Appendix # Comparison with OECD GLP Principle No. 1 and CSCL GLP Compliance Criteria

No. 1 OECD Principles of Good Laboratory Practice (as revised in 1997)	The Good Laboratory Practice for test facilities conducting tests of New Chemical Substances etc.
SECTION I **INTRODUCTION** **Preface** Government and industry are concerned about the quality of non-clinical health and environmental safety studies upon which hazard assessments are based. As a consequence, OECD Member countries have established criteria for the performance of these studies. To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member countries have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980, an international group of experts established under the Special Programme on the Control of Chemicals developed the "OECD Principles of Good Laboratory Practice" (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These Principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)]. In 1995 and 1996, a new group of experts was formed to revise and update the Principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original Principles adopted in 1981. The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.	**Chapter 1 General Rules** **Purposes** Article 1. These standards are established in order to ensure the quality of the study results by prescribing basic principles to be followed by the test facility when conducting the studies stipulated in the Ministerial Ordinance Specifying Items for Tests Pertaining to New Chemical Substances and Studies Pertaining to the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances (Prime Minister's Office, Ministry of Health and Welfare, Ministry of International Trade and Industries, Ministerial Ordinance No. 1 of 13th July, 1974).
1. Scope These Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field. Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.	**Scope** Article 2 These standards shall apply to the studies stipulated in the Ministerial Ordinance Specifying Items for Tests Pertaining to New Chemical Substances and Studies Pertaining to the Hazardous Properties of Priority Assessment Chemical Substances and Monitoring Chemical Substances.
2. Definitions of Terms 2.1 *Good Laboratory Practice* 1. Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. 2.2 *Terms Concerning the Organisation of a Test Facility*	**Definition of Terms**

	1. *Test facility* means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.	(2) Test facility means the persons, premises and its operational unit(s) that are necessary for conducting the study. For a study which is conducted at more than one site (hereinafter referred to as a "Multi-Site Study"), the test facility comprises the sites, which individually or collectively can be considered to be test facilities.
	2. *Test site* means the location(s) at which a phase(s) of a study is conducted.	
	3. *Test facility management* means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice.	(3) Test Facility Management means the person(s) who has the authority and responsibility for the organisation and functioning of the test facility according to these standards.
	4. *Test site management* (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.	(4) Test Site Management (limited to cases where he is appointed) means the person(s) responsible for ensuring that the delegated test facility are conducted in accordance with these standards.
	5. *Sponsor* means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.	(5) Sponsor means an entity which commissions the study to the test facility.
	6. *Study Director* means the individual responsible for the overall conduct of the nonclinical health and environmental safety study.	(6) Study Director means the individual responsible for the overall conduct of the study.
	7. *Principal Investigator* means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.	(7) Principal Investigator (limited to cases where he is appointed) means an individual who, for a Multi-Site Study, acts on behalf of the Study Director and has a certain responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report and ensuring that these standards are followed.
	8. *Quality Assurance Programme* means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.	(8) Quality Assurance Unit means an organisation which is independent of study conduct and is designed to assure the Test Facility
	9. *Standard Operating Procedures (SOPs)* means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.	(9) Standard Operating Procedures (SOPs) means documents which describe how to perform activities not specified in detail in study plans or test guidelines.
	10. *Master schedule* means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.	(10) Master schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a relevant test facility.
2.3	*Terms Concerning the Non-Clinical Health and Environmental Safety Study*	
	1. *Non-clinical health and environmental safety study*, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.	(1) Safety study (hereinafter referred to as "study") means an experiment or set of experiments to obtain data on the properties or the safety of the test substance intended for submission to Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, and Ministry of the Environment, associated with the report.
	2. *Short-term study* means a study of short duration with widely used, routine techniques.	
	3. *Study plan* means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.	(11) Study plan means a document which defines the objectives and experimental design for the conduct of the study, and, if any amendments are made, includes those amendments.
	4. *Study plan amendment* means an intended change to the study plan after the study initiation date.	(12) Study plan amendment means an intended change to the study plan after the study initiation date.
	5. *Study plan deviation* means an unintended departure from the study plan after the study initiation date.	(13) Study plan deviation means an unintended departure from the study plan after the study initiation date.
