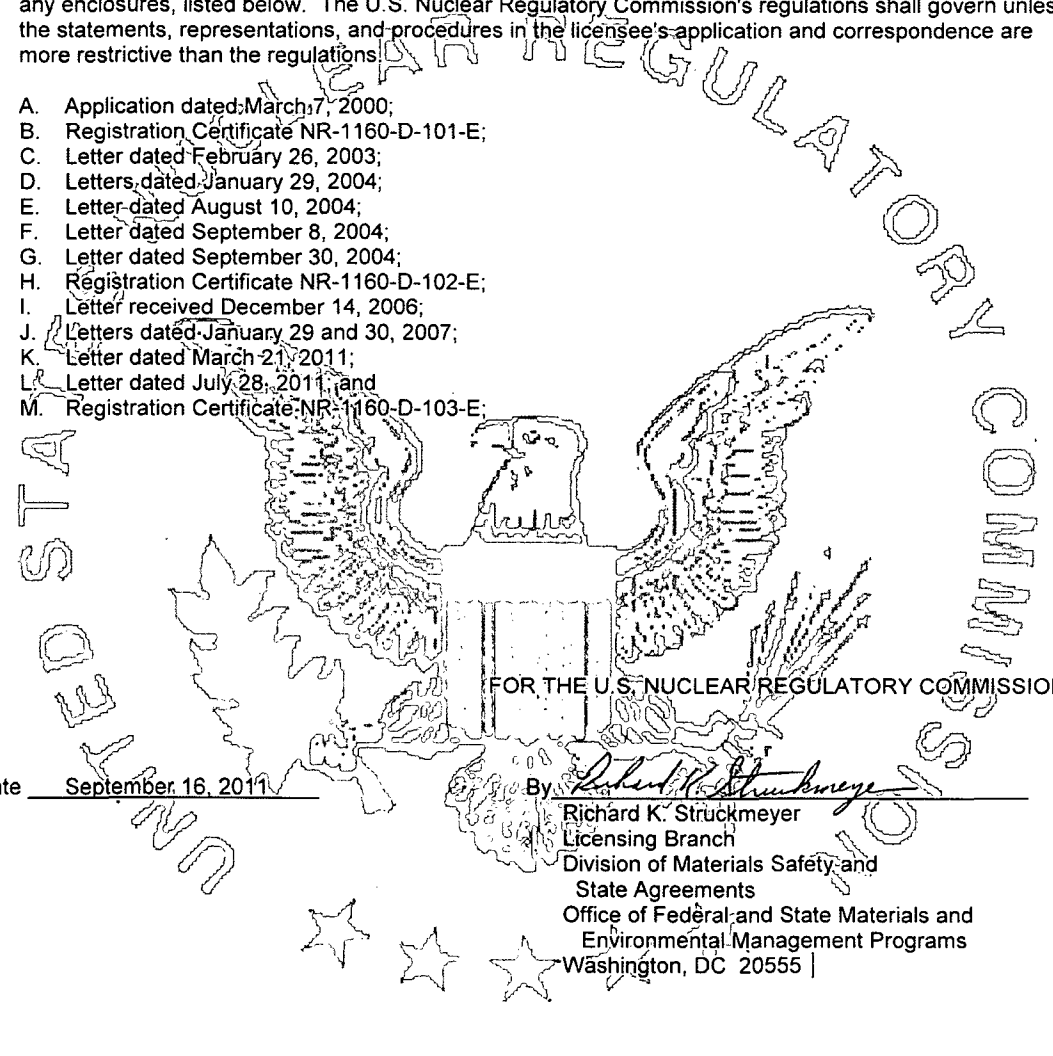
13. The licensee may distribute only from its facilities located at 1308 Continental Drive, Suite J, Abingdon, Maryland.

