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Management System of Shenzhen Institute of Advanced Technology, Chinese Academy of Sciences on Bio-safety

Chapter 1 General

Article 1 Shenzhen Institute of Advanced Technology, Chinese Academy of Sciences (SIAT) Bio-safety Management Committee is responsible for consulting, guiding, evaluating, and supervising various laboratory-related bio-safety matters to ensure the safety of employees, visitors, communities, and the environment.

Article 2 The laboratory biological safety management system implements a four-tier management system: the Director-General (legal representative) - Bio-safety Management Committee - Bio-safety Office of the Institute - laboratory liaison officer.

Article 3 In accordance with the *Bio-security Law of the People 's Republic of China*, the scope of authority of the Bio-safety Management Committee includes: experimental activities involving human infectious pathogenic microorganisms, animal pathogenic microorganisms and plant pathogenic microorganisms; genetic modification of animals, plants, and microorganisms using biotechnology techniques such as gene knockout or knock-in, transgenesis, or induced mutation. Specifically, this applies to laboratories at SIAT involved in activities related to human, animal, or plant pathogenic microorganisms, animal laboratories, and laboratories conducting genetic editing and modification techniques.

Chapter 2 Bio-safety Management Organizational Structure

Article 4 The Bio-safety Management Committee consists of one chairman, two deputy chairmen (appointed by the Director-General), and several members (at least three, with at least one representative recommended by the relevant department heads). The Institute's Bio-safety Office is the executive agency of the Biological Safety Management Committee, consisting of one head and one secretary (appointed by the President), with the Director of Office serving as a member of the Bio-safety Management Committee. The Institute's Bio-safety Committee and/or Bio-safety Office are established by each institute based on the scale of experiments, with at least one full-time staff member responsible, and the head shall be someone with a relevant professional background. The Institute's Bio-safety Office is the executive agency of the Institute's Bio-safety Committee. If there is no Bio-safety Committee, the Bio-safety Office of the Institute is responsible for executing bio-safety matters. The Institute's Bio-safety Office accepts business guidance from the Institute's Bio-safety Office and leadership from the Institute's Bio-safety Management Committee. The laboratory liaison officer is responsible for the laboratory's bio-safety and is the laboratory's bio-safety administrator.

Article 5 Committee members serve a term of three years. In case of member resignation or changes, the member list must be promptly replenished or updated.

Chapter 3 Working Responsibilities

Article 6 The Bio-safety Management Committee is responsible for consulting, guiding, evaluating, and supervising laboratory-related biological safety matters.

(I) Responsibilities of the Committee Chairman: responsible for the management of bio-safety in the Institute, establishing a bio-safety management system, implementing the assignment of bio-safety management responsibilities and personnel; convening regular bio-safety management meetings, making decisions on major issues related to laboratory bio-safety; approving and issuing important documents such as laboratory bio-safety manuals and biological hazard assessments; chairing the revision of this Charter.

(II) Responsibilities of the deputy chairmen of the Committee: assist the chairman in managing the Committee; when necessary, convene meetings on behalf of the President; maintain contact with the Bio-safety Office and supervise the work of the Committee.

(III) Responsibilities of the members of the Bio-safety Management Committee

1. Under the convocation of the chairman and deputy chairmen, participate in meetings, review documents such as laboratory Bio-safety manuals, Bio-safety regulations, and operating procedures.

2. Under the delegation of the chairman and deputy chairmen, guide the Institute's Bio-safety Management Office, the Institute's Bio-safety Committee, and research institutes' Bio-safety Office to carry out safety and health surveillance, quality management, and personnel training work.

(IV) Responsibilities ofthe Institute's Bio-safety Management Office:

1. Document control: review and manage laboratory Bio-safety manuals, Bio-safety regulations, operating procedures, and SOPs; track and interpret the latest developments in laboratory Bio-safety management at home and abroad, and timely convey them to ensure that laboratory operations comply with relevant national standards.

2. Safety: review contingency plans for laboratory biological safety emergencies, conduct risk assessments for actual or potential safety incidents in laboratories, provide recommendations for handling and improvement; supervise and inspect the implementation of regulations on laboratory Bio-safety protection, microbial strain preservation and use, three-waste disposal, and disinfection and sterilization; guide emergency handling oflaboratory Bio-safety incidents.

