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GLP Comparison

Side-by-Side Comparison between

Federal Regulations For

FDA GLP vs. EPA FIFRA GLP vs. EPA TSCA GLP

Notes:

Red and italic sections indicate differences between regulations.
Brackets, [ ], indicate sections moved with in a regulation for better comparison.

By: R. Vanderpool
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Title 21--Food and Drugs CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES PART 58--GOOD LABORATORY PRACTICE FOR ***NONCLINICAL LABORATORY*** STUDIES Code of Federal Regulations Title 21, Volume 1, Parts 1 to 99 Revised as of April 1, 1999 From the U.S. Government Printing Office via GPO Access CITE: 21CFR58.1	Title 40--Protection of Environment CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY PART 160--GOOD LABORATORY PRACTICE STANDARDS Federal Insecticide, Fungicide, and Rodenticide Act Code of Federal Regulations Title 40, Volume 16, Parts 150 to 189 Revised as of July 1, 1999 From the U.S. Government Printing Office via GPO Access CITE: 40CFR160.1	TITLE 40--PROTECTION OF ENVIRONMENT CHAPTER I--ENVIRONMENTAL PROTECTION AGENCY (CONTINUED) PART 792--GOOD LABORATORY PRACTICE STANDARDS Toxic Substances Control Act Code of Federal Regulations Title 40, Volume 24, Parts 790 to END Revised as of July 1, 1999 From the U.S. Government Printing Office via GPO Access CITE: 40CFR792.1
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Subpart A--General Provisions **Sec. 58.1 Scope** (a) This part prescribes good laboratory practices for conducting ***nonclinical laboratory*** studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, ***including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products***. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act. (b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.	**Subpart A--General Provisions** **Sec. 160.1 Scope.** (a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18 and 24(c) of the ***Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),*** as amended (7 U.S.C. 136a, 136c, 136f, 136q and 136v(c)) and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, 348). (b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after October 16, 1989.	**Subpart A--General Provisions** **Sec. 792.1 Scope.** (a) This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to ensure the quality and integrity of data submitted pursuant to testing consent agreements and test rules issued under section 4 of *the* ***Toxic Substances Control Act (TSCA)*** (Pub. L. 94-469, 90 Stat. 2006, 15 U.S.C. 2603 et seq.). (b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after September 18, 1989. (c) It is EPA's policy that all data developed under section 5 of TSCA be in accordance with provisions of this part. If data are not Developed in accordance with the provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999] Effective Date Note: At 64 FR 399, Jan. 5, 1999, in Sec. 58.1, paragraph (a) was amended by removing ``507,'', effective May 20, 1999.		data are reliable and adequate.
Subpart A--General Provisions **Sec. 58.3 Definitions.** As used in this part, the following terms shall have the meanings specified: ***(a) Act means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392))*** (b) ***Test article*** means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act. (c) ***Control article*** means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test	**Subpart A--General Provisions** **Sec. 160.3 Definitions.** As used in this part the following terms shall have the meanings specified: ***Test substance*** means a substance or mixture administered or added to a **test system** in a study, which substance or mixture: (1) Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or (2) Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (1) of this definition, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph. ***Control substance*** means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a	**Subpart A--General Provisions** **Sec. 792.3 Definitions.** As used in this part the following terms shall have the meanings specified: ***Test substance*** means a substance or mixture administered or added to a test system in a study, which substance or mixture is used to develop data to meet the requirements of a TSCA section 4(a) test rule and/or is developed under a TSCA section 4 testing consent agreement or section 5 rule or order to the extent the agreement, rule or order references this part. ***Control substance*** means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a

system in the course of a ***nonclinical laboratory*** study for the purpose of establishing a basis for comparison with the test article.	basis for comparison with the test substance for known chemical or biological measurements.	basis for comparison with the test substance for chemical or biologicaI measurements.
(d) ***nonclinical laboratory*** study means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their ***safety***. The term does ***not include studies utilizing human subjects or clinical studies or field trials in animals***. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article	***Study*** means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its ***effects, metabolism, product performance*** (efficacy studies only as required by 40 CFR 158.640), **environmental** and ***chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media***. The term ``study'' does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.	***Study*** means any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its ***effects, metabolism, environmental and chemical fate, persistence, or other characteristics in humans, other living organisms, or media***. The term ``study'' does not include basic exploratory studies carried out to determine whether a test substance or a test method has any potential utility.
(e) Application for research or marketing permit includes: (1) A color additive petition, described in part 71. (2) A food additive petition, described in parts 171 and 571. (3) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for use, which use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in Secs. 170.35 and 570.35. (4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in Sec. 180.1. (5) An investigational new drug application, described in part 312 of this chapter. (6) A new drug application, described in part 314. (7) Data and information regarding an over-the-counter drug for human use, submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in part 330.	Application for research or marketing permit includes: (1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3, 4 or 24(c). (2) An application for an experimental use permit under FIFRA section 5. (3) An application for an exemption under FIFRA section 18. (4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408. (5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409. (6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B). (7) Any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.	

(8) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in parts 109 and 509. (9) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in Sec. 314.300 of this chapter. (10) A Notice of Claimed Investigational Exemption for a New Animal Drug, described in part 511. (11) A new animal drug application, described in part 514. (12) [Reserved] (13) An application for a biological product license, described in part 601. (14) An application for an investigational device exemption, described in part 812. (15) An Application for Premarket Approval of a Medical Device, described in section 515 of the act. (16) A Product Development Protocol for a Medical Device, described in section 515 of the act. (17) Data and information regarding a medical device submitted as part of the procedures for classifying such devices, described in part 860. (18) Data and information regarding a medical device submitted as part of the procedures for establishing, amending, or repealing a performance standard for such devices, described in part 861. (19) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in subpart D of part 1003. (20) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such product, described in section 358 of the Public Health Service Act. (21) Data and information regarding an electronic		

product submitted as part of the procedures for obtaining a variance from any electronic product performance standard as described in Sec. 1010.4. (22) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from any electronic product performance standard, as described in Sec. 1010.5.		
(f) Sponsor means:	Sponsor means:	Sponsor means:
(1) A person who initiates and supports, by provision of financial or other resources, a ***nonclinical laboratory*** study;	(1) A person who initiates and supports, by provision of financial or other resources, a study;	(1) A person who initiates and supports, by provision of financial or other resources, a study;
(2) A person who submits a ***nonclinical*** study to the Food and Drug Administration in support of an application for a research or marketing permit; or	(2) A person who submits a study to the EPA in support of an application for a research or marketing permit; or	(2) A person who submits a study to the EPA in response to ***a TSCA section 4(a) test rule and/or a person who submits a study under a TSCA section 4 testing consent agreement or a TSCA section 5 rule or order to the extent the agreement, rule or order references this part***; or
(3) A testing facility, if it both initiates and actually conducts the study.	(3) A testing facility, if it both initiates and actually conducts the study.	(3) A testing facility, if it both initiates and actually conducts the study.
	Carrier means any material, including but not limited to feed, water, soil, nutrient media, with which the test substance is combined for administration to a test system.	***Carrier*** means any material, including but not limited to, feed, water, soil, and nutrient media, with which the test substance is combined for administration to a test system.
	EPA means the U.S. Environmental Protection Agency.	***EPA*** means the U.S. Environmental Protection Agency.
	Experimental start date means the first date the test substance is applied to the test system.	***Experimental start date*** means the first date the test substance is applied to the test system.
	Experimental termination date means the last date on which data are collected directly from the study.	***Experimental termination date*** means the last date on which data are collected directly from the study.
	FDA means the U.S. Food and Drug Administration.	***FDA*** means the U.S. Food and Drug Administration.
	FFDCA means the Federal Food, Drug and Cosmetic	

