

**1.0 INTRODUCTION**

This procedure describes the operating practices used by the Quality department for Receipt & Shipping of ION detectors by Grinnell Fire Protection Systems Company, Westlake.

**2.0 SCOPE**

The purpose of this procedure is to document the methods used by the Quality Assurance Department to verify that the 612I and 912I Ion detectors conform to the requirements of the U. S. Nuclear Regulatory Commission prior to distribution.

**3.0 DEFINITIONS**

RSO – Radiation Safety Officer

**4.0 RESPONSIBILITIES**

It is the responsibility of the inspector to carry out all checks in accordance with this procedure.

It is the responsibility of the Radiation Safety Officer to oversee the receipt and shipment of the Ion Detectors.

**5.0 PROCEDURE**

**5.1 Preliminary activities.**

Verify that the part number and quantity is correct according to the receiver.


Inspect the packaging for damage that would compromise the integrity of the sealed ion chamber. If the packaging is damaged and evidence of detector damage is apparent, contact the RSO immediately. Upon determination that the extent of the damage has compromised the integrity of the sealed source, immediately quarantine the damaged items. Perform a wipe test of the packaging and wrap the items with plastic sheeting. Attach a DO NOT USE tag to the package.

**DO NOT USE**

The quality characteristics of these items are being evaluated. Under no circumstances, may this product be shipped until ALL items of the sample units pass the quality checks. Please see the RSO for the status of this shipment.

If no apparent signs of damage exist, pull a random sample of the detector shipment according to the Lot Tolerance Percent Defective Chart shown below.

Lot size	Sample size	Acceptance No.
1 to 30	All	0
31 to 50	30	0
51 to 100	37	0
101 to 200	40	0
201 to 300	43	0
301 to 400	44	0
401 to 2,000	45	0
2,001 to 100,000	75	0

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Perform an inspection of the random sample based upon the Quality Characteristics listed below. After samples have been pulled, quarantine the balance of the shipment and attach a DO NOT USE tag to the items.

## 5.2 Quality Characteristics

### 5.2.1 Design Conformance:

- Verify that the sample lot conforms to the current design requirements submitted to the U.S. Nuclear Regulatory Commission by reviewing the current set of prints and bill of material.
- Verify that the point of use label conforms to the current design requirements.

NOTE! 100% of the sample must pass the design conformance section of the inspection process. If any failures exist, contact the RSO immediately to arrange the return of goods to the supplier.

### 5.2.2 Safety Features

- Review Amersham and Tyco Electronic Products group wipe test results that accompany the shipment. Forward to the RSO.
- Perform a wipe test on the sample detectors according to the method described below. The leak test threshold is specified in Nuclear Regulatory Commission guidelines as .005 microcuries of removable contamination.


#### Wipe Test Activities for the Inspector

1. Open 5 ion smoke detectors and place on inspection bench.
2. Remove one wet alcohol swab from the packet.
3. Wipe all accessible surfaces of the exterior of the 5 detectors.
4. Place the wet alcohol swab in the plastic sleeve of the Wipe test form.
5. Remove one dry alcohol swab from the packet.
6. Wipe the same exterior surfaces of the 5 detectors.
7. Place the dry alcohol swab in the plastic sleeve of the Wipe test form.
8. Label the wipe test form 1 through 5 as well as each detector box. Re-pack the five detectors and place in a separate box from the lot received.
9. Continue in quantities of 5 units until the correct sample size has been completed. Label each form and individual detector boxes accordingly.
10. Place all wiped detectors in the quarantined area.
11. Attach the "Awaiting Wipe Test Results DO NOT USE" tag to the box.
12. Deliver the wipe test forms to the RSO.

#### Wipe Test Activities for the RSO

1. Mail the wipe test forms to the consultant.
2. Upon receipt of the results, make the following determination based upon the following options.

#### Options

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- A. Analysis of ALL samples indicate less than .005 microcuries of removable contamination. Release stock to inventory and notify shipping that all detectors have been approved for shipment for customer orders.
- B. Analysis of all samples indicate more than .005 microcuries of removable contamination exists. Return entire lot to the supplier and notify them that the entire lot must be wipe tested.

**5. Shipping**

- When completing sales order for ION detectors the stock clerk will
  - Pull inventory from boxes marked "ACCEPTABLE PRODUCT"
  - Complete the shipping log book.
  - Apply an exterior package label to the outside of the carton


**6.0 RECORDS**

6.1 The quality records generated include

Responsible	Location	Record	Retention Period	Disposition
Inspector	QA office	Shipping Log Book	5 years	Destroy
Inspector	QA office	Inspection reports	5 years	Destroy
TEPG	QA office	Amersham wipe test results	5 years	Destroy
QA manager	QA office	Grinnell wipe test results	5 years	Destroy
QA manager	QA office	TEPG wipe test results	5 years	Destroy

**7.0 RECORD OF CHANGE**

ISSUE DATE	DESCRIPTION OF CHANGE	APPROVED BY
06-01-98	New procedure	Radiation Safety Officer QA Manager Director of Operations
10/16/98	Updated for license requirements Sample size	Radiation Safety Officer QA Manager Director of Operations
11/04/98	changed acceptance criteria for 2001-100,000 from 1 to 0	Radiation Safety Officer QA Manager Director of Operations