3. Health surveillance: responsible for regular surveys and understanding ofthe health status and health surveillance of laboratory personnel, decide on necessary special medical monitoring and preventive medical procedures; assist in providing emergency assistance and treatment measures for accidents.

4. Quality management: review laboratory Bio-safety-related operating procedures, regularly supervise and inspect the implementation of related management systems and operating procedures, and urge rectification; responsible for organizing Bio-safety reviews and risk assessments ofrelevant research programs.

5. Personnel training: organize education, training, and assessment of Bio-safety-related laws, regulations, and basic first aid knowledge for personnel involved in Bio-safety experiments in the Institute; implement Bio-safety responsibilities.

Article 7 The Bio-safety Office of each institute is the executive agency of the Bio-safety Management Committee and is responsible for implementing committee resolutions. Its main responsibilities include: supervising the implementation of relevant management systems for laboratory personnel admission, training, and health surveillance; responsible for laboratory Bio-safety and technical regulations, and consulting work; responsible for handling laboratory safety incidents and preparing written reports for filing.

Article 8 The laboratory Bio-safety administrator is the research group leader or laboratory head responsible for comprehensive Bio-safety work, determining and authorizing entry personnel for the laboratory; supervising the implementation of relevant regulations and SOPs, correcting violations, and having the right to terminate experiments; appointing laboratory Bio-safety administrators to specifically conduct daily supervision and management of laboratory Bio-safety; on-site handling and investigation of laboratory safety incidents, reporting to the Bio-safety Office; conducting Bio-safety assessment reviews of relevant laboratory research programs and operating procedures before implementation.

(I) Laboratory heads shall be responsible for the safety of all employees, visitors, contractors, communities, and the environment within the scope of their laboratories.

(II) Laboratory heads shall establish clear admission policies and proactively inform all employees, visitors, and contractors of potential risks they may face.

(III) Laboratory heads shall provide continuous training and continuing education opportunities for employees to ensure they are capable of performing their assigned duties.

(IV) Laboratory heads shall respect the personal rights and privacy of employees in Bio-safety management work.

Article 9 According to the regulations formulated by the Bio-safety Committee, the laboratory Bio-safety responsible person shall be responsible for the design, implementation, maintenance, and improvement of the laboratory Bio-safety management system under the guidance ofthe Bio-safety Office.

(I) Laboratory Bio-safety administrators, appointed by the laboratory Bio-safety responsible person, shall be responsible for developing and maintaining laboratory Bio-safety plans, contingency plans, and training plans; correcting behaviors that violate Bio-safety operating procedures; coordinating relevant investigations in the event of accidents; inspecting and supervising the effective management and safety disposal of laboratory wastes; conducting regular internal safety inspections of technical methods, procedures, schemes, materials, and equipment in the laboratory; inspecting and supervising the implementation of disinfection and sterilization measures in the laboratory.

(**I**) Laboratory personnel and visitors shall actively receive education, training, and guidance from the Institute's various levels ofBio-safety management committees and Bio-safety offices. Fully understand and comprehend the risks associated with their work. Consciously comply with the management regulations and requirements of the laboratory. Under conditions permitting physical health, accept the laboratory's immunization plan and other health management regulations. Voluntarily report personal conditions that may be unsuitable for specific tasks. Do not violate management regulations under any pressure. Have the responsibility and obligation to avoid causing Bio-safety incidents or accidents due to personal reasons. If there is suspicion ofpersonal infection, it shall be reported immediately. Identify any hazards or deviations from Bio-safety management regulations proactively and report them immediately.

Article 10 The laboratory safety management system shall be adapted to the scale of the laboratory, the complexity of activities, and the risks involved. Effective measures and regulations shall be taken and specified for the following aspects: personnel training and assessment; maintenance, procurement, updating, and disposal of equipment and instruments; implementation, tracking, and research of safety measures.

Article 11 Laboratory administrators are responsible for the writing of policies, procedures, plans, programs, and guidance documents, and laboratory heads are responsible for review. The documents shall be disseminated to all laboratory users, personnel, and managers by the laboratory administrator and ensured to be understandable and implementable.

