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# 上海市实验动物机构许可证 验收评审规则

Rules of Accreditation for Shanghai  
Laboratory Animal Care and Use  
Institution

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上海市实验动物质量监督检验站

**Shanghai Quality Monitoring Centre for Laboratory Animals**



# 评审内容 Context

## □ 1、组织机构 **Organization**

1.1 领导：（1）★有明确的主管领导负责本单位的实验动物工作，该领导了解国家、行业 and 地方的有关法律和法规。

1.2 机构：（1）★有专职管委会或领导小组。  
（2）★有实验动物保护、福利、伦理小组。

注：★为一票否决项目

1.1 Director : (1) ★A director responsible for programs related to institutional laboratory animals and familiar with relevant laws and regulations of national, local government and business should be available.

1.2 Institution : (1) ★A specialized managing committee or a leading group should be available.  
(2) ★A laboratory animal care, welfare and ethic group should be available.

Note: ★ Items not in compliance with will be unconditional veto for accreditation

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# 评审内容 Context

## □ 2、人员 **Personnel**

### □ 2.1 管理人员：

- (1) .具有医学、生物学或畜牧兽医医学等专业大专以上学历。
- (2) .中级以上技术职务，从事实验动物专业工作达三年以上。
- (3) .屏障设施管理人员需经过专业培训

### 2.1 Management :

- (1) Personnel possesses college degree or above in medicine, biology or veterinary, etc.
- (2) Personnel possesses intermediate professional grade or above, involving in laboratory animals for more than 3 years.
- (3) Management staff of barrier facility should have been trained relevantly.

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# 评审内容 Context

## □ 2.2 从业人员

(1).★取得实验动物从业人员上岗证。

(2) .每年体检合格。

## □ 2.3 劳动保护

有劳动保护措施：

普通级：有工作服、口罩、手套、鞋帽。

屏障设施内：净化服、口罩、手套、鞋帽。

有危险性的动物实验室应设置应急冲洗设施。

## □ 2.2 Staff

(1) ★Certificate for qualified laboratory animal staff should be available.

(2) Pass annual physical examination.

## □ 2.3 Labor protection

Labor protecting measurements should be available:

Common level: working coats, overalls masks, gloves, shoe covers and head covers.

Within barrier facility: sanitized overalls, masks, gloves, shoe covers and head covers.

For animal laboratory involving hazardous material, emergency showers should be installed.

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# 评审内容 Context

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## □ 3、环境与设施 Environment and facilities

### □ 3.1 外部环境

- (1) .有独立的场所。
- (2) .周围50米内无影响动物饲养的污染源。
- (3) .室外环境整洁卫生，三废处理符合环保要求

### □ 3.1 Exterior environment

- (1)Independent facility should be available.
- (2)No pollution source affecting animal husbandry within 50m of surrounding area.
- (3)The outdoor environment should meet sanitation requirement.The treatment of three wastes (gas, water and residue) meets environmental requirement.

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# 评审内容 Context

## □ 3.2 内部环境

- (1) .人流、物流、气流组织合理，避免交叉感染。
- (2) .★有清洗、消毒、灭菌设备。
- (3) .★有防止野生动物入内的措施。
- (4) .★有消防设备、紧急出口。
- (5) .★内环境指标应符合国标：GB14925-2001

## □ 3.2 Interior environment

- (1) .Human pass, animal/material flow and air flow are justified to avoid cross-contamination.
- (2) ★Washing, sanitizing and sterilizing equipments should be available.
- (3) ★Preventive measures for intrusion of wild animals should be available.
- (4) ★Fire protection equipments and emergency exits should be available.
- (5) ★The indoor environment indices should in compliance with National Standard GB14925-2001.

