

Guidelines for designation as facilities for producing laboratory animals designated by the Japanese Minister of Agriculture, Forestry and Fisheries

1 Submission of application forms

Regarding designation as a facility for producing laboratory animals by the Japanese Minister of Agriculture, Forestry and Fisheries, the manager of the facility shall apply to the Japanese Minister of Agriculture, Forestry and Fisheries through the animal health authorities of the exporting country by submitting the following documents.

The Japanese animal health authorities will ask for further information if necessary.

[Submitted documents]

(1) Outline of the facility

Provide the following information.

- ① name
- ② address
- ③ name and title of the manager
- ④ geographic situation
- ⑤ detailed route from the airport to the facility
- ⑥ status of wild inhabitants in the surrounding area
- ⑦ number of employees (by occupation)
- ⑧ total number of employees and veterinarians attending to the relevant animals etc.

(2) Table of contents of the Standard operation procedures (including the procedures for breeding and keeping of animals, quarantine, disease prevention measures, details of the measures to be taken at disease occurrence etc. Hereinafter referred to as “SOPs”).

(3) Site map (which shows the location of each building within the site)

(4) Floor plan of the facility where dogs and cats to be exported to Japan will be kept (which shows doorways, change rooms, anterior rooms, animal rooms, examination rooms, isolation rooms, autopsy rooms, laboratories, cages, sterilization equipments such as autoclaves, disinfection equipments, water supply and drainage systems, incinerators, feeding rooms, workers’ flow lines, etc.)

(5) Department, address and manager of the animal health authorities of the exporting country directly supervising the facility

(6) Other reference information

2 Inspection of the site applied for designation

After accepting the application forms etc. specified in 1, the Japanese animal health authorities examine the documents and perform on-site inspections to check whether the facility meets the requirements specified in item 5 of the standard notification and the “detailed designation standards for facilities to be designated by the Minister of Agriculture, Forestry and Fisheries for producing laboratory animals” provided in the attachment.

3 Designation of production facility

As a result of the examination conducted according to item 2, upon acknowledgment that the relevant facility is qualified for the designation, the Japanese animal health authorities will disclose the name, address, etc. of the facility through announcement and notify accordingly the animal health authorities of the exporting country.

4 Inspection of designated facility

The Japanese animal health authorities conduct on-site inspections of the designated facilities, either regularly or as needed, in the presence of the animal health authorities of the exporting country to check whether the facilities continue to meet the requirements prescribed in item 5 of the standard notification and the requirements prescribed in the detailed designation standards. The designated facilities are required to disclose or submit the SOPs specified in items 9 and 11, repair records specified in item 13 and breeding and rearing records etc. specified in item 14 of the detailed designation standards, and are required to make improvements if necessary.

5 Reconstruction or remodel of the designated facilities

The manager of the facility shall submit an application for reconstruction or remodel to the Japanese Minister of Agriculture, Forestry and Fisheries through the animal health authorities of the exporting country before conducting any reconstruction or extension of the designated facility or making any other alterations to items 5 through 8 of the detailed designation standards (except for minor alterations. Hereinafter referred to as “reconstruction etc.”).

The Japanese animal health authorities check whether the submitted application meets the requirements prescribed in item 5 of the standard notification and the requirements prescribed in the detailed designation standards and, if necessary, conduct on-site inspections to judge whether the facility remains qualified for the designation.

6 Alterations to information submitted by designated facilities

If there is any alteration to the information submitted by the designated facility, or if the facility is no longer used for production of laboratory animals to be exported to Japan, the manager of the facility shall notify the Japanese animal health authorities immediately through the animal health authorities of the exporting country.

7 Revocation of designation

Upon acknowledgment that the designated facility fails to meet the requirements prescribed in item 5 of the standard notification or the requirements prescribed in the detailed designation standards, the Japanese animal health authorities can revoke the designation of the relevant facility. The same applies to a facility, which has not exported laboratory animals to Japan for one year or more.