	Act, as amended (21 U.S.C. 321 et seq). ***FIFRA*** means the Federal Insecticide, Fungicide and Rodenticide Act as amended (7 U.S.C. 136 et seq). ***Reference substance*** means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.	***TSCA*** means the Toxic Substances Control Act (15 U.S.C, 2601 et seq.) ***Reference substance*** means any chemical substance or mixture, or analytical standard, or material other than a test substance, feed, or water, that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance for known chemical or biological measurements.
(g) Testing facility means a person who actually conducts a ***nonclinical laboratory*** study, i.e., actually uses the test article in a test system. ***Testing facility includes any establishment required to register under section 510 of the act that conducts nonclinical laboratory studies and any consulting laboratory described in section 704 of the act that conducts such studies***. Testing facility encompasses only those operational units that are being or have been used to conduct ***nonclinical laboratory*** studies.	Testing facility means a person who actually conducts a study, i.e., actually uses the test substance in a test system. ``Testing facility'' encompasses only those operational units that are being or have been used to conduct studies.	Testing facility means a person who actually conducts a study, i.e., actually uses the test substance in a test system. ``Testing facility'' encompasses only those operational units that are being or have been used to conduct studies.
(h) Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.	Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.	Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.
(i) Test system means any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. Test system also includes appropriate groups or components of the system not treated with the test or control articles.	Test system means any animal, plant, microorganism, ***chemical or Physical matrix, including but not limited to soil or water***, or subparts thereof, to which the test, control, or ***reference substance*** is administered or added for study. ``Test system'' also includes appropriate groups or components of the system not treated with the test, control, or ***reference substance***.	Test system means any animal, plant, microorganism, chemical or physical matrix, including but not limited to, soil or water, or Components thereof, to which the test, control, or ***reference substance*** is administered or added for study. ``Test system'' also includes appropriate groups or components of the system not treated with the test, control, or ***reference substance***.
(j) Specimen means any material derived from a test	Specimens means any material derived from a test system	Specimen means any material derived from a test system

system for examination or analysis. (k) Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a ***nonclinical laboratory*** study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. (l) Quality assurance unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of ***nonclinical laboratory*** studies. (m) Study director means the individual responsible for the overall conduct of a ***nonclinical laboratory*** study. (n) Batch means a specific quantity or lot of a test or control article that has been characterized according to Sec. 58.105(a). (o) Study initiation date means the date the protocol is signed by the study director. (p) Study completion date means the date the final report is signed by the study director.	for examination or analysis. Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. ``Raw data'' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. Quality assurance unit means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies. Study director means the individual responsible for the overall conduct of a study. Batch means a specific quantity or lot of a test, control, or ***reference substance*** that has been characterized according to Sec. 160.105(a). Study initiation date means the date the protocol is signed by the study director. Study completion date means the date the final report is signed by the study director. ***Vehicle*** means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.	for examination or analysis. Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. ``Raw data'' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. Quality assurance unit means any person or organizational element, Except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies. Study director means the individual responsible for the overall conduct of a study. Batch means a specific quantity or lot of a test, control, or ***reference substance*** that has been characterized according to Sec. 792.105(a). Study initiation date means the date the protocol is signed by the study director. Study completion date means the date the final report is signed by the study director. ***Vehicle*** means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989] Effective Date Note: At 64 FR 399, Jan. 5, 1999, Sec. 58.3 was amended by removing and reserving paragraph (e)(9), effective May 20, 1999.		
Subpart A--General Provisions **Sec. 58.10 Applicability to studies performed under grants and contracts.** When a sponsor conducting a ***nonclinical laboratory*** study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a ***nonclinical laboratory*** study that must be conducted in compliance with the provisions of this part.	**Subpart A--General Provisions** **Sec. 160.10 Applicability to studies performed under grants and contracts.** When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.	**Subpart A--General Provisions** **Sec. 792.10 Applicability to studies performed under grants and contracts.** When a sponsor or other person utilizes the services of a consulting Laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.
Subpart A--General Provisions **No Comparable**	**Subpart A--General Provisions** **Sec. 160.12 *Statement of compliance or non-compliance.*** Any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types: (a) A statement that the study was conducted in accordance with this part; or (b) A statement describing in detail all differences between the practices used in the study and those required by this part; or (c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know	**Subpart A--General Provisions** **Sec. 792.12 *Statement of compliance or non-compliance.*** Any person who submits to EPA a test required by a testing consent agreement or a test rule issued under section 4 of TSCA shall include in the submission a true and correct statement, signed by the sponsor and the study director, of one of the following types: (a) A statement that the study was conducted in accordance with this part; or (b) A statement describing in detail all differences between the practices used in the study and those required by this part; or (c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know

	whether the study was conducted in accordance with this part.	whether the study was conducted in accordance with this part.
Subpart A--General Provisions **Sec. 58.15 Inspection of a testing facility.** (a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies within the scope of this part. The records inspection and copying requirements ***shall*** not apply to quality assurance unit records of findings and problems, or to actions recommended and taken. (b) The Food and Drug Administration will not consider a ***nonclinical laboratory*** study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. The determination that a ***nonclinical laboratory*** study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to the Food and Drug Administration.	**Subpart A--General Provisions** **Sec. 160.15 Inspection of a testing facility.** (a) A testing facility shall permit an authorized employee or ***duly designated representative*** of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements ***should*** not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, ***except that EPA may seek production of these records in litigation or formal adjudicatory hearings***. (b) EPA will not consider reliable for purposes of supporting an application for a research or marketing permit any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to EPA.	**Subpart A--General Provisions** **Sec. 792.15 Inspection of a testing facility.** (a) A testing facility shall permit an authorized employee or ***duly designated representative*** of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements ***shall*** not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, ***except the EPA may seek production of these records in litigation or formal adjudicatory hearings***. (b) EPA will not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered reliable does not, however, relieve the sponsor of a required test of any obligation under any applicable statute or regulation to submit the results of the study to EPA. (c) Since a testing facility is a place where chemicals are stored or held, it is subject to inspection under section 11 of TSCA.
Subpart A--General Provisions **No Comparable**	**Subpart A--General Provisions** **Sec. 160.17 *Effects of non-compliance*.** (a) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part.	**Subpart A--General Provisions** **Sec. 792.17 *Effects of non-compliance.***