Article 12 Bio-safety management system documents typically include management manuals, procedural documents, operating instructions, operating records, and safety manuals for quick use by on-site personnel.

Article 13 Laboratory heads and principle investigators shall guide all personnel in the use of relevant safety management system documents and implementation document requirements, and assess their understanding and application abilities.

Chapter 4 Meeting System

Article 14 Bio-safety Management Committee Meetings shall be convened with the attendance of two-thirds (inclusive) or more of the members; resolutions of the meetings shall be made public only with the consent of two-thirds (inclusive) or more of the members with voting rights present.

Article 15 Bio-safety Management Committee Meetings shall be held approximately every six months to summarize the work of the previous phase, arrange and deploy the work of the next phase. In the event of a Bio-safety accident in the Bio-safety laboratory of the unit, changes in national Bio-safety laws and regulations, and other events requiring a resolution from the Bio-safety Management Committee, an interim meeting may be convened.

Article 16 The chairman shall preside over the meeting, and in the absence of the President, the deputy chairmen shall preside over the meeting on behalf of the President.

Article 17 The Bio-safety Office is a permanent executive agency of the Bio-safety Management Committee. During the adjournment of the Bio-safety Management Committee, the Bio-safety Office shall, in accordance with the resolutions of the Bio-safety Management Committee, perform Bio-safety management functions within its jurisdiction and make temporary decisions. All temporary decisions shall be reported at the next Bio-safety Management Committee Meeting and become formal resolutions only with the approval of the meeting.

Article 18 Attendance and meeting minutes shall be formed at each meeting, and supervision by internal and external personnel shall be accepted.

Chapter 5 Supervision and Inspection

Article 19 The Bio-safety Management Committee has the right to request rectification within a time limit and record serious violations of Bio-safety-related regulations or major Bio-safety accidents by departments or individuals.

Article 20 Committee members have the right to propose amendments to this Charter, and if more than two-thirds of all members agree, the amendment shall take effect.

Article 21 The Bio-safety Management Committee accepts complaints and suggestions from the public regarding Bio-safety management work at SIAT, promptly communicates and negotiates with laboratory administrators through the Bio-safety Office, and retains written reports.

Chapter 6 Bio-safety Management System Documents

Article 22 The basic elements of Bio-safety management system documents include management measures, personnel involved, implementation environment, facilities and equipment, infectious substances, physical and chemical hazards, emergency measures, operating standards and methods, supporting data, and records.

Article 23 The formulation and modification of all documents shall be primarily based on current effective international, national, Guangdong provincial, and Shenzhen municipal laws, regulations, rules, etc., especially regarding the management of live pathogenic microorganisms or components, experimental animals, human materials, hazardous chemicals, anesthetics, psychotropic drugs, and related waste disposal requirements.

Article 24 The laboratory Bio-safety responsible person must, based on the characteristics of this discipline and laboratory, be responsible for drafting a safety manual (quick reference document for rapid reading, referring to existing relevant documents within the Institute) applicable to this laboratory, for laboratory personnel to read and ensure its availability in the work area at all times. The safety manual includes (but is not limited to) the following contents: emergency phone numbers and contacts, laboratory floor plans, emergency exits, evacuation routes, laboratory signage system; biological, radiation, mechanical, electrical, and chemical hazards; emergency medical treatment measures; fire protection; personal protective equipment; handling of hazardous waste, provisions and procedures for incidents and accidents.

Article 25 Each laboratory shall develop targeted and operational Standard Operating Procedures (SOP) according to the specific experimental objects, the completeness of laboratory facilities, and the level of personnel qualifications, which all personnel must be proficient in and strictly adhere to. The requirements for SOP formulation content include (but not limited to): user permissions and qualification requirements, potential hazards, functionality of facilities and equipment, objectives of activities, specific operating procedures, protective and safe operating methods, emergency measures, basis for document formulation, precautions, etc.

Article 26 Each laboratory shall formulate laboratory access regulations according to its specific circumstances, and prominently display them at the laboratory entrance, which all entering personnel must comply with. Access regulations shall include (but not be limited to) the following contents: scope of application, responsible person and scope of authority, access standards, norms to be followed when entering the laboratory.

