

FELASA Guidelines for the Accreditation of Health Monitoring Programmes and
Testing Laboratories involved in Health Monitoring

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1. Preamble

Defining the health status of animals used in research is key to the reliable interpretation of results obtained from experiments involving the use of animals, and in obtaining reproducible experimental results. Microbiological standardisation has reduced the numbers of animals used by reducing the variation within and between test groups. It has also improved the overall health of laboratory animals, thus improving their welfare, and has reduced human health risks due to zoonotic disease. The Federation of European Laboratory Animal Science Associations (FELASA) has a long tradition of publishing recommendations on health monitoring of breeding and experimental colonies of rodents and rabbits (Kraft *et al.*, 1994; Rehbinder *et al.*, 1996; Nicklas *et al.*, 2002), and also for other species such as dogs, cats, and pigs (Rehbinder *et al.*, 1998), non-human primates (Weber *et al.*, 1999), and small ruminants (Rehbinder *et al.*, 2000).

They describe the methods to be used, frequency of sampling, sample size and organisms to be monitored. These recommendations are now widely used and breeders or users commonly report on health monitoring of their animal colonies, using the phrase “in accordance with FELASA recommendations”.

It is the intention, through guidelines, to establish working procedures for a FELASA accreditation process of health monitoring programmes and for testing laboratories involved in health monitoring. An accreditation board will assess compliance with these guidelines. FELASA accreditation should be viewed as complementary to other quality systems, for example as described for diagnostic labs by Homberger *et al.* (1999), and for animal units by Howard *et al.* (2004).

The Accreditation Board evaluates programmes after voluntary application for accreditation. Official FELASA accreditation can be given to health monitoring

schemes and/or to laboratories if they conform to the quality standards described in the FELASA recommendations, as assessed by the Accreditation Board.

Only health monitoring programmes (related to defined microbiological units) or diagnostic laboratories that have been accredited by FELASA are entitled to use the term “FELASA-accredited”.

This document defines the operation of FELASA accreditation of health monitoring programmes for laboratory animal units, and of FELASA accreditation of testing laboratories involved in health monitoring.

Whereas many other accreditation schemes emphasise the use of a robust quality system and validated test systems, the FELASA accreditation process emphasises the scientific relevance of procedures implemented, competency of staff, interlaboratory / proficiency testing of laboratories, and appropriate procedures for managing animals submitted for health monitoring.

Ultimately, these guidelines aim at promoting further standardisation of laboratory animals by increasing the significance and reliability of health monitoring reports through FELASA accreditation of health monitoring programmes and testing laboratories.

2. Definitions

A site is a clearly defined area within which are located several facilities with interactions of people and animals. At the site level, common services and procedures may exist that can be used by, or be applicable to, several facilities situated on that site.

A facility describes a physically separated entity consisting of one or more microbiological units.

The term unit is here understood to describe a self-contained microbiological entity. Space and traffic of personnel and goods essentially separate units (Nicklas *et al.*, 2002).

Health monitoring is here understood to describe the complete surveillance of the overall health status of a specific animal unit population, including observation of clinical and experimental abnormalities, as well as data generated by routine laboratory testing. The results are typically summarised in a *health monitoring report* containing current and historical data (see Nicklas *et al.*, 2002).

3. Requirements for accreditation

Institutions applying for accreditation are requested to complete an application form and to supply at least the information which is addressed in this report and the attached appendices (Appendix 1 or 2). All submissions must be in English, but they may be supported by additional documents (e.g., SOPs) written in the national language.

If a facility applying for accreditation takes the decision not to follow the FELASA recommendations for health monitoring (e.g., agents, sample size, frequency), justification for any deviations must be provided.

4. FELASA accreditation board

The accreditation board consists of a Chairperson and 4-6 members. The FELASA Executive Committee selects the suitable candidates and from these the FELASA Governing Board will elect a Chairperson and the accreditation board. Members are selected on the basis of competency and experience. Qualifications for the

accreditation board members should be at least the same as for the persons responsible for devising and maintaining health monitoring policies.

Only 3 members will be involved in an accreditation process. From among these 3 members a Project Manager will be selected. All are selected in a way that avoids conflicts of interest. If necessary, the accreditation board is supported by a corresponding liaison officer from the country of the applicant. The liaison officer has no voting rights and is not necessarily present at board meetings. His/her role is to facilitate communication between the applicant and the accreditation board. The liaison officer will be nominated by the association of the applicant's home country and will be elected by the accreditation board.

The board will reach decisions by a majority vote. The FELASA accreditation board will be appointed for 4 years, and members may be re-nominated. Initially, at least two members will be appointed for 2 years only and thereafter part of the board will be replaced every 2 years. The FELASA governing board has the authority to replace individual members and dissolve the accreditation board, if it so determines.

