

## The standards of the rearing environment for laboratory animals in Japan

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### Abstract

In Japan, the Architectural Institute of Japan (AIJ) provides guidelines for laboratory animal facilities and equipment. Guidelines are not legally binding but serve as the authority for proper facilities and equipment management.

The first guideline draft, proposed in 1966, was comprehensively revised from 1979 to 1983 and version 1 was published in 1983. Revision was begun by the AIJ and version 3 followed in 1996.

The AIJ published the latest guidelines in June 2007. Revisions involved technical engineering experts working for 2 years with laboratory animal experts. Main references for guidelines are the US National Institutes of Health (NIH) Design Policy and Guidelines and ILAR guidelines for the care and use of laboratory animals.

Information on facilities and equipment reflects technical advances but, due to the lack of sufficient objective scientific evidence and information, rearing environment standards for laboratory animals have not been reviewed since version 1 was published. An organization on guideline revisions, including the specification of laboratory animal rearing environments, must be set up.

**Keywords:** Japan, laboratory animals, rearing environment, guideline preparation, issues and themes

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### Preparation of laboratory animal facility guidelines in Japan

The environment for laboratory animal facilities in Japan is described in "Guideline for laboratory animal facilities construction and equipment."

In 1966, a draft of the guideline was proposed (Fig. 1) as the first standard specifying how laboratory animal facilities were to be constructed and what equipment was needed in Japan. Facilities were constructed and prepared based on this draft. Ten years after this draft appeared, people began asking to review it. It was then reviewed and revised. After extensive revision, the Japanese Association for Laboratory Animal Science issued the "Guideline for laboratory animal facilities construction and equipment" as version 1. As with the guideline draft, version 1 was used for facility construction, control, and operation for some time. A decade later, parts of the guideline were no longer suited to changing conditions. The Japanese Association for Laboratory Animal Science was reluctant to revise it, however. Engineers who had prepared version 1 then asked the Architectural Institute of Japan to revise it, and started working on it with those concerned with laboratory animals. It took several years to study and revise version 1, and the Institute issued version 2 in 1996. Ten years have passed since version 2 was issued, and circumstances have again changed.

- The 3R Principles were recognized in Japan, and researchers using laboratory animals became more aware of the need to improve the situation of nonhuman sentient beings used in laboratory experiments.
- Individually ventilated cages became widespread.
- Animals undergoing gene recombination were prioritized for use in experiments.
- People became more interested in the importance of security at such facilities.

Government ministries in Japan have recently started revising standards and guidelines covering animal experiments (Fig. 2). The Ministry of the Environment, which is in charge of animal affairs, first revised the Law of Humane Treatment and Management of Animals and the Basic Rule for Keeping and Managing Laboratory Animals, including the 3R Principles in laws and regulations. Other ministries followed suit so that ministry organizations and facilities conducted animal experiments more humanely. The Science Council of Japan published the "Guideline for Proper Conduct of Animal Experiments." The Architectural Institute, in turn, began revising version 2 of the guideline, and version 3 was issued this June. Many engineers worked to revise version 2, and worked on version 3 in cooperation with personnel concerned with laboratory

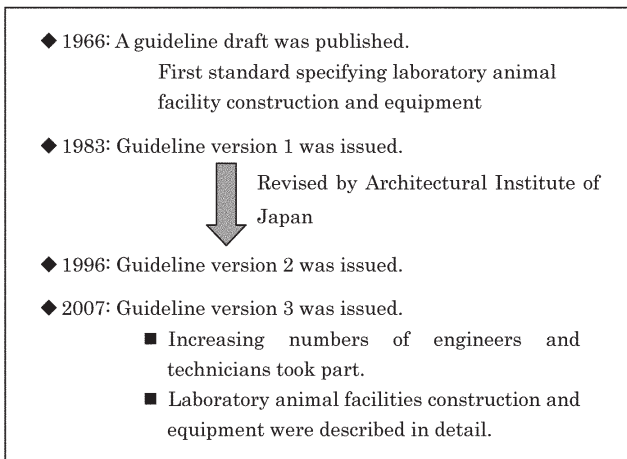


Fig. 1. Preparation of Laboratory Animal Facility Guidelines in Japan

animals. Version 3 describes facility construction and equipment in greater detail than version 2. They also referenced the US National Institutes of Health Design Policy and Guidelines in preparing version 3.

**Rearing environments in Japan**

The guideline describes the environment for rearing laboratory animals (Table 1) (AIJ, 2007).

Many opinions were stated on cage size, for example. Some people said cages should be big enough to rear the number of animals required. Others said that differences in European and Japanese physiques should be considered in determining cage handling. No individual standards for cage size yet exist in Japan, however. The ILAR standards are regarded as basic and all guideline versions have been prepared based on NIH and ILAR standards. The ILAR standards are to be revised, but will be exclusively adopted in Japan.



