



To [REDACTED]
[REDACTED]
From [REDACTED] Named Information and Compliance Support Officer
Date Wednesday 25th April 2018
Time 11.30
Venue [REDACTED]
Subject Hypoxic Chamber
Pages 2
Our Ref [REDACTED]

Policy-

Compliance Assurance Meetings (CAMs) are a management tool, designed to ensure Governance outside of the Act, to protect individuals, ensure due process and systems are implemented within the division of University Biomedical Services. This process will ensure the University upholds the highest standards of animal welfare and good practice relating to animal care and use.

NOTE: A CAM meeting does not replace the investigation of an incident by the Home Office or other authority. Therefore for example, where the local inspector deems appropriate a Home Office non-compliance investigation may run in parallel or sequentially with a CAM.

Event-

On 30th January five out of seven rats were found dead during morning checks, these rats were in a hypoxic chamber in [REDACTED] in [REDACTED]. The seven rats had been placed into the hypoxic chamber (10% oxygen) on the 29th January following an injection of [REDACTED] at approximately 11am. This was carried out by the Animal Technician for [REDACTED] animals were checked at approximately 2pm that afternoon. The normal afternoon checks revealed 10% oxygen at 15.40pm by [REDACTED] staff.

It has become evident that the purge switch on the back of the carbon dioxide pump for the hypoxic chamber was not switched on so that the carbon dioxide levels steadily rose overnight resulting in the death of 5 animals. The levels of Carbon Dioxide (CO₂) were recorded at 4% (30th January) by verbal recording by [REDACTED] staff. Two animals were recovered and were placed back in normoxic conditions and recovered. A post mortem has been conducted on the five animals that died to confirm cause of death.

[REDACTED] staff involved were remorseful of the event. Observations are recorded daily on detailed sheets, which are completed by [REDACTED] staff, these sheets also record the oxygen, temperature and relative humidity levels of the chamber. In addition, daily detailed records are maintained on silica gel and soda lime changes. Maintenance, running and training for the use of the hypoxic chamber has been carried out by a senior technician for another group whose expertise is considered at all times. The chamber was retrospectively set up to test with some rats in to observe, it was noted that they showed signs of laboured breathing commensurate with CO₂ toxicity which is how the problem was identified.

[REDACTED]



Compliance Assurance Meeting

Following the incident the Home Office Inspector was contacted to report the incident via the Deputy Director who met with [REDACTED] staff regarding records and training to prevent recurrence of the incident:

1. Record carbon dioxide and oxygen levels.
2. Ensure anyone who is involved and handling the hypoxic chamber is trained and others retrained and assessed for competency in a phased way to ensure that adequate supervision is carried out by an experienced and knowledgeable trainer and competence assessed and recorded.
3. Review SOPs for operating and maintaining the hypoxic chamber and include a step-by-step checklists for setting up and maintenance which are retained with the equipment and checked off daily for the maintenance.
4. Ensure training records show continued training and are kept up to date.
5. Have alarm installed on hypoxic chamber to alarm when CO₂ levels are increased. Allowing for someone to attend before it becomes critical.

A Compliance Assurance Meeting has been selected as the most appropriate means of action to ensure governance and compliance and, setting processes in place to impress there is no repetition of this event.

Meeting-

There was some discussion regarding the wording of the event, an inaccuracy has been amended and highlighted.

Further explanation regarding the Hypoxia chamber settings and issues with the switch were relayed, and discussed describing a crude system which is in need of review.

Training records, DOPs and SOPs have been implemented since the incident. Staff have been retrained and all signed off as competent.

The regulatory framework was set out by the ELH in detail with regard to roles of Licensees, Named Persons and their responsibilities under the Act.

The PIL holder said that he had worked with a hypoxia chamber in another facility and knew the principle but the switches were different, he had set the chamber up the day before and all was in order. A procedure was performed on the animals prior to them being placed into the chamber, the procedure log was completed. The movement of the animals into the chamber (a regulated procedure) was not recorded on the Log of Procedures by PILH.

The animals in the chamber should be double checked and that CO₂ is on, check all settings and switches and observe if there are less active animals. It was agreed that this was an operational error, but one which could be prevented. The ELH requested a tick box procedure and sign off to ensure a paperwork trail is implemented.

Action 1

The Home Office Inspector suggested there should be a CO₂ alarm fitted and used in addition to an Oxygen sensor. An alarm system is being implemented which will include animal monitoring, this

[REDACTED]



was encouraged by the ELH who requested information about alarms on other Hypoxia equipment in other UBS facilities.

Action 2

Training logs for the PIL holder should be double checked and re-training implemented where there is evidence of lack of competency. Records should show progression with all PIL procedures and the Named Persons (NACWO, NTCO) should be involved to ensure competency and understanding of their A(SP)A responsibilities.

Action 3

The NACWO has been aware of a change to the site for subcutaneous injections. Sugon is typically injected into the scruff, on this occasion however, it was injected into the back to avoid handling over the injected area when administering further injections.

The nature of the research requires a high level of consistency in how the work is performed. PPL holder will ensure PILH consistency and explain to the PIL holder this is not appropriate for them to act autonomously. The PPLh will have discussions and reach decisions with the NACWO and NVS regarding the implementation of standardised Licensed procedures throughout their group.

Action 4

Actions -

1. A tick box procedure and sign off to ensure a paperwork trail is to be implemented.

PIL Supervisor

2. An alarm system will be fitted to the chamber and used whenever the chamber is used¹. Equipment in other UBS facilities should be investigated².

PPL holder¹ and NCSO²

3. Training logs for the PIL holder and re-training implemented to ensure competency and understanding of A(SP)A responsibilities.

NACWO, NTCO

4. Ensure consistency of research, discuss decisions with the NACWO and NVS and implement standardisation of Licensed procedures.

PPL holder

CC: [REDACTED] Home Office inspector

Glossary of terms

AA	A procedure performed without anaesthesia
AB	A procedure performed under anaesthesia, from which the animal recovers
A(SP)A	Animal (Scientific Procedures) Act 1986 Amended
AWERB	Animal Welfare and Ethical Review Body
CAM	Compliance Assurance Meeting
DOPs	Direct Observation Procedures
ELH	Establishment Licence Holder





HOI	Home Office Inspector
NVS	Named Veterinary Surgeon
NACWO	Named Animal Care and Welfare Officer
NICSO	Named Information and Compliance Officer
NTCO	Named Training and Competency Officer
PIL	Personal Licence (Procedures Individual Licence)
PILh	Personal Licence (Procedures Individual Licence) holder
PPL	Project Licence (Procedures Project Licence)
SC	Standard Conditions (of either PIL or PPL)
SPD	Standard Operating System
UBS	University Biomedical Services