	6. *Test system* means any biological, chemical or physical system or a combination thereof used in a study.	(14) Test system means any system of analytical or measurement equipment for physical/chemical data collection (hereinafter referred to as "physical/chemical test systems"), any system of animal/botanical/microbial organisms to be used in a study, or part of thereof, or any system of cultured cells (hereinafter referred to as

	"biological test systems") or a combination thereof used in a study.
7. *Raw data* means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10, below.	(15) Raw data means the results of the original observations, and all original test facility records and documentation, or verified copies thereof, which are necessary for the reconstruction of the study and its evaluation. Raw data also include, for example, photographs, microfilm, microfiche copies, computer records, recording tapes, recorded data from automated instruments, or any other electronic medium that has been recognised as capable of providing secure storage of information for a time period as stated in Article 32, below.
8. *Specimen* means any material derived from a test system for examination, analysis, or retention.	(16) Specimen means any material derived from a test system for examination, analysis, or retention.
9. *Experimental starting date* means the date on which the first study specific data are collected.	(17) Experimental starting date means the date on which the first study-specific data are collected.
10. *Experimental completion date* means the last date on which data are collected from the study.	(18) Experimental completion date means the last date on which data are collected from the study.
11. *Study initiation date* means the date the Study Director signs the study plan.	(19) Study initiation date means the date the Study Director signs or stamps the study plan.
12. *Study completion date* means the date the Study Director signs the final report.	(20) Study completion date means the date the Study Director signs or stamps the final report.
2.4 *Terms Concerning the Test Item*	
1. *Test item* means an article that is the subject of a study.	(21) Test substance means a chemical substance that is the subject of a study.
2. *Reference item* ("control item") means any article used to provide a basis for comparison with the test item.	(22) Reference substance means any chemical substance used to compare with the test substance.
3. *Batch* means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.	(23) Batch means a specific quantity or lot of a test substance or reference substance produced within a certain period of time in such a way that it could be expected to be of a uniform character.
4. *Vehicle* means any agent which serves as a carrier used to mix, disperse, or solubilize the test item or reference item to facilitate the administration/ application to the test system.	(24) Vehicle means any substance which serves as a carrier used to mix, disperse, or solubilise the test substance or reference substance to facilitate the exposure or administration to the test system.
SECTION II **GOOD LABORATORY PRACTICE PRINCIPLES**	
1. Test Facility Organisation and Personnel	**Chapter 2 Organisation and Personnel**
1.1 *Test Facility Management's Responsibilities*	Test Facility Management's Responsibilities
1. Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.	Article 4 Each Test Facility Management should ensure that these standards are complied with, in its test facility and, at a minimum, it should:
2. At a minimum it should:	
a) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice;	(1) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these standards;
b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;	(2) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;
c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;	(3) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;
d) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;	(4) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;
e) ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures;	(5) ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures;

f) ensure that there is a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these Principles of Good Laboratory Practice;	(6) ensure that a Quality Assurance Personnel is designated and assure that the quality assurance responsibility is being performed in accordance with these standards;
g) ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated. Replacement of a Study Director should be done according to established procedures, and should be documented.	(7) designate an individual with the appropriate qualifications, training, and experiences as the Study Director before each study is initiated. Replacement of a Study Director should be done according to established procedures, and should be documented.
h) ensure, in the event of a multi-site study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented.	(16) ensure, in the event of a Multi-Site Study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented.
i) ensure documented approval of the study plan by the Study Director;	(8) ensure the documented approval of the study plan by the Study Director;
j) ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel;	(9) ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel;
k) ensure the maintenance of an historical file of all Standard Operating Procedures;	(10) ensure the maintenance of a historical file of all Standard Operating Procedures;
l) ensure that an individual is identified as responsible for the management of the archive(s);	(11) designate a person responsible for the management of archive(s);
m) ensure the maintenance of a master schedule;	(12) maintain a master schedule;
n) ensure that test facility supplies meet requirements appropriate to their use in a study;	(13) ensure that test facility supplies meet requirements appropriate to their use in a study;
o) ensure for a multi-site study that clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality Assurance Programme(s) and study personnel;	(17) ensure for a Multi-Site Study that clear lines of communication exist between the Study Director, Principal Investigator(s) (limited to cases where he is appointed), the Quality Assurance personnel and study personnel;
p) ensure that test and reference items are appropriately characterised;	(14) ensure that test and reference substances are appropriately characterised and controlled;
q) establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.	(15) establish the procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these standards.