Article 27 Laboratories shall establish personal and technical files for all personnel, including personal identification information, job risk descriptions and informed consent, learning and training materials, annual assessment materials, personal health information, etc.

Chapter 7 Risk Assessment

Article 28 Risk assessment aims to eliminate, reduce, and control laboratory risks to the maximum through dynamic management of laboratory risks.

Article 29 The Bio-safety Management Committee is responsible for overall management of laboratory and laboratory-related hazards; the laboratory Bio-safety responsible person and Bio-safety administrators jointly conduct regular hazard identification and risk assessments of this laboratory and related laboratory activities, formulate measures and plans to effectively control existing risks, review the effectiveness, and report to the Bio-safety Management Committee.

Article 30 Laboratory management shall solicit opinions from laboratory personnel and instruments and equipment suppliers when conducting risk management.

Article 31 Laboratory Bio-safety administrators shall truthfully fill out and update the laboratory risk registration form for archival purposes.

Article 32 Hazards typically arise from the following: known or unknown characteristics of biological factors; defects, wear, or failures of facilities and equipment; human errors in operation and failure to report in a timely manner; unavoidable accidents and incidents; misuse, malicious use, and improper disposal of experimental materials.

Article 33 Assessors can identify hazards through regular inspection of the work environment and observation of various factors such as personnel, instruments and equipment, biological samples, chemicals, and list all hazards found; inquire with personnel about safety issues encountered and unreported shortcomings orally or through questionnaires; obtain available information from industry associations, trade unions, technical experts, etc.; obtain hazard information from instruments and equipment manufacturers and suppliers.

Article 34 Risk assessment is required in the following situations: Uncertainty about how hazards may cause harm; the same activity is associated with multiple hazards, and it is not known whether these hazards will interact to produce new or more significant risks; any changes in the work area may affect the effectiveness of existing control measures.

Article 35 In practice, risk assessment is not required in the following cases and risk control can be carried out directly: specific risk control is required by existing regulations, then follow these requirements directly; relevant practice procedures or other guidance indicate applicable control methods for the laboratory, then follow the relevant guidance; relevant risk control measures exist in the industry and are applicable to the laboratory, then adopt them directly.

Article 36 Risk levels are divided into 5 levels: extremely dangerous, work cannot continue; highly dangerous, immediate rectification is required; moderately dangerous, rectification is required; slightly dangerous, attention is required; minor danger, acceptable.

Article 37 Risk levels for hazard sources can be determined based on: violation of laws and regulations; accidents that have occurred without effective measures being taken; serious violations or major hidden dangers; subjective determination by the Bio-safety Management Committee or laboratory head, etc.

Article 38 Regular risk assessments are required. When the following situations occur, additional assessments of the entire system or specific elements are required:

(I) Carrying out new laboratory activities or intending to change evaluated laboratory activities (including related facilities, equipment, personnel, scope of activities, management, etc.), risk assessment shall be conducted in advance or re-conducted;

(II) When accidental events or accidents involving biological risks occur (even if no harm is caused);

(III) When relevant policies, regulations, standards, etc., change;

(IV) When significant changes occur in standard operating procedures;

(V) When hazards or Bio-safety issues not found in the original assessment report are discovered;

Article 39 If the risk assessment results determine that the entire system is to be controlled, comprehensive control measures will be taken, such as formulating or modifying rules and procedures, rewards and punishments, training; if the assessment results determine that specific hazards are to be controlled, corresponding technical and managerial measures will be taken to control them.

Article 40 Regular reassessment of risks to determine the effectiveness of risk control measures is required. If the control measures specified in the risk management plan fail to achieve the expected results and residual risks have not reached an acceptable level, flexible measures shall be implemented based on actual conditions, including mitigation, prevention, transfer, or avoidance of risks, until the risks are effectively controlled.

Chapter 8 Bio-safety Management of Experimental Projects

Article 41 For experimental projects involving biological hazards, relevant materials must be submitted for review based on *Bio-safety Management of Experimental Projects* when the project is proposed.