The FELASA accreditation board has the authority to decide on whether or not to accredit programmes on behalf of FELASA.

The accreditation board will maintain up-to-date records of health monitoring programmes and testing laboratories accredited.

Confidentiality of accreditation board members will be assured (see 6.1).

5. Accreditation process

5.1 Programme issues: process and duration

5.1.1 *Submission of the application for FELASA accreditation*

The applicant, i.e. a named representative of the institution, company, laboratory, etc., shall send all pertinent documents to the FELASA secretariat (secretariat@felasa.eu). All documents should be submitted electronically (e-mail) to ease their distribution among accreditation board members. It is expected that the applicant will provide all information that is requested in Appendices 1 or 2, as appropriate. An application form and other details are available at secretariat@felasa.eu.

5.1.2 Receipt of the application

The FELASA secretariat will acknowledge receipt of each application in writing and will provide the applicant with an estimate of the duration and course of the accreditation process, including the date by which a decision will be announced. The Board will process only complete applications, and it is the applicant's responsibility to ensure that all necessary information and supporting documents are addressed and included.

5.2 Evaluation by the FELASA Accreditation Board

Accreditation involves thorough examination of each application and subsequent discussion within the accreditation board. If deemed necessary, the board may seek clarification or further information from the applicant. Decisions will be by majority vote of voting members of the accreditation board.

The duration of the accreditation process should not exceed 6 months. However, the decision as to whether a programme or a laboratory will be accredited may be postponed until information has been submitted as requested by the accreditation board.

5.3 Communication of the Accreditation Board's decision

As soon as the FELASA accreditation board has reached a decision on whether or not to endorse the application, the FELASA secretariat shall inform the applicant of the

outcome. In case of rejection, the reasons shall be clearly stated in writing.

Unsuccessful applications, including all details relating to them, will be maintained in confidence by the accreditation board.

The FELASA web site (<http://www.felasa.eu>) may show numbers of applications approved or rejected; they may be published, for instance on an annual basis.

5.4 Results of accreditation:

Three results of evaluation are possible:

- approval
- provisional approval (applicant should take specific actions within a certain time). Approval will only be granted if appropriate action is taken.
- non-approval.

In all cases, the accreditation board will communicate with, and feedback to, the applicant giving reasons for decisions made and to provide comments for further improvements.

FELASA will issue documents confirming the accredited status. In addition, FELASA may publish a list of laboratories and facilities/units that are accredited, only with the agreement of the laboratory or the facility management. Non-accredited facilities and programmes will not be listed.

5.5 Appeals

In the event of an adverse decision by the Accreditation Board, the applicant may write an appeal to the accreditation Board for consideration within 30 days of the adverse decision. The Accreditation Board will deliver its final decision within 90 days of the appeal. If the applicant is not satisfied with this decision, he or she may request mediation with the FELASA Board.

6. Review of application and documentation

The review will be based on the criteria set out under the heading 'Requirements for accreditation'. The Board may seek supplementary information and clarification of any relevant items from the Applicant.

6.1 Confidentiality

The FELASA accreditation process will be conducted and maintained in strict confidence. No member of the accreditation board shall disclose details of any application. All persons involved in the application process will be required to sign a confidentiality agreement. The accreditation board will not disclose information relating to its discussions until the final decision has been reached.

Only the chairperson of the accreditation board, the Project Manager and the corresponding liaison officer are authorised to contact the applicant during the review process.

6.2 External expertise

Should the accreditation board feel that any issue arising from an application is outside its area of expertise, the chairperson may authorise consultation of external experts.

6.3 Site visits

The FELASA accreditation board reserves the right to conduct site visits. In the unlikely event of a site visit being deemed necessary, the board will provide at least 10 days advance notice of the visit and will contact the applicant to provide names of the persons selected for the site visit. In order to reassure the applicant of confidentiality, the selection of the site visitors will be by agreement between the board and the applicant.

7. Requirements for maintaining accreditation

Accreditation will be valid for a maximum of 5 years.

It is anticipated that monitoring programmes and laboratories will continue to advance and, where appropriate, techniques will be modified in the light of experience, new scientific knowledge (e.g., new agents, development of advanced methods) and demands from scientists or customers. Testing laboratories are encouraged to introduce and validate new methods to ensure continued progress in the detection of infections, thus contributing to improved quality of laboratory animals.

Persons responsible for a health monitoring programme or a testing laboratory are required to submit an annual report before the anniversary date of the granting of accreditation, declaring adherence to the conditions specified on the application and describing any deviations. For health monitoring programmes, adherence to the requirements must be documented by provision of an annual report, including the latest health monitoring report.