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# 评审内容 Context

## □ 3.3 区域布置

- (1) ★动物实验区与动物饲养区应分开设置。
- (2) 前区包括：办公室、值班室、休息室、配电室、监控室、库房、卫生间、一般走廊等。
- (3) 动物实验区包括：隔离检疫室、缓冲室、清洁物品储藏室、清洁走廊、实验室、手术室、污染走廊、动物运动场等。
- (4) 辅助设施：兽医室、洗刷消毒室、淋浴室、动物洗浴室、解剖室、动物废弃物处理室等、

## □ 3.3 Facility layout

- (1) ★The animal testing area and breeding area should be separated.
- (2) Front area includes: office, duty room, cafe room, electrical distribution room, monitoring room, storage room, lavatory, common corridor etc.
- (3) Animal testing area includes: isolated quarantine room, locker, clean material storage room, clean corridor, laboratory, surgery room, return corridor and animal exercise yard.
- (4) Supplementary facilities: veterinarian room, cleaning and sterilization room, shower room, animal bathroom, necropsy room, animal waste treating room, etc

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# 评审内容 Context

## □ 3.4 特殊动物实验设施

(1) .放射性、感染性和化学毒性动物实验设施应经有获有关部门批准。

## □ 3.5 动物尸体与废弃物的处理

(1).有专门的动物废弃物暂存间或设备。

(2).有密闭式动物尸体冷冻储存间或冰柜。

(3).★动物废弃物与动物尸体应进行无害化处理。无条件处理动物尸体的应委托专业火化单位处理，并签定有关委托协议

## □ 3.4 Special animal laboratory facility.

(1)Test facilities involving radioactive, infectious diseases and chemical toxic material should be authorized by relevant department.

## □ 3.5 Treatment of animal corpses and waste

(1)a special animal waste temporary storage room or treating equipment should be available.

(2)An airtight animal corpses frozen room or refrigerator should be available.

(3) ★ Animal waste and corpses should be deharmful treated before disposing. The facility without animal corpses treatment condition should consign to specialized cremation agency and an agreement should be signed.

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# 评审内容 Context

## □ 4、建筑要求 **Construction requirements**

### □ 4.1围护结构

围护结构的材料应满足保温、隔热、防火、防潮、无毒、少产尘等要求。

### □ 4.2 内墙和顶棚

- (1) 表面应平整、光滑、不起尘、避免眩光、便于除尘，应减少凹凸面、阴阳角为圆形，并易清洗消毒。
- (2) 内墙面和顶棚应采用难燃、不开裂耐清洗、耐腐蚀、表面光滑、不易吸水发霉的材料。

### □ 4.1 Space containment structure

Material for space containment structure should meet requirements such as: heat preservation, heat insulation, fire-resistant, moisture proof, poisonless, less-dust-producing, etc.

### □ 4.2 Interior wall and ceiling

- (1) The surface should be flat, smooth, non-dust-producing, refraction free and easy-to-clean. Convex-concave shapes should be reduced as much as possible; the inside and exposed corners should be rounded, easy to clean and sterilize.
- (2) Material for the surface of interior wall and ceiling should be unflammable, non-cracking, washing and corrosion tolerated, smooth surface, water absorbing and mould proof material.

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# 评审内容 Context

## □ 4.3 地面

应平整、耐磨、耐腐蚀、易清洗、避免眩光、不开裂、无渗漏。

## □ 4.4 走廊

净宽度不小于1.5m，便于交通。

## □ 4.5 门

应平整坚固、耐腐蚀，屏障环境的门应有良好的气密性。

## □ 4.6 活动场所

大动物应有动物活动场所。

## □ 4.3 Ground

Flat, abrasion and corrosion tolerated, easy-to-clean, refraction free, non-cracking and non-leaking.

## □ 4.4 Corridors

Net width should be no less than 1.5m to facilitate the transportation.

## □ 4.5 doors

Doors should be flat, firm, corrosion tolerated.

Doors within the barrier environment should be air-tight.

## □ 4.6 Playground

Large animals should have playground.

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# 评审内容 Context

## □ 4.7 送、排风系统

- (1).屏障环境和隔离环境应采取管道送排风，保持正压，避免短路、死角和断流。
- (2).应有备用送排风机。
- (3).排风应符合环保要求。室外进排风口应有防雨和防鸟、虫及防逆风装置。排风管道应有防冷凝水倒流装置。

## □ 4.7 Air flow system

- (1).The barrier and isolated environment should be equipped with air supply and exhaust ducts running with consistent positive pressure. Short circuit, dead angles and discontinuous supply should be avoided.
- (2).Back up ventilators and exhausters should be in place.
- (3).Ventilation should reach environmental protection requirement. The outdoor air intakes and exits should be equipped with devices impervious against rain, birds, insects and headwind. Exhaust ducts should avoid condensing water counterflow.