Article 42 The relevant experimental personnel shall strictly follow the risk control methods proposed by the Committee and the laboratory Bio-safety responsible person, as well as the experimental material management requirements and related operating procedures; the laboratory Bio-safety administrator is responsible for regularly tracking the effectiveness of risk control.

Article 43 The Bio-safety administrator conducts preliminary reviews of content and format to ensure completeness and correctness of information, and conducts initial reviews. If the experimental project does not involve various types of hazards, or if the hazards involved have been assessed and risks eliminated with existing control methods, it does not need to be reviewed by the Bio-safety Management Committee and is considered approved; if the hazard is newly identified, not assessed by the laboratory or Bio-safety committee, or lacks effective risk control methods, after review by the Bio-safety Office of the Institute, it is submitted to the Bio-safety Management Committee for discussion.

Article 44 The Committee's review follows the requirements of *Risk Assessment* for risk assessment, discusses whether there are control methods to reduce or eliminate risks, and truthfully records the review results, including risk assessment results, control methods, expected control effects, whether to allow related experiments to proceed, and issues to be noted during the experiment. When necessary, a full committee meeting may be convened for discussion.

Article 45 Relevant experiments can only proceed after evaluation and approval.

Article 46 If experiments are carried out without passing the review and without making corresponding control measures for potential risks, the responsibility lies with the experimental personnel and their research groups.

Chapter 9 Instruments and Equipment Management

Article 47 This System applies to all laboratory-related instruments and equipment, including but not limited to microbial and cell culture incubators, constant-temperature shakers, refrigerators, centrifuges of various specifications, fume hoods, Bio-safety cabinets, vortex mixers, crushers, sterilizers, cage washers and eye washers, sprinkler, emergency protective equipment, etc.

Article 48 Laboratory personnel must regulate their work according to this System.

Article 49 Laboratory administrators are responsible for the daily operation, maintenance, and supervision of instruments and equipment use, and arrange for professionals to conduct regular inspections.

Article 50 All facilities in the laboratory shall comply with relevant construction and installation regulations, and all instruments used shall be certified for safe use.

Article 51 Large-scale and valuable instruments and equipment and precision instruments in the laboratory are assigned to personnel familiar with equipment operation, use, and maintenance by the laboratory head for safekeeping, registration, and documentation. Users and maintenance personnel of instruments and equipment must undergo professional technical training or be assigned by the laboratory head.

Article 52 Instruments and equipment shall be used within the validity period of verification and calibration, and self-check or forced inspection shall be conducted according to the requirements of the calibration cycle for equipment with high frequency ofuse.

Article 53 For main instruments and equipment, we shall establish use records, operating procedures, precautions, relevant technical parameters, and maintenance records, and place them in a visible and easy-to-read position next to the instruments. Users of instruments must strictly follow the operating procedures and keep records of instruments and equipment use.

Article 54 The power supply used for instruments and equipment must meet the power supply requirements of the instruments and equipment. Instruments and equipment with electrical use must be properly grounded. Power sockets shall not be overloaded. When instruments and equipment experience power failure protection during use, power shall only be restored after the cause of the power failure is identified. Equipment with electrical safety hazards, such as leakage, damaged power sockets, poor grounding, and poor insulation, is not allowed to be used.

Article 55 In case of abnormalities during the use of instruments and equipment, it shall be promptly recorded in the instruments' random file, and repairs must be performed by professionals, with maintenance records kept.

Article 56 After the use of instruments and equipment is completed, they must be inspected and cleaned according to routine upkeep to keep them in good condition.

Article 57 All instruments and equipment shall be affixed with unique identification and signs indicating approved use, restricted use, and prohibited use. Autoclaves and large washing machines must have emergency operation procedures prominently displayed.

Article 58 Long-term electrical equipment (such as refrigerators, incubators) shall be regularly inspected.

Article 59 Instruments and equipment that may produce certain hazards due to malfunctions or operational errors must be equipped with corresponding safety protection devices.

Article 60 Before using instruments and equipment that directly contacts contaminants, it must be confirmed that the corresponding safety protection device can be used normally. After completing experimental work, instruments and equipment that come into contact with contaminants must be cleaned and disinfected accordingly.