	Test Site Management's Responsibilities
3. When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2 g), i), j) and o).	Article 5 When a phase of a study is conducted at any of the test facilities, each Test Site Management (limited to cases where he is appointed) should have all the responsibilities as defined in Article 4 with the following exceptions: (6), (7), (8), (9), (16) and (17).
1.2 *Study Director's Responsibilities*	**Study Director's Responsibilities**
1. The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.	Article 6 The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report. These responsibilities should include at a minimum, the following functions. The Study Director should:
2. These responsibilities should include, but not be limited to, the following functions. The Study Director should:	
a) approve the study plan and any amendments to the study plan by dated signature;	(1) approve the study plan and any amendments to the study plan by dating and affixing signature or stamp (seal); amendments to the study plan, if any, should clearly state the details of and reasons for the amendments.
b) ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study;	(2) ensure that the Quality Assurance Unit have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance Unit as required during the conduct of the study;
c) ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;	(3) ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;
d) ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the	(10) ensure that the study plan and the final report for a Multi-Site Study identify and define the role of any Principal Investigator(s) (limited to cases where he is appointed) and any test facilities involved in the conduct

conduct of the study; e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study; f) ensure that all raw data generated are fully documented and recorded; g) ensure that computerised systems used in the study have been validated; h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these Principles of Good Laboratory Practice; i) ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.	of the study; (4) ensure that the procedures specified in the study plan are followed, and when any deviations from the study plan and Standard Operating Procedures are found, record and assess the impact on the quality and integrity of the study, and take appropriate corrective action if necessary; Above should be documented. (5) ensure that all raw data generated are fully documented and recorded on paper or in appropriate electronic media; (6) ensure that necessary measures have been taken in order for the computerised systems used in the study to work properly; (7) sign or stamp and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these standards; (8) ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting materials are archived; (9) keep him/her away from work to avoid any possible adverse influence on the study, if the study personnel has any health problem which could affect adversely the conduct of the study, until it improves.
1.3 *Principal Investigator's Responsibilities* The Principal Investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice.	**Principal Investigator's Responsibilities** Article 7. The Principal Investigator (limited to cases where he is appointed) will ensure that the delegated phases of the study are conducted in accordance with these standards.
1.4 *Study Personnel's Responsibilities* 1. All personnel involved in the conduct of the study must be knowledgeable in those parts of the Principles of Good Laboratory Practice which are applicable to their involvement in the study. 2. Study personnel will have access to the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s). 3. All study personnel are responsible for recording raw data promptly and accurately and in compliance with these Principles of Good Laboratory Practice, and are responsible for the quality of their data. 4. Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.	**Study Personnel's Responsibilities** Article 8. Study personnel's responsibilities are as follows: (1) All personnel involved in the conduct of the study must be knowledgeable in those parts of these standards which are applicable to their involvement in the study. (2) Study personnel will comply with the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s). (3) All study personnel are responsible for recording raw data promptly and accurately and in compliance with these standards, and are (4) Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. Study personnel having any health problems which could affect adversely the conduct of the study should communicate that to the appropriate person.
2. Quality Assurance Programme 2.1 *General* 1. The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice. 2. The Quality Assurance Programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures. 3. This individual(s) should not be involved in the conduct of the study being assured.	**Chapter 3 Quality Assurance Unit** **General** Article 9. The test facility should have documented Quality Assurance Provisions to assure that studies performed are in compliance with these standards. 2. The Quality Assurance Unit should comprise individuals who are designated by and directly responsible to the Test Facility Management and who are familiar with the test procedures. 3. The persons in charge above should not be involved in the conduct of the study being assured.

	4. Quality Assurance Standard Operating Procedures should specify, at a minimum, the following functions: (1) Study audits or inspections (2) Inspection of the test facility and of the archive(s) (3) Audit of the final report (4) Preparation of the Quality Assurance Report (5) Audits or inspections mainly for the process related to the quality of the study 5. Every time the Standard Operating Procedures in the preceding paragraph is prepared or revised, it shall be retained with the date and reason.