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# 评审内容 Context

## □ 4.8 给排水

- (1). 普通环境应符合城市生活饮用水要求。
- (2). ★屏障环境设施内应使用无菌水，避免设置上下水道，必须设置时上下水管道和笼头应使用不生锈、耐腐蚀、不造成无菌水二次污染的材料制成。下水道应安装密封式下水口。
- (3). 洗刷间下水道内径不小于75mm，兔以上大动物不小于200mm。
- (4). 进入下水道的有害物质应进行无害化处理。
- (5). 应有专用的化粪池。

## □ 4.8 Water supply and sewerage

- (1). Common environment water supply should in compliance with urban drinking water.
- (2). ★ Water used in the barrier environment must be sterilized. Avoid installing water supply and drainage system within the facility. When unavoidable, the pipes and faucets must be made of rustless and corrosion tolerated material to avoid secondary contamination. Seal off drainage should be used.
- (3). ID of the drainage in the cleaning room should be no less than 75mm. For animals larger than rabbits should be no less than 200 mm.
- (4). Before letting into the drainage, the hazardous materials should be deharmful treated.
- (5). Septic tank should be available.

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# 评审内容 Context

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## □ 4.9 通讯

屏障环境以上设施应安装内外通话设备。

## □ 4.10 电气

(1) .屏障环境以上设施应双路供电或配置应急不间断电源（UPS）。

(2) .电器设备应暗装，电气管线应暗敷，进入洁净区的管线应可靠密封。

## □ 4.9 Communication

Verbal communicators between inside and outside should be equipped within barrier environment.

## □ 4.10 Electrics

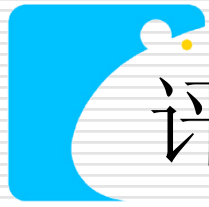
(1) .Dual-power supply or UPS should be equipped for barrier facility.

(2) .Installation of electrical equipment, wires and tubes should be concealed. Wires and tubes in the clean zone should be sealed effectively.

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# 评审内容 Context

## □ 4.11 室内环境监测仪

- (1) .室内应有温湿度计等仪器。屏障设施内还应安装梯度微压计或安装温湿度、氨浓度和室内气压传感器。
- (2) .屏障以上设施应有火警、故障、温湿度、氨浓度、压差报警系统。

## □ 4.11 Indoor environment monitor instruments

- (1) Indoor humituremeter etc. should be available. Gradient tasimeters or humiture, ammonia concentration transducer and indoor baroceptor should be available in barrier facility.
- (2) Fire, fault, humiture, ammonia concentration and pressure difference alarm system should be available in barrier facility.

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# 评审内容 Context

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- 5、动物实验用品 **Animal test materials**

- 5.1 动物

- ★应使用具有“实验动物生产许可证”的繁育单位的实验动物。并保存实验动物质量合格证明以备查。

- 5.2 饲料

- ★宜饲喂有生产许可证的单位生产的饲料。

- 5.1 Animals

- ★ Laboratory animals should be produced by approved laboratory animal breeding companies. Keep the certificate for future inspection.

- 5.2 Feed

- ★ Animals should be provided with feed produced by approved manufacturers

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# 评审内容 Context

## □ 5.3 饮用水

- (1) .★普通级动物饮用城市生活用水。
- (2) .★清洁级以上动物使用灭菌水。

## □ 5.4 垫料

有良好的吸湿性，粉尘少，无异味、毒性、杂质，消毒灭菌后使用。

## □ 5.3 Drinking water

- (1) ★General grade animals drink urban water.
- (2) ★ Clean grade animals or above drink sterile water.

## □ 5.4 Bedding

Good hygroscopicity, little dust, without abnormal odor, poisonless and impurity-free. Use after sterilization.

