

June 21, 2004

EA-04-074
NMED No. 040050

David Watson
Vice President, Corporate Engineering
Pepperidge Farm, Inc.
595 Westport Avenue
Norwalk, CT 06851-4482

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$7,500
(NRC Inspection Report No. 99990001/2004003)

Dear Mr. Watson:

This refers to the NRC inspection conducted on March 3, 2004, at your facility located in Norwalk, Connecticut, to review the circumstances associated with the loss of a moisture sensor device containing 36 millicuries of cesium-137 (Cs-137). The inspection was initiated after a representative from the State of Connecticut informed the NRC that a device with a radioactive source was missing from your facility. The NRC subsequently verified, through conversations with a representative from your company, that the device was missing and that your employees believed it had been sent to a salvage yard. As described in the NRC inspection report sent to you on April 22, 2004, four apparent violations of NRC requirements were identified during the NRC inspection. In the letter accompanying the report, you were notified that, although no enforcement action was being taken at that time, two of the four apparent violations were being considered for escalated enforcement action.

In our April 22, 2004 letter forwarding the inspection report, you were also provided the opportunity to request a predecisional enforcement conference or to respond to the apparent violations in written correspondence to the NRC. On May 3, 2004, Mr. Tom Rieth, of your staff, communicated via telephone with Ms. Donna Janda, of the NRC Region I staff, indicating that you declined the opportunity to attend a predecisional enforcement conference, but would respond in writing regarding the apparent violations. In your response dated May 10, 2004, you provided additional corrective actions that have been implemented to prevent recurrence of the violations.

Based on the information developed during the inspection, and the information provided in your response, the NRC has confirmed that four violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The most significant violation involved the failure to maintain control of the device containing the Cs-137 radioactive source. This violation occurred when the device was taken out of service along with other equipment when production ceased at the facility. From

your review, you concluded that the device was most likely inadvertently sent to a salvage yard in Norwalk, Connecticut for recycling. At the salvage yard, the device would have been shredded, bailed, and sent with other scrap metal to a metal processing company. Although searches were performed to locate the device, the device and its source were never found.

This violation is of concern to the NRC because the failure to control the device resulted in the likely entry of radioactive material into the metal recycling process. The loss of the device had the potential to provide substantial unintended radiation dose to an individual if the source had been removed from the shielded position. However, given that the device was most likely sent directly to a salvage yard and then shredded at the salvage yard, the potential for a substantial radiation dose to individuals is considerably lower than if the device was lost intact. Nevertheless, the NRC considers the failure to control licensed radioactive material to be a serious matter. Therefore, this violation is being categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a Severity Level III violation involving the loss of control of radioactive material with this level of radioactivity. Because your facility has not been the subject of an escalated enforcement action 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 VI.C.2 of the Enforcement Policy. Credit for corrective action is warranted because your corrective actions were considered prompt and comprehensive. These actions included (1) conducting an inventory and searches for the remaining equipment that incorporate licensed radioactive sources at the Norwalk facility and at other facilities operated by your company; (2) conducting a search of the salvage yard; (3) alerting two metal processing companies regarding shipments of potentially contaminated metal from the salvage yard; and (4) revising your facility closing procedure to include requirements for examination for existing NRC licenses and proper disposal of licensed devices. Therefore, application of the normal civil penalty assessment process would not result in a civil penalty in this case.

However, the revised Enforcement Policy published December 18, 2000 (effective February 16, 2001), provides that, notwithstanding the normal civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed in this type of case to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material (see section VII.A.1(g) of the Enforcement Policy). Therefore, 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 \$7,500 for this Severity Level III violation. In addition, issuance of this Notice constitutes escalated enforcement action, that may subject you to increased inspection effort.

The NRC has also determined that three Severity Level IV violations of NRC requirements occurred. The violations involved (1) the failure to appoint an individual responsible for having knowledge of the appropriate regulations and requirements and having the authority to take required actions to comply with appropriate regulations and actions; (2) the failure to appropriately dispose of a device (the moisture sensor device) that had not been in use for longer than two years; and (3) the loss of an x-ray fluorescence analyzer containing less than 1.0 millicurie of iron-55 (Fe-55). The violations are fully described in the subject inspection report and are also cited in the attached Notice.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you may reference any previous correspondence that is applicable to this case to avoid repetitive submissions. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC 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> (the Public Electronic Reading Room).

