Quality improvement policy

Contents

1 Introduction

Utrecht University (UU) and the UMC Utrecht find it important to guarantee both the quality in the animal-experiment chain and the welfare of the animals kept in the two establishments. The Animal Welfare Body Utrecht (*Instantie voor Dierenwelzijn Utrecht*, hereafter AWB Utrecht) makes a substantial contribution to this goal, by providing supervision and advice throughout the entire animal-experiment chain. The AWB Utrecht's supervisory and advisory tasks, some of which are laid

down in the Netherlands' Experiments on Animals Act (*Wet op de dierproeven*, Wod) art. 14c, are described in detail on our website.

This quality policy sets out the ways in which the AWB Utrecht fulfils these tasks in a transparent and comprehensible manner.

2 Purpose

This quality policy documents the processes and procedures with which the AWB, along with the animal facilities and all parties involved in the animal-experiment chain, advises and supervises the housing and care of laboratory animals, and the design, execution and evaluation of experiments. Our aim with this policy is to promote quality awareness within the facilities, and encourage a 'culture of care'.

This culture is based on animal welfare, well-designed and well-conducted experiments and application of the 3Rs (replacement, reduction and refinement). The approach described in this policy is intended to minimise the risk of unnecessary negative impacts on the welfare of laboratory animals, and thereby also minimising the chance of violating legislation, regulations and internal policy. Moreover, it aims to promote the highest possible quality for research using animals.

3 Scope

This Quality Policy pertains to the entire laboratory animal chain and all laboratory animal facilities under the responsibility of the licence holders Utrecht University and UMC Utrecht. This policy and its implementation have therefore been made known and available to AWB Utrecht staff and laboratory animal coordinators, representatives of the laboratory animal facilities, those responsible in the chain and all Wod-qualified and registered employees of Utrecht University and the UMC Utrecht, as well as other licensees who conduct animal experiments in one of the establishment licence holders' facilities who have designated the AWB Utrecht as an internal supervisor.

4 General method

The quality policy describes how the AWB:

1. informs employees, disseminates knowledge, advises and facilitates knowledge exchange,
2. records and tests qualifications and competences,
3. audits the entire animal-experiment chain in different ways,
4. saves and analyses the monitoring results, and uses the results of this analysis to initiate quality improvement,
5. along with those involved in the chain, continually encourages a mentality that values quality and the culture of care,

and in which cases and how the AWB Utrecht works with other partners in the chain.

The AWB Utrecht bases its actions in carrying out these tasks on national and international legislation and regulations, national Codes of Practice and internal policy.

At least once every three years, the quality policy is evaluated to verify that it still accurately describes how the quality in the animal-experiment chain and the welfare of the animals is being guaranteed. An annex is added to this quality policy every year, describing more specifically the plans for the coming year (Annex 3), and listing a number of key points that will receive additional attention in the year in question. The AWB Utrecht determines these points on the basis of, among other things, an evaluation of the audits it has conducted, inspections by the Netherlands Food and Consumer Products Authority (NVWA), internal policy documents and/or recommendations and Codes of Practice from the Netherlands National Committee for the Protection of Animals Used for Scientific Purposes (NCad), or guidelines from other sources. Suggestions from employees in the animal-experiment chain are also considered when determining these key points.

The licence holders and managers of the animal facilities are informed of the main results (findings of internal audits and NVWA inspections) and the action taken.

5 Knowledge sharing and implementation

The AWB Utrecht keeps its staff as up to date as possible on the latest developments in legislation and regulations, the 3Rs and quality of animal experiments. To this end, it subscribes to a number of Dutch and international journals and newsletters, and its staff are active members of various national and international networks that are concerned with the quality of animal experiments, animal welfare and the 3Rs. AWB staff members also attend congresses, symposia and continuing-education activities, and encourage others working in the chain to participate in these activities as well. They share knowledge in several ways with employees in the animal-experiment chain. The AWB Utrecht maintains an open-door policy in this regard: it aims to be accessible to its employees in the chain, one that listens, an organisation that supports and advises (if necessary, on an emergency basis) on matters of animal welfare, high-quality research and legislation and regulations.

5.1 Introductory meeting

All new principal investigators, animal technicians and animal caretakers, as well as those working for a qualification or exemption for designing and/or carrying out of animal experiments, are invited by the AWB Utrecht to participate in an introduction meeting. In this meeting, the new employees are given an orientation to the organisation of the animal-experiment chain at the UU and UMC Utrecht. There is also a discussion about the ethics of conducting animal experiments, addressing responsibility for welfare, quality, culture of care and transparency about animal experiments.