	(b) Submission of a statement required by Sec. 160.12 which is false may form the basis for cancellation, suspension, or modification of the research or marketing permit, or denial or disapproval of an application for such a permit, under FIFRA section 3, 5, 6, 18, or 24 or FFDCA section 406 or 409, or for criminal prosecution under 18 U.S.C. 2 or 1001 or FIFRA section 14, or for imposition of civil penalties under FIFRA section 14	(a) The sponsor or any other person who is conducting or has conducted a test to fulfill the requirements of a testing consent agreement or a test rule issued under section 4 of TSCA will be in violation of section 15 of TSCA if: (1) The test is not being or was not conducted in accordance with any requirement of this part; (2) Data or information submitted to EPA under this part (including the statement required by Sec. 792.12) include information or data that are false or misleading, contain significant omissions, or otherwise do not fulfill the requirements of this part; or (3) Entry in accordance with Sec. 792.15 for the purpose of auditing test data or inspecting test facilities is denied. Persons who violate the provisions of this part may be subject to civil or criminal penalties under section 16 of TSCA, legal action in United States district court under section 17 of TSCA, or criminal prosecution under 18 U.S.C. 2 or 1001. (b) EPA, at its discretion, may not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any study which was not conducted in accordance with this part. EPA, at its discretion, may rely upon such studies for purposes of showing adverse effects. The determination that a study will not be considered reliable does not, however, relieve the sponsor

		of a required test of the obligation under any applicable statute or regulation to submit the results of the study to EPA. (c) If data submitted to fulfill a requirement of a testing consent agreement or a test rule issued under section 4 of TSCA are not developed in accordance with this part, EPA may determine that the sponsor has not fulfilled its obligations under section 4 of TSCA and may require the sponsor to develop data in accordance with the requirements of this part in order to satisfy such obligations.
Subpart B--Organization and Personnel **Sec. 58.29 Personnel.** (a) Each individual engaged in the conduct of or responsible for the supervision of a ***nonclinical laboratory*** study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. (b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a ***nonclinical laboratory*** study. (c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol. (d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems. (e) Personnel engaged in a ***nonclinical laboratory*** study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and	**Subpart B--Organization and Personnel** **Sec. 160.29 Personnel.** (a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. (b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study. (c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol. (d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test, control, and ***reference substances*** and test systems. (e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination	**Subpart B--Organization and Personnel** **Sec. 792.29 Personnel.** (a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. (b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study. (c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol. (d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test, control, and ***reference substances*** and test systems. (e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination

control articles. (f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the ***nonclinical laboratory*** study shall be excluded from direct contact with test systems, test and control articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a ***nonclinical laboratory*** study.	of test systems and test, control, and ***reference substances***. (f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, and test, control, and ***reference substance***, and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.	of test systems and test, control, and ***reference substances***. (f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test, control, and ***reference substances*** and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.
Subpart B--Organization and Personnel **Sec. 58.31 Testing facility management.** For each ***nonclinical laboratory*** study, testing facility management shall: (a) Designate a study director as described in Sec. 58.33, before the study is initiated. (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study. (c) Assure that there is a quality assurance unit as described in Sec. 58.35. (d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable. (e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled. (f) Assure that personnel clearly understand the functions they are to perform.	**Subpart B--Organization and Personnel** **Sec. 160.31 Testing facility management.** For each study, testing facility management shall: (a) Designate a study director as described in Sec. 160.33 before the study is initiated. (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study. (c) Assure that there is a quality assurance unit as described in Sec. 160.35. (d) Assure that test, control, and ***reference substances*** or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable. (e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled. (f) Assure that personnel clearly understand the functions they are to perform.	**Subpart B--Organization and Personnel** **Sec. 792.31 Testing facility management.** For each study, testing facility management shall: (a) Designate a study director as described in Sec. 792.33 before the study is initiated. (b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study. (c) Assure that there is a quality assurance unit as described in Sec. 792.35. (d) Assure that test, control, and ***reference substance*** or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable. (e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled. (f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented. [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.	(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.
Subpart B--Organization and Personnel **Sec. 58.33 Study director.** For each ***nonclinical laboratory*** study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director shall assure that: (a) The protocol, including any change, is approved as provided by Sec. 58.120 and is followed. (b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified. (c) Unforeseen circumstances that may affect the quality and integrity of the ***nonclinical laboratory*** study are noted when they occur, and corrective action is taken and documented. (d) Test systems are as specified in the protocol. (e) All applicable good laboratory practice regulations are followed.	**Subpart B--Organization and Personnel** **Sec. 160.33 Study director.** For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that: (a) The protocol, including any change, is approved as provided by Sec. 160.120 and is followed. (b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified. (c) Unforseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented. (d) Test systems are as specified in the protocol. (e) All applicable good laboratory practice regulations are followed.	**Subpart B--Organization and Personnel** **Sec. 792.33 Study director.** For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that: (a) The protocol, including any change, is approved as provided by Sec. 792.120 and is followed. (b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified. (c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented. (d) Test systems are as specified in the protocol. (e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study. [43 FR 60013, Dec. 22, 1978; 44 FR 17657, Mar. 23, 1979]	(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.	(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.
Subpart B--Organization and Personnel **Sec. 58.35 Quality assurance unit.** (a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. (b) The quality assurance unit shall: (1) Maintain a copy of a master schedule sheet of all ***nonclinical laboratory*** studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director. (2) Maintain copies of all protocols pertaining to all ***nonclinical laboratory*** studies for which the unit is responsible. (3) Inspect each ***nonclinical laboratory*** study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study	**Subpart B--Organization and Personnel** **Sec. 160.35 Quality assurance unit.** (a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. ***The quality assurance unit shall conduct inspections and maintain records appropriate to the study.*** (b) The quality assurance unit shall: (1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance, and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director. (2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible. (3) Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person	**Subpart B--Organization and Personnel** **Sec. 792.35 Quality assurance unit.** (a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are inconformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study. ***The quality assurance unit shall conduct inspections and maintain records appropriate to the study.*** (b) The quality assurance unit shall: (1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director. (2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible. (3) Inspect each study at intervals adequate to ensure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person

inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.	performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.	performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for re-inspection. Any problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.
(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.	(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.	(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.
(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.	(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation,	(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.
(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the ***nonclinical laboratory*** study.	(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.	(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.
(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.	(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.	(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.
(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees of the Food and Drug Administration.	(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.	(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.
(d) A designated representative of the Food and Drug Administration shall have access to the written procedures established for the inspection and may request	(d) ***An authorized employee*** or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may	(d) **An authorized employee** or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may