14. The licensee shall file periodic reports as specified in Section 32.29(c), 10 CFR Part 32.

NRC FORM 374A COMMISSION	U.S. NUCLEAR REGULATORY	PAGE 3 of 3 PAGES
MATERIALS LICENSE SUPPLEMENTARY SHEET		License Number 19-23974-01E
		Docket or Reference Number 030-37898
		Amendment No. 01

15. Except as specifically provided otherwise by this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 7, 2000;
- B. Registration Certificate NR-1160-D-101-E;
- C. Letter dated February 26, 2003;
- D. Letters dated January 29, 2004;
- E. Letter dated August 10, 2004;
- F. Letter dated September 8, 2004;
- G. Letter dated September 30, 2004;
- H. Registration Certificate NR-1160-D-102-E;
- I. Letter received December 14, 2006;
- J. Letters dated January 29 and 30, 2007;
- K. Letter dated March 21, 2011;
- L. Letter dated July 28, 2011; and
- M. Registration Certificate NR-1160-D-103-E;



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date September 16, 2011 By Richard K. Struckmeyer

Richard K. Struckmeyer
 Licensing Branch
 Division of Materials Safety and
 State Agreements
 Office of Federal and State Materials and
 Environmental Management Programs
 Washington, DC 20555 |



Attachment 7

Environics USA's State of Maryland Possession license

The following document is enclosed as a example of the State level possession license.

See Next page.



MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230
410-537-3000 • 1-800-633-6101 • www.mde.state.md.us

Martin O'Malley
Governor

Robert M. Summers, Ph.D.
Secretary

Anthony G. Brown
Lieutenant Governor

NOV 9 2011

Rolf Meinholtz, Radiation Safety Officer
Environics USA, Inc.
1308 Continental Drive, Suites J & K
Abingdon, MD 21009-2304

RE: Radioactive Material License #MD-25-047-01

Dear Mr. Meinholtz:

Your requested amendment to radioactive materials license number MD-25-057-01 is enclosed. Please review it carefully to ensure that it reflects all modifications included in your letter received in this office on September 28, 2011.

Should you require further assistance, please contact Mr. Raymond E. Manley at (410) 537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301. Also, you may contact this office via facsimile at 410-537-3198.

Sincerely,

Roland G. Fletcher, Manager IV
Radiological Health Program
Air and Radiation Management Administration

Rm
RGF/REM/BJP/cc

Enclosure(s): License amendment (04)
Code (03250)



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 1 of 5

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. The license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below.

Licensee		3. License No.:	MD-25-057-01
1. Name:	Environics USA, Inc	4. Amendment No.:	04 Code 03250
2. Address:	1308 Continental Drive, Suites J & K Abingdon, Maryland 21009-2304	5. Expiration Date:	January 31, 2016
6. Radioactive material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of activity which licensee may possess at any one time	
A. Americium-241	A. Foil source: Nuclear Radiations Development, Inc. Model A-001 and Amersham Corporation Model AMM	A. 1000 sources; not to exceed 160 microcuries each	
B. Americium-241	B. Foil source: Amersham Corporation Model AMM and Nuclear Radiations Development, Inc. Model A-001	B. 1000 sources; not to exceed 160 microcuries each	
C. Hydrogen-3	C. Ritverc GmbH model BH 3.21	C. Two sources, not to exceed 27 millicuries each	
D. Nickel-63	D. Sealed Source: Eckert & Ziegler Nuclitec GmbH model NBCB17139	D. 10 millicuries per source; maximum number of sources not to exceed 500	
E. Hydrogen-3	E. Sealed Source: Ritverc GmbH Model BH 3.21	E. 8.1 millicuries per source; maximum number of sources for device listed in 9E. not to exceed 30.	
F. Nickel-63	F. Sealed Source: IPL NER-004R or AEA NBCQ8681	F 15 millicuries per source: Maximum number of Sources not to exceed 2.	