Detailed designation standards for facilities to be designated by the Minister of Agriculture, Forestry and Fisheries for producing laboratory animals

- 1 The designated facility shall be approved by the animal health authorities of the exporting country as a facility for producing laboratory animals, shall be regularly inspected by the animal health authorities of the exporting country and shall keep the inspection records for at least two years.
- 2 The designated facility shall not be engaged in any activities involving the rabies virus, except for handling of the virus for serological rabies tests in laboratories designed to prevent virus leaks.
- 3 The designated facility shall have tight security to restrict any entry of unauthorized personnel.
- 4 The animals raised at the designated facility (hereinafter referred to as “the animals”) shall not be infected with rabies nor likely to be infected with rabies and shall satisfy one of the following:
 - (1) The animals have been raised in the designated facility ever since they were born.
 - (2) The animals were introduced from sites other than the designated facility and have been raised in isolation from animals other than those in the same lot for at least 180 days after their introduction.
 - (3) The animals were introduced after receiving effective inactivated vaccination against rabies several times so as to acquire sufficient antibodies for preventing rabies infection (0.5 IU/ml in serum) and after at least 180 days since the date of blood sampling for antibody test.
- 5 The designated facility shall be surrounded by fences etc. to prevent escape of animals or entry of other animals from the outside.
- 6 The designated facility shall have necessary facilities such as change rooms, animal rooms, anterior rooms, examination rooms, laboratories, etc. and shall be equipped with disinfection instruments and disinfectants effective against rabies and other animal infectious diseases.
- 7 The facility for breeding and keeping dogs or cats for laboratory use to be exported to Japan (hereinafter referred to as “rearing facility”) of the designated facility shall be completely isolated from animals with poor health status than the relevant dogs or cats for laboratory use.

- 8 The rearing facility shall meet the following requirements:
- (1) The doorways of the rearing facility and animal rooms or anterior rooms shall be able to be locked to prevent escape of animals or entry of other animals from the outside.
 - (2) The windows and air vents of the rearing facility shall be covered by wire netting etc. to prevent entry of other animals etc. from the outside.
 - (3) Water supply and drainage systems shall be established inside or nearby the rearing facility to enable cleaning and disinfection of the inside or outside of the animal rooms and instruments etc.
 - (4) Surfaces of floors, walls and ceilings in the rearing facility shall be smooth and easily cleaned, shall be made of impermeable materials, shall be equipped with appropriate slopes and drainage systems, and shall be easily disinfected.
 - (5) The doorway of the facility shall be equipped with disinfection equipment such as pools for hand and sole disinfection.
 - (6) The animal rooms shall be designed to enable easy monitoring of the animals' conditions.
- 9 The designated facility shall provide standard operation procedures (SOPs) written in Japanese or English. The SOPs shall be established for facility management, animal care, disease prevention measures, measures to be taken at disease occurrence, etc.
- 10 The facility manager and the animal manager shall supervise employees to comply with the SOPs mentioned in the item 9.
- 11 The designated facility shall be provided with equipment for making definite diagnosis of rabies. If the designated facility consigns the definite diagnosis of rabies to another laboratory, the SOP shall specify the name of the laboratory, the procedures for examination and delivery of samples, etc. and shall be complied with.
- 12 The designated facility shall dispose the corpses, excretions, sewage etc. from the facility in a sanitary manner, i.e. by means of disinfection, incineration, etc.
- 13 The designated facility shall conduct regular inspections of the facility and equipment. Any breakage or breakdown found in the facility or equipment shall be repaired immediately, and the repair record shall be kept for at least 2 years.
- 14 The breeding and keeping records shall include the following information written in Japanese or English and shall be kept for at least 2 years.
- (1) species
 - (2) birth date
 - (3) sex
 - (4) individual identification
 - (5) facility of origin (name and address)
 - (6) date of birth or introduction to the facility

- (7) rearing record since birth or introduction
- (8) dates and results of testing and research, mating, vaccination, examination, etc.
- (9) others

15 Animals shall be cared by those who have sufficient knowledge about nutrition, health and disease of animals.

16 If animals are divided into lots within the rearing facility, in principle, each lot shall be cared by those who exclusively attend to the lot and wear uniforms exclusively designed for the lot.