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# 评审内容 Context

## □ 5.5 笼具

- (1).采用无毒，耐腐蚀、高温，易清洗、消毒灭菌，耐冲击的材料制成。
- (2).需牢固，结实，动物不易逃逸。
- (3).笼具大小应符合国标GB14925-2001。
- (4).验收时笼器具应放置到位。

## □ 5.5 Cages

- (1)Cages should be made of poisonless, corrosion tolerated, high temperature resistant, easy-to-clean and sterilize, shockproof materials.
- (2)Cages should be firm and strong enough to avoid animals escaping.
- (3)Size of the cages should meet the National Standards GB14925-2001
- (4)The cages should have been placed during auditing.

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# 评审内容 Context

- 6、动物房及笼器具的消毒 **Sterilization of animal rooms, cages and racks**
- 6.1 动物房
  - (1) .熏蒸法。
  - (2) .酚类、氧化剂、卤素类消毒剂擦洗。
  - (3) .其他。
- 6.2 笼器具
  - (1) .酚类、氧化剂、卤素类消毒剂擦洗。
  - (2) .新洁尔酶，过氧乙酸浸泡。
  - (3) .其他
- 6.1 Animal rooms
  - (1) Fumigation
  - (2) Scrubbing with phenols, oxidants or halogen disinfectants.
  - (3) Other methods
- 6.2 Cages and racks
  - (1) Scrubbing with phenols, oxidants or halogen disinfectants.
  - (2) Dip in benzalkonium bromide or peracetic acid.
  - (3) Other methods

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# 评审内容 Context

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## □ 7、动物福利及动物处死 **Animal welfare and euthanasia**

### □ 7.1 动物福利

(1) .要善待动物和保护动物。

(2) .有条件的单位可在动物房内播放音乐，在笼器具内放置一些玩具

### □ 7.2 动物处死

(1) .CO<sub>2</sub>窒息处死。(2) .麻醉处死。(3) .空气注入处死。(4) .断脊椎处死。

(5) .其他。

### □ 7.1 Animal welfare

(1) Animals should be well treated and protected.

(2) If condition permits, music can be played in animal rooms and enrichments available in cages.

### □ 7.2 Animal euthanasia

(1) Suffocate with CO<sub>2</sub>

(2) Anesthesia

(3) Injecting air into vessels

(4) Cervical dislocation

(5) Other methods

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# 评审内容 Context

## □ 8、规章制度 **Rules and regulations**

### □ 8.1 管理

- (1) .有领导、管理及工作人员名册。
- (2) .有完善的管理制度和操作规程。
- (3) .有动物福利和伦理方面的规程。
- (4) .如有放射性、传染病和化学毒性等特殊试验应有有关的部门特批个案报告及准予批复。

### □ 8.1 Management

- (1) A name list of the director, management team and staff should be available..
- (2) Well defined management rules and operating procedures should be available.
- (3) Animal welfare and ethic procedures should be available.
- (4) If special tests involving radioactive or infectious diseases and chemical toxic substance, reports submitted to relevant department and approval certificate for individual case should be available.

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# 评审内容 Context

## □ 8.2 实验室

- (1) 不同品种、品系和不同微生物按分类级别要求，在不同的设施（设备）中开展动物实验。
- (2) ★同一饲养人员不得同时饲养不同微生物等级的实验动物。

## □ 8.3 应急措施

有应急预案或应急处理措施。

## □ 8.2 Laboratory

- (1) Animals of different species and strains and different microorganisms should be tested in different facilities(equipments) according to their grades.
- (2) ★ Individual breeder cannot breed different microbial level animals at the same time.

## □ 8.3 Emergency handling

A scheduled emergency plan or handling method should be available.

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# 评审内容 Context

## □ 8.4 记录

- (1) .有规章、计划、会议等记录。
- (2) .有实验动物、环境指标和设施设备运行等各项记录。
- (3) .有自检或委托质检记录。

## □ 8.4 Records

- (1) .Records of regulations, plans and meetings should be available.
- (2) .Records of laboratory animals, environmental targets and operation of facility and equipments should be available.
- (3) .Records of internal or authorized QC should be available.

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# 评审结果 **Results**

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- 符合 **Granted**
- 基本符合 **Basically qualified**
- 不符合 **Failed**

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谢谢

Thank you

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