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 2 of 5

License Number: MD-25-057-01

Amendment Number: 04

CONDITIONS

9. Authorized Use(s):

A. To be received in modules for assembly of the Envionics Model ChemPro 100 and to be received as completed product for distribution as exempt products as described in sealed source registry number NR-1160-D-101-E. Distribution is authorized pursuant to NRC distribution license 09-23918-01E being active and showing the address of this license as an authorized distribution location.

B. To be received in modules for assembly of Envionics Model M90, Chemical Agent Detector and the MGD-1 Multi Gas Detector to be received as completed product for distribution as exempt products as described in sealed source registry number NR-1160-D-102-E. Distribution is authorized pursuant to NRC distribution license 09-23918-01E being active and showing the address of this license as an authorized distribution location.

C. Former Draeger Safety, Inc models 5000, 5600, 5700, STR0000, or Envirosecure IMS 7100 for research and development only. SSD registry NR-8199-D-801-E.

D. For use in Chempro-100i (Nickel-63) device not for distribution in the United States.

E. To be received in modules for assembly of Envionics ENVI Series gas and aerosol detector to be received as completed product for distribution as exempt products as described in sealed source registry number NR-1160-D-103-E. Distribution is authorized pursuant to NRC distribution license 09-23918-01E being active and showing the address of this license as an authorized distribution location.

F. For use in Smith's Detection model APD 2000 for comparison purposes only. Not for re-sale.

10. The authorized place of storage is the licensee's address stated in Item 2. The licensee is authorized to perform demonstrations throughout Maryland, **except for item 9C, 9D, and 9F.** The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address.

11A. The radiation protection program shall be under the supervision of Rolf Meinholtz.

11B. Radioactive material shall be used by, or under the supervision of Rolf Meinholtz.

12. The licensee shall comply with all appropriate provisions of COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation," and shall possess a copy of these regulations.

13. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for three (3) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 3 of 5

License Number: MD-25-057-01

Amendment Number: 04

CONDITIONS

- 14A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- 14B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.
- 14C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
- 14D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230, describing the equipment involved, the test results, and the corrective action taken.
- 14E. Test for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.
- 15. Sealed sources containing radioactive material shall not be opened.
- 16. The licensee shall not transfer possession or control of radioactive material, or products containing radioactive material as a contaminant except by transfer to a specifically licensed recipient.
- 17. The licensee shall not modify nor implement any material changes to the radiation safety program without the approval of the Department.
- 18. The licensee shall file reports pursuant to COMAR 26.12.01.01 § C.28(a)(2).
- 19. Radioactive material shall be transported in accordance with COMAR 26.12.01.01 § T.
- 20. Each point-of sale package shall be marked or labeled pursuant to Title 10 CFR 32.29(b).



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 4 of 5

License Number: MD-25-057-01

Amendment Number: 04

CONDITIONS

- 21A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Nor shall the licensee falsify, tamper with, or render inaccurate any monitoring device or method.
- 21B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.
22. The licensee shall not transfer ownership and/or control of this license to any person or entity without providing required information regarding the transfer for the Agency's review and without receiving written authorization for the transfer by the Agency.
23. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:
 - Application dated May 7, 2008, with attachments;
 - Email dated November 18, 2008.
 - Letter dated January 14, 2009, with attachments, giving new contact information and modified NRC distribution licenses.
 - Letter dated November 16, 2010, requesting possession of two Hydrogen-3 sources for research and development.
 - Electronic mail dated January 11, 2011, with attached Nickel-63 data sheet
 - Electronic mail dated January 11, 2011 from NRC (John Jankovich) stating that SSD registration not needed for distribution to Canada only.



Department of the Environment

RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 5 of 5

License Number: MD-25-057-01

Amendment Number: 04

CONDITIONS

- Letter dated January 14, 2011, with attachments requesting possession of Nickel-63.
- Electronic mail from John Jankovich dated March 7, 2011, confirming e-mails of June 10, 2010 and January 11, 2011.
- Letter dated September 9, 2011, with attachments, requesting addition of ENVI Series and APD 2000 devices.
- Letter with attachments dated September 27, 2011, with additional information for ENVI Series.

COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT



Roland G. Fletcher, Manager IV
Radiological Health Program

October 31, 2011

BJP

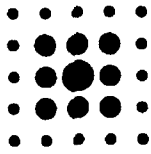
BJP
10/31/2011
JK
11/7/11



Attachment 8

**Environics USA's Canadian device Certificate for
ChemPro100; Certificate # 185-0001-0-2017 and
M-90, Certificate # 185-0002-0-2017**

See Next Page



Environics



Canadian Nuclear
Safety Commission

Commission canadienne
de sûreté nucléaire

P.O. Box 1046, Station B
Ottawa, Ontario
K1P 5S9

C.P. 1046, Succursale B
Ottawa (Ontario)
K1P 5S9

Fax: (613) 995-5086

Télécopieur : (613) 995-5086

Directorate of Nuclear
Substance Regulation

Our file Votre référence

Our file Votre référence

Telephone: 1-888-229-2672

28-185-0001

August 15, 2011

Mr. Rolf Meinholtz
Environics USA
1308 Continental Drive, Suite
Abingdon, Maryland 21009
United States of America

Subject: Radiation Device Certificate # R-185-0001-1-2017

Dear Mr. Meinholtz:

Please find enclosed a copy of the above certificate issued pursuant to the *Nuclear Safety and Control Act* for the following Radiation Device:

Environics ChemPro 100, ChemPro 100i, ChemPro FX and ChemPro PD Detectors

You are requested to verify the accuracy of the information contained in the certificate and to immediately inform the CNSC of any omissions or discrepancies.

The radiation device has been certified on the basis of the information submitted pursuant to section 12 of the *Nuclear Substances and Radiation Devices Regulations* and identified on the certificate. Any change in the design of your equipment may necessitate a new certification.

This radiation device may be decertified at any time pursuant to paragraphs 21(1)(b) and 37(2)(a) of the *Nuclear Safety and Control Act*, subject to the provisions of sections 14 and 15 of the *Nuclear Substances and Radiation Devices Regulations*.

If you have any questions or require clarification on CNSC regulatory requirements for certification, licensing or transportation, please do not hesitate to contact the undersigned at the address above.

Yours sincerely,

Karine Glenn
Transport Specialist
Directorate of Nuclear Substance Regulation

Enclosure(s)

Canada

Certificate

for
Radiation Device

Certificate Number R-185-0001-1-2017	Date of Issue August 15, 2011	Date of Expiry November 30, 2017
--	---	--

The radiation device identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the *Nuclear Safety and Control Act* and section 12 of the *Nuclear Substances and Radiation Devices Regulations*.

Manufacturer:	Environics Oy
Make and Model:	Environics ChemPro 100, ChemPro 100i, ChemPro FX and ChemPro PD Detectors
Device Type:	ELECTRON CAPTURE DETECTOR
Description:	Reference CNSC Application Nos. 33607, 41828 and 44156.

The ChemPro line of radiation devices consists of chemical detection devices using ion mobility spectrometry technology. They are designed for harsh environments of military or civilian operations. The ChemPro 100, 100i and PD are portable devices which can be installed in a static mount. The ChemPro FX is the fixed site adaptation of the ChemPro 100 technology.

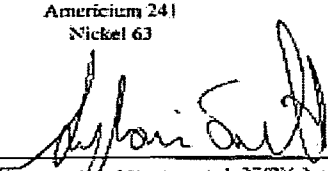
There is no shutter or source locking mechanism in any of the ChemPro line device models. The source is contained within a source box, which is in turn placed in the sensor unit installed within the instrument casing. The sensor unit is 4.6 cm long, 2.2 cm wide and 1.22 cm high and is the same in all models. Shielding is provided by lead blocks.