5.2 Website and newsletter

The AWB Utrecht maintains a website which people involved in the chain can visit for information about legislation and regulations and internal policy, for advice and support in processes before, during and after animal experiments, as well as the latest developments in the 3Rs within and outside UU/UMC Utrecht. The most important new information, including news about important meetings and refresher courses, is published in the monthly newsletter.

5.3 Knowledge sharing and dialogue

AWB Utrecht staff members instruct researchers, in the Laboratory Animal Science course, and biomedical students of both UU and HU (*Hogeschool Utrecht*), in various parts of the curriculum, about legislation and regulations pertaining to animal experiments, and about housing and welfare of laboratory animals. To promote knowledge exchange and 'Continuous Professional Development' the AWB Utrecht organises courses, workshops and symposia in cooperation with both local and national experts on a variety of subjects involving the 3Rs, quality of animal experiments and ethics. It also organises rotating workshops, together with others working in the chain, intended to familiarise colleagues with each other's research and educational practices and thus to encourage new viewpoints and forms of collaboration.

In addition, the AWB Utrecht provides targeted knowledge exchange and dialogue. Every other year the AWB Utrecht visits the various departments of UU and UMC Utrecht (the 'Tour d'IvDU') for a mutual exchange of information and new insights. It also shares relevant information such as new guidelines with others involved in the animal-experiment chain, on request and voluntarily, and brings together experts to promote and implement knowledge sharing.

6 Qualification and competence

6.1 Recording and testing qualification

Before starting work with UU or UMC Utrecht, researchers, animal technicians and animal caretakers must report to the AWB Utrecht. The AWB Utrecht then checks their diplomas and certificates to see whether they possess the correct qualifications and the required knowledge of the animal species with which they will work (Art. 9 and/or 13f2 Wod). If the person is not properly or wholly qualified, the AWB Utrecht and the person involved design a path to acquiring the proper qualification, or to apply to the NVWA for an exemption. Interns working with laboratory animals under the supervision of a qualified person during their internship must also report to the AWB. The AWB Utrecht will check to what degree the planned procedures with animals are appropriate to the intern's education and experience, and can give their permission with conditions attached.