2.2 *Responsibilities of the Quality Assurance Personnel* 1. The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should: a) maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule; b) verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented; c) conduct inspections to determine if all studies are conducted in accordance with these Principles of Good Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed. Inspections can be of three types as specified by Quality Assurance Programme Standard Operating Procedures: - Study-based inspections, - Facility-based inspections, - Process-based inspections. Records of such inspections should be retained. d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies; e) promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable; f) prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.	**Quality Assurance Personnel's Responsibilities** Article 10. Quality Assurance Personnel's responsibilities include, at a minimum, the following functions. They should: (1) maintain copies of all approved study plans, Standard Operating Procedures and an up-to-date copy of the master schedule; (2) verify that the study plan contains the information required for compliance with these standards. This verification should be documented; (3) conduct audits or inspections to determine if all studies are conducted in accordance with these standards. Audits or inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed. The results of these audits and inspections should be documented and retained; (5) audit the final reports to confirm that the methods, procedures and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies; (4) promptly report any audit or inspection results in writing to the Test Facility Management and to the Study Director, and to the Test Site Management and to the Principal Investigator(s), when applicable. If a problem which is sufficiently serious to affect the quality of the study is found, the recommendations for the solution should be made to the Test Facility Management and the Study Director along with the follow-up audit or inspection schedule. The details of these events should be documented. (6) if it is found that the final report contents are appropriate, promptly report any audit or inspection results in writing to the Test Facility Management and to the Study Director, when applicable, to the Test Site Management and, to the Principal Investigator(s); (7) prepare and sign or stamp a quality assurance statement, to be included in the final report, which specifies the types of audits/inspections and their dates, including the phase(s) of the study audited or inspected, and the dates that audit/inspection results were reported to the Test Facility Management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.
3. Facilities 3.1 *General*	**Chapter 4 Facilities** **General**

1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to 7inimize disturbance that would interfere with the validity of the study.	Article 11. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.
2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.	2. Different activities are appropriately separated in the test facility in order to conduct each study properly.
3.2 *Test System Facilities*	**Test System Facilities**
	Article 12. Test system facilities should conform to the following criteria:
1. The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.	(1) The test facility should have a sufficient number of rooms, areas or space to assure appropriate conduct of the study.
2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.	(2) In order to prevent any untoward effects on the test system, the test facility should have appropriate rooms, areas, space, installations or structure to assure the isolation of the test systems as needed and depending on the nature of test. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of the test systems.
3. There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.	(3) There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.
3.3 *Facilities for Handling Test and Reference Items*	**Facilities for Handling Test and Reference Substances**
1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.	Article 13. To prevent contamination or mix-ups, there should be rooms or areas separately from test system facilities having the following functions;
	(1) Receipt and storage of the test and/or reference substances.
	(2) Mixing of a test or reference substance with a vehicle.
	(3) Storage of the mixture of a test or reference substance with a vehicle.
2. Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.	2. The above-mentioned storage rooms or areas should be adequate to preserve identity, concentration, purity, and stability of the test and reference substances and each of their mixtures with a vehicle, and should have the capacity to store hazardous substances, that could adversely affect the test systems, separately form the test systems.
3.4 *Archive Facilities*	**Archive Facilities**
Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.	Article 14. Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test substances and specimens. Archive design and archive conditions should protect contents from untimely deterioration (including the contract archiving services).
3.5 *Waste Disposal*	**Waste Disposal Facilities**
Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.	Article 15. Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.
4. Apparatus, Material, and Reagents	**Chapter 5 Apparatus, Equipment, Reagents, and Materials**
	Apparatus and Equipment
1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.	Article 16. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study, should be suitably located and of appropriate design and adequate capacity.
2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of	2. Apparatus and equipment used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, comply with national or international standards of measurement.

measurement.	
	3. In cases where apparatus and/or equipment are repaired due to failure or breakage, the date, the details and personnel involved
	Material
3. Apparatus and materials used in a study should not interfere adversely with the test systems.	Article 18. Apparatus, equipment and materials used in a study should not interfere adversely with the test systems.