Each device incorporates one source foil, which can be either up to 5.92 MBq of Am-241 or up to 370 MBq of Ni-63. The source foil is 17.3 mm long x 10.0 mm wide x 0.25 mm high (Am-241) or 20 mm x 10 mm x 0.05 mm (Ni-63). The Am-241 source meets ANSI 77C2222 classification. The Ni-63 source meets ANSI 77C4X212 classification.

Refer to Summary Evaluations (CNSC Document No. 3772749) for additional information.

The radiation device may contain any of the following nuclear substances in a quantity not exceeding the corresponding quantity indicated:

Nuclear Substance	Maximum Quantity
Americium 241	5.92 MBq
Nickel 63	370 MBq


 Designated Officer pursuant to paragraph 37(2)(a) of the
Nuclear Safety and Control Act

Original

Canada

Summary Evaluation

For certificate no. R-185-0001

(Not part of the certificate but to be provided with certificate)

1. Identification of Radiation Device

Device Type:	Analyzer
Manufacturer:	Environics
Model(s):	ChemPro 100, ChemPro 100i, ChemPro PD, ChemPro FX

2. Device Description

The ChemPro line of radiation devices consists of chemical detection devices using open loop ion mobility spectrometry technology. Four models are covered by this certificate: the ChemPro 100, ChemPro 100i, ChemPro PD and ChemPro FX.

There is no shutter or source locking mechanism in any of the ChemPro line device models. The source is contained within a source box, which is in turn placed in the sensor unit installed within the instrument casing. The sensor unit is 4.6 cm long, 2.2 cm wide and 1.22 cm high and is the same in all models. Shielding is provided by lead blocks. To prevent unintentional access to the source, the sensor unit is assembled using six Resistorx security button head screws.

Each device incorporates one source foil, which can be either Am-241 or Ni-63. The source foil is 17.3 mm long x 10.0 mm wide x 0.25 mm high (Am-241) or 20 mm x 10 mm x 0.05 mm. (Ni-63). These dimensions are greater than the 3.6 mm openings for the air path through the source. This precludes the possibility of the source foil being lost from the source box due to vibration or accident.

The Am-241 source meets ANSI 77C22222 classification. The Ni-63 source meets ANSI 77C4X212 classification.

3. General Arrangement

An illustration of the sensor unit is shown in Drawing #ED01031 [3]. Illustrations of the device models are also shown in Figures 1, 2 and 3.

4. Intended Use

The ChemPro line device models are designed for harsh environments of military or civilian operations to detect harmful gases and vapors. The ChemPro 100, 100i and PD are portable devices which can be installed in a static mount. The ChemPro FX is the fixed site adaptation of the ChemPro100 technology.

5. Authorized Nuclear Substances

This device is authorized to contain the following nuclear substance(s):

Nuclear Substance	Maximum Activity		Source Manufacturer	Special Form Certificate no.
	Source	Device		
Am-241	5.92 MBq	5.92 MBq	QSA Global	N/A
Am-241	5.92 MBq	5.92 MBq	NRD	N/A
Ni-63	370 MBq	370 MBq	Eckert & Ziegler	N/A

Note(s): Each device uses either Am-241 or Ni-63. There is only one source per device.

6. Maximum Expected Radiation Dose

Nuclear Substance	Activity (MBq)	Dose rate (uSv/h)		
		@ 5 cm	@ 25 cm	@ 100 cm
Am-241	5.92	0.35	<0.1	No measurable dose
Ni-63	370	No measurable dose	No measurable dose	No measurable dose

Note(s): These devices do not incorporate a shutter.

7. Conditions of Use and Storage

The device is designed for indoor and outdoor use and can operate in temperature ranges from -30°C to 55°C at a relative humidity ranging from 0 to 95% and storage temperature range from -40°C to 71°C. It can withstand corrosive environments, vibration and shock incidents expected to be encountered during storage, installation (for the ChemPro100 FX) and use

8. Leak Test

Periodic leak testing is not required to be performed for these devices.

