

3 March 2022

Allison Giddins
Quality Assurance Manager
Envigo RMS UK Ltd
Station Road
Blackthorn Bicester
Oxon OX25 1TP
United Kingdom

Dear Ms. Giddins:

The AAALAC International Council on Accreditation has reviewed the report of the recent site visit to Envigo RMS Hillcrest, Leicestershire, United Kingdom. The Council commends you and the staff for providing and maintaining a high quality programme of laboratory animal care and use. Especially noteworthy were the open communication, evidenced in part by a transparent and collaborative attitude during the site visit; the engaged, professional, and knowledgeable staff including Barrier Managers, Named Animal Care and Welfare Officers, and Animal Technicians; the strong and professional commitment of the Named Veterinary Surgeon, demonstrated by the involvement in all the animal care and use programme areas; the effective canine preventive dental care programme; and the state-of-the-art enriched hamster cages. The Council is pleased to inform you that the programme conforms with AAALAC International standards as set forth by the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123); United Kingdom implementing legislation; and the *Guide for the Care and Use of Laboratory Animals*, NRC 2011. Therefore, **FULL ACCREDITATION** is awarded.

Council acknowledges receipt of the correspondence dated 18 November 2021 detailing actions taken relative to concerns expressed by the site visitors during the exit briefing. Specifically, the items addressed satisfactorily included: improving documentation practices of controlled drugs; reassessing the social housing of female rabbits; reviewing and upgrading the flooring in rabbit cages where necessary; increasing the provision of bedding to hamsters and dogs; posting A(SP)A Schedule 1 in required areas; planning to conduct a risk assessment for personnel working in the rabbit barrier area; and considering repairs to the rabbit barrier area floor.

Enclosed are further recommendations for improvement of the animal care and use programme. The Council on Accreditation notes that there is no obligation for institutions to make programme changes based on suggestions for improvement. Implementation of suggestions is, however, one means of promoting a high quality animal care and use programme.

AAALAC International requires an Annual Report detailing changes made during the year in accredited units. Submission of this report is a requirement for continued accreditation. If your institution chooses to implement programme modifications in response to the suggestions described in the enclosure, the Annual Report provides an opportunity to summarize the actions taken. In the interim, AAALAC International expects to be apprised in a timely manner of significant programmatic changes or concerns should they occur. Please note that, at your request, AAALAC International will provide your institution with a separate letter simply verifying that your animal care and use programme is accredited.

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Should you have any questions regarding your participation in the AAALAC International accreditation programme, please feel free to contact the staff at the Executive Office.

Sincerely,

A handwritten signature in cursive script that reads "Gaylen L. Edwards".

Gaylen L. Edwards, D.V.M., Ph.D.
President, Council on Accreditation

GLE:cma
001885

Enclosure

**Envigo RMS Hillcrest
Leicestershire, United Kingdom
File # 001885**

Suggestions for Improvement:

1. Although there was a very committed Animal Welfare and Ethical Review Body (AWERB), the composition and activities deviated from requirements in the following ways:
 - a. The nonaffiliated member of the AWERB was a scientist and laboratory animal user.
 - b. The AWERB did not perform periodic inspections of the animal facilities.

The *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC 2011 (pp. 24-25) states: “Committee membership includes the following: ...at least one public member to represent general community interests in the proper care and use of animals. Public members should not be laboratory animal users, affiliated in any way with the institution, or members of the immediate family of a person who is affiliated with the institution.” “The committee is responsible for oversight and evaluation of the entire Programme and its components as described in other sections of the *Guide*. Its oversight functions include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use; regular inspection of facilities and animal use areas; regular review of the Programme; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution”. The AWERB composition and activities should be reviewed in order to assure that the oversight of the animal care and use programme is adequate. Council acknowledges the correspondence dated 18 November 2021 indicating that AWERB members will be invited to visit all areas during veterinary audits, when possible. However, Council suggests that the AWERB assess suitability of the current nonaffiliated (public) member according to the recommendations of the *Guide* and schedule regular inspections of facilities and animal use areas by AWERB members.

2. An emergency and Business Continuity Plan (BCP) was in place that addressed natural disasters and mechanical failures. However, the plan did not address threats posed by animal rights extremist activities as well as personnel harassment and assault, facility trespassing, arson, or vandalism. The *Guide* (p. 23) states that “While contingency plans normally address natural disasters, they should also take into account the threats that criminal activities such as personnel harassment and assault, facility trespassing, arson, and vandalism pose to laboratory animals, research personnel, equipment and facilities, and biomedical research at the institution”. The emergency and BCP should include consideration of criminal activity and the response to maintain a functional programme. Council acknowledges the correspondence dated 18 November 2021 indicating that there are injunction notices on the outer gates at each location in the UK that state the individual processes and how they should be carried out if such threats/criminal activity or animal protests occur. Council recommends consideration of similar information for inclusion in the emergency and BCP.
3. Although there was annual maintenance of the cage washer located in Building 27 and the cleaning process was validated at the time the equipment was acquired, there was no routine programme established to monitor the effectiveness of sanitation. In Building 27, clean and

soiled materials were stored together in the same area. The *Guide* (p. 73) states “Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended”. A regular evaluation of sanitation effectiveness should be considered, and the storage practices of clean materials should be re-evaluated to avoid the risk of cross-contamination. Council acknowledges the correspondence dated 18 November 2021 indicating that the Veterinary Science Team will work with the Envigo Health Monitoring Laboratory to trial swabbing of cages from different production facilities as part of the routine monthly monitoring schedule. However, Council recommends to also review the practice of storing soiled and clean materials in the same area.

4. In the central storage area, there was bedding and dog, rodent and poultry feed stored on pallets together with supplies used in the facility, including detergents and disinfectants. According to the institutional practices, feed could be stored for three to four weeks, depending on the number of animals housed. The temperature and relative humidity of this area was not monitored nor controlled. The ETS 123, Appendix A (p. 9) states that “Storerooms should be designed, used and maintained to safeguard the quality of food and bedding. These rooms should be vermin and insect-proof. Other materials, which may be contaminated or present a hazard to animals or staff, should be stored separately”. In addition, the *Guide* (p. 141) states that “Bedding and food should be stored in a separate area free from vermin and protected from the risk of contamination from toxic or hazardous substances. Areas used for food storage should not be subject to elevated temperatures or relative humidity for prolonged periods”. The storage conditions of feed should be reviewed. Council acknowledges the correspondence dated 18 November 2021 indicating that two Darka readers will be installed to monitor the temperature and relative humidity in the storage area. However, Council recommends a review of storage practices for conformance with recommendations of ETS123 and the *Guide*.