**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 19, 2017

EA-17-063

Ms. Sherrilyn Johnson
Plant Manager
Hill's Pet Nutrition
2325 Union Pike
Richmond, IN 47374

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 99990003/2017001(DNMS) – HILL'S PET NUTRITION

Dear Ms. Johnson:

On March 22, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Richmond, Indiana, with continued in-office review through April 18, 2017. The purpose of the inspection was to review an incident that was reported to the NRC on December 2, 2016, involving the removal of a general licensed fixed gauge from installation at your facility. The in-office review included a review of the circumstances of the findings observed during the on-site inspection. Mr. Edward Harvey of my staff conducted a final exit meeting by telephone with Ms. Jackie Vanderpool of your staff on April 19, 2017, to discuss the inspection findings. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the licensee's failure to remove from installation a generally licensed fixed gauge in accordance with instructions provided by labels on the device or have an authorized person remove the gauge from installation, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 31.5(c)(3).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with Ms. Vanderpool at the inspection exit meeting on April 19, 2017.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Aaron McCraw at 630-829-9650 or aaron.mccraw@nrc.gov within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 99990003/2017001(DNMS); EA-17-063," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, it will be open for public observation, and the NRC will issue a press release to announce the time and date of the conference.

Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Please be advised that the number and characterization of the apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and

Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Edward Harvey if you have any questions regarding this inspection. Mr. Harvey can be reached at 630-829-9819.

Sincerely,

***/RA Christine Lipa Acting for/***

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 999-90003
License No. 10 CFR 31.5

Enclosure:
IR 99990003/2017001(DNMS)

cc w/encl: Ms. Vanderpool, EOHS Manager
State of Indiana

Letter to Ms. Sherrilyn Johnson from John Giessner, dated May 19, 2017

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 99990003/2017001(DNMS) – HILL'S PET NUTRITION

DISTRIBUTION w/encl:
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John Giessner
Christine Lipa
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| NAME | EHarvey:cl | | AMcCraw | | RSkokowski | | JGiessner CLipa for | |
| DATE | 5/16/2017 | | 5/16/2017 | | 5/18/2017 | | 5/19/2017 | |

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**Region III**

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| Docket No. | 999-90003 |
| License No. | 10 CFR 31.5 |
| Report No. | 99990003/2017001(DNMS) |
| EA No. | EA-17-063 |
| Licensee: | Hill's Pet Nutrition |
| Facility: | 2325 Union Pike<br>Richmond, IN 47374 |
| Inspection Date: | March 22, 2017 |
| Exit Meeting Date: | April 19, 2016 |
| Inspector: | Edward Harvey, Health Physicist |
| Approved By: | Aaron T. McCraw, Chief<br>Materials Inspection Branch<br>Division of Nuclear Materials Safety |

Enclosure

## EXECUTIVE SUMMARY

### Hill's Pet Nutrition
### NRC Inspection Report 99990003/2017001(DNMS)

On March 22, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced reactive inspection to review the facts and circumstances associated with the gauge removal incident that occurred at Hill's Pet Nutrition on November 28, 2016. The incident was of concern to the NRC because the gauge was removed from installation by two individuals employed by a contractor who did not possess a specific license to perform the removal. As a result, the appropriate procedures were not followed and the gauge was removed from installation with the shutter mechanism in the open position.

Following the incident, the licensee contracted a health physics consultant to provide an assessment of the dose received by the contractors. During the inspection, the inspector validated the assumptions used by the consultant for the dose assessment and determined that there were no personnel exposures of regulatory concern as a result of this incident.

The inspector identified one apparent violation for failure to remove a generally licensed fixed gauge from installation in accordance with instructions on the gauge label or have a specific licensed individual remove the gauge from installation, as required by 10 CFR 31.5(c)(3).

## REPORT DETAILS

### 1 Program Overview and Inspection History

Hill's Pet Nutrition (licensee) is authorized by a general license under Title 10 of the *Code of Federal Regulations* (CFR) Section 31.5 to use fixed gauges for continuous density level measurements. Licensed material is authorized to be used at the licensee's pet food manufacturing plant in Richmond, Indiana. The licensee possessed a total of four fixed gauging devices. At the time of the inspection, all of the devices were out of service and secured in storage. Three of the fixed gauges were still in the initial packaging and had not yet been initially installed by the manufacturer. The devices were managed by the licensee's Environmental Occupational Health & Safety (EOHS) Manager.

The licensee had no previous inspection history prior to this inspection.

### 2 Sequence of Events

#### 2.1 Inspection Scope

The inspector reviewed the licensee's investigation of the incident. In addition, the inspector interviewed selected licensee staff and its contractors, reviewed selected records, and observed related equipment and facilities.