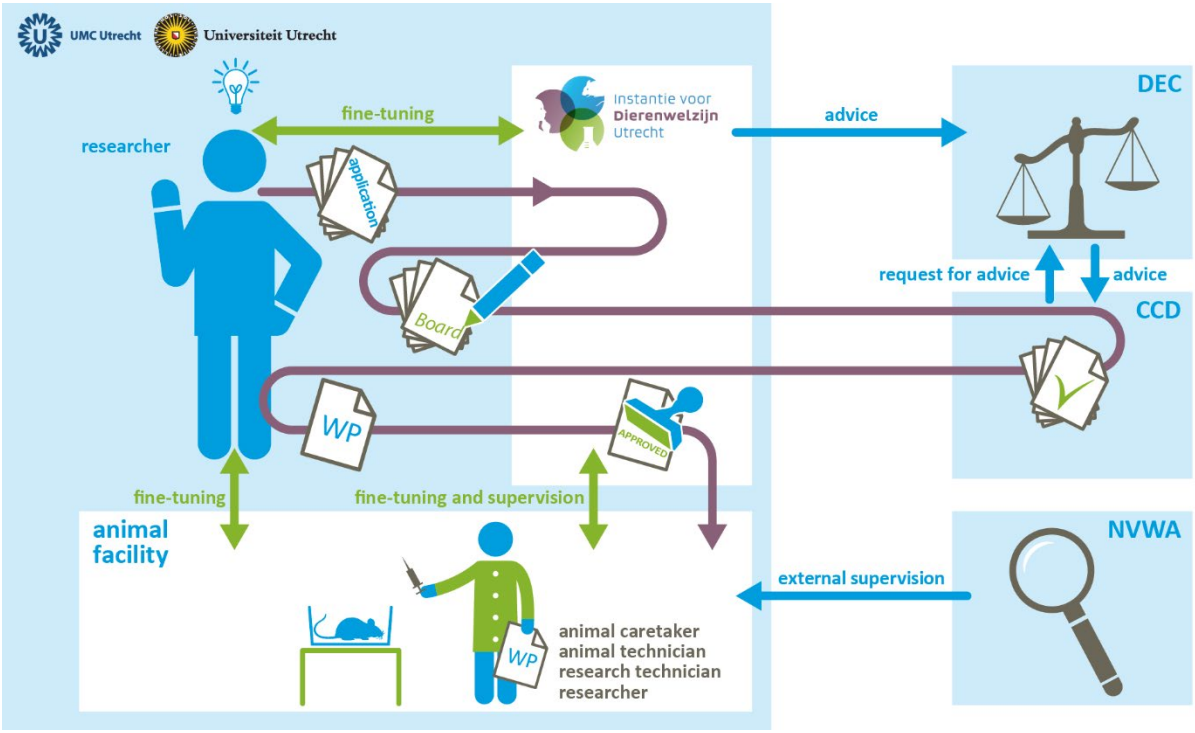
6.2 Recording and testing competence

In accordance with the Wod, qualified researchers, animal technicians and animal caretakers must be demonstrably competent in the procedures they perform with animals. One of the AWB Utrecht's tasks is monitoring the required competence as described in article 13F3C of the Wod. Some of the facilities have recorded the competences of animal technicians and animal caretakers in a centralised system. However, there is no comparable central overview of competences yet, either for all facilities, or for researchers and animal technicians associated with research groups. In these cases, the AWB Utrecht tests competence by asking questions before the start of the experiment starts and during randomly conducted audits of procedures (see sec. 7). People involved with animal studies must also continue to develop their professional skills, and the AWB follows their development. Currently the policy of recording and testing competences in accordance with the National Guide to Continuing Professional Development in animal experimentation has been worked out in conjunction

with a working group of staff members who function as a sounding board. This guide explains in more detail how the AWB shapes this role as a process guide and supervisor.

7 Advising and auditing in the animal-experiment chain

The quality of the animal-experiment chain is tested using various kinds of audits. We refer to the ensemble of audits as the audit programme. The audits can evaluate the chain as a whole, the coordination between its various parts or the separate parts. The attached infographic clearly shows the points in the chain where the AWB Utrecht advises and supervises, with more detailed explanation in the sections that follow.



7.1 Before the experiments

7.1.1 Project licence

Before writing a project proposal, researchers can ask for non-binding advice about its content and design, and the about the legal frameworks currently in force. Before the project may be submitted for evaluation to the Central Authority for Scientific Procedures on Animals (*Centrale Commissie Dierproeven*, CCD) and its advisory body, the Animal Ethics Committee (*Dierexperimentencommissie*, DEC), the AWB Utrecht advises the researcher about form and content, and assesses whether the project proposal contains sufficient information to properly evaluate the animal experiments that it entails. The assessment is carried out by a wide range of experts: two animal welfare officers, an expert in replacing animal experiments, a veterinary pathologist, and a scientist working in the same field. A communications advisor also assesses the Non-Technical Summary. An animal welfare officer is present at the meeting where the DEC puts together its recommendations to the CCD and, if

necessary, can provide additional information and advise the researcher in answering questions from the DEC and/or CCD.

7.1.2 Work Protocol

Once the project licence has been issued, the researcher must describe the planned study in a work protocol which includes a procedures checklist. The AWB Utrecht verifies that the work protocol fits in the framework of the project licence, that the animal experiments are designed to answer the research question with a minimum number of animals, and if the procedures planned for the animals are as refined (i.e. involving the least discomfort) as possible. It also assesses whether the employees involved have the required qualifications, and if so, if they have the required competences, using advice from the designated veterinarian, the biological safety officer and the animal facility. They may also seek advice from a statistician. If necessary, the AWB Utrecht will issue a recommendation (which may be binding) about modifying the work protocol.

If a work protocol turns out not to fit within the framework of the project licence, the AWB Utrecht will advise the researcher about whether it is necessary to apply to change the work protocol or simply to report the change to the CCD. The AWB's recommendations are based on the CCD's Guide to policy rules on reporting (note: in Dutch): Toelichting beleidsregels meldingen.

Researchers must also fill in a work protocol and procedures checklist for animal studies not requiring a project licence, known as below-threshold experiments. The AWB Utrecht will assess these projects to make sure that a project licence is not in fact necessary, and gives advice about designing and conducting the experiment.

7.2 During the experiments

The AWB Utrecht initiates several types of audits in the workplace during the course of the animal experiments. These are both scheduled audits and audits resulting from incident reports or alerts. Audit results are always shared with the auditees and, if applicable, with the animal facility in question, the principal investigator and the laboratory-animal coordinator involved. If the results give cause to do so, agreements are made about follow-up actions and if necessary, a follow-up audit is scheduled. The AWB Utrecht also responds to desired modifications in the study and to reports of 'unexpected discomfort' during ongoing animal studies.

