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Technical report Laboratory Animal Science*

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Based on the work of Zenichi Sato,
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May 6, 1986

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May 29, 1986

Mr. Nasir/UNIDO and Dr. Sang Seop Han/KRICT

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1. Introduction

Following the first trip to the Korea Research Institute of Chemical Technology (KRICT), Republic of Korea, in 1985, I visited the institute again on May 6 - 21 and May 29 - June 12, 1986. The purpose of this visit was (a) to give advice in more detail on the items defined in the first-trip report (my report dated April 20, 1986) and (b) to check the proceeding status of construction work of a new research center, the Toxicology Research Center, of KRICT. A brief summary of the advice given is described in each section of this report. The construction work proceeded satisfactorily. During the visit, it was unavoidable to spend more time discussing impending matters of construction, rather than facility-management plans.

2. Standard Operating Procedures (SOPs)

Advice was provided on the contents of the following two SOPs, and the title of each part was determined. The articles in each SOP will be prepared by the KRICT staff.

2.1 SOPs for animal husbandry in safety studies

Contents

- 1) Significance, purpose, and scope of animal husbandry
- 2) Organization and duties of the staff
- 3) Outline of the facility
- 4) Control of the facility
- 5) Control of the facility equipment
- 6) Control of breeding
- 7) Health care and safety control for the staff
- 8) Prevention of disasters and maintenance of safety
- 9) Utilization of the facility
- 10) Education and training of the staff
- 11) Records

2.2 SOPs for productin of high-quality experimental animals

Contents

- 1) General rules**
- 2) Detailed rules**
 - a) Control of raw materials**
 - b) Control of environmental and sanitary conditions**
 - c) Control of mass-production of the mouse and rat**
 - d) Control of breeding and supply of the mouse and rat**
 - e) Breeding control**
 - f) Quality control**
 - g) Maintenance of equipment**
 - h) Maintenance of safety**
 - i) Records and reports**
 - j) Related documents and data**

3. Summary of Advice

3.1 Production of experimental animals

The animal production plan could not be formed, because the experimental schedules have not been fixed. The personnel plan for animal production has already been settled, so that the production of animals will be initiated as soon as the construction work is finished. The animals and their control systems are as follows.

Species and strain: Mouse: ICR, dds
Rat: SD, F344, Wistar

Genetic control: Closed colony for both species

Microbiological control: SPF

3.2 Management

The new center of KRICT is aimed at performing safety studies in compliance with the GLP and breeding experimental animals for the studies. In future, the whole facility space is planned to serve as the laboratory for safety studies. Based on these plans, the management plans were formed.

(1) Animal husbandry for safety studies

The outline of the SOP was defined, as shown in 2.1. All articles of the SOP have not yet been completed, but basic materials were all prepared.

(2) Production of experimental animals

The outline of the SOP was defined, as indicated in 2.2. As the general and detailed rules were fully discussed, it is easy to complete the SOP.

(3) Facility and equipment

The principles were decided for management of the building, air-conditioning system, and others common to the safety study performance and animal production.

3.3 Quality control of animals

Emphasis was put on the quality control, in which process animals produced should be examined for their quality, leading to supply of good-quality animals for experiments. In case that animals are not of acceptable quality, the cause should be made clear by monitoring the environment (temperature, humidity, illumination, noise, etc.), breeding conditions (cage, bedding, water, feed), nutritional conditions of the feed, contamination of animals or materials with poisonous substances, genetic background of animals, and microbiological factors. The system which enables the staff to take these actions as the base of quality control was formed. Especially, microbiological monitoring is urgently needed. The other tests are covered by the SOP for production of experimental animals.

3.4 Environmental conditions

A one-month trial run of the facility equipment revealed that the environmental conditions were well controlled as follows. The found values complied with the international standards.

