INSPECTION RECORD

Region: III **Inspection Report No.** 2017001 **License Nos.** 21-23805-01; 21-23805-02E
Docket Nos. 030-32705; 030-32698

Licensee: Air Products and Controls, Inc. d/b/a Apollo America
25 Corporate Drive
Auburn Hills, MI 48326

Locations Inspected: Same as above

Licensee Contact: John Schertel, RSO **Telephone No**. 248-332-3900

Program Code: 03214 / 03251 **Priority**: 5

Type of Inspection: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

Last Inspection Date: 04/05/2012 **Date of This Inspection**: 03/02/2017

Next Inspection Date: 03/02/2022 (X) Normal ( ) Reduced

Summary of Findings and Actions:

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: Ryan Craffey, Health Physicist

/RA/ Date 6/30/2017
Signature

Approved: Aaron T. McCraw, Chief, MIB

/RA/ Date 7/7/2017
Signature

PART I – LCENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

LICENSE NO. 21-23805-01

AMENDMENT #	DATE	SUBJECT
06	06/14/17	New RSO and AU (corrective action from this inspection)
05	03/06/13	License Renewal

LICENSE NO. 21-23805-02E

AMENDMENT #	DATE	SUBJECT
09	05/09/13	License Renewal
08	04/09/13	New contact and distribution address
07	10/01/12	Authorization to distribute under 10 CFR 32.14 instead of 10 CFR 32.26

2. INSPECTION AND ENFORCEMENT HISTORY:

Each report documents the inspection of both licenses.

REPORT #	DATE	TYPE	RESULTS
12-001	04/05/12	Routine	No violations
07-001	05/15/07	Routine	No violations
02-001	04/18/02	Routine	No violations

3. INCIDENT/EVENT HISTORY:

No incidents or events since the last routine inspection.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Air Products and Controls, Inc., doing business as Apollo America, Inc., assembled and distributed smoke and heat detectors for use in commercial and industrial ventilation systems. Some of these detectors utilized ionization detector heads, each of which contained 0.9 microcuries of Americium-241. The licensee did not manufacture the detector heads itself, but rather received them pre-made from a manufacturer in the United Kingdom. The licensee incorporated these heads into the final detector assemblies, and packaged them for initial distribution to exempt persons.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: All

The inspector toured the facility in Auburn Hills, Michigan, to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector interviewed staff and management, who demonstrated and/or discussed the implementation of licensee procedures for material receipt (including contamination surveys of incoming detectors), product assembly and labeling, semiannual physical inventories, radiation awareness training, and emergency response.

The inspector reviewed documentation of recent physical inventories, survey meter calibrations, worker instructions for product assembly and labeling, the content of the licensee's radiation awareness training, and data related to the distribution of licensed material.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter with a Model 44-9 pancake probe calibrated on September 20, 2016, the inspector conducted independent surveys in the vicinity of the ionization chamber smoke detector storage area, and in areas where the detectors were incorporated into final products. The inspector found no readings that would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Oversight of the Radiation Safety Program

During an initial review of the radiation safety program, the inspector identified violations of Conditions 11 and 12 of NRC Materials License No. 21-23805-01 (Amendment 05), which identifies the licensee's RSO and sole AU, respectively, as William E. Ryan.

Contrary to these requirements, the inspector found that Mr. Ryan had retired in April 2015 and no longer fulfilled these duties. In his place, the licensee delegated the responsibilities of RSO and AU to two of the licensee's compliance managers (one full-time and one part-time). The managers jointly maintained responsibility for the security of radioactive material, provided radiation safety awareness training to staff, performed leak tests for incoming and outgoing shipments of ionization detector heads, completed semi-annual inventories of radioactive material, and compiled annual exempt distribution reports. The inspector found that the compliance managers had satisfactorily maintained the above aspects of the radiation safety program. Although the licensee did not document these delegations in writing, each individual clearly understood the duties and responsibilities that had been delegated to them upon retirement of the listed RSO and AU.