	Reagents
4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.	Article 17. Chemicals, reagents, and solutions should be labelled to indicate name, source of supply, concentration, date of preparation, expiry date and specific storage instructions. 2. Although altered or expired reagents should not be used in a study, the expiry date may be extended on the basis of documented evaluation or analysis.
5. Test Systems	**Chapter 6 Test Systems**
5.1 *Physical/Chemical*	**Physical/Chemical Test Systems**
	Article 19. The physical/chemical test systems should comply with the following matters;
1. Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.	(1) Apparatus and equipment used for the measurements of physical/chemical data should be suitably located and of appropriate design and adequate capacity.
	(2) Apparatus and equipment used for the measurements of physical/chemical data should be maintained and regulated in good condition according to Standard Operating Procedures. In cases where apparatus and/or equipment are repaired due to failure or breakage, the date, the details and personnel involved should be documented and retained.
2. The integrity of the physical/chemical test systems should be ensured.	(3) The accuracy of physical/chemical test systems should be checked by measuring the reference substance, provided, however, that this shall not apply if the verification is not required in the study method.
5.2 *Biological*	**Biological Test Systems**
	Article 20. The biological test systems should comply with the following matters;
1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.	(1) Proper conditions should be established and maintained for the housing, culturing, handling and storage of biological test systems, in order to ensure the quality of the data.
2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.	(2) Newly received biological test systems should be monitored for abnormalities in a suitable housing or containers so as to avoid contamination or infection to other biological test systems and the results should be recorded. (3) In the preceding item, if there is any unusual mortality or morbidity affecting the whole lot of the test system, the said lot should not be used in the studies and, when appropriate, should be humanely destroyed. (4) At the experimental starting date, the relevant biological test system should be free of any disease or condition that might interfere with the purpose or conduct of the study. (5) Biological test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.
3. Records of source, date of arrival, and arrival condition of test systems should be maintained.	(6) Records of source, date of receipt, and condition on receipt of biological test systems should be maintained.
4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.	(7) Biological test systems should be acclimatised to the test environment for an adequate period before the first exposure or administration of the test or reference substance.
5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.	(8) All information needed to properly identify the biological test systems should appear on their housing or containers. Individual biological test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification.

6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented. 7. Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.	(9) During use, housing or containers for test systems should be cleaned at appropriate intervals and kept in sanitised conditions. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed when appropriate. Use of pest control agents should be documented.
6. Test and Reference Items 6.1 *Receipt, Handling, Sampling and Storage* 1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained. 2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded. 3. Storage container(s) should carry identification information, expiry date, and specific storage instructions. 6.2 *Characterisation* 1. Each test and reference item should be appropriately identified (e.g., code, Chemical Abstracts Service Registry Number [CAS number], name, biological parameters). 2. For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known. 3. In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study. 4. The stability of test and reference items under storage and test conditions should be known for all studies. 5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments. 6. A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.	**Chapter 7 Test and Reference Substances** **Receipt, Handling, Sampling and Storage** Article 21. Records including test substance and reference substance characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained. 2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured as much as possible and contamination or mix-ups are precluded. 3. Storage container(s) should carry identification code, expiry date and specific storage instructions. **Characterisation** Article 22. Each test and reference substance should be appropriately identified with an identification code, Chemical Abstracts Service Registry Number (CAS number), name and biological parameters. 2. For each study, the identity, including lot number, purity, composition, concentrations, or other characteristics to appropriately define each lot of the test or reference substances should be known. 3. In cases where the test substance is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test substance subject to the study. 4. The stability of test and reference substances under storage and test conditions should be known for all studies. 5. If the test substance is exposed or administered after mixing with a vehicle, the homogeneity, concentration and stability of the test substance in that vehicle should be determined. 6. A sample for analytical purposes from each batch of the test substance should be retained for all studies except short-term studies.