Article 61 A designated person shall be assigned to regularly maintain and manage safety equipment and experimental facilities/equipment to ensure that they are in good working condition. (For example, Bio-safety cabinets shall undergo routine testing once a year, with special attention to regular replacement of high-efficiency filters. Regular maintenance and inspection of centrifuge buckets and rotors shall be carried out).

Article 62 Long-unused electrical instruments and equipment shall be periodically powered on to dehumidify.

Article 63 Refrigerators shall be regularly defrosted and cleaned, and problems shall be repaired promptly. Personal items and items unrelated to experiments are prohibited from being stored in laboratory refrigerators, especially food.

Article 64 Inspection, maintenance, and use records of instruments must be properly kept for accident investigation purposes.

Article 65 Emergency protective equipment, such as fire extinguishers and fire masks, must be ensured to be within their validity period; emergency showers and eye washers need to be wiped and flushed regularly to ensure clean water quality, smooth water flow, and relevant maintenance records shall be kept.

Chapter X Experimental Material Management

Article 66 When selecting, purchasing, collecting, receiving, inspecting, using, and storing experimental materials in the laboratory, their quality certification shall be inspected to ensure that the quality meets standards and safety is ensured.

Article 67 Regular evaluation of suppliers of important consumables and services shall be conducted, and evaluation records and a list of approved suppliers shall be kept.

Article 68 A list of all hazardous materials shall be established, including their sources, receipt, use, disposal, storage, transfer, authorization for use, time, quantity, as well as destruction, scrapping, etc. Relevant records shall be kept by the laboratory safely for no less than 20 years.

Article 69 Laboratories using hazardous materials shall have reliable storage facilities, physical measures, management procedures, and personnel to ensure material safety and security. Once accidents such as material leakage, loss, or theft are discovered, contingency plans shall be activated immediately.

Article 70 Laboratory hazardous materials shall be used and managed in accordance with the relevant national regulations, such as the *General Rules for the Storage of Common Chemicals* (GB15603-1995).

Chapter XI Biochemical Reagent Management

Article 71 Flammable, explosive, and dangerous substances shall be issued according to experimental needs and shall not be stockpiled in the laboratory but placed in a cool and ventilated place.

Article 72 Highly toxic reagents, psychotropic drugs, and anesthetics shall be managed with dual-lock, requiring approval from the Center's responsible person and Office of Laboratory Management before issuance. When issued, two people shall jointly weigh and register the amount used.

Article 73 All reagents must be clearly labeled, indicating the name, concentration, potential hazards, as well as the manufacture, opening, expiration, or disposal date ofthe chemicals.

Chapter XII Experimental Animal Management

Article 74 The introduction of experimental animals shall comply with the Regulations on the Management of Experimental Animals and the *Guangdong Province Regulations on the Management of Experimental Animals* and possess an animal qualification certificate.

Article 75 Unless necessary for work and approved by the Experimental Animal and Management Committee and Bio-safety Management Committee, the introduction of animals carrying unknown microbial and parasitic backgrounds is prohibited; introduced animals must undergo strict isolation quarantine observation according to the *Regulations on the Management of Experimental Animals* and the *Guangdong Province Regulations on the Management of Experimental Animals*.Suspected sick animals shall be promptly inspected and handled.

Article 76 Experimental animals in the facility shall undergo regular health monitoring every year, and sentinel animals shall be tested regularly.

Article 77 In case of abnormal death of experimental animals, the cause shall be promptly investigated and recorded, and appropriate measures shall be taken according to the situation.

Article 78 Experimental animals shall not be kept outside the scope of the license.

Article 79 Laboratories feeding small animals such as mice shall have automatic traps to prevent escaped animals.

Chapter XIII Genetically Modified Organism Management

Article 80 Genetically modified organisms obtained using recombinant DNA technology as experimental materials, such as transgenic and gene knockout organisms, shall avoid escape or entry into the market.

Article 81 The operation of slow viruses and adenovirus vectors as recombinant DNA technology carriers shall be conducted at a protection level overall based on the hazard level and protection requirements of the parent virus. After proving the harmless nature of the recombinant, the protection level can be reduced as appropriate.