testing facility management to certify that inspections are being implemented, performed, documented, and followed-up in accordance with this paragraph. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	request testing facility management to certify that inspections are being implemented, performed, documented, and followed up in accordance with this paragraph.	request testing facility management to certify that inspections are being implemented, performed, documented, and followed up in accordance with this paragraph.
Subpart C--Facilities **Sec. 58.41 General.** Each testing facility shall be of suitable size and construction to facilitate the proper conduct of ***nonclinical laboratory*** studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study. [52 FR 33780, Sept. 4, 1987]	**Subpart C--Facilities** **Sec. 160.41 General.** Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. ***Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies.*** Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.	**Subpart C--Facilities** **Sec. 792.41 General.** Each testing facility shall be of suitable size and construction to facilitate the proper conduct of studies. ***Testing facilities which are not located within an indoor controlled environment shall be of suitable location to facilitate the proper conduct of studies***. Testing facilities shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.
Subpart C--Facilities **Sec. 58.43 Animal care facilities.** (a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) Separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.	**Subpart C--Facilities** **Sec. 160.43 Test system care facilities.** (a) A testing facility shall have a sufficient number of animal rooms or other ***test system*** areas, as needed, to ensure: proper separation of species or test systems, isolation of individual projects, quarantine ***or isolation*** of animals or other test systems, and routine or specialized housing of animals ***or other test systems***. ***(1) In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is***	**Subpart C--Facilities** **Sec. 792.43 Test system care facilities.** (a) A testing facility shall have a sufficient number of animal rooms or other ***test system*** areas, as needed, to ensure: proper separation of species or test systems, isolation of individual projects, quarantine ***or isolation*** of animals or other test systems, and routine or specialized housing of animals ***or other test systems***. ***(1) In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is***

	unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium, or housing unit.	***unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium, or housing unit.***
	(2) Aquatic toxicity tests for individual projects shall be isolated to the extent necessary to prevent cross-contamination of different chemicals used in different tests.	***(2) Aquatic toxicity tests for individual projects shall be isolated to the extent necessary to prevent cross-contamination of different chemicals used in different tests.***
(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.	(b) A testing facility shall have a number of animal rooms or other test system areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test, control, and ***reference substances*** known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.	(b) A testing facility shall have a number of animal rooms or other test system areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test, control, and ***reference substance*** known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.
(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.	(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory test system diseases. These areas shall provide effective isolation for the housing of test systems either known or suspected of being diseased, or of being carriers of disease, from other test systems.	(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory test system diseases. These areas shall provide effective isolation for the housing of test systems either known or suspected of being diseased, or of being carriers of disease, from other test systems.
(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.	(d) ***Facilities shall have proper provisions for collection and disposal of contaminated water, soil, or other spent materials.*** When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.	(d) ***Facilities shall have proper provisions for collection and disposal of contaminated water, soil, or other spent materials.*** When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.
[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	***(e) Facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the protocol.***	***(e) Facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the protocol.***
	(f) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from	***(f) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from***

	deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol. ***(g) For freshwater organisms, an adequate supply of clean water of the appropriate hardness, pH, and temperature, and which is free of contaminants capable of interfering with the study, shall be available as specified in the protocol.*** ***(h) For plants, an adequate supply of soil of the appropriate composition, as specified in the protocol, shall be available as needed.***	***deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol.*** ***(g) For freshwater organisms, an adequate supply of clean water of the appropriate hardness, pH, and temperature, and which is free of contaminants capable of interfering with the study shall be available as specified in the protocol.*** ***(h) For plants, an adequate supply of soil of the appropriate composition, as specified in the protocol, shall be available as needed.***
Subpart C--Facilities **Sec. 58.45 Animal supply facilities.** There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means. [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	**Subpart C--Facilities** **Sec. 160.45 Test system supply facilities.** (a) There shall be storage areas, as needed, for feed, ***nutrients, soils***, bedding, supplies, and equipment. Storage areas for feed ***nutrients, soils***, and bedding shall be separated from areas where the test systems are located and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means. ***(b) When appropriate, plant supply facilities shall be provided. As specified in the protocol, these include:*** ***(1) Facilities for holding, culturing, and maintaining algae and aquatic plants.*** ***(2) Facilities for plant growth, including, but not limited to greenhouses, growth chambers, light banks, and fields.*** ***(c) When appropriate, facilities for aquatic animal tests shall be provided. These include, but are not limited to, aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.***	**Subpart C--Facilities** **Sec. 792.45 Test system supply facilities.** (a) There shall be storage areas, as needed, for feed, nutrients, soils, bedding, supplies, and equipment. Storage areas for feed, ***nutrients, soils***, and bedding shall be separated from areas where the test systems are located and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means. ***(b) When appropriate, plant supply facilities shall be provided. These include:*** ***(1) Facilities, as specified in the protocol, for holding, culturing, and maintaining algae and aquatic plants.*** ***(2) Facilities, as specified in the protocol, for plant growth, including but not limited to, greenhouses, growth chambers, light banks, and fields.*** ***(c) When appropriate, facilities for aquatic animal tests shall be provided. These include but are not limited to aquaria, holding tanks, ponds, and ancillary equipment, as specified in the protocol.***

Subpart C--Facilities **Sec. 58.47 Facilities for handling test and control articles.** (a) As necessary to prevent contamination or mixups, there shall be separate areas for: (1) Receipt and storage of the test and control articles. (2) Mixing of the test and control articles with a carrier, e.g., feed. (3) Storage of the test and control article mixtures. (b) Storage areas for the test and/or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures.	**Subpart C--Facilities** **Sec. 160.47 Facilities for handling test, control, and *reference substances*.** (a) As necessary to prevent contamination or mixups, there shall be separate areas for: (1) Receipt and storage of the test, control, and *reference substances*. (2) Mixing of the test, control, and *reference substances* with a carrier, e.g., feed. (3) Storage of the test, control, and *reference substance* mixtures. (b) Storage areas for test, control, and/or *reference substance* and for test, control, and/or *reference mixtures* shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.	**Subpart C--Facilities** **Sec. 792.47 Facilities for handling test, control, and *reference substances*.** (a) As necessary to prevent contamination or mixups, there shall be separate areas for: (1) Receipt and storage of the test, control, and *reference substances*. (2) Mixing of the test, control, and *reference substances* with a carrier, e.g., feed. (3) Storage of the test, control, and *reference substance* mixtures. (b) Storage areas for test, control, and/*or* **reference** *substance* and for test, control, and/or *reference mixtures* shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.
Subpart C--Facilities **Sec. 58.49 Laboratory operation areas.** Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by *nonclinical laboratory* studies. [52 FR 33780, Sept. 4, 1987]	**Subpart C--Facilities** **Sec. 160.49 Laboratory operation areas.** Separate laboratory space *and other space* shall be provided, as needed, for the performance of the routine and specialized procedures required by studies.	**Subpart C--Facilities** **Sec. 792.49 Laboratory operation areas.** Separate laboratory space *and other space* shall be provided, as needed, for the performance of the routine and specialized procedures required by studies.
Subpart C--Facilities **Sec. 58.51 Specimen and data storage facilities.** Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.	**Subpart C--Facilities** **Sec. 160.51 Specimen and data storage facilities.** Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.	**Subpart C--Facilities** **Sec. 792.51 Specimen and data storage facilities.** Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.
Subpart D--Equipment	**Subpart D--Equipment**	**Subpart D--Equipment**