The annual report must summarise significant deviations, such as changes in key personnel (see Appendix 1.1 and 2.1), methodologies, changes in the scope of the accreditation (such as the animal species), health monitoring programme, rooms and microbiological units. Failure to report significant deviations may lead to termination of accreditation.

The template for the annual report can be downloaded from the FELASA web site

(<http://www.felasa.eu>) or obtained from the FELASA secretariat

(secretariat@felasa.eu). The report should be addressed to the FELASA secretariat.

Failure to submit a report by due date and a reminder by FELASA will lead to termination of accreditation.

7.1 Renewal

After a period of 5 years, FELASA accreditation will lapse and the persons responsible for a FELASA accredited health monitoring programme or laboratory will be required to submit a new application, if continued accreditation is required.

7.2. Site visits

Site visits may be carried out as described under 6.3.

8. Fees

The FELASA accreditation programme is a non-profit making venture, but is required to be economically self-supporting. A modest income may be produced to support FELASA activities, or to waive or reduce accreditation fees in less wealthy countries. Applications for accreditation will be processed only after an application fee has been received. The Accreditation Board will propose annually a scale of fees for the accreditation of laboratories and health monitoring programmes to the FELASA board. The fee is non-refundable, irrespective of the outcome of the accreditation application.

The amount of the application fee and for an annual fee for European and non-European applications can be requested from the FELASA secretariat (secretariat@felasa.eu).

Members of the FELASA accreditation board will not receive remuneration, but direct costs incurred as a result of secretarial requirements or travel will be reimbursed.

The accreditation board will prepare an annual budget for approval by the FELASA governing board.

9. References

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Acknowledgements: We thank Ron Boot and Evanthia Petridou for useful comments
and suggestions.

Appendix 1

Information to be provided for the FELASA Accreditation of Health Monitoring Programmes

1. Qualifications of persons responsible for aspects of health monitoring

All persons involved in the health monitoring programme should be trained to the standard appropriate to their function (see below)

- 1.1 Responsible Person for devising and maintaining health monitoring policies including the generation of health monitoring reports

Qualification Required:

- Qualified to FELASA Category D (Nevalainen *et al.*, 1999), or equivalent
- Evidence of relevant continuing education
- Documented job description

- 1.2 Responsible Persons for carrying out Health Monitoring Procedures

In-house health monitoring should include observation of behaviour, recording of clinical signs, observation of reproductive data and detection of changes in experimental data.

Persons carrying out sampling of animals from the microbiological unit require specific training in this field. They must also be sufficiently trained to understand the procedures required for the collection, handling and shipping of samples required for specific tests.

The person responsible must be qualified to at least FELASA Category A (Wilson *et al.*, 1995) or B (Nevalainen *et al.*, 2000), or equivalent, and have the necessary experience to recognise the changes listed above.

2. Description of the site/unit(s)

The applicant must provide a plan of the site, with identification of the animal facilities to which the health monitoring programme is applicable.

2.1 The unit to be monitored

The applicant must provide a floor plan of every microbiological unit for which accreditation is sought.

2.2 Animals

The applicant must provide:

- A list of species and approximate numbers of animals maintained in the unit
- Immune status of the animals (e.g., immunodeficient, immunocompetent)
- The origin of animals and method of introduction
- Frequency with which animals are introduced into the unit
- Housing: cage type(s), housing systems (e.g., non-barrier/barrier housing, specific housing systems used such as IVC, isolator)

2.3 Experimental procedures

Applicants must summarise the types of experiments in place in the unit, including:

- A short description of the types of experiment in use at the unit
- Duration of experiments; a description of special measures, such as ‘all-in all-out’ systems

2.4 Risk assessment

- If biological materials are introduced into the unit, a description of how they are tested
- Experimental requirements may exist that increase the risk of introducing unwanted agents. Examples may include the removal of organs/cells from

animals which may be subsequently re-introduced to the unit following experimental procedures outside the unit; the re-introduction of animals into the unit following sub-lethal irradiation, or imaging procedures, carried out outside the unit.

- How does the health monitoring programme account for these additional risks?

3. The health monitoring programme

The applicant must describe the health monitoring procedures in use in the unit. The following information should be included:

- Are live animals and/or samples (e.g., organs, swabs) submitted to the laboratory?
- Types of samples collected and procedures used for their collection and storage.
- If samples only are submitted to the laboratory, are necropsies carried out on any animals from the unit?
- Methods for shipping animals and samples to the testing laboratory, including a summary of shipping conditions.
- Is testing carried out by an in-house or external laboratory? The laboratory(-ies) must be identified. The applicant is responsible for the laboratory's work if testing data from a well-recognised testing laboratory which is not FELASA accredited are exceptionally included in a FELASA accredited health report.