#### 2.2 Observations and Findings

The licensee submitted a letter to the NRC, dated December 2, 2016 that explained that, on November 28, 2016, the licensee had used an unauthorized contractor to remove a general licensed fixed gauge from installation. The fixed gauge was manufactured by Berthold Technologies and contained 50 millicuries (mCi) of cesium-137 (Cs-137). The letter included a chronology of events, beginning with the removal of the gauge by a sheet metal contractor at approximately 11:41 AM. The contractors placed the gauge on the floor immediately after removal without following the instructions provided by the label, and then left the area for lunch at approximately 12:10 PM. The contractors returned from lunch at 1:00 PM and found that three electrical contractors were removing the detection system for the device. At 2:10 PM, the Maintenance Planner found the gauge lying face down on the floor and notified the EOHS Manager that it needed to be locked out. The EOHS Manager closed and locked the shutter at approximately 3:30 PM.

The NRC performed a reactive inspection at the licensee's facility on March 22, 2017. The inspector discussed with the licensee the sequence of events, its root cause analysis, and its corrective actions to prevent recurrence of a similar event. In addition, the inspector toured the facility to verify the location of the gauge both during the incident and in storage after the incident.

Title 10 of the *Code of Federal Regulations* (CFR) Section 31.5(c)(3) requires, in part, that licensees assure that the removal from installation involving radioactive materials, its shielding, or containment, are performed in accordance with the instructions provided by the labels or by a person holding a specific license to perform such activities. The inspector identified the licensee's use of an unauthorized contractor to remove from

installation the generally licensed fixed gauge as an apparent violation of 10 CFR 31.5(c)(3).

The root cause of this incident and apparent violation was failure to implement controls to prevent unauthorized access to the gauge while in service. As immediate corrective actions, the licensee has adequately secured the device in storage until a decision is made as to whether or not they will reinstall the device to service. Should the licensee decide to reinstall the gauge into service, along with the other gauges in storage, they have committed to (1) contracting the vendor, or another specific licensed entity, to install the fixed gauges; (2) providing training to internal staff, contractors, and new hires regarding the gauge location, safety, and procedures; (3) providing refresher training to contractors on an annual basis; (4) installing additional signage regarding radiation safety requirements at the sites of all fixed gauges; (5) installing physical controls such that the fixed gauges cannot be removed without a key secured by the EOHS Manager; (6) developing a means to ensure that a verification of legibility of all signage is to be performed with the required periodic shutter tests; and (6) updating their standard operating procedure (SOP) to reflect all of the aforementioned commitments.

If the licensee decides that they will not be reinstalling the gauge, they have committed to contracting with the vendor, or another specific licensed entity, to properly dispose of the gauges.

### 2.3 Conclusions

The inspector identified one apparent violation for failure to remove a generally licensed fixed gauge from installation in accordance with instructions provided by the gauge's label or have an authorized person remove the gauge from installation, as required by 10 CFR 31.5(c)(3).

## 3 Dose Assessment

### 3.1 Inspection Scope

The inspector reviewed the dose assessment provided by a health physics consultant who was contracted by the licensee. In addition, the inspector interviewed selected licensee staff and its contractors, reviewed selected records, and observed related equipment and facilities.

### 3.2 Observations and Findings

Following the incident, the licensee contracted a health physics consultant to provide an assessment of the dose received by the contractors. The consultant interviewed the contractors to determine the amount of time spent at various distances from the gauge. Based on this information, in addition to the dose rates provided in the Sealed Source Device Registry for this gauge, the health physics consultant estimated that the two sheet metal contractors received a total extremity dose of 206.5 millirem (mrem) and a total whole body dose of 4.5 mrem. The consultant stated that all other staff were far enough away from the gauge that their exposures were less than low background or 2 milliroentgens per hour.

The inspector met with the two individuals employed by the sheet metal contractor who removed the gauge and observed them demonstrate a mock removal and placement of the device in relation to the location where they performed additional work activities. This demonstration validated the assumptions used by the consultant for the dose assessment and the inspector determined that there were no personnel exposures of regulatory concern as a result of this incident.

3.3 Conclusions

The inspector determined that no individuals received exposures of regulatory concern as a result of this incident. No violations were identified during the assessment of personnel exposures.

## 4 Exit Meeting Summary

The NRC inspector presented the inspection findings during a preliminary exit meeting on March 22, 2017. The licensee acknowledged the findings presented. A final, telephonic exit meeting was conducted on April 19, 2017, between the NRC and the EOHS Manager.

ATTACHMENT: SUPPLEMENTAL INFORMATION

## SUPPLEMENTAL INFORMATION

## PARTIAL LIST OF PERSONS CONTACTED

# Larry Brooker, Engineering Manager
# Sherrilyn Johnson, Plant Manager
#* Jackie Vanderpool, EOHS Manager

# Attended preliminary exit meeting on March 22, 2017
* Attended final, telephonic exit meeting on April 19, 2017

## LIST OF PROCEDURES USED

87103: Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87124: Fixed and Portable Gauge Programs