7.2.1 Audits

The purpose of the ***Checklist for Monitoring Animal Experiments*** (Annex 1a; CMD) is to assess at work-protocol level whether laboratory animals are being housed and cared for, and procedures are clearly being administered, in conformance with the work protocol, project licence, legislation and regulations in force and internal guidelines. The principal investigator ensures that the CMD assessment is carried out by a colleague (peer review) within two weeks of the start of the study and then at agreed-upon intervals.

Site visits (Annex 1b) are intended to monitor the animals' welfare and to check whether they are being housed and cared for in conformance with the applicable legislation and regulations and internal guidelines (facilities audit), whether experiments are carried out in conformance with the project licence, the work protocol, applicable legislation and regulations and internal guidelines

(project audit), and whether procedures are being competently carried out (procedures audit). Site visits may be announced or unannounced, and may be conducted by animal welfare officers or the designated veterinarian, if desired or necessary assisted by colleagues from the animal-experiment chain (peer review).

The ***incident audit*** (Annex 1c) is intended as an immediate, structured response to a report or alert related to animal welfare or execution of procedures, reported by an animal caretaker, animal technician, representative of an animal facility, department within an animal facility or supplier, principal investigator and/or study director. If desired, these reports may be dealt with confidentially. An incident audit may also be carried out in response to a report of unexpected discomfort (see 7.2.3). The AWB Utrecht finds a solution for the short and long term, along with the person reporting, the other parties involved and those responsible. If the situation is complex, the response audit may culminate in a ***chain audit*** (Annex 1d), which investigates the underlying causes of the incident.

Subject audits (Annex 1e) are ULS-wide audits for specific subjects, assessing the extent to which internal procedures stemming from legal requirements or internal policy are adequately being followed and are sufficiently effective. They are always announced in advance. The subjects of these audits are determined annually by the AWB. When all the audits of a particular subject have been concluded, the AWB Utrecht makes an overall evaluation of the findings and shares it with all involved, with all names deleted for confidentiality. ULS-wide actions that result from these findings are incorporated by the AWB Utrecht in that year's quality improvement plan.

7.2.2 Modifications to the animal experiments

If a researcher wishes to modify an ongoing study, they must contact the AWB. The AWB Utrecht will assess whether the desired modification fits within the framework of the project licence, whether the objective stated in the work protocol can still be achieved and if the modification will adversely affect the animals' welfare. If necessary, the ABW will recommend either submitting an amendment or notification to the CCD.

7.2.3 Reporting unexpected discomfort

If one or more animals experience unexpected discomfort during the course of the animal experiments, then the researcher must report this to the AWB Utrecht. If necessary, the AWB will steer the decision(s) to be taken with regard to removing the animals from the experiment or terminating the entire study. The AWB Utrecht takes into consideration the animal's discomfort, the expected effects on the experiment results and the appropriate legislation and regulations.

7.3 After the experiments

7.3.1 Welfare evaluations

After every animal study has ended, and at intervals if studies take place in two or more different years, the principal investigator sends a welfare evaluation to the AWB Utrecht. The welfare evaluation contains a summary of the course of the experiment as it relates to the animals' welfare and the quality of the research, as documented in the welfare log. The purpose of the welfare evaluation is to provide information about how the experiment ran, and what (if anything) went

differently than anticipated. The latter situations in particular are used by AWB Utrecht and the researcher as points for improvement in similar situations in future. The welfare evaluation also provides information for the annual register of animal experiments.

7.3.2 Annual meeting and register of experiments

Every year, the AWB Utrecht sends the data on the animal experiments conducted at UU and UMC Utrecht to the NVWA. The departments' laboratory animal coordinators provide the data to the AWB Utrecht in a timely manner. The AWB Utrecht checks the data received and meets with the laboratory animal coordinators to discuss these experiments as well as planned research and educational activities with animals, development of alternatives and other matters of interest to the AWB Utrecht. Action arising from these meetings is incorporated in the annual quality-improvement plan.

7.3.3 Project evaluation

The CCD may ask for an interim or retrospective project evaluation as a condition of the project licence. It will always do so when severe discomfort is involved. The project evaluation is assessed by the DEC and CCD. The AWB Utrecht alerts the principal investigator to this condition at the beginning and again at the end of the project, and requests the researcher to keep the necessary information up to date during the course of the project.