7. Standard Operating Procedures 7.1 A test facility should have written Standard Operating Procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to Standard Operating Procedures should be approved by test facility management. 7.2 Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published text books, analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures. 7.3 Deviations from Standard Operating Procedures related to the study should be documented and	**Chapter 8 Standard Operating Procedures** **General** Article 23. A test facility should have written Standard Operating Procedures approved by Test Facility Management that are intended to ensure the quality and integrity of the data generated by that test facility. 2. Revisions to Standard Operating Procedures should require written approval of the Test Facility Management. 3. Every time the Standard Operating Procedures is prepared or revised, it shall be retained with the date and reason. 4. Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures. 5. Deviations from Standard Operating Procedures related to the study should be documented and should be

should be acknowledged by the Study Director and the Principal Investigator(s), as applicable.	acknowledged by the Study Director and, if appointed, the Principal Investigator(s).
	Matters to be Described in Standard Operating Procedures
7.4 Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples.	Article 24. Standard Operating Procedures should be available for, at a minimum, the following categories of test facility activities.
1. *Test and Reference Items*	(1) Test and Reference Substances
Receipt, identification, labelling, handling, sampling and storage.	Receipt, identification, labelling, handling, sampling, storage and mixing with vehicle
2. *Apparatus, Materials and Reagents*	
a) *Apparatus*	(2) Apparatus and Equipment
Use, maintenance, cleaning and calibration.	Operation, checking, cleaning, maintenance and calibration
b) *Computerised Systems*	(3) Computerised Systems
Validation, operation, maintenance, security, change control and back-up.	Validation, operation, checking, maintenance, , security, change control and back-up
c) *Materials, Reagents and Solutions*	(4) Reagents etc.
Preparation and labelling.	Preparation, storage and labelling
3. *Record Keeping, Reporting, Storage, and Retrieval*	(5) Record Keeping, Reporting, Storage, and Retrieval
Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.	Identification code, data collection, preparation of reports, indexing systems, handling of data (including the use of computerised systems)
4. *Test System (where appropriate)*	(6) Test System (where appropriate)
a) Room preparation and environmental room conditions for the test system.	a. Room or area and environmental room conditions for the test system.
b) Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.	b. Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system
c) Test system preparation, observations and examinations, before, during and at the conclusion of the study.	c. Test system preparation, observations and examinations, before, during and at the conclusion of the study
d) Handling of test system individuals found moribund or dead during the study.	d. Handling of test system individuals found moribund or dead during the study
e) Collection, identification and handling of specimens including necropsy and histopathology.	e. Collection, identification and handling of specimens (including necropsy and histopathology)
f) Siting and placement of test systems in test plots.	f. Siting and placement of test systems in test plots.
5. *Quality Assurance Procedures*	(7) Quality Assurance Unit
Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.	Operation of Quality Assurance Unit in planning, scheduling, performing, documenting and reporting audits or inspections
	(8) Protective measures concerning safety and hygiene
8. Performance of the Study	**Chapter 9 Performance of the Study**
8.1 *Study Plan*	**Study Plan**
1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified in Section 2.2.1.b., above. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.	Article 25. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dating and signing or placing a stamp by the Study Director on it and verified for compliance with these standards by Quality Assurance personnel as specified in the Article 10 above.
	Amendments to the Study Plan
2. a) Amendments to the study plan should be justified and approved by dated signature of the	Article 26. Amendments to the study plan should be justified in writing and approved by dating and signing or

Study Director and maintained with the study plan.	placing a stamp by the Study Director on it and maintained with the original study plan.
b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.	2. Deviations from the study plan should be documented with the reason and approved by dating and signing or placing a stamp on it in a timely fashion by the Study Director and/or, if appointed, Principal Investigator(s) and maintained with the study raw data.
3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.	
8.2 *Content of the Study Plan*	**Content of the Study Plan**
The study plan should contain, but not be limited to the following information:	Article 27. The study plan should contain, at a minimum, the following information:
1. *Identification of the Study, the Test Item and Reference Item*	(1) Identification of the Study, the Test substance and Reference substance
a) A descriptive title;	a. Title ;
b) A statement which reveals the nature and purpose of the study;	b. The nature and purpose of the study;
c) Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);	c. Name, abbreviation, or identification code of test and reference substances;
d) The reference item to be used.	