Sec. 58.61 Equipment design. Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance. [52 FR 33780, Sept. 4, 1987]	**Sec. 160.61 Equipment design.** Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.	**Sec. 792.61 Equipment design.** Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.
Subpart D--Equipment **Sec. 58.63 Maintenance and calibration of equipment.** (a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized. (b) The written standard operating procedures required under Sec. 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation. (c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and	**Subpart D--Equipment** **Sec. 160.63 Maintenance and calibration of equipment.** (a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized. (b) The written standard operating procedures required under Sec. 160.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/ or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation. (c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the dates of the operations, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and	**Subpart D--Equipment** **Sec. 792.63 Maintenance and calibration of equipment.** (a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized. (b) The written standard operating procedures required under Sec. 792.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation. (c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and

when the defect was discovered, and any remedial action taken in response to the defect. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	when the defect was discovered, and any remedial action taken in response to the defect.	when the defect was discovered, and any remedial action taken in response to the defect.
Subpart E--Testing Facilities Operation **Sec. 58.81 Standard operating procedures.** (a) A testing facility shall have standard operating procedures in writing setting forth ***nonclinical laboratory*** study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management. (b) Standard operating procedures shall be established for, but not limited to, the following: (1) Animal room preparation. (2) Animal care. (3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles. (4) Test system observations. (5) Laboratory tests. (6) Handling of animals found moribund or dead	**Subpart E--Testing Facilities Operation** **Sec. 160.81 Standard operating procedures.** (a) A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management. (b) Standard operating procedures shall be established for, but not limited to, the following: (1) Test system area preparation. (2) Test system care. (3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and ***reference substances***. (4) Test system observations. (5) Laboratory or other tests. (6) Handling of test systems found moribund or dead	**Subpart E--Testing Facilities Operation** **Sec. 792.81 Standard operating procedures.** (a) A testing facility shall have standard operating procedures in writing, setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management. (b) Standard operating procedures shall be established for, but not limited to, the following: (1) Test system room preparation. (2) Test system care. (3) Receipt, identification, storage, handling, mixing, and method of sampling of the test, control, and ***reference substances.*** (4) Test system observations. (5) Laboratory or other tests. (6) Handling of test systems found moribund or dead

during study. (7) Necropsy of animals or postmortem examination of animals. (8) Collection and identification of specimens. (9) Histopathology. (10) Data handling, storage, and retrieval. (11) Maintenance and calibration of equipment. (12) Transfer, proper placement, and identification of animals. (c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures. (d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained. [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]	during study. (7) Necropsy of test systems or postmortem examination of test systems. (8) Collection and identification of specimens. (9) Histopathology. (10) Data handling, storage and retrieval. (11) Maintenance and calibration of equipment. (12) Transfer, proper placement, and identification of test systems. (c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures. (d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.	during study. (7) Necropsy of test systems or postmortem examination of test systems. (8) Collection and identification of specimens. (9) Histopathology. (10) Data handling, storage and retrieval. (11) Maintenance and calibration of equipment. (12) Transfer, proper placement, and identification of test systems. (c) Each laboratory or other study area shall have immediately available manuals and standard operating procedures relative to the laboratory or field procedures being performed. Published literature may be used as a supplement to standard operating procedures. (d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.
Subpart E--Testing Facilities Operation **Sec. 58.83 Reagents and solutions.** All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.	**Subpart E--Testing Facilities Operation** **Sec. 160.83 Reagents and solutions.** All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.	**Subpart E--Testing Facilities Operation** **Sec. 792.83 Reagents and solutions.** All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration,storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.
Subpart E--Testing Facilities Operation	**Subpart E--Testing Facilities Operation**	**Subpart E--Testing Facilities Operation**

Sec. 58.90 Animal care.	**Sec. 160.90 Animal and other test system care.**	**Sec. 792.90 Animal and other test system care.**
(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.	(a) There shall be standard operating procedures for the housing, feeding, handling, and care of ***animals and other test systems.***	(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals and other test systems.
(b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.	(b) All newly received test systems from outside sources shall be isolated and their health status or ***appropriateness for the study*** shall be evaluated***. This evaluation shall be*** in accordance with acceptable veterinary medical practice or scientific methods.	(b) All newly received test systems from outside sources shall be isolated and their health status or appropriateness for the study shall be evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice or scientific methods.
(c) At the initiation of a ***nonclinical laboratory*** study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.	(c) At the initiation of a study, test systems shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If during the course of the study, the test systems contract such a disease or condition, the diseased test systems should be isolated, if necessary. These test systems may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.	(c) At the initiation of a study, test systems shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If during the course of the study, the test systems contract such a disease or condition, the diseased test systems should be isolated, if necessary. These test systems may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.
(d) Warm-blooded animals, ***excluding suckling rodents***, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification. All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.	(d) Warm-blooded animals, ***adult reptiles***, and **adult terrestrial amphibians** used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require these test systems to be removed from and returned to their test system-housing units for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification ***(e.g., tattoo, color code, ear tag, ear punch, etc.)***. All information needed to specifically identify each test system within the test system-housing unit shall appear on the outside of that unit. ***Suckling mammals and juvenile birds are excluded from the requirement of individual identification unless otherwise specified in the protocol.***	(d) Warm-blooded animals, adult reptiles, and adult terrestrial amphibians used in laboratory procedures that require manipulations and observations over an extended period of time, or in studies that require these test systems to be removed from and returned to their test system-housing units for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, color code, ear tag, ear punch, etc.). All information needed to specifically identify each test system within the test system-housing unit shall appear on the outside of that unit. Suckling mammals and juvenile birds are excluded from the requirement of individual identification unless otherwise specified in the protocol.
	(e) Except as specified in paragraph (e)(1) of this	(e) Except as specified in paragraph (e)(1) of this