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August 3, 1998

ASSIGNMENT NUMBER: 98-81

Mr. Reed Timko  
Grinnell Fire Protection Systems  
835 Sharon Drive  
Westlake, OH 44145

SUBJECT: ACKNOWLEDGMENT OF REQUEST FOR SAFETY EVALUATION

Dear Mr. Timko:

This letter acknowledges the receipt of your July 20, 1998, application that requested an safety evaluation of the Model Lo-Pro Series 612I and 912I. We have performed a cursory review of your application and determined that enough information has been provided to allow a technical reviewer to initiate the evaluation process. Applications are assigned to technical reviewers on a first-in basis. Therefore, your application will be assigned in turn. Please note that the technical reviewer may contact you to request information that was omitted from your application or to obtain clarification of technical issues concerning your application. If you have any questions concerning the status of your application, please contact me at (301) 415-7273. Please reference the assignment number listed above in your questions or correspondence.

Please be aware that your request may be subject to the NRC's application fees in accordance with 10 CFR Part 170. Therefore, a copy of your application has been forwarded to the License Fee and Debt Collection Branch for approval of the fee category and amount. If you have any questions concerning the fees associated with your application, please contact the License Fee and Debt Collection Branch at (301) 415-7554.

Sincerely,

Steven L. Baggett, Deputy Branch Chief  
Materials Safety Branch  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

NUCLEAR REGULATORY COMMISSION  
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY  
(FAX 301-415-5369)

DATE: 10/16/98

FROM: Seung Lee

PHONE NUMBER: 301-415-5787

TO: Mr. Reed Timko

TO: \_\_\_\_\_

FAX NUMBER: 1-408-871-1870

FAX NUMBER: \_\_\_\_\_

TO: \_\_\_\_\_

TO: \_\_\_\_\_

FAX NUMBER: \_\_\_\_\_

FAX NUMBER: \_\_\_\_\_

**MESSAGE:**

please respond to the attached questions.  
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1. In your application, Section 2 is not included. Please provide that section.
2. The drawings you have submitted in your application have confidential notice. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.790. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. For each document or page, please submit two copies. One copy should be an unmarked copy containing all information. The second copy should have removed from it, all information that you wish to be held proprietary. This second copy will be placed in the NRC's public document room. While it is allowable, please refrain from submitting proprietary information in support of a registration unless necessary. Keep in mind that all registration certificates in the Sealed Source and Device Registry, and all NRC licenses are considered to be in the public domain, and are therefore may be viewed by any member of the public who requests to see them.
3. Please clarify the following:
  - a. Manufacturer name and address  
Thorn Security Limited vs. Tyco Electronic Products Group  
Technology Centre 160 Billet Road  
The Summit Walthamstow London  
Hanworth Road E17 5DR  
Sunbury-on-Thames United Kingdom  
Middlesex  
TW16 5DB
  - b. Maximum activity  
1  $\mu$ Ci vs. 0.9  $\mu$ Ci
  - c. Will only AMM 1001H sealed source be used?
4. The quality assurance/quality control (QA/QC) procedures submitted do not satisfy the requirements in Appendix C to Regulatory Guide (RG) 6.9 (enclosed). Please review your QA/QC procedures and address all issues of non-conformance. Note that your procedures may be more restrictive, however, your procedures should meet the RG 6.9 standards at a minimum unless you provide an alternative. Particular items identified during our review include:
  - a. Your QA/QC procedures do not provide sufficient detail regarding the information that will be verified during incoming, assembly, and final inspections and audits, to demonstrate that the product distributed has been checked to ensure that it is manufactured and assembled in accordance with the drawings and specifications submitted in your application, that all safety features are intact, that there is no removable contamination, and that the radiation levels are within the maximum levels specified in your application. Please submit additional information that addresses these concerns.
  - b. The leak test requirement prior to initial distribution of the product is not specified in your application. The leak test threshold specified in the RG 6.9 is 0.005 microcurie. In addition, the RG 6.9 specifies that, although up to 75 units may be

tested with a single wipe test, the threshold remains at 0.005 microcurie. Please submit your procedures that are in accordance with the minimum requirements specified in the RG 6.9.

- c. Please submit corrected procedures which are in accordance with the minimum sampling rates in the RG 6.9.
  - d. Regarding disposition of failed lots, please note that, per the RG, the acceptance number for failure of lots is zero. For lots that fail inspection, they must be either (1) 100% rejected, or (2) 100% retested for the inspection criteria that the sample unit failed. It is not clear that your procedures are in accordance with this. Please submit additional information demonstrating that disposition of failed lots will meet this as a minimum.
5. Please provide clear labeling in drawing no. 515455 in Attachment E5.

# TRANSMISSION REPORT

01.01.2040 00:00

301 415 5369

DATE TIME	DURATION	REMOTE ID	MODE	PAGES	RESULT
01.01 00:00	01'03"	4408711870	ECM	3	O.K.