8 Standards of external parties

Since the quality of the animal experiments depends to a great extent on the quality supplied by crucial suppliers such as animal breeders and feed suppliers, the AWB Utrecht is part of a national partnership (ASAP) that jointly audits these crucial suppliers. It also assesses whether the animals' welfare and the quality of the research is guaranteed in collaborations with outside parties in which the animal study (or part of it) is conducted at a different facility. If applicable, it also takes advice from the other facility's AWB into account.

When laboratory animals are offered to a shelter for adoption, the AWB conducts an on-site audit to ensure that the animals are being given to a trustworthy party.

9 The AWB's own functioning

The AWB Utrecht looks critically at its own functioning in the animal-experiment chain, and is transparent and verifiable for those involved in the chain as well as outside parties such as the media and animal-protection organisations. It therefore asks for feedback on its communication, advising and assessing at various points: following an advisory process (with licence applications), after finishing the fine-tuning of a work protocol and with the annual registration of animal experiments. The AWB's functioning is also subject to assessment by the NVWA.

10 Continuous quality improvement

This policy describes the ways in which UU and UMC Utrecht currently have guaranteed quality in the animal-experiment chain. However, UU and UMC Utrecht are aware that the field is constantly developing. Accordingly, they are continually interested in developments that may improve research quality and the 3Rs. Therefore this policy will be evaluated regularly (at least every three years), and if necessary updated. Areas that are currently being worked on are listed in Annex 3. This annex is updated annually.

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Annexes

ANNEX 1

This annex describes the various types of audits in greater detail. It indicates who is responsible for carrying out each type of audit, who carries out the audit (auditor) and who undergoes the audit as an auditee. The purpose, method and criteria are shown as well as the steps to take to arrive at an constructive conclusion.

ANNEX 1A

Checklist for monitoring animal experiments
Responsibility
The principal investigator
Auditor
An animal caretaker, animal technician, research analyst or researcher (including principal investigator)
Auditee
The principal investigator and/or the study director
Purpose
The purpose of the monitoring is to assess whether laboratory animals are being housed and cared for, and procedures are being clearly administered, in conformance with the work protocol, project licence, applicable legislation and regulations and internal guidelines.
Method
The auditee ensures that an auditor performs an audit of one or more work protocols. Although the auditee may carry out the audit, we urgently recommend that it be done by a colleague who is not involved in the experiment. The audit is carried out using the *Checklist for monitoring animal experiments* (CMD).
Criteria
Annex 2
Preparation
The principal investigator informs the auditor of the location of the following documents: A. Project licences (including justified recommendation), work protocols and AWB Utrecht recommendations B. Study dossiers C. Reports from previous inspections and/or audits D. Training dossiers (CPD) regarding qualification and competence
Performing the audit
The auditor performs the audit in conformance with the CMD. The auditor works in consultation with the auditee in such a way that animal welfare, experiments and safety are not threatened.

Follow-up
The principal investigator sees to it that action points resulting from the monitoring of the animal experiments are put into practice. The concrete steps to take to solve the issues requiring action are recorded in the welfare log, modification form and/or an e-mail exchange with the AWB.
Conclusion
The auditor reports the findings and the measures to be taken directly to the auditee using the CMD. The principal investigator keeps the CMD in the study dossier with the animals.
Evaluation
During subsequent audits the auditor evaluates the follow-up to the previous issues requiring action. At least once every three years, the AWB Utrecht audits the degree to which CMDs are filled out, as well as their contents, and the follow-up on completed CMDs.

ANNEX 1B

Site visits
Responsibility
IvDU, designated veterinarian (art. 14 Wod) associated with the establishment
Auditor
Animal welfare officer, designated veterinarian and/or unit head of a department not involved
Auditee
Depending on the purpose: a supervisor/unit head, a representative of an animal facility or part of an animal facility or a supplier, or the principal investigator and/or a study director.
Purpose
The purpose of site visits is: A. to check that the laboratory animals at the facility are being housed and cared for in conformance with applicable legislation and regulations and internal guidelines (Annex 2) B. to monitor the welfare of the animals C. to inspect whether experiments are being conducted in conformance with the project licence, work protocol, applicable legislation and regulations and internal guidelines (Annex 2) and that their recordkeeping is complete and clear.
Method
The auditor comes to a particular laboratory-animal facility, either announced (at a time agreed with the auditee) or unannounced, to conduct an audit. If the audit is scheduled, the auditor determines the scope (limits) of the audit beforehand and informs the auditee. If the audit is unannounced, then the auditor informs the auditee of the scope within a reasonable time.
Criteria
Annex 2