Chapter XIV Microorganism Management

Article 82 Laboratories using microorganisms as experimental materials shall strictly carry out activities in accordance with the *Regulations on Bio-safety Management of Pathogenic Microorganism Laboratories* (State Council Decree No. 424).

Article 83 Various types of pathogenic microorganism experiments shall be conducted in corresponding Bio-safety level laboratories, referring to the Ministry of Health's *List of Human Infectious Pathogenic Microorganisms* and the Ministry of Agriculture's *Classification List of Animal Pathogenic Microorganisms*.

Chapter XV Laboratory Waste Management

Article 84 The classification, recycling, and disposal of various laboratory wastes shall strictly adhere to relevant regulations such as the *Regulations on the Management of Medical Wastes* (State Council Decree No. 380), the *Management Measures of Medical and Health Institutions on Medical Wastes* (Ministry of Health Decree No. 36), the *Standard of Packaging Bags, Containers and Warning Symbols Specific to Medical Waste* (State Environmental Protection Administration HJ421- 2008), the *Regulations on the Safety Management of Hazardous Chemicals* (State Council Decree No. 591), and the *General Requirements for Plant Bio-safety Laboratory* (GB/T27428-2022).

Article 85 The handling measures for various laboratory wastes, including microbial cultures, animal tissues and carcasses, plant tissues and cultures, and biochemical waste, shall be formulated, implemented, and recorded by the laboratory head, with supervision from the Bio-safety Management Committee.

Article 86 Laboratories shall ensure the availability of sharps containers for disposal. Used sharps and sharp waste shall be disposed of in sharps containers, with attention paid to not exceed three-fourths of the total volume.

Chapter XVI Bio-safety Inspection

Article 87 The Bio-safety Management Committee shall organize a comprehensive inspection of Bio-safety in level two Bio-safety laboratories at least every six months. The inspection content includes the operation of the Bio-safety management system, the completeness and implementation of Bio-safety management regulations, the status of laboratory facilities, equipment, and personnel, the functionality and status of emergency equipment, alarm systems, and evacuation procedures, the protection and control of flammable, infectious, radioactive, and toxic substances, and the disposal of waste.

Article 88 The Bio-safety Committee or Bio-safety Office of the Institute shall conduct routine inspections at least every six months. The inspection content includes the execution of the Bio-safety management system, the implementation of Bio-safety governance regulations, the status of facilities, equipment, and personnel, the functionality and status of emergency equipment, alarm systems, and evacuation procedures, the protection and control of flammable, infectious, radioactive, and toxic substances, and the disposal of waste.

Article 89 The laboratory Bio-safety responsible person is responsible for the comprehensive management of laboratory Bio-safety, inspecting and supervising the work of Bio-safety administrators, conducting quarterly inspections of departmental Bio-safety work. The inspection content includes the work records of Bio-safety administrators, the transportation, storage, use, and disposal of bacterial (toxic) strains, the disinfection and sterilization of Bio-safety laboratories, the disposal of infectious wastes, the operation and maintenance of Bio-safety equipment, the reserve of protective materials, and personnel health surveillance.

Article 90 The laboratory Bio-safety administrator is responsible for the daily Bio-safety supervision and inspection of the laboratory. The content includes the implementation of Bio-safety management system, compliance with personal protective requirements, and the standardization of Bio-safety operations by laboratory personnel, as well as prompt identification and correction of violations to prevent Bio-safety accidents.

Article 91 When the laboratory management finds any non-compliance with the laboratory's Bio-safety management system requirements, corresponding measures shall be taken according to the seriousness of the situation, and if necessary, reported to the Bio-safety Management Committee.

Article 92 The Bio-safety Management Committee has the right to request relevant laboratories to promptly correct any issues identified during inspections. When necessary, corrective measures or rectifications shall be formulated and implemented, followed by tracking and verification, and documentation of changes to the management system as a result.

Chapter XVII Bylaw

Article 93 When national laws, regulations, norms, and local policies change, the latest laws, regulations, norms, and policies shall prevail.

Article 94 This System shall come into effect from the date of issuance, and the original *Management System of Shenzhen Institute of Advanced Technology, Chinese Academy of Sciences on Bio-safety* (SYK ZI [2017] No. 27) shall be repealed simultaneously.