

Inspection items in JAPIC certification of animal research facilities

1. Facility Characteristics and Scale

- (1) Overview of the animal rearing and housing facility (including floor plans and related documents)
- (2) Types of animal experiments primarily conducted
- (3) Records of animal species housed and used over the past three years (including genetically modified animals)
- (4) Number of personnel conducting animal experiments, number of animal care and management staff (including indication of whether services are outsourced), and number of personnel holding qualifications related to laboratory animals

2. Regulations and Organizational Structure

- (1) The institutional regulations must comply with the [Act on Welfare and Management of Animals](#), the [Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals](#), and the Basic Policy on Animal Experimentation of each relevant ministry ([MHLW](#), [MAFF](#), [MEXT](#)), as well as the [Standards relating to the Methods of Destruction of Animals](#). Consideration shall also be given, to the extent feasible, to the [Manual of Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals](#), and to the [Guidelines for Proper Conduct of Animal Experiments](#).
- (2) The organizational structure including the Institutional Animal Care and Use Committee (IACUC) and its roles and positioning should be appropriately defined. Furthermore, it should outline fundamental matters concerning the conduct of animal experiments and the care and use of experimental animals with consideration for animal welfare, as well as facilities, safety management, and education and training.
- (3) The head of the institution should bear ultimate responsibility for animal experimentation and receive all the necessary reports from relevant personnel.

3. Institutional Animal Care and Use Committee (IACUC)

- (1) The composition of the committee must comply with the ministerial (MHLW, MAFF, MEXT) guidelines, and the number of committee members should be appropriate.
- (2) Operational procedures—including requirements for quorum, participation in deliberations, decision-making, and meeting frequency—should be appropriate.
- (3) Procedures for reviewing animal experiment protocols, confirming final reports (completion reports), and reviewing protocol amendments after approval should be appropriate. Training in experimental techniques and breeding plans should also be included as items subject to committee review.
- (4) Records, including committee comments and the responses provided by principal investigators, should be properly maintained for protocol reviews (including pre-checks performed by the committee secretariat(s)) and confirmation of experiment completion reports.
- (5) The number of reviewed protocols categorized by SCAR pain categories should be compiled.
- (6) Judgments concerning pain categorization and the establishment of humane endpoints should be reviewed appropriately.
- (7) Standard operating procedures (SOPs) and manuals relating to the 3Rs—such as anesthesia and analgesia methods, euthanasia methods, and humane endpoints—should be established and properly implemented.
- (8) Procedures concerning the handling of exempt animals and surplus animals, as well as the management of animal reuse or multiple surgical procedures, should be appropriate.
- (9) Activities for enhancing animal welfare and/or Post Approval Monitoring (PAM), where implemented, should be conducted appropriately.

4. Animal Experiment Protocols and Final Reports (Completion Reports)

- (1) Animal experiment protocols should comprehensively address items related to the 3Rs.
- (2) Final reports (completion reports) should also comprehensively address items related to the 3Rs.

5. Self-Inspection, Self-Evaluation, and Third-Party Verification

- (1) Procedures regarding frequency, responsible personnel, and methods of implementation should be established and appropriately executed. Records should be maintained, and a checklist covering all required items should be used.
- (2) Issues identified through self-inspection should be appropriately followed up, and the follow-up actions should be documented.

6. Education and Training

- (1) The IACUC should be appropriately involved in education and training activities.
- (2) The target personnel, frequency, and content of the education and training should be appropriate, and records of education and training should be maintained.
- (3) Education and training in techniques related to the 3Rs should be conducted appropriately, and records should be maintained.
- (4) Education and training concerning zoonoses, the [Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases](#), [the Rabies Prevention Act](#), biosafety, and responses to pathogen contamination and other safety management issues should be conducted appropriately, with records maintained.