9. Emergency and Accident Response

Emergency and accident response are to be dealt with in accordance with the emergency procedure provided in the *ChemPro 100 Operator and Unit Support Manual* [4], the *ChemPro FX User and Maintenance Manual* [5], and the *ChemPro PD Operator and Unit Support Manual* [6] and the *Nuclear Substances and Radiation Devices Regulations*.

10. Design, Testing and Manufacturing Quality Assurance

The radiation device is manufactured in accordance with an ISO 9001 compliant quality assurance system as detailed in the *Environics OY Quality Plan for ACADS (RNLA) Project* [7].

11. Inspection, Maintenance and Servicing

The radiation device is to be inspected and maintained in accordance with the requirements set out in the *ChemPro 100 Operator and Unit Support Manual* [4], the *ChemPro FX User and Maintenance Manual* [5], and the *ChemPro PD Operator and Unit Support Manual* [6]. Servicing of the sensor unit by the user is not permitted.

12. Transport Packaging

The radiation device is placed in a plastic "Pelican" case for transport as an excepted package.

*Note: When containing Ni-63, the radiation device is exempted from the *Packaging and Transport of Nuclear Substances Regulations* for transport in Canada following the sale to the end user.*

13. Authorized Accessories and Configurations

There are no accessories for use with these devices that have an impact on radiological safety.

14. Reference Documents

No.	Document Description	Date of document	CNSC Document Number
1	Original application for certification of radiation device	2008-09-08	3285054
2	Amendment request for addition of Ni-63	2010-11-09	3634225
3	Sensor Unit Drawing (drawing #ED01031), Appendix B of original application	2008-09-08	3285054
4	<i>ChemPro 100 Operator and Unit Support Manual</i>	2011-05-12	3772134
5	<i>ChemPro FX User and Maintenance Manual</i>	2011-05-12	3772134
6	<i>ChemPro PD Operator and Unit Support Manual</i>	2011-05-12	3772134
7	<i>Environics OY Quality Plan for ACADS (RNLA) Project</i>	2008-09-08	3285054
8	Certification assessment	2011-08-10	3771301

15. Attachments



Figure 1: ChemPro 100 or 100i



Figure 2: ChemPro PD

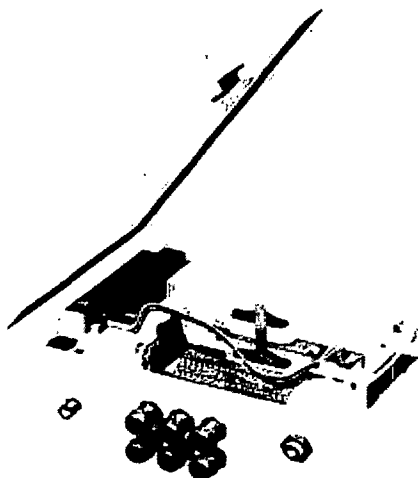


Figure 3: ChemPro FX

Appendix 10: Pregnant worker Program

The Code of Federal Regulations in 10 CFR, part 19 "Notices, instructions and reports to Workers, Inspections and Investigations," in Section 19.12, "Instructions to Workers" requires instructions to all workers regarding the health and protection issues related to working with Radioactive materials, specifically to minimize exposure or the effects. These instructions must be "commensurate with the potential radiological health protection problems present in the work place."

The US NRC regulations regarding the protection are specified in 10 CFR, Part 20, "Standards for the Protection against Radiation" and section 20.1208, "Dose to an Embryo/Fetus."

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of--

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclide in the embryo/fetus and radionuclide in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

These regulations require the licensees to ensure that the dose to an embryo/ fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5mSv). Section 1208 also requires the licensee to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman."



this is determined through the use of individual monitoring devices that the company will issue once the pregnancy is declared and must be worn by the declared pregnant woman at all times with in the workplace to allow for the monitoring of any exposure during the pregnancy.

"Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermo luminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices."