Preparation
The preparation can entail the study of the following documents: A. Project licences (including justified recommendation), work protocols and recommendations from AWB Utrecht B. Study dossiers C. Reports from previous inspections (NVWA) or audits D. Study programme dossiers (CPD) regarding qualification and competence
Performing the audit
The auditee must cooperate fully with the audit. The auditor acts in concert with the auditee so as not to threaten animal welfare, the experiments or safety.
Follow-up
The report mentions an owner and an expected reply date for all issues requiring action and/or conclusions. The concrete steps to take to solve the issues requiring action are recorded in the audit report, welfare log, modification form or an e-mail exchange between the auditor and the responsible researcher.
Report
The auditor reports their findings and the measures to be taken to the auditee within 10 working days in the audit report. If the nature of the findings requires taking immediate action, then the auditor informs the auditee to this effect during or immediately upon concluding the audit.
Cause analysis and measures
The auditee will respond within 10 working days of receipt of the draft report, although the report may contain a different reply date based on the nature of the findings. The auditee will state the causes of the findings, as well as measures to be taken in the short and long term, in the audit report and e-mail the report to the auditor.
Conclusion
After any factual inaccuracies have been corrected, the definitive report is sent to: the auditee(s), the principal investigator of the project (art. 9 Wod), the study director named in the work protocol (art. 9 Wod) and to the relevant laboratory animal coordinator(s). If necessary, the report is also sent to supervisors, the management of the department concerned, the contact person for the laboratory animal facility, the operational manager for laboratory animals, the management of the relevant laboratory animal facility and/or the licence holder.
Evaluation
During subsequent audits the auditor evaluates the follow-up to the previous audit's action points.

ANNEX 1C

Incident audit
Responsibility
IvDU or designated veterinarian (art. 14 Wod) for the facility

Auditor
Animal welfare officer, designated veterinarian and/or quality AWBU assurance officer
Auditee
Depending on the purpose: a representative of an animal facility or part of an animal facility, a supplier, the principal investigator and/or a study director.
Purpose
The purpose of the incident audit is: A. To respond immediately and systematically to a notification of an incident or situation concerning animal welfare or the execution of procedures; the incident/situation may be reported by an animal caretaker, animal technician, a representative of an animal facility or unit within an animal facility or a supplier, a principal investigator and/or a study director B. to find both a short- and long-term solution, together with the person who reported the incident/situation, those involved and those responsible
Method
The auditor arranges with the auditee to perform an audit at a particular laboratory animal location, or has one or more meetings. If there is only one meeting, a site-visit checklist (form) is filled out, or a chain audit form if there are more meetings or a more complex problem.
Criteria
Annex 2
Preparation
Preparation may entail studying the following documents: A. project licences (including justified recommendation), work protocols and recommendations from AWB Utrecht B. study dossiers C. reports from previous inspections (NVWA) or audits D. study programme dossiers (CPD) pertaining to qualification and competence
Performing the audit
The auditee must cooperate fully with the audit. The auditor acts in concert with the auditee so as not to threaten the animal's welfare, the experiments or safety.
Follow-up
The report mentions an owner and an expected reply date for all issues requiring action and/or conclusions. The concrete steps to take to solve the issues requiring action are recorded in the incident report, the welfare log, modification form or an e-mail exchange between the auditor and the principal investigator.
Report
The auditor reports their findings and the measures to be taken to the auditee within 10 working days using the incident report. If the nature of the findings requires taking immediate action, then the auditor informs the auditee to this effect during or immediately upon concluding the audit.

Cause analysis and measures
The auditee will respond within 10 working days of receipt of the draft report, although the report may contain a different reply date based on the nature of the findings. The auditee will state the causes of the findings in the audit report, as well as measures to be taken in the short and long term, and e-mail the report to the auditor.
Conclusion
After any factual inaccuracies have been corrected, the definitive report is sent to: the auditee(s), the principal investigator of the project (art. 9 Wod), the study director named in the work protocol (art. 9 Wod) and to the relevant laboratory animal coordinator(s). If necessary, the report is also sent to supervisors, the management of the relevant department, the contact person for the laboratory animal facility, the operational manager for laboratory animals, the management of the relevant laboratory animal facility and/or the licence holder.
Evaluation
During subsequent audits the auditor evaluates the follow-up to the previous issues requiring action.

