



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

August 13, 2018

EA-18-043

Ishmael Sparkman, Jr.
Director of Plastic Operations – Keyser
Automated Packaging Systems, Inc.
58 Industrial Lane
Keyser, WV 26726

SUBJECT: AUTOMATED PACKAGING SYSTEMS, INC., NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY - \$8,500 - NRC INSPECTION REPORT NO. 99990001/2018001

Dear Mr. Sparkman:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC's) enforcement decision for the apparent violations identified during an NRC inspection of activities conducted by Automated Packaging Systems, Inc. (APS) at your Keyser, West Virginia facility. The inspection was conducted to review the circumstances associated with a lost generally-licensed device (a fixed gauge containing a sealed americium-241 source) as reported by APS to the NRC on March 28, 2018 (Event Notification #53296). During the inspection, the NRC identified five apparent violations, two of which were considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The NRC discussed the apparent violations during a telephonic exit meeting with you and Chris Knox, the APS Corporate EH&S Manager, on June 6, 2018. The apparent violations were also described in the NRC inspection report sent to you with a letter dated July 16, 2018 (ML18204A260)¹.

In the NRC letter transmitting the inspection report, we provided you an opportunity to address the apparent violations before we made our final enforcement decision by attending a pre-decisional enforcement conference (PEC), providing a written response, or requesting alternative dispute resolution (ADR). In the letter, we also informed you that we had sufficient information regarding the apparent violations and APS's corrective actions to make an enforcement decision without the need for a PEC. Based on your telephone call on July 17, 2018, with Arthur Burritt, Chief, NRC Region I Commercial, Industrial, R&D, and Academic Branch, and your subsequent electronic mail message to Mr. Burritt on July 20, I understand that APS does not require a PEC or ADR and does not intend to send a written response. Therefore, based on the information developed during the inspection, the NRC determined that the violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them were described in detail in the subject inspection report.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

The two violations considered for escalated enforcement related to the loss of the generally-licensed device. Specifically, in November 2016, the gauge, an NDC Technologies, Model 103 fixed gauge containing a 150 millicurie americium-241 sealed source, was removed from service and, at some point the following year, was likely inadvertently disposed as scrap metal. This is contrary to Title 10 of the Code of Federal Regulations (CFR) Part 31.5(c), which requires, in part, that generally licensed devices are transferred or disposed of only to other general licensees or to entities authorized to receive such material. Additionally, although the gauge was discarded in 2017, APS did not identify that it was missing until March 2018. However, on May 1, 2017, APS submitted to the NRC an annual registration for its generally licensed devices. The registration form includes language attesting that licensees have completed a physical inventory of their devices. However, the APS staff signing the form did not recognize the inventory requirement, and it was not performed. Therefore, submittal of the registration form constituted the provision of incomplete and inaccurate information to the NRC, contrary to 10 CFR 30.9.

Each of these violations has been categorized at SL III in accordance with the NRC's Enforcement Policy. In particular, the NRC considered that the gauge was likely sent to a scrap metal yard, limiting the likelihood of widespread public exposure to the source. However, the improper disposal of the device created a possibility that members of the public (including scrap yard workers) could receive some radiation exposure. There is also a potential that the gauge was processed and the resulting product contains residual contamination from the source. Additionally, the NRC determined that the violation related to the inaccurate registration form is appropriately assessed at SL III after considering that, had the inventory been performed, APS would have identified earlier that the gauge was missing and may have been better able to locate it.

For SL III violations involving the loss of regulated material, the NRC typically exercises discretion to propose imposition of a civil penalty of at least the base amount, in accordance with Section 2.3.4 of the Enforcement Policy. Therefore, to emphasize the importance of maintaining security and control of sealed sources and devices, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$8,500 as listed in Section 8, Table A, Item f.2 of the Enforcement Policy.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Arthur Burritt, Chief, Commercial, Industrial, R&D, and Academic Branch, Division of Nuclear Materials Safety, NRC Region I, at 610-337-5069 within 10 days of the date of this letter. You may also contact both ICR and Mr. Burritt for additional information. Your submitted signed agreement to mediate

using the NRC ADR program would stay the 30-day time period for payment of the civil penalties and the written response, as identified in the enclosed notice, until the ADR process is completed.

For the SL III violation related to the provision of incomplete and inaccurate information to the NRC, because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. After considering the corrective actions planned and implemented by APS, including enhancing site procedures to include staff training and inventory requirements and hiring a contractor to maintain the gauges, the NRC concluded that Corrective Action credit is warranted. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty for this violation.

The three additional violations have been categorized in accordance with the NRC Enforcement Policy at SL IV. The violations involved failures by APS to: (1) perform required leak and/or operational tests of its generally licensed devices; (2) maintain records of prior testing of the devices; and, (3) lock the shutter and perform quarterly inventories of a standby device. The circumstances surrounding these violations are documented in detail in the Notice as well as in the aforementioned inspection report. These violations are being cited because they were identified by the NRC. In consideration that these additional violations shared a common root cause of loss of program knowledge related to management of generally-licensed devices, the NRC has categorized them collectively as a single SL IV problem.

The NRC has concluded that information regarding: (1) the reasons for the violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the dates when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 99990001/2018001. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading_rm/adams.html. To the extent possible, your response should not include any personal privacy, or proprietary information so that it can be made available to the Public without redaction.

Issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection oversight. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA John B. Giessner for:/

David C. Lew
Regional Administrator

Docket No.: 99990001
License No.: GL-657303-19

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254, "Payment Methods"

cc w/enclosures: Chris Knox, Corporate EH&S
State of West Virginia

SUBJECT: AUTOMATED PACKAGING SYSTEMS, INC., NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY - \$8,500 - NRC INSPECTION REPORT NO. 99990001/201800 DATED AUGUST 13, 2018

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DATE	7/23/18	7/24/18	7/25/18	7/25/18		NLO via email 8/6/18
OFFICE	RI/DNMS					RA
NAME	J Trapp/JMT*					D Lew/JGiessner for
DATE	8/6/18					8/7/18

* See previous concurrence page

OFFICIAL RECORD COPY

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Automated Packing Systems, Inc.
Keyser, West Virginia

Docket No. 99990001
License No. GL-657303-19
EA-18-043

During an NRC inspection completed on June 6, 2018, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. ESCALATED VIOLATION SUBJECT TO A CIVIL PENALTY

10 CFR 31.5(a) states, in part, that a general license is issued to commercial and industrial firms to acquire, receive, possess, use or transfer, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

10 CFR 31.5(c)(8)(i) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

Contrary to the above, as of November 2016, a general licensee did not transfer or dispose of a device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section. Specifically, Automated Packaging Systems, Inc. possessed a 150 mCi Am-241 source contained in a device (a fixed gauge distributed under a general license), and can no longer account for the gauge.

This is a Severity Level III violation. (Enforcement Policy Section 6.7)
Civil Penalty - \$8,500 (EA-18-043)

II. ESCALATED VIOLATION NOT SUBJECT TO CIVIL PENALTY

10 CFR 31.2 states, in part, that general licenses provided in this part are subject to the general provisions of Part 30 of this chapter (Secs. 30.1 through 30.10).

10 CFR 30.9(a) states, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

10 CFR 31.5(c)(13) states, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section shall register devices containing at least 1 millicuries of americium-241 annually with the Commission, and shall furnish information about each device including certification by the responsible representative of the general licensee that the information has been verified through a physical inventory and checking of label information.

Contrary to the above, on May 1, 2017, a general licensee provided information to the Commission that was not complete and accurate in all material respects. Specifically, Automated Packaging Systems, Inc., a general licensee that possessed or used three devices containing at least 1 millicurie of americium-241, submitted a registration form with information about each device including certification by the responsible representative of the general licensee that the information had been verified through a physical inventory and checking of label information. However, the information had not been verified through a physical inventory and checking of label information because one of the listed devices had been missing since approximately November 2016.

This is a Severity Level III violation. (Enforcement Policy Section 6.9)

III. NON-ESCALATED VIOLATIONS

A. 10 CFR 31.5(c)(2) states, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label.

Contrary to the above, as of April 5, 2018, a general licensee did not assure that its devices were tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator at no longer than six-month intervals or at such other intervals as are specified in the label. Specifically, Automated Packaging Systems, Inc. used two NDC Technologies Model-103 gauges, each containing 150 mCi of americium-241, and did not assure that the devices were tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator at the interval specified in the label (3 years); possessed one additional NDC Technologies Model-103 gauge in storage and did not assure that the device was tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator at the interval specified in the label (10 years); and used one NDC Technologies Mode-302 gauge, containing up to 200 mCi of krypton-85, and did not assure proper operation of the on-off mechanism and indicator at no longer than six-month intervals.

- B. 10 CFR 31.5(c)(4) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section shall maintain records showing compliance with the requirements of 31.5(c)(2). The licensee shall retain each record of a test for leakage or radioactive material for three years after the next required leak test is performed or until the sealed source is transferred or disposed of and each record of a test of the on-off mechanism and indicator for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

Contrary to the above, as of April 5, 2018, a general licensee possessed byproduct material in four devices pursuant to the general license in paragraph (a) of this section and did not maintain records showing compliance with the requirements of 31.5(c)(2). Specifically, Automated Packaging Systems, Inc. possessed three NDC Technologies Model-103 gauges, each containing 150 mCi of americium-241, and one NDC Technologies Model-302 gauge, containing up to 200 mCi of krypton-85, and did not retain any records of past tests for leakage of radioactive material or of tests of the on-off mechanisms and indicators.

- C. 10 CFR 31.5(c)(15) states, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

Contrary to the above, as of April 5, 2018, a general licensee possessed byproduct material in a device pursuant to the general license in paragraph (a) of this section that was not in use for longer than 2 years. The licensee did not lock the shutter on the device in the closed position and, although the device had been kept in standby for future use, the licensee did not perform quarterly physical inventory of the device. Specifically, Automated Packaging Systems, Inc. had placed a generally-licensed device (an NDC Technologies Model-103 thickness gauge, containing 150 millicuries of americium-241), into standby for more than two years and was storing it without locking the shutter closed or performing quarterly inventories.

This is a Severity Level IV problem (Enforcement Policy Sections 6.7 and 6.3)

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the dates when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 99990001/2018001. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as "Reply to a Notice of Violation; EA-18-043," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738,

with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region 1, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 16409, and to the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254, "Payment Methods," and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to Payment of Civil Penalty, and Answer to a Notice of Violation, should be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance Boulevard, King of Prussia, PA, 19406, and the Document Control Center, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of

information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you are required to post this Notice within two working days of receipt.

Dated this 13th day of August 2018