



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive B MSC 7982  
Bethesda, Maryland 20892-7982  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

August 7, 2018

Re: Animal Welfare Assurance  
#A3738-01 (OLAW Case S)

Dr. Michael Caulfield  
President, Research Models & Services  
Envigo  
8520 Allison Pointe Blvd., (b) (4)  
Indianapolis, Indiana 46250

Dear Dr. Caulfield,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 1, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Envigo RMS, Inc., following up on an initial report on June 19, 2018. According to the information provided, OLAW understands that 94 adult mice, 51 litters, and 3 adult rats died due to high animal room temperature caused by a malfunctioning air handling unit. The high temperature alarm notified the production manager who went to the facility, noticed a problem with the air handler, and notified a service contractor. The cause of the problem was a buildup of pollen and debris on the coils and cooling fins.

The corrective action consisted of cleaning the unit. Although the rodents had been monitored during the repair, some deaths occurred overnight. A preventive maintenance plan was implemented to include regular cleaning of the heating, ventilation, and air conditioning coil and cooling fins and to increase frequency of cleaning during times of excessive pollen.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



August 1, 2018

Brent C. Morse, DVM, DACLAM  
Acting Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institute of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Email: [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)

Dear Dr. Morse:

Re: Assurance# A3738-01 – Envigo RMS, Inc. (Envigo RMS)

As a follow up to the June 19, 2018 correspondence regarding the heating ventilation and cooling (HVAC) failure at our Haslett, Michigan facility, we are submitting this final report on the incident.

On June 17, 2018, the production manager of the high-security barrier in Haslett, Michigan received a high-temperature alarm through the (b) (4) monitoring system. Once on site, the manager noticed that one of the four air handling units, AHU#3, was intermittently starting and stopping. A service contractor was notified and arrived within four hours of the phone call and repaired HVAC unit AHU#3.

The high temperature inside one of the animal rooms resulted in the mortality of 94 adult mice, 51 mouse litters, and three adult rats. None of these affected animals were under PHS-funded contracts or grants.

A cross-functional team involving employees from Quality Assurance, Engineering/Facilities, and Production Management conducted a Root Cause Analysis of the incident. The HVAC technician diagnosed the problem as a thermal overload on the air conditioning compressors due to the buildup of debris on the coils and cooling fins. Once the coils and cooling fins were cleaned, the unit operated normally. It was noted that the units had been cleaned earlier in the year, but this was an excessive year for pollen and other airborne debris. During and after the time of the repair, a group leader and animal technician were called into the barrier to perform animal checks and monitor the temperature in the affected room. At that time, they did not discover any animals they believed to be in distress from the heat. The next morning, all animal cages were checked, and it was discovered that several animal deaths occurred overnight.

Although the coils and cooling fins had been cleaned in early spring, there was no documented preventative maintenance plan in place. The corrective and preventative action plan includes the following:

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Envigo RMS, Inc.

[envigo.com](http://envigo.com)



- Adding an HVAC coil and cooling fin cleaning schedule to the preventative maintenance program for the facility with emphasis on more frequent cleaning in the early spring and early summer
- Adding increased frequency of monitoring and cleaning to the preventative maintenance schedule during years of excessive pollen and airborne debris

Sincerely,

(b) (6)

Michael Caulfield  
President and Institutional Official, Envigo RMS, Inc.

cc: Krishnan Kolappaswamy, DMV, PhD, Director and Attending Veterinarian, RMS  
Joseph F. Curlee, Jr., DVM, Chair, Envigo RMS IACUC

**Envigo**

8520 Allison Pointe Blvd, Suite 400, Indianapolis, IN 46250, United States

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## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, August 01, 2018 9:34 AM  
**To:** IACUC Office; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Mike Caulfield; Krishnan Kolappaswamy; Buddy Curlee  
**Subject:** RE: Final Report - Assurance A3738-01 - Envigo RMS, Inc.

Thank you for providing this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** IACUC Office [mailto:IACUC.Office@envigo.com]  
**Sent:** Wednesday, August 01, 2018 8:50 AM  
**To:** OLAW-DOA Annual Reports (NIH/OD) <olawarp@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Mike Caulfield <mike.caulfield@envigo.com>; Krishnan Kolappaswamy <krishnan.kolappaswamy@envigo.com>; Buddy Curlee <buddy.curlee@envigo.com>  
**Subject:** Final Report - Assurance A3738-01 - Envigo RMS, Inc.



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To Whom It May Concern:

Please see the attached final report regarding Assurance A3738-01 from Mike Caulfield, President and Institutional Official, Envigo RMS, Inc.

Thank you,

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A3738-5  
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ENVIGO

June 19, 2018

Brent C. Morse, DVM, DACLAM  
Acting Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
E-mail: [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)

Dear Dr. Morse:

Re: Assurance# A3738-01 – Envigo RMS, Inc. (Envigo RMS)

In accordance with Assurance A3738-01 and PHS Policy IV.F.3, Envigo RMS provides this preliminary report of noncompliance regarding an incident that resulted in animal deaths.

On 17JUN2018, the production manager of the high security barrier in Haslett, Michigan received a high-temperature alarm through the Siemens monitoring system. Once on site, it was noticed that one of the four air handling units (AHU#3) was intermittently starting and stopping. A service contractor was notified and arrived within four hours of the phone call and repaired the HVAC unit (AHU#3).

The high temperature inside one of the animal rooms resulted in the mortality of 94 adult mice, 51 litters, and three adult rats. None of these affected animals were under PHS-funded contracts or grants. Envigo's Quality Assurance Department will conduct an in-depth root cause analysis and will generate a corrective and preventative action (CAPA) plan. Within 30 business days, a final report will be sent to OLAW summarizing the root cause(s) and the CAPA plan.

Sincerely,

(b) (6)

Michael Caulfield  
President and Institutional Official, Envigo RMS, Inc.

cc: Krishnan Kolappaswamy, DVM, PhD, Director and Attending Veterinarian, RMS  
Joseph F. Curlee, Jr., DVM, Chair, Envigo RMS IACUC

**Envigo**

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**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, June 21, 2018 6:17 AM  
**To:** IACUC Office  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary Report - Assurance A3738-01 - Envigo RMS, Inc.

Thank you for this preliminary report. We will open a new case file.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

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**From:** IACUC Office [mailto:IACUC.Office@envigo.com]  
**Sent:** Wednesday, June 20, 2018 4:04 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Mike Caulfield <mike.caulfield@envigo.com>; Krishnan Kolappaswamy <krishnan.kolappaswamy@envigo.com>; Buddy Curlee <buddy.curlee@envigo.com>  
**Subject:** Preliminary Report - Assurance A3738-01 - Envigo RMS, Inc.



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Dear Dr. Morse,

Please see the attached preliminary report regarding Assurance A3738-01 from Mike Caulfield, President and Institutional Official, Envigo RMS, Inc.

Thank you,

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