ANNEX 1D

Chain audits
Responsibility
AWB Utrecht
Auditor
Animal welfare officer, AWB Utrecht quality assurance officer and/or external auditor
Auditee
Depending on the purpose: a researcher, a representative of a division or department, the AWB Utrecht, the DEC Utrecht or the principal investigator and/or a study director, or another link in the animal-experiment chain.
Purpose
The purpose of the chain audits is to assess whether: A. the evaluation and review process is conducted in accordance with the Wod B. the coordination between the various links in the chain is structured, organised and traceable C. internal procedures resulting from the legal guidelines or internal policy are properly complied with D. an experiment is conducted in accordance with the project licence, the work protocol, relevant legislation and regulations and internal guidelines (Annex 2)
Method
The auditor consults with the auditee to conduct an audit of a specific work protocol, a process or the entire chain. The auditor must clearly communicate the scope (limits) of the chain audit.
Criteria
Annex 2

Preparation
The preparation may include studying the following documents: A. Project licences (including justified recommendation), work protocols and recommendations by AWB Utrecht B. Study dossiers C. Reports from previous inspections (NVWA) or audits D. Training dossiers pertaining to qualification and competence E. Procedure descriptions and internal policy
Performing the audit
The auditee must cooperate fully with the audit. The auditor acts in concert with the auditee so as not to threaten animal welfare, the experiments or safety.
Follow-up
The report mentions an owner and an expected reply date for all issues requiring action and/or conclusions. The concrete steps to take to solve the issues requiring action are recorded in the chain audit report, the welfare log, modification form or an e-mail exchange with the auditor.
Report
The auditor reports his/her findings and the measures to be implemented to the auditee within 10 working days by means of the chain-audit report. If the nature of the findings requires taking immediate action, then the auditor informs the auditee to this effect, during or immediately upon concluding the audit.
Cause analysis and measures
The auditee will respond within 10 working days of receipt of the draft report, although the report may contain a different reply date based on the nature of the findings. The auditee will state the causes of the findings in the audit report, as well as measures to be taken in the short and long term, in the audit report and e-mail the report to the auditor.
Report and Conclusion
After any factual inaccuracies have been corrected, the definitive report is sent to: the auditee(s), the relevant laboratory animal coordinator(s), supervisors, the management of the relevant department, the contact person for the laboratory animal facility, the operational manager for laboratory animals, the management of the laboratory animal facility and/or the licensee.
Evaluation
During subsequent audits, the auditor evaluates whether there has been follow-up to the previous issues requiring action, and if so, evaluates its quality.

ANNEX 1E

Subject audits
Responsibility
AWB Utrecht

Auditors
Two animal welfare officers and/or external auditors
Auditee
Depending on the purpose: a researcher, a representative of a division or department, the AWB Utrecht, the DEC Utrecht or the principal investigator and/or a study director or another link in the animal-experiment chain
Purpose
The purpose of subject audits is to determine the extent to which internal procedures resulting from legal requirements or internal policy for specific subjects are adequately being complied with ULS-wide.
Method
The auditors consult with the auditee to conduct an audit pertaining to a particular subject. The auditor communicates clearly about the scope (limits) of the subject audit.
Criteria
Annex 2
Preparation
In a subject audit, a questionnaire is designed specific to that subject. Additional preparation may include the study of the following documents: A. Reports from previous inspections (NVWA) or audits B. Procedure descriptions and internal policy
Performing the audit
The auditee must cooperate fully with the audit. The auditors act in concert with the auditee so as not to threaten animal welfare, the experiments or safety.
Follow-up
The report mentions an owner and an expected reply date for all issues requiring action and/or conclusions. The concrete steps to take to solve the issues requiring action are recorded in the audit report, welfare log, modification form or an e-mail exchange with the auditors.
Report
The auditors report their findings and the measures to be implemented to the auditee within 10 working days by means of the audit report. If the nature of the findings requires taking immediate action, then the auditors inform the auditee to this effect during or immediately upon concluding the audit.
Cause analysis and measures
The auditee will respond within 10 working days of receipt of the draft report, although the report may contain a different reply date based on the nature of the findings. The auditee will state the causes of the findings, as well as measures to be taken in the short and long term, in the audit report and e-mail the report to the auditor.

Report and Conclusions
After any factual inaccuracies have been corrected, the definitive report is sent to: the auditee(s), the relevant laboratory animal coordinator(s), supervisors, the management of the relevant department, the contact person for the laboratory animal facility, the operational manager for laboratory animals, the management of the laboratory animal facility and/or the licensee.
Evaluation
Once all the audits of a particular subject have been concluded, the AWB performs an overall evaluation of the findings, and shares them (anonymised) with those involved. Overall actions to be taken, resulting from these findings, are initiated under the direction of the AWB Utrecht.