<u>Item</u>	<u>Target value</u>	<u>Found vlaue</u>	<u>Judgment</u>
Temperature	20 - 26°C	23 - 25°C	Complies
Humidity	40 - 60%	45 - 55%	Complies
Frequency of ventilations	10 - 15 times/hr	<15 times/hr	Complies
Rate of air stream	13 - 18 cm/sec	12 - 15 cm/sec	Complies
Odor	20 ppm ammonium	(not examined because no animals were housed)	
Noise	60 dB	40.5 - 46.5 dB	Complies

3.5 Apparatus (cages and racks)

In principle, apparatus such as cages and racks to be used for breeding are made in Korea as much as possible. The trial products obtained so far are not good in quality. However, continuous guidance will lead to satisfactory results. The cage sizes for the respective animal species were selected on the basis of mean sizes of foreign products.

3.6 Feed

Feed manufacturers in Korea have no experience in making feed for experimental animals. As a result of discussion between the KRICT staff and the factory members, the following were decided.

- (a) The feed for experimental animals is made in the same factory as that for domestic animals because separate production of the two types of feed is impossible for the time being. In production of the feed for experimental animals, the residue of feed for domestic animals is carefully removed from machines.
- (b) Strict quality control is performed; the analyses for chemical and antibacterial contaminants are carried out by KRICT, and analyses of nutritional elements, by the factory.
- (c) The standards for contents of nutritional elements and limits of contaminants were fixed in reference to the foreign standards (the list attached hereto).

3.7 Water and bedding

Presently, water for human drink is used for animals. However, to check the quality of water exactly, advice was given to perform the quality tests of water periodically including the test for contaminants such as cadmium, arsenic, lead, mercury, and other chemical substances. It was also decided that 2 - 3 ppm of chlorine would be added to the water to be used in BS animal rooms.

The quality of bedding is more or less unstable. Advice was provided to analyze the bedding for contaminants. I advised the KRICT staff on the previous occasion to perform the analyses periodically, but they had not taken them into action. Since the quality of water and raw materials for bedding obtainable in Korea is not stable, more efforts are necessary to settle this problem.

3.8 Status of construction work and disinfection of the building

The new center now under construction is the first high-level, barriered facility in Korea. By this reason, there have been many troubles in construction work, but despite them, the building is nearly completed at a satisfactory level. The final judgment will be made after completion of disinfection of the building starting June 10, 1986.

The disinfection of the building will be performed by washing the inside and outside of the barriered rooms with water and then with a disinfectant, and finally by fumigating the inside with formalin gas. After that, the test for microorganisms in air will be done. The final judgment will be gained around June 25, 1986.

3.9 Design of the facility for non-rodents and facility maintenance plan

A facility to accommodate non-rodents such as the dog and rabbit was designed. KRICT has no capacity in space, personnel, or finances for breeding the non-rodents by themselves. Therefore, the non-rodents will be bred by a breeding company, to which instruction and guidance were given. The method for animal husbandry to be taken is almost the same as that for the rodents; some special points in quarantine of the non-rodents were instructed. My visit was so limited in time that the SOP preparation could not be initiated.

4. Recommendations

(1) It is important for KRICT to take time for mastering the techniques necessary for the new center, which is the first BS facility for KRICT. The immediate thing to do is to complete the SOPs for animal husbandry and production of animals. As described in the text, the outlines for the SOPs were already established. According to the outlines, the details should urgently be defined. Main parts of the SOPs are as follows (most of which are common to the SOP for animal husbandry in safety studies and the SOP for production of animals).

- (a) Records
- (b) Acceptance procedure for animals
- (c) Quarantine
- (d) Animal husbandry
- (e) Animal facility
- (f) Equipment
- (g) Apparatus
- (h) Materials
- (i) Observation of general health of animals
- (j) Macroscopic observation of animals
- (k) Statistical analysis

(2) It should urgently be needed to establish the microbiological, genetic, pathological, and biochemical testing systems for quality control of animals.

- (3) The laboratory staff should be educated to have a general concept of laboratory animal science. It is especially important that through the education, all staff members deeply understand the necessity of preventing cruelty to animals and the ethics for animal experiment.

- (4) The construction of the facility for non-rodents was already started. Sufficient control will be needed for efficient construction work.

- (5) KRICT should start the staff training for animal care of the primates.

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