Fig. 2. Changes in Laboratory Animal Circumstances in Japan

Before version 3 was issued, criteria for checking the laboratory animal rearing environment (Table 2) (AIJ, 2007) were studied referencing ILAR standards, e.g., the maximum temperature for rearing rabbits was changed in version 3. Those who work with laboratory animals pointed out that the original maximum temperature was too high, so it was reduced to the optimum value.

Except for this point, however, guidelines were not changed as much as version 1. Criteria were determined after studying rearing standards abroad, rearing experience, results of environmental measurement, and results of related research. Criteria also considered the macroenvironment in the secondary enclosure. As time passes, optimum rearing methods will change. Even today, opinions differ very much among people about rearing environments. Even though standard values must be reviewed, however, we do not have enough data to do so. Not enough research is being done to determine

Table 1. Recommended Space for Laboratory Animals in Japan (Extract)

Animals	Weight (g)	Floor Area / Animal (cm <sup>2</sup> )	Height (cm)
Mice	< 10	38.70	12.7
	Up to 15	51.60	12.7
	Up to 25	77.40	12.7
	25 < <sup>a</sup>	96.75 ≤	12.7
Rats	< 100	109.65	17.8
	Up to 200	148.35	17.8
	Up to 300	187.05	17.8
	Up to 400	258.00	17.8
	Up to 500	387.00	17.8
	500 < <sup>a</sup>	451.5 ≤	17.8
Hamsters	< 60	64.50	15.3
	Up to 80	83.85	15.3
	Up to 100	103.20	15.3
	100 < <sup>a</sup>	122.55 ≤	15.3
Guinea pigs	< 350	387.00	17.8
	350 < <sup>a</sup>	651.45 ≤	17.8

<sup>a</sup> Larger animals might require more space to meet the performance standards.

Table 2. Criteria for Checking Laboratory Animal Rearing Environments in Japan

Environmental factor	Mice	Rats	Hamsters	Guinea pigs	Rabbits	Monkeys	Cats	Dogs
Temperature	20 - 26°C				18 - 24°C	18 - 28°C		
Relative humidity	40 - 60% (Relative humidity shall not drop to 30% or less nor rise to 70% or above.)							
Cleanliness	Dust	ISO Class 7 (NASA Class 10,000) (Barrier area where no animals are reared)						
	Descend bacterium	≤ 3* (Barrier area where no animals are reared) ≤ 30 (General-purpose area where no animals are reared)						
	Odor	Ammonia concentration shall not exceed 20 ppm.						
Air velocity	≤ 0.2 m/s in animal living areas							
Atmospheric pressure	Static pressure difference: The Static pressure shall be 20 Pa higher than that of peripheral corridors. (SPF barrier area) Static pressure difference: The Static pressure shall be 150 Pa higher than that of interior. (Isolator)							
Ventilation	6 - 15 times/h (The optimum value shall be determined based on supply and exhaust.)							
Illumination	150 - 300 lx (40-85 cm above the floor)							
Noise	≤ 60 dB(A)							

\* : When a Schale of 9 cm in diameter is opened for 30 minutes. (Blood agar medium, 48 h culture)

the optimum rearing environment. People in Japan understand that the rearing environment affects animal experiments, but few are interested in doing something about it. People are now more interested in toys for animals and improving cage sizes, thinking of what toys are best for which animals and how cage sizes should not limit animal activities. Regarding environmental enrichment, we believe that the microenvironment of the primary enclosure should be reviewed. Considering industrial safety and health, we believe that current rearing environment standards should be reviewed.

#### Issues and themes on current standards

The basic problem in Japan is that no organization has been set up to continuously review guidelines and criteria for checking rearing environments. Even the Japanese Association for Laboratory Animal Science hesitates to organize a group that could continuously review facilities construction and equipment. The Architectural Institute of Japan issuing the current guidelines also hesitates. If people think that guidelines should be revised, they should ask the society to set up a revision committee and obtain the society's approval. After years of study, a new version of the guideline will be issued, but then the committee will be disbanded.

Optimum rearing environments and equipment and facilities will change as technologies advance and the needs of society change. We believe an organization should be set up to continuously discuss whether guideline should be revised. Setting up such an organization would also enable the collection and storage of materials and data. If the organization uses data from different fields, guidelines could be revised more efficiently, producing more useful guidelines.

#### Themes to be considered in revising rearing environment guidelines and standards

Ministries in Japan have specified laws and regulations to control animal experiments, and requested optimum rearing environments but did not specify concrete recommendations. Individual facilities judge optimum rearing environments, but should be following standard guidelines.

We should determine whether legal regulation is needed to ensure optimum rearing environments. The Science Council of Japan is proposing that evaluation by a third party be made to ensure that animal experiments are conducted properly. Evaluation of the rearing environment could thus become this third-party evaluation. Environment monitoring should be also set up to efficiently measure and evaluate rearing environments. In conclusion, I fear that Japan looks only at laboratory animal rearing environments overseas.

I think Japan should consider the optimum rearing environment and disseminate its own opinions and information abroad.

#### Reference

Architectural Institute of Japan (2007) Guideline for laboratory animal facilities construction and equipment. Tokyo: Adthree (in Japanese).

