

Routine for fulfilling the competence requirements in the Regulation on animal research

Document responsible: PMSK NMBU

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Changes since the previous version:

1. PURPOSE AND SCOPE

Section 24 and Annex E of the Norwegian Regulation on Animal Research (hereafter called “the regulation”), and EU Directive 2010/63/EU, set requirements for theoretical and practical training for persons working with research animals.

The purpose of this routine is to ensure that everyone who works with research animals at NMBU have education and practical training in accordance with the legislation.

The routine applies to everyone who plan and/or perform experiments with research animals at NMBU, as well as those who do daily supervision and care of research animals.

2. DEFINITIONS

Work with research animals: Planning and performing of experiments, care and supervision of research animals and/or euthanasia of research animals, as defined in the regulation.

Users: Persons who plan and/or carry out experiments with animals at NMBU. This includes the responsible applicant and co-workers in experiments (including also field assistants that work hands-on with animals), but not the permanent staff at NMBU's approved animal facilities.

EU Guide: European Commission guidance document describing competence requirements and educational programmes for theoretical and practical training of persons working with research animals: "European Commission Education and Training Framework".¹

Animal facility manager: Appointed person at one of NMBU's approved animal facilities who has delegated control responsibility to follow up and control experiments.

Responsible applicant: The responsible applicant for a given FOTS ID with legal responsibility as described in Section 28 of the Regulation.

¹ EU Guide https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

Modules: Compulsory, species- and/or function-specific theoretical and practical modules with defined learning objectives as described in the European Commission guidance document (EU Guide, see footnote 1).

PMSK NMBU: Appointed person at NMBU with special control responsibility, cf. §§ 5 and 25 of the Regulation

Staff animal facility: The employees at NMBU's approved animal facilities who are responsible for the supervision and care of research animals. Includes both permanent and temporary employees and employees on an hourly basis (including students).

3. REQUIREMENTS FOR BASIC THEORETICAL AND PRACTICAL COMPETENCE

a) General requirements

All persons who are to work with research animals must have undergone courses/education adapted to the role and tasks and to the animal species they will work with. This applies to both theoretical and practical competence.

Courses/education/training shall comply with the requirements in Appendix E of the Regulation, as well as the requirements and module descriptions in the EU Guide².

b) Requiredr documentation for users and registration in FOTS

Everyone who plans and/or carries out experiments with animals must be registered in FOTS. This applies to the responsible applicant and all co-workers in an experiment.

Registration in FOTS of new users shall be done by PMSK NMBU.

To be registered in FOTS, the user must have approved courses/education as stated in point (a) above. Documentation of theoretical and practical competence (course certificate, documentation of practical skills, etc.) must be submitted and approved by PMSK before a user account in FOTS is created.

Persons who have taken courses abroad that satisfy the requirements as described in point (a) may be registered in FOTS on condition that module 1 (National regulations cf. EU Guide²) will be implemented as soon as practical possible.

Detailed guidance for users on registration in FOTS, including documentation requirements, can be found in a separate guidance document for FOTS applications ("Guidance for FOTS-applications").

² EU Guide: https://ec.europa.eu/environment/chemicals/lab_animals/pdf/guidance/education_training/en.pdf

Persons who exclusively contribute their specialist expertise within a very specific procedure may exceptionally be allowed to be registered in FOTS and listed as co-worker on an experiment without fulfilling the competence requirements in point (a). Such exemption shall be particularly justified and shall also be described and justified in the relevant FOTS application. The exemption shall be in accordance with the guidelines described in the EU Guide³. Exemptions will not be granted repeatedly for the same person and will be granted solely on the condition that the employee:

- has highly specialised veterinary medical/technical specialist expertise that is absolutely necessary to carry out a very specific procedure in the experiment
- if the person is not a veterinarian, they can only contribute with their specialist expertise under the continuous guidance of an experienced and registered user
- cannot have any responsibility for the planning and design of the experiment
- are not a regular participant in experiments with animals

c) Documentation requirements for staff NMBU

The animal facility manager is responsible for ensuring that documentation of courses/education for the staff at their animal facility is archived and available to PMSK NMBU and at the request of Mattilsynet.

4. REQUIREMENTS FOR MAINTENANCE AND UPDATING OF COMPETENCE

a) General requirements

Everyone who works with research animals must maintain their competence through continuous practice and education as specified in Section 24, 2nd, paragraph, of the Regulation.

Updating may, for example, take place through formal theoretical or practical courses, participation in relevant conferences/meetings, "on the job training" (such as local training/training at an animal facility at NMBU, or secondments at other institutions), or other types of activities that contribute to maintain competence of relevance to work with research animals.

Updates should be done regularly and should be documented.

b) Special requirements for users

The individual user is responsible for maintaining his/her competence and document such continuing education in FOTS. Documentation (course certificates/attests, etc.) must be uploaded and stored in FOTS on the user's profile.

³ Page 11 of the EU Guide

The frequency and need for updating shall be adapted to the tasks and roles of the user and must at least be carried out every 5 years.

PMSK NMBU shall check that users have documented updating of competence. This shall be done by checking the responsible applicant's user profile in FOTS when submitting FOTS applications, and for co-workers on FOTS-applications as random checks in FOTS.

Responsible applicants who have animal research course that are older than 5 years and who have not updated and/or have not worked with laboratory animals in the last 5 years must participate/commit to participate at the first opportunity in NMBU's update course before they can submit an application for experiments in FOTS.

c) Special requirements for staff NMBU

Permanent employees at NMBU's animal facility should complete continuing education/updating at least every second year. Requirements for updating will also apply to temporary employees and employees on an hourly basis if they work with laboratory animals at NMBU for more than 2 years.

The facility manager must ensure that documentation of continuing education for employees is archived so that it is available to PMSK NMBU and to the authorities upon request.

The facility manager shall facilitate and encourage the employees to carry out continuing education/updating.

5. REQUIREMENTS RELATING TO PRACTICAL SKILLS AND SUPERVISION

a) General requirements

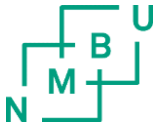
Everyone who works with research animals shall be supervised when performing their tasks until they have demonstrated necessary competence and skills; c.f. §24 of the Regulation.

Practical training and assessment of skills must be documented.

b) Responsibilities and roles

Everyone who works with laboratory animals is responsible for the quality of their own work, that they do not perform tasks for which they have not been trained and/or have assessed as competent, and that the need for training is reported to their immediate supervisor.

PMSK NMBU is responsible for controlling that all users meet the competence requirements as stated in §§ 24 and 25 of the Regulation.



The responsible applicant is responsible for ensuring that all who participate in the planning and performing experiments are specified in the FOTS application, and that they are only given and perform tasks for which they have been considered competent.

Users are responsible for storing documentation of practical skills on their individual's user profile in FOTS.

The facility manager is responsible for archiving the documentation of practical skills for staff NMBU so that it is available to PMSK NMBU and upon request from the authorities.

c) Requirements relating to supervisors and supervision of practical training

Practical training in general supervision and care, as well as in general and/or commonly used procedures, shall as a rule be carried out under the supervision of the staff at the animal facilities at NMBU.

For special techniques, supervision may be carried out in the research group provided that the supervisor is competent and experienced in relevant procedure(s) and fulfils all formal requirements for basic and updated competence as stated in points 3 and 4 of this routine.

Cases of doubt or dispute concerning supervisors and guidance shall be decided by PMSK NMBU.