ANNEX 2 – RELEVANT LEGISLATION AND REGULATIONS AND INTERNAL GUIDELINES

- Wet op de dierproeven (Experiments on Animals Act), www.wetten.nl, 1977, effective as of 18 December 2014, Stb.2014, 473.
- Dierproevenbesluit (Experiments on Animals Decree), www.wetten.nl, 1977, effective as of 18 December 2014, Stb.2014, 473.
- Dierproevenregeling (Experiments on Animals Regulations), www.wetten.nl, 1977, effective as of 18 December 2014, Stb.2014, 473.
- AWB Utrecht: Tasks and responsibilities in the animal-experiment chain, 2020

If applicable:

- AWB Utrecht Internal policy documents, https://www.ivd-utrecht.nl/nl/wet-regels-en-richtlijnen/intern-beleid/, 2020
- Code of Practice, Monitoring Laboratory Animal Welfare, 2000
- Code of Practice, Immunising Laboratory Animals, 2000
- Code of Practice, Animal Experiments in Cancer Research, 1999
- *Kwaliteitshandboek Gemeenschappelijk Dierenlaboratorium* (Quality Handbook, Central Laboratory Animal Facility), chapters A through E (Starling)
- Recommendations by Netherlands National Committee for the Protection of Animals Used for Scientific Purposes (NCad), *Indicatoren, beheer en benutting van gegevens voor monitoren van proefdiergebruik en 3V-alternatieven* (indicators, management and use of data for monitoring use of laboratory animals and 3Rs alternatives), parts 1 and 2, 2015
- NCad Recommendations, *Genetisch gemodificeerde dieren in voorraad gedood* (Killing stocks of genetically modified animals), 2015
- NCad Recommendations, *Transitie naar proefdiervrij onderzoek* (Transition to animal-testing-free research), 2016
- NCad Recommendations, *Alternatieve dodingsmethoden bij proefdieren* (Alternative methods for killing laboratory animals), 2016
- NCad Recommendations, *Proeven met honden en katten* (Experiments with dogs and cats), 2016
- NCad Recommendations and Code of Practice, *Herplaatsing van voormalige proefdieren* (Reassigning 'used' laboratory animals), 2016
- NCad Recommendations and Code of Practice, *Voorkómen, herkennen en bestrijden van pijn bij proefdieren* (Preventing, Recognising and Combating Pain in Laboratory Animals), 2016
- NCad Recommendations, *Handreiking Synthesis of Evidence in het proefdieronderzoek* (Guide to Synthesis of Evidence in laboratory-animal research) part I, 2016; part II, 2019
- NCad Recommendations and Code of Practice, *Motiveren door restricteren?* (Motivation by restriction?) 2018
- NCad Recommendations and Code of Practice, *Genetisch gemodificeerde dieren. 'Dood of gedood voor gebruik in fok of dierproef*' (Genetically modified animals. 'Using dead or killed animals in breeding or testing') – part 2 *Kwaliteitscriteria* (quality criteria). 2018

ANNEX 3 – QUALITY IMPROVEMENT PLAN FOR SEPT 2020-SEPT 2021

The annual quality improvement plan indicates where the focus on quality improvement lies for September 2020 to September 2021.

Knowledge sharing and implementation

- Update website AWB Utrecht
- Write overall animal experiment policy
- Promote tunnel handling of mice and training laboratory animals
- Evaluation of environmental enrichment
- Investigate options for social housing of male mice
- Further implementation of course Experimental Design
- Implementation of ARRIVE guidelines

Qualification and competence

- Development and implementation of policy on Continuous Professional Development
- Development of methodology for registering competences
- Incorporate species-specific knowledge in qualification control system
- Set up national training for 13F3A

Advising and auditing in the animal-experiment chain

- Theme audit: individual housing; analysing results
- Theme audit: weekend-shift; analysing results
- Theme audit: anaesthesia, analgesia and postoperative care

Critical suppliers and partners

- Animal Supplier Audit Partners: audit of feed supplier and request results
- Pilot project Beyond Animal Testing Index (BATI)

Processes and forms

- Modifying breeding protocol
- Explore options of Lean Six Sigma
- Optimising internal procedures welfare log
- Revise audit- and CMD-forms
- Inventory of processes and risks of retrospective assessment (CCD)
- Reporting unexpected discomfort: Establish guidelines and care for various department

AWB Utrecht functioning

- Improve project and proces monitoring
- Request internal feedback
- Set up intercollegiate system audit