2. *Information Concerning the Sponsor and the Test Facility*	(2) Information Concerning the Test Facility and the Sponsor;
a) Name and address of the sponsor;	a. Name and address of the Test Facility and the Sponsor;
b) Name and address of any test facilities and test sites involved;	
c) Name and address of the Study Director;	b. Name and affiliation of the Study Director;
d) Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).	c. Name and affiliation of Principal Investigator(s) (limited to cases where he is appointed) and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).;
3. *Dates*	(3) Dates
a) The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed.	a. The date of approval of the study plan by signing or placing a stamp by the Study Director on it.
b) The proposed experimental starting and completion dates.	b. The proposed experimental starting and completion dates.
4. *Test Methods*	(4) Test Methods
Reference to the OECD Test Guideline or other test guideline or method to be used.	Test method to be used and test guideline to be referred to.
5. *Issues (where applicable)*	(5) Issues (where applicable)
a) The justification for selection of the test system;	a. The justification for selection of the test system;
b) Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information;	b. Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information;
c) The method of administration and the reason for its choice;	c. The method of exposure or administration and the reason for its choice;
d) The dose levels and/or concentration(s), frequency, and duration of administration/ application;	d. The dose levels and/or concentration(s), frequency and duration of exposure or administration;
e) Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).	e. Detailed information on the experimental design, including a description of the chronological procedure of the study; analysis, measurements, observations and examinations to be performed; type and frequency of analysis; , and statistical methods to be used.
6. *Records*	(6) Records
A list of records to be retained.	A list of records and materials to be retained.

8.3 *Conduct of the Study*	**Conduct of the Study**
	Article 28. Implementation of the Study should comply with the following matters;
1. A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.	(2) A unique identification code should be given to each study and the code should be displayed on the relevant records or specimens. The code should enable the specimens to confirm their origin.
2. The study should be conducted in accordance with the study plan.	(1) The study should be conducted in accordance with the Study Plan and the Standard Operating Procedures under the Study Director's
3. All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.	(3) Except for direct computer inputs, all data generated during the conduct of the study should be recorded directly, promptly, accurately, legibly, and indelibly by the individual involved in the study. These entries should be signed and dated, or have a stamp placed on them.
4. Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.	(4) Any change in the data, except direct computer input, should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or stamped by the individual making the change.
5. Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.	(5) When data are input directly in a computer, the individual(s) responsible for the data entries should confirm whether the accurate data are input and record the date of entry and their own names. (6) Any changes of the data directly entered into a computer should be securely recorded along with reason for the change(s), date, personnel involved. And, where possible, the records of the change(s) are made searchable retrospectively by entering separately.
9. Reporting of Study Results	**Chapter 10 Reporting of Study Results**
9.1 *General*	**General**
	Article 29. Reporting of the study results should comply with the following matters;
1. A final report should be prepared for each study. In the case of short term studies, a standardised final report accompanied by a study specific extension may be prepared.	(1) A final report should be prepared for each study.
2. Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.	(3) When the reports related to the relevant study prepared by the Principal Investigators (limited to cases where they are appointed) or other scientists involved are attached to a final report, the relevant reports should be dated and signed or stamped by the preparer.
3. The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.	(2) The final report should be dated and signed or stamped by the Study Director to indicate acceptance of responsibility for the validity of the data. It should be stated that the relevant study has been conducted according to these standards.
4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.	(4) Corrections and additions to a final report should be in the form of amendments without obscuring the previous entry. Amendments should clearly specify the reason for the corrections or additions and should be dated and signed or stamped by the Study Director. Any corrections and additions to a final report should be notified to the Quality Assurance Unit.
5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.	Attachment of Quality Assurance Statement Article 30 . The final report should include a Quality Assurance Statement listing the following matters with signature or stamp by (1) Types of audits or inspections made and their date (2) Phase(s) of the study audited or inspected (3) Date of any audit or inspection results which were reported to the Test Facility Management and to the Study Director and, if appointed, Principal Investigator(s).