	section, test systems of different species shall be housed in separate rooms when necessary. Test systems of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to test, control, or ***reference substances*** or test system mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made. ***(1) Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in separate rooms, provided that they are adequately segregated to avoid mixup and cross contamination.*** (2) [Reserved]	section, test systems of different species shall be housed in separate rooms when necessary. Test systems of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to test, control, or ***reference substances*** or test system mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made. ***(1) Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in separate rooms, provided that they are adequately segregated to avoid mixup and cross contamination.*** (2) [Reserved]
(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.		
(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.	(f) Cages, racks, ***pens, enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding,*** rearing and breeding areas, and accessory equipment, shall be cleaned and sanitized at appropriate intervals.	(f) Cages, racks, pens, enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding, rearing, and breeding areas, and accessory equipment, shall be cleaned and sanitized at appropriate intervals.
(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.	(g) Feed, ***soil***, and water used for the test systems shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed, soil, or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.	(g) Feed, soil, and water used for the test systems shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed, soil, or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean. (i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987; 54 FR 15924, Apr. 20, 1989; 56 FR 32088, July 15, 1991]	(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean. (i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used. ***(j) All plant and animal test systems shall be acclimatized to the environmental conditions of the test, prior to their use in a study.***	(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean. (i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used. ***(j) All plant and animal test systems shall be acclimatized to the environmental conditions of the test, prior to their use in a study.***
Subpart F--Test and Control Articles **Sec. 58.105 Test and control article characterization.** (a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. ***In those cases where marketed products are used as control articles, such products will be characterized by their labeling.*** (b) The stability of each test or control article shall be determined ***by the testing facility or by the sponsor either***: (1) Before study initiation, or (2) concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.	**Subpart F--Test, Control, and *Reference Substances*** **Sec. 160.105 Test, control, and *reference substances* characterization.** (a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or ***reference substance*** shal1 be determined for each batch and shall be documented ***before its use in a study***. Methods of synthesis, fabrication, or derivation of the test, control, or ***reference substance*** shall be documented by the sponsor or the testing facility, ***and the location of such documentation shall be specified.*** (b) ***When relevant to the conduct of the study the solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date.*** The stability of the test, control, or reference substance shall be determined	**Subpart F--Test, Control, and *Reference Substances*** **Sec. 792.105 Test, control, and *reference substances* characterization.** (a) The identity, strength, purity, and composition, or other characteristics which will appropriately define the test, control, or ***reference substance*** shall be determined for each batch and shall be documented ***before its use in a study***. Methods of synthesis, fabrication, or derivation of the test, control, or ***reference substance*** shall be documented by the sponsor or the testing facility, ***and such location of documentation shall be specified.*** (b) ***When relevant to the conduct of the study the solubility of each test, control, or reference substance shall be determined by the testing facility or the sponsor before the experimental start date.*** The stability of the test, control or **reference substance** shall be determined

	before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.	before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.
(c) Each storage container for a test or control article shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.	(c) Each storage container for a test, control, or ***reference substance*** shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or **reference substance**. Storage containers shall be assigned to a particular test substance for the duration of the study.	(c) Each storage container for a test, control, or ***reference substance*** shall be labeled by name, chemical abstracts service number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test, control, or ***reference substance***. Storage containers shall be assigned to a particular test substance for the duration of the study.
(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by Sec. 58.195.	(d) For studies of more than 4 weeks experimental duration, reserve samples from each batch of test, control, and ***reference substances*** shall be retained for the period of time provided by Sec. 160.195.	(d) For studies of more than 4 weeks experimental duration, reserve samples from each batch of test, control, and ***reference substances*** shall be retained for the period of time provided by Sec. 792.195.
(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)	***(e) The stability of test, control, and reference substances under storage conditions at the test site shall be known for all studies.***	***(e) The stability of test, control, and reference substances under storage conditions at the test site shall be known for all studies.***
[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]		
Subpart F--Test and Control Articles	**Subpart F--Test, Control, and *Reference Substances***	**Subpart F--Test, Control, and *Reference Substances***
Sec. 58.107 Test and control article handling.	**Sec. 160.107 Test, control, and *reference substance* handling.**	**Sec. 792.107 Test, control, and reference substance handling.**
Procedures shall be established for a system for the handling of the test and control articles to ensure that:	Procedures shall be established for a system for the handling of the test, control, and ***reference substances*** to ensure that:	Procedures shall be established for a system for the handling of the test, control, and ***reference substances*** to ensure that:
(a) There is proper storage.	(a) There is proper storage.	(a) There is proper storage
(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.	(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.	(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process. (d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.	(c) Proper identification is maintained throughout the distribution process. (d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.	(c) Proper identification is maintained throughout the distribution process. (d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.
Subpart F--Test and Control Articles **Sec. 58.113 Mixtures of articles with carriers.** (a) For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: (1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control article in the mixture. (2) To determine the stability of the test and control articles in the mixture as ***required by the conditions of the study either:*** (i) Before study initiation, or (ii) Concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.	**Subpart F--Test, Control, and *Reference Substances*** **Sec. 160.113 Mixtures of substances with carriers.** (a) For each test, control, or ***reference substance*** that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: (1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test, control, or ***reference substance*** in the mixture. ***(2) When relevant to the conduct of the study, to determine the solubility of each test, control, or reference substance in the mixture by the testing facility or the sponsor before the experimental start date.*** (3) To determine the stability of the test, control, or ***reference substance*** in the mixture before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis ***of each batch.*** (b) Where any of the components of the test, control, or ***reference substance*** carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the	**Subpart F--Test, Control, and *Reference Substances*** **Sec. 792.113 Mixtures of substances with carriers.** (a) For each test, control, or ***reference substance*** that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: (1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test, control, or **reference substance** in the mixture. ***(2) When relevant to the conduct of the experiment, to determine the solubility of each test, control, or reference substance in the mixture by the testing facility or the sponsor before the experimental start date.*** (3) To determine the stability of the test, control or ***reference substance*** in the mixture before the experimental start date or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch. (b) Where any of the components of the test, control, or ***reference substance*** carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the

(b) [Reserved] (c) Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown. [43 FR 60013, Dec. 22, 1978, as amended at 45 FR 24865, Apr. 11, 1980; 52 FR 33781, Sept. 4, 1987]	earliest date shall be shown. ***(c) If a vehicle is used to facilitate the mixing of a test substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.***	earliest date shall be shown. ***(c) If a vehicle is used to facilitate the mixing of a test substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.***
Subpart G--Protocol for and Conduct of a *Nonclinical Laboratory* Study **Sec. 58.120 Protocol.** (a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, ***as applicable***, the following information: (1) A descriptive title and statement of the purpose of the study. (2) Identification of the test and control articles by name, chemical abstract number, or code number. (3) The name of the sponsor and the name and address of the testing facility at which the study is being	**Subpart G--Protocol for and Conduct of a Study** **Sec. 160.120 Protocol.** (a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol ***shall contain but shall not necessarily be limited to*** the following information: (1) A descriptive title and statement of the purpose of the study. (2) Identification of the test, control, and ***reference substance*** by name, chemical abstracts service (CAS) number or code number. (3) The name and ***address*** of the sponsor and the name and address of the testing facility at which the study is	**Subpart G--Protocol for and Conduct of A Study** **Sec. 792.120 Protocol.** (a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information: (1) A descriptive title and statement of the purpose of the study. (2) Identification of the test, control, and ***reference substance*** by name, chemical abstracts service (CAS) number or code number. (3) The name and address of the sponsor and the name and address of the testing facility at which the study is