7. Safety Management (Including Regulations under Other Laws, Limited to Items Related to Animal Experimentation)

- (1) The rearing and breeding of genetically modified animals must comply with the [Cartagena Act](#) and be conducted appropriately. Collaboration between the IACUC and the Recombinant DNA Safety Committee should be appropriate.
- (2) Biosafety procedures must be appropriate.
- (3) Procedures related to chemical safety, the [Poisonous and Deleterious Substances Control Act](#), and the [Narcotics and Psychotropics Control Act](#) must be appropriate.
- (4) Procedures related to the [Act on the Regulation of Radioisotopes, etc](#) and related regulations must be appropriate.
- (5) Safety and health protection for experimental personnel must be ensured, particularly regarding the prevention of zoonoses, laboratory animal allergies (including exposure prevention measures), animal bites and scratches, and needle-stick injuries.
- (6) Procedures for maintaining equipment requiring statutory inspections (autoclaves, biological safety cabinets, etc.) must be established and properly executed, with records maintained.
- (7) Procedures for responding to natural disasters must be established.

8. Outsourcing

- (1) When animal experiments are outsourced to external institutions, the operational status of the contractor should be verified, and the protocol review by the institution's own IACUC should also be conducted.

9. Animal Housing Environment and Facilities

- (1) Procedures for maintaining facility operational systems (barrier or conventional types) and for entry/exit control should be established, properly implemented, and recorded.
-Handwashing, gowning procedures, control of movement lines, etc.
- (2) Procedures for managing the housing environment—such as temperature, humidity, ventilation frequency, odor control, and positive/negative pressure adjusted to experimental requirements and animal species—should be established, properly implemented, and recorded.
- (3) Procedures for microbiological monitoring should be established, properly implemented, and recorded.
- (4) Procedures for environmental monitoring of the housing area should be established, properly implemented, and recorded.
- (5) Procedures for facility maintenance, including filter replacement, should be established, properly implemented, and recorded.
- (6) Procedures for responding to abnormalities in the facility or among personnel must be established, and emergency contact systems must be in place.

- (7) Procedures for preventing animal escape and for responding in the event of escape should be established and properly implemented.
 - Step-over barrier for rodents, drain covers, preventing access by unauthorized personnel, notification to relevant authorities, etc.
- (8) Measures should be taken to prevent adverse impacts on the surrounding environment.
 - Waste, wastewater, odors, pests, noise, etc.
- (9) Measures should be taken to prevent intrusion by pests or other harmful organisms from outside through drains, loading/unloading areas, and similar routes.
- (10) Disposal of animal carcasses, infectious waste, used bedding, and other waste generated during animal care must be conducted appropriately.
- (11) Wastewater generated from animal care and related operations must be treated appropriately.
- (12) Laboratories (including test rooms and operating rooms) should be properly operated.
 - Procedures for animal entry/exit, presence or absence of housing, escape prevention measures, approval by the institutional head for designation as an animal experiment area, etc.

10. Animal Care and Management

- (1) Procedures for appropriate animal care and management should be established, properly implemented, and recorded.
 - Housing cages appropriate for animal species and characteristics
 - Selection of bedding, drinking water, feed; their sterilization status; their supply/storage methods
 - Individual identification methods
 - Procedures for responding to abnormal animals
 - Verification of animal numbers and conditions by laboratory animal managers
 - Animal sources, husbandry histories, medical histories, etc.
 - Information sharing among laboratory animal managers, experimenters, and caretakers
- (2) Procedures for cleaning and disinfecting animal housing facilities should be established, properly implemented, and recorded.
- (3) Procedures for quarantine, acclimatization, and operations from animal arrival to experiment initiation should be established, properly implemented, and recorded.
- (4) Pigs, dogs, nonhuman primates must be managed appropriately in accordance with relevant laws (the [Act on the Prevention of Infectious Diseases in Livestock](#), the [Rabies Prevention Act](#), the [Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases](#), the [Act on the Prevention of Adverse Ecological Impacts Caused by Designated Invasive Alien Species](#), etc.), with records maintained.
- (5) Environmental enrichment should be implemented except in cases where it would impede the proper conduct of experiments.
- (6) Procedures for veterinary care should be established, properly implemented, and recorded (where applicable).

11. Public Disclosure of Information

- (1) The content and method of public disclosure should be appropriate.

12. Other Items

- (1) Additional institutional initiatives related to animal welfare that are independently defined in institutional regulations, where applicable.