3.1 Scheduled (routine) health monitoring

The applicant must provide the following information:

- Types of animals submitted for testing [e.g., retired breeders, sham-treated sentinels, in-contact sentinels, dirty bedding-sentinels, etc.]. Any specific measures taken to increase the risk of agent transmission to animals submitted for health testing. A description of the animals used as sentinels
- If animals to be tested are introduced into the unit from outside, additional information should be given (e.g., origin, microbiological quality)
- Species, stock(s)/strain(s), immune status
- Age of animals and duration of exposure of sentinels
- Overview of the agents to be monitored. Frequency of testing [separately for every agent together with the method(s) used]
- Sample size (number of animals) per agent
- Justifications for reporting agents as *Not Tested*, and their non-inclusion in the health monitoring programme
- What measures are taken when unexpected positive results are received from the testing laboratory?

3.2. Clinical observation / abnormalities

The applicant must summarise how clinical observations and abnormalities are reported within the health monitoring programme

In addition to scheduled testing, are clinically sick (or dead) animals submitted for laboratory testing/necropsy? If so, how frequently (i.e., occasionally /always)?

The applicant must provide a copy of the most recent health monitoring report for the unit

Appendix 2

Information to be provided for the FELASA Accreditation of Testing Laboratories involved in Laboratory Animal Health Monitoring

1. Background

To obtain FELASA Accreditation, the laboratory must provide evidence of written procedures defining the disciplines, sampling procedures and testing methodologies, for which it is seeking FELASA Accreditation. In addition, the laboratory must relate these to the animal species for which it is seeking accreditation. A laboratory could seek accreditation for all procedures used to detect at least the agents recommended by FELASA for the particular species, or within specific disciplines (bacteriology, serology, histopathology, parasitology, molecular biology).

The Application Form must be submitted in English.

2. Staff

All persons involved in health testing should be trained to the standard appropriate to their function (see below)

2.1 Responsible Person for Maintaining and Running a Testing Laboratory

All procedures must be performed or supervised by a person carrying an academic degree in biology / natural sciences, veterinary medicine or medicine, or equivalent.

This person needs additional experience in laboratory animal diagnostics in the categories and species the laboratory is accredited for. Experience in laboratory

animal science comparable with at least the level of FELASA category C is also required.

2.2 Person(s) conducting health testing procedures

A person conducting health testing procedures should fulfil the following criteria:

Qualification Required:

- Documented training or education in microbiological techniques, and expertise and demonstrable experience in the field (microbiology, virology, parasitology, pathology, molecular biology) for which accreditation is sought
- Documented job description

3. Subcontracting

Subcontracting to a non-FELASA accredited laboratory is acceptable in specific cases, e.g. because of the need for further expertise. If such sub-contracting is on a regular basis, it is necessary to provide the qualification of the specialists involved. The laboratory is responsible for the subcontractor's work if the subcontractor is not FELASA accredited.

4. Procedures

Applicants must provide a description of methods, procedures and equipment used in health testing.

Specifically, information should be provided on the following points:

- If transportation of samples/animals is organised by the laboratory, how animals and samples are transported to the testing laboratory, including shipping conditions

- Time between arrival of animals/samples and testing. Description of the location / containers in which animals are housed prior to being euthanised, and euthanasia and anaesthesia methods used
- A description of the procedures used for the receipt of samples/animals, sample/animal identification, storage of animals/samples, reporting of results and data tracking.
- Are samples pooled from one or from different animals?
- A description of the testing procedure to include:
 - Recording of behaviour, and clinical observations (prior to euthanasia)
 - Blood sampling
 - Whole body examination: description of necropsy procedures
 - Gross pathology, which organs are inspected
 - Parasitology: samples and procedures
 - Bacteriology: sites, media used routinely, incubation, identification methods (for each agent or group of agents), reference organisms used
 - Serology: agents, methods, antigens, primary and confirmatory methods
 - PCR: samples, agents; controls, reference organisms, technology used
 - Histopathology: animals, samples / organs, methods
- Additional methods and procedures
- Confirmation of unexpected or positive testing results (methods and external laboratories used)

5. Quality control

The applicant must summarise the following:

- Ring tests and/or interlaboratory comparisons: documented results of interlaboratory comparisons, frequency

6. Health Testing Reports

Laboratories that have been accredited under FELASA will be entitled to use the FELASA logo on health testing reports.

The laboratory report must contain a footnote indicating the methodologies for which the laboratory is FELASA accredited.