9.2 *Content of the Final Report* The final report should include, but not be limited to, the following information: 1. *Identification of the Study, the Test Item and Reference Item* a) A descriptive title; b) Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.); c) Identification of the reference item by name; d) Characterisation of the test item including purity, stability and homogeneity. 2. *Information Concerning the Sponsor and the Test Facility* a) Name and address of the sponsor; b) Name and address of any test facilities and test sites involved; c) Name and address of the Study Director; d) Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable; e) Name and address of scientists having contributed reports to the final report. 3. *Dates* Experimental starting and completion dates. 4. *Statement* A Quality Assurance Programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data. 5. *Description of Materials and Test Methods* a) Description of methods and materials used; b) Reference to OECD Test Guideline or other test guideline or method. 6. *Results* a) A summary of results; b) All information and data required by the study plan; c) A presentation of the results, including calculations and determinations of statistical significance; d) An evaluation and discussion of the results and, where appropriate, conclusions. 7. *Storage* The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.	**Content of the Final Report** Article 31. The final report should include, at a minimum, the following information: (1) Identification of the Study, the Test and Reference Substances a. Title and the purpose of study; b. Name, abbreviation, or identification code of test and reference substances; c. Characterisation of the test substance (including purity, stability and homogeneity); (2) Information Concerning the Test Facility and the Sponsor; a. Name and address of the test facility and the sponsor; b. Name and affiliation of the Study Director; c. Name(s) and affiliation(s) of the Principal Investigator(s) (limited to cases where he is appointed) and the phase(s) of the study delegated; d. Name(s) of Study Personnel and their split of work; e. Names and affiliations of specialists and the part(s) of the final report to which they contributed. (3) Dates a. Study initiation date; b. Experimental starting and completion dates; (4) Description of Materials and Test Methods a. Description of materials used; b. Reference to test method and test guidelines; (5) Any environmental factors which might interfere adversely with the quality of the study results. (6) Results a. A summary of results; b. All information and data required by the study plan; c. A description of the results (including determinations of statistical testing); d. An evaluation, consideration, and conclusion based on the results; (7) Storage The location(s) where the study plan, samples of test and reference substances, specimens, raw data and the final report are to be stored.
10. Storage and Retention of Records and Materials	**Chapter 11 Storage and Retention of Records and Materials** **Retention Period**

10.1	The following should be retained in the archives for the period specified by the appropriate authorities:	Article 32. The following records and materials should be retained in the archives for the period specified below;
		(1) Master schedule;
	a) The study plan, raw data, samples of test and reference items, specimens, and the final report of each study;	2) The study plan, raw data, and the final report of each study;
	b) Records of all inspections performed by the Quality Assurance Programme, as well as master schedules;	(3) Records of all audits or inspections performed by the Quality Assurance Unit;
	c) Records of qualifications, training, experience and job descriptions of personnel;	(4) Records of qualifications, training, experience and job descriptions of personnel;
	d) Records and reports of the maintenance and calibration of apparatus;	(5) Records and reports of the maintenance and calibration of apparatus;
	e) Validation documentation for computerised systems;	(6) Validation documentation for computerised systems;
	f) The historical file of all Standard Operating Procedures;	(7) The historical file of all Standard Operating Procedures;
	g) Environmental monitoring records.	(8) Environmental monitoring records;
	In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.	The archive materials listed (1) to (8) above should be retained for 10 years after receiving the notification according to the provisions of Item 1 or 2 of Article 4; Item 2, 3 or 8 of Article 5; Item 3 of Article 10; or Item 2 of Article 14 of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc (Act No.117 of 16th October, 1973, hereinafter referred to as "Chemical Substance Control Low (CSCL)")
		(9) Test and reference substances, and any other samples;
		(10) Specimens;
		The archive materials listed (9) and (10) should be retained for 10 years after receiving the notification according to the provisions of Item 1 or 2 of Article 4; Item 2, 3 or 8 of Article 5; Item3 of Article 10 or Item 2 of Article 14 of CSCL, or for as long as they can be kept under ideal conditions without deterioration of their quality, whichever is shorter.
		Manner of Archiving
		Article 33. Operation of archiving should comply with the following matters;
10.2	Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.	(1) Records and materials retained in the archives should be indexed so as to facilitate orderly storage and retrieval.
10.3	Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.	(2) Test Facility Management should designate the person responsible for the management of archive(s) in archive facilities. Standard
		(3) Only personnel authorised by the person responsible for the management of archive(s) or Test Facility Management should have access to the archives. Access into the archives and movement of material in and out of the archives should be properly recorded.
		Transfer of Archiving Materials
10.4	If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).	Article 34 If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(ies).