conducted.	being conducted.	being conducted.
	(4) The proposed experimental start and termination dates.	***(4) The proposed experimental start and termination dates.***
	(5) Justification for selection of the test system.	***(5) Justification for selection of the test system.***
(4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.	(6) ***Where applicable***, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.	(6) ***Where applicable***, the number, body weight, sex, source of supply, species, strain, substrain, and age of the test system.
(5) The procedure for identification of the test system.	(7) The procedure for identification of the test system.	(7) The procedure for identification of the test system.
(6) A description of the experimental design, including the methods for the control of bias.	(8) A description of the experimental design, including methods for the control of bias.	(8) A description of the experimental design, including methods for the control of bias.
(7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.	(9) ***Where applicable***, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or ***reference substances*** before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose orconduct of the study if present at levels greater than established by the specifications.	(9) ***Where*** applicable, a description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test, control, or ***reference substances*** before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.
	(10) The route of administration and the reason for its choice.	***(10) The route of administration and the reason for its choice.***
(8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.	(11) Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or ***reference substance*** to be administered and the method and frequency of administration.	(11) Each dosage level, expressed in milligrams per kilogram of body or test system weight or other appropriate units, of the test, control, or ***reference substance*** to be administered and the method and frequency of administration.
(9) The type and frequency of tests, analyses, and	(12) The type and frequency of tests, analyses, and measurements to be made.	(12) The type and frequency of tests, analyses, and measurements to be made.

measurements to be made. (10) The records to be maintained. (11) The date of approval of the protocol by the sponsor and the dated signature of the study director. (12) A statement of the proposed statistical methods to be used. (b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]	(13) The records to be maintained. (14) The date of approval of the protocol by the sponsor and the dated signature of the study director. (15) A statement of the proposed statistical method to be used. (b) All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the study director, dated, and maintained with the protocol.	(13) The records to be maintained. (14) The date of approval of the protocol by the sponsor and the dated signature of the study director. (15) A statement of the proposed statistical method. (b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.
Subpart G--Protocol for and Conduct of a *Nonclinical Laboratory* Study **Sec. 58.130 Conduct of a *nonclinical laboratory* study.** (a) The ***nonclinical laboratory*** study shall be conducted in accordance with the protocol. (b) The test systems shall be monitored in conformity with the protocol. (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data. (d) Records of gross findings for a specimen from	**Subpart G--Protocol for and Conduct of a Study** **Sec. 160.130 Conduct of a study.** (a) The study shall be conducted in accordance with the protocol. (b) The test systems shall be monitored in conformity with the protocol. (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data. (d) In animal studies where histopathology is required,	**Subpart G--Protocol for and Conduct of A Study** **Sec. 792.130 Conduct of a study.** (a) The study shall be conducted in accordance with the protocol. (b) The test systems shall be monitored in conformity with the protocol. (c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data. (d) In animal studies where histopathology is required,

postmortem observations ***should*** be available to a pathologist when examining that specimen histopathologically. (e) All data generated during the conduct of a ***nonclinical laboratory*** study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]	records of gross findings for a specimen from postmortem observations ***shall*** be available to a pathologist when examining that specimen histopathologically. (e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.	records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically. (e) All data generated during the conduct of a study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.
No Comparable	**Subpart G--Protocol for and Conduct of a Study** **Sec. 160.135 Physical and chemical characterization studies.** ***(a) All provisions of the GLP standards shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies) of test, control, or reference substances.***	**Subpart G--Protocol for and Conduct of A Study** **Sec. 792.135 Physical and chemical characterization studies.** ***(a) All provisions of the GLPs shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility, and persistence (such as biodegradation, photodegradation, and chemical degradation studies).***

	(b) The following GLP standards shall not apply to studies, other than those designated in paragraph (a) of this section, designed to determine physical and chemical characteristics of a test, control, or reference substance: Sec. 160.31 (c), (d), and (g) Sec. 160.35 (b) and (c) Sec. 160.43 Sec. 160.45 Sec. 160.47 Sec. 160.49 Sec. 160.81(b) (1), (2), (6) through (9), and (12) Sec. 160.90 Sec. 160.105 (a) through (d) Sec. 160.113 Sec. 160.120(a) (5) through (12), and (15) Sec. 160.185(a) (5) through (8), (10), (12), and (14) Sec. 160.195 (c) and (d)	***(b) The following GLP standards shall not apply to studies designed to determine physical and chemical characteristics of a test, control, or reference substance:*** Section 792.31 (c), (d), and (g) Section 792.35 (b) and (c) Section 792.43 Section 792.45 Section 792.47 Section 792.49 Section 792.81(b) (1), (2), (6) through (9), and (12) Section 792.90 Section 792.105 (a) through (d) Section 792.113 Section 792.120(a) (5) through (12), and (15) Section 792.185(a) (5) through (8), (10), (12), and (14) Section 792.195 (c) and (d)
	Subparts H-I [Reserved]	**Subparts H-I [Reserved]**
Subpart J--Records and Reports **Sec. 58.185 Reporting of *nonclinical laboratory* study results.** (a) A final report shall be prepared for each ***nonclinical laboratory*** study and shall include, but not necessarily be limited to, the following: (1) Name and address of the facility performing the study and the dates on which the study was initiated and completed. (2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol. (3) Statistical methods employed for analyzing the data.	**Subpart J--Records and Reports** **Sec. 160.185 Reporting of study results.** (a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following: (1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed, ***terminated, or discontinued.*** (2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol. (3) Statistical methods employed for analyzing the data.	**Subpart J--Records and Reports** **Sec. 792.185 Reporting of study results.** (a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following: (1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed, ***terminated, or discontinued.*** (2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol. (3) Statistical methods employed for analyzing the data.

(4) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics.	(4) The test, control, and ***reference substances*** identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics.	(4) The test, control, and ***reference substances*** identified by name, chemical abstracts service (CAS) number or code number, strength, purity, and composition, or other appropriate characteristics.
(5) Stability of the test and control articles under the conditions of administration.	(5) Stability and, ***when relevant to the conduct of the study the solubility*** of the test, control, and **reference substances** under the conditions of administration.	(5) Stability, and ***when relevant to the conduct of the study, the solubility*** of the test, control, and ***reference substances*** under the conditions of administration.
(6) A description of the methods used.	(6) A description of the methods used.	(6) A description of the methods used.
(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.	(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.	(7) A description of the test system used. Where applicable, the final report shall include the number of animals or other test organisms used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.
(8) A description of the dosage, dosage regimen, route of administration, and duration.	(8) A description of the dosage, dosage regimen, route of administration, and duration.	(8) A description of the dosage, dosage regimen, route of administration, and duration.
(9) A description of all cirmcumstances that may have affected the quality or integrity of the data.	(9) A description of all circumstances that may have affected the quality or integrity of the data.	(9) A description of all circumstances that may have affected the quality or integrity of the data.
(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.	(10) The name of the study director, the names of other scientists or professionals and the names of all supervisory personnel, involved in the study.	(10) The name of the study director, the names of other scientists or professionals and the names of all supervisory personnel, involved in the study.
(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.	(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.	(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.
(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study.	(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, ***including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed***.	(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, ***including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed***.