A declared pregnant woman is defined in 10 CFR, Section 20.1003,

"Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant."

as a woman who has voluntarily informed her employer, in writing, of her pregnancy and of the estimated date of conception. (see appendix 11 for examples of a "Declaration of Pregnancy, Instructions for the Declared pregnant woman." Once this declaration is made to the employer and until the individual monitoring devices are obtained the declared pregnant worker is to be restricted in her access to locations or work that might result in radiation does due to workplace exposure.

Note that these regulations and requirements in no way allow for the limitation or termination of the worker due to a pregnancy. However in the interests and legal protection of the employer and company for these stipulations the woman must declare her pregnancy. If in the case that a woman becomes pregnant and does not declare her pregnancy to her employer then the employer may document this and be used in any legal proceedings.

At the Simplest the intent of the pregnant worker regulations is to limit whenever possible the dose to the embryo/fetus and at all times of the declared pregnancy, to employ individual monitoring devices to track and record the actual exposure and any does received by the worker and embryo/fetus that is due to workplace exposure.

For legal reasons these records will be held as long as the company is in operation.



Appendix 11: Pregnant worker Program forms.

DECLARATION OF PREGNANCY
To: _____
In accordance with relevant EUSA policy and in accordance with Federal and State Guidelines related to ("Dose to an Embryo or Fetus"), I am declaring that I am pregnant. I believe that I became pregnant in
_____ Month _____ Year
I understand that the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 500 mSvrem (unless that dose has already been exceeded between the time of conception and submitting this declaration). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy. I understand that Envionics USA will obtain individual dose monitoring devices as needed and monitor them to ensure the above stated dose limit.
Signature
Printed Name
Date
CL Ex. F (Declare Pregnancy) 1-25-07 Page 1 of 1

INSTRUCTIONS FOR WOMEN WORKING WITH RADIATION

I have received verbal instructions concerning the potential risks involved for pregnant women exposed to radiation, including a copy of U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" (Rev. 3, 6/99).

The radiation safety officer (RSO) has encouraged me to ask for additional information if needed, and I am aware that the RSO is available to answer any questions I may have regarding the issue of radiation exposure to an embryo/fetus.

Signature

Printed Name

Date

RSO Signature

Date



INSTRUCTIONS FOR DECLARED PREGNANT WOMEN

I have received verbal instructions on personnel monitoring (PM) requirements for declared pregnant women conducting activities involving sources of radiation, in accordance with the requirements of my employer's radiation safety program, the terms and conditions of my employer's radioactive materials license (and/or certification of registration, as applicable)

I have been instructed to wear my assigned PM badge at waist level to estimate the embryo/fetus dose. I am aware that the fetal dose is not allowed to exceed 500 millirem during the entire pregnancy as a result of occupational radiation exposures (unless that dose has already been exceeded between the time of conception and submitting my declaration of pregnancy), and that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy. I must make every effort to maintain the fetal dose as low as reasonably achievable (ALARA), and I will strive to abide by the regulatory recommendation to limit fetal dose to 50 millirem or less in any one month. I understand that records of fetal dose are maintained with my dose records.

The radiation safety officer has encouraged me to ask for additional information if needed, and to review information on the potential risks involved for pregnant women exposed to radiation, particularly U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.13.

Signature

Printed Name

Date

RSO Signature

Date



Appendix 12: Possession of APD2000

Environics has requested and received approval to possess two APD2000 detectors for comparison use only to be received from a customer as part of a device sale. (see line F on the State of Maryland possession license.) Environics USA will have and maintain these APD 2000 units and they will be stored in the Radiations storage closet when not being used.

These units will be added to the device database as test items and wipe tested as required by the device registry. Once Environics USA determines that it no longer wishes to possess the APD2000 units it will arrange for the proper disposal of the APD 2000 and provide to the State of Maryland documentation to validate the correct and final disposition of the units.