Sincerely,

/RA/ James T. Wiggins **Acting For/**

Hubert J. Miller
Regional Administrator

Docket No. 99990001
General License

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/encl:
State of Connecticut

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Enforcement Coordinators

RII, RIII, RIV

S. Gagner, OPA

H. Bell, OIG

P. Lohaus, OSTP

G. Caputo, OI

L. Tremper, OC

R. Tadesse, OEDO

E. Wilson, OI-RI

G. Pangburn, RI

F. Costello, RI

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NAME	JNick JN		DHolody RJU for		KFarrar KLF		GPangburn GCP		HMiller JTW for	
DATE	5/19/04		6/07/04		6/04/04		6/02/04		6/10/04	
OFFICE	HQ/OE									
NAME	FCongel *									
	6/16/04									

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* Concurrence for HQ/OE via telecon from S. Merchant to J. Nick on 6/16/04.

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Pepperidge Farm, Inc.
Norwalk, Connecticut
EA-04-074

Docket No. 99990001
General License
NMED No. 040050

During an NRC inspection conducted on March 3, 2004, four violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes a civil penalty for one of the violations 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 violations and associated civil penalty are set forth below:

I. VIOLATION ASSESSED A CIVIL PENALTY

10 CFR 31.5(c)(8)(i) requires, in part, that the general licensee shall transfer or dispose of the device containing byproduct material only by transfer to another general licensee, or to a person authorized to receive the device by a specific license.

Contrary to the above, on an indeterminate date in September 2003, the licensee transferred a Kay-Ray/Sensall Model No. 7107 moisture sensor device (Serial No. 7107-12), a generally-licensed device containing approximately 36 millicuries of cesium-137 (Cs-137) to another person not authorized to receive the device. Specifically, the licensee put the device into the normal metal recycling process for disposal. As a result, the device was subsequently sent to a salvage yard and then to a metal recycling center, which are both not authorized to receive the device.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$7,500

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

A. 10 CFR 31.5(c)(12) requires that persons possessing byproduct material under a general license shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and with the authority for taking required actions to comply with appropriate regulations and requirements.

Contrary to the above, from approximately June 2003 until March 2004, the general licensee did not have an individual responsible for having knowledge of the appropriate regulations and requirements and with the authority for taking required actions to comply with appropriate regulations and requirements pertaining to generally-licensed devices. Specifically, the project engineer responsible for the generally-licensed devices was transferred to another facility in approximately June 2003 and a replacement was not designated.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 31.5(c)(15) states, in part, that persons possessing byproduct material in a generally-licensed device may not hold devices that are not in use for longer than 2 years.

Contrary to the above, the general licensee held a device that was not in use for longer than 2 years. Specifically, the general licensee held a Kay-Ray/Sensall Model No. 7107 moisture sensor device (Serial No. 7107-12), a generally-licensed device containing approximately 36 millicuries of cesium-137 (Cs-137), that had not been in use since 1992, a period longer than 2 years.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 31.5(c)(8)(i) requires, in part, that the general licensee shall transfer or dispose of the device containing byproduct material only by transfer to another general licensee, or to a person authorized to receive the device by a specific license.

Contrary to the above, on an indeterminate date between July 2003 and September 2003, the licensee transferred an Oxford Instruments Model LABX-7 1001 x-ray fluorescence analyzer, a generally-licensed device containing less than 1.0 millicurie of iron-55 (Fe-55) to another person not authorized to receive the device. Specifically, the licensee could not find the device after a search of the facility and the licensee does not know the whereabouts of the device.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Pepperidge Farm, Inc. (the Licensee) is required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation, EA-04-074" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 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. Should the Licensee fail to answer within 30 days of the date of this Notice, an order imposing the civil penalty will be issued. 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, EA-04-074" and may: (1) deny the violations 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 factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply 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 a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, 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 response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: F. Congel, 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.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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 withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 21st day of June 2004.