In addition to the competencies demonstrated throughout the inspection, the full-time compliance manager also had a bachelor's degree in occupational safety and health, and 15 years of experience and numerous training courses in material hazards (including radiation) and emergency preparedness. The part-time compliance manager had 30 years of experience with regulatory affairs and had completed similar training courses.

The inspector determined that the root cause of these violations was an oversight by the licensee in appointing a new RSO and AU. As corrective action, on March 22, 2017, after preparing and collecting the necessary documentation, the licensee submitted a request to name the full-time compliance manager as the new RSO and AU. On June 14, 2017, the Region III Materials Licensing Branch approved the request and amended the possession license, after determining that the full-time compliance manager already possessed the requisite qualifications to serve as RSO and as AU.

B. Labeling of Ionization Chamber Smoke Detectors

During a tour of the facility, the inspector identified a violation of 10 CFR 32.15(d)(2)(i)(B), which requires that each ionization chamber smoke detector has a label containing the quantity of activity.

The inspector found that two models of detector head, designated as "55000-225" and "55000-550GAM", were labeled to contain "0.9 Ci Am-241". The inspector performed surveys on the detectors, and determined from the readings indistinguishable from background that these detector heads in fact did not contain such a large quantity of radioactive material. The inspector discussed the discrepancy with the licensee, who confirmed that all of their detectors, including these particular models, only contained 0.9 µCi of Am-241. The inspector evaluated the labeling of the other models in the licensee's storage area, and found no other examples of this discrepancy.

As corrective action, the licensee quarantined the detectors with erroneous labels, and subsequently returned them to the manufacturer for relabeling. The licensee also committed to performing inspections on incoming ionization detector heads specifically to ensure that they were properly labeled with the correct activity.

The licensee also performed extent of condition and root cause analyses for the mislabeled ionization detector heads. The extent of condition analysis identified no additional examples of labeling discrepancies. The root cause analysis determined that the discrepancy arose during a short window of time in 2014 when the manufacturer of these detector heads switched to new labeling equipment which initially utilized a typeface lacking the "µ" character needed to properly abbreviate microcuries. The manufacturer soon replaced or updated the typeface with one that did contain the "µ" character, however it does not appear that it recognized the discrepancy on the labels in question before doing so.

The inspector determined therefore that the root cause of this violation was an oversight by the licensee's manufacturer.

C. Reporting Americium Exports

During a discussion of the distribution of ionization chamber smoke detectors, the inspector identified a violation of 10 CFR 110.54(b), which requires the submission of reports of americium exports to the NRC's Office of International Programs (OIP).

The inspector learned through this discussion that the licensee routinely exported some of its products, including ionization chamber smoke detectors. Since March 2013, the licensee had exported ionization chamber smoke detectors to Canada, the United Kingdom, Brazil, Mexico, Saudi Arabia, Pakistan, and Panama. The licensee did not maintain authorization to export under a specific license; therefore, these exports were done under the general license established by 10 CFR 110.23(a). However, the licensee had not filed a report with OIP of these americium exports in any previous calendar year. The current (and presumably, the previous) staff were not aware that such reports were required.

Note that although Pakistan is listed in 10 CFR 110.29 as a *restricted destination*, the licensee did not exceed the limitations in 10 CFR 110.23(a)(5) for americium-241 exports under the general license to this destination.

The inspector determined that the root cause of the violation was a lack of understanding of reporting requirements.

As corrective action, on March 22, 2017, the licensee submitted a report of americium exports that were made in 2016 to the NRC's OIP, and committed to submit them in the future whenever such exports were made in a calendar year.

5. PERSONNEL CONTACTED:

Wayne Clason – Product Supervisor
Louise Laing – Vice President of Operations
Colleen Neil – Operations Staff
John Schertel – Compliance Manager, RSO, and AU

Attended exit meeting on June 27, 2017

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