Appendix 13: Safety Audit reports

Audit Report July 14th 2011 and actions



Successful Device Approvals

July 14, 2011

Timo Jaakkola, CEO
Environics USA, Inc.
1308 Continental Drive, Suite J
Abingdon, MD 21009

**RE: Annual Radiation Safety
Program Audit**

Dear Timo:

Enclosed is the report for the audit of Environics Radiation Safety Program which I conducted on July 6, 2011. This was an initial audit performed by IRSC, Inc.

Summary of Existing Licenses and Device Registrations

State of Maryland Possession License No: MD-25-057-01

NRC Exempt Device Registration No. NR-1160-D-101-E

NRC Exempt Device Registration No. NR-1160-D-102-E

State Inspection:

Your last state inspection was on March 4, 2009. No violations were issued.

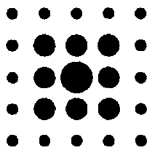
Your last NRC inspection was on November 11, 2009. No violations were issued.

Summary of Recent Radiation Safety Program Changes:

You currently have a pending application with the Canadian Nuclear Safety Commission for a device certification of chemical agent detectors using Ni-63 sources.

You currently have a pending application with the US NRC for an exempt device registration for the ENVI Series. We will need to amend your state of Maryland possession license to add additional ENVI devices once your device registration has been

17 Norfolk Rd., Holbrook, MA 02343 USA Ph. 877.266.0794 (U.S.)
781.767.2176 (outside U.S.) Fax: 781.207.0453 www.irsc-inc.com



issued.

Items For Correction:

There were no records of annual radiation safety program audits as required by D1102a(ii).

Environics does not currently have any survey meters. Outgoing packages are required to be surveyed as per 49 CFR 173.424(d). Survey meters are required to survey packages which may appear to be wet or damaged as per D.906b (iii). Survey meters are an additional method of evaluating the possible presence of radioactive contamination in addition to wipe testing devices. We suggest you purchase either two Ludlum Model 3 detectors with 44-1 probes or more sensitive meters such as the Thermo Radeye B20 and then establish a routine for surveys of areas where instruments containing radioactive sources are serviced or stored.

A copy of the recipient's license is required to be reviewed and retained when transferring unregistered devices as required under condition 15 of your Maryland Radioactive Materials License and C40(c)(d).

Recommendations:

The container with waste IMS systems is not properly labeled. It should be labeled "Caution, Radioactive Waste," preferably with a detailed description of the contents.

Currently radiation safety training is performed on an as needed basis. Please establish an annual schedule for radiation safety refresher training. Since there are only two individuals using devices containing sources it is not necessary to have a formal class, but you can have materials available regarding radiation safety practices and workers rights, and users can sign off that these materials have been reviewed.

Please update your radiation safety manual to include procedures for pregnant worker declarations.

The flow level in the hood should be calibrated on an annual basis. Since you are in the process of installing a new hood, it might be a good idea to also install a digital flow meter indicator.

The most recent 6 month inventory is a few days past due. Inventories are being consistently performed and you have a comprehensive system for verifying inventory.

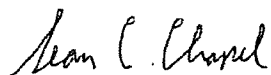
We clarified that under 49 CFR 173.422(a) that at minimum, ground packages in the US must be labeled as UN2911. Since you are now labeling all packages with the IATA UN2911 label it will not be an issue. Please update page 10 in your procedures regarding these requirements.

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781.767.2176 (outside U.S.) Fax: 781.207.0453 www.irsc-inc.com

Please retain a copy of this report with your records to verify that a program audit was conducted for this year.

If you have any questions please don't hesitate to call me at 781.767.2176 or email me at schapel@irsc-inc.com.

Sincerely,



Sean C. Chapel
President

17 Norfolk Rd., Holbrook, MA 02343 USA Ph. 877.266.0794 (U.S.)
781.767.2176 (outside U.S.) Fax: 781.207.0453 www.irsc-inc.com



Official copies of Audit reports and actions undertaken due to them are on file in the public portion of Environics USA's Radiation records. (See RSO for assistance.)