(13) The locations where all specimens, raw data, and the final report are to be stored. (14) The statement prepared and signed by the quality assurance unit as described in Sec. 58.35(b)(7). (b) The final report shall be signed and dated by the study director. (c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible. [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]	(13) The locations where all specimens, raw data, and the final report are to be stored. (14) The statement prepared and signed by the quality assurance unit as described in Sec. 160.35(b)(7). (b) The final report shall be signed and dated by the study director. (c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible. ***Modification of a final report to comply with the submission requirements of EPA does not constitute a correction, addition, or amendment to a final report.*** (d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the test facility.	(13) The locations where all specimens, raw data, and the final report are to be stored. (14) The statement prepared and signed by the quality assurance unit as described in Sec. 792.35(b)(7). (b) The final report shall be signed and dated by the study director. (c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible. ***Modification of a final report to comply with the submission requirements of EPA does not constitute a correction, addition, or amendment to a final report.*** (d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the test facility.
Subpart J--Records and Reports **Sec. 58.190 Storage and retrieval of records and data.** (a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a ***nonclinical laboratory*** study shall be retained.	**Subpart J--Records and Reports** **Sec. 160.190 Storage and retrieval of records and data.** (a) All raw data, documentation, ***records***, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained ***after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.***	**Subpart J--Records and Reports** **Sec. 792.190 Storage and retrieval of records and data.** (a) All raw data, documentation, ***records***, protocols, specimens, and final reports generated as a result of a study shall be retained. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained ***after quality assurance verification. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.***

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations. (c) An individual shall be identified as responsible for the archives. (d) Only authorized personnel shall enter the archives. (e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval. (Information collection requirements approved by the Office of Management and Budget under control number 0910-0203) [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]	(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations. (c) An individual shall be identified as responsible for the archives. (d) Only authorized personnel shall enter the archives. (e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.	(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents orspecimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations. (c) An individual shall be identified as responsible for the archives. (d) Only authorized personnel shall enter the archives. (e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.
Subpart J--Records and Reports **Sec. 58.195 Retention of records.** (a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter. (b) Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a ***nonclinical laboratory*** study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is ***shortest***:	**Subpart J--Records and Reports** **Sec. 160.195 Retention of records.** (a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter. (b) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for whichever of the following periods is **longest**:	**Subpart J--Records and Reports** **Sec. 792.195 Retention of records.** (a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter. (b)(1) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the effective date of the applicable final test rule.

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the ***nonclinical laboratory*** study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section.	***(1) In the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor holds any research or marketing permit to which the study is pertinent.***	(2) In the case of negotiated testing agreements, each agreement will contain a provision that, except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the publication date of the acceptance of a negotiated test agreement. (3) In the case of testing submitted under section 5, except for those items listed in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least five years following the date on which the results of the study are submitted to the agency.
(2) A period of at least 5 years following the date on which the results of the ***nonclinical laboratory*** study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit. (3) In other situations (e.g., where the ***nonclinical laboratory*** study does not result in the submission of the study in support of an application for aresearch or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.	(2) A period of at least 5 years following the date on which the results of the study are submitted to the EPA in support of an application for a research or marketing permit. (3) In other situations (e.g., where the study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.	
(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.	(c) Wet specimens, samples of test, control, or ***reference substances***, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, and biological fluids, do not need to be retained after quality assurance verification. In no	(c) Wet specimens, samples of test, control, or ***reference substances***, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. Specimens obtained from mutagenicity tests, specimens of soil, water, and plants, and wet specimens of blood, urine, feces, biological fluids, do not need to be retained after quality assurance verification. In no case

	case shall retention be required for longer periods than those set forth in paragraph (b) of this section.	shall retention be required for longer periods than those set forth in paragraph (b) of this section.
(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by Sec. 58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraphs (a) and (b) of this section.	(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by Sec. 160.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.	(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by Sec. 792.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.
(e) Summaries of training and experience and job descriptions required to be maintained by Sec. 58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.	(e) Summaries of training and experience and job descriptions required to be maintained by Sec. 160.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.	(e) Summaries of training and experience and job descriptions required to be maintained by Sec. 792.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.
(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by Sec. 58.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.	(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by Sec. 160.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.	(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by Sec. 792.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.
[(h) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer. **]**	(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.	(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.
	(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.	***(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.***
(g) Records required by this part may be retained either as original records or as true copies such as photocopies,	(i) Records required by this part may be retained either as original records or as true copies such as photocopies,	(i) Records required by this part may be retained either as original records or as true copies such as photocopies,

microfilm, microfiche, or other accurate reproductions of the original records. [43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989]	microfilm, microfiche, or other accurate reproductions of the original records.	microfilm, microfiche, or other accurate reproductions of the original records.
Subpart K--Disqualification of Testing Facilities **Sec. 58.200 Purpose.** (a) The purposes of disqualification are: (1) To permit the exclusion from consideration of completed studies that were conducted by a testing facility which has failed to comply with the requirements of the good laboratory practice regulations until it can be adequately demonstrated that such noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study; and (2) To exclude from consideration all studies completed after the date of disqualification until the facility can satisfy the Commissioner that it will conduct studies in compliance with such regulations. (b) The determination that a ***nonclinical laboratory*** study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.	**No Comparable**	**No Comparable**
Subpart K--*Disqualification of Testing Facilities* **Sec. 58.202 Grounds for disqualification.** The Commissioner may disqualify a testing facility upon finding all of the following:	**No Comparable**	**No Comparable**

(a) The testing facility failed to comply with one or more of the regulations set forth in this part (or any other regulations regarding such facilities in this chapter); (b) The noncompliance adversely affected the validity of the ***nonclinical laboratory*** studies; and (c) Other lesser regulatory actions (e.g., warnings or rejection of individual studies) have not been or will probably not be adequate to achieve compliance with the good laboratory practice regulations.		
Subpart K-- ***Disqualification of Testing Facilities*** **Sec. 58.204 Notice of and opportunity for hearing on proposed disqualification.** (a) Whenever the Commissioner has information indicating that grounds exist under Sec. 58.202 which in his opinion justify disqualification of a testing facility, he may issue to the testing facility a written notice proposing that the facility be disqualified. (b) A hearing on the disqualification shall be conducted in accordance with the requirements for a regulatory hearing set forth in part 16 of this chapter.	**No Comparable**	**No Comparable**
Subpart K-- ***Disqualification of Testing Facilities*** **Sec. 58.206 Final order on disqualification.** (a) If the Commissioner, after the regulatory hearing, or after the time for requesting a hearing expires without a request being made, upon an evaulation of the administrative record of the disqualification proceeding, makes the findings required in Sec. 58.202, he shall issue a final order disqualifying the facility. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the testing facility of the action.	**No Comparable**	**No Comparable**

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in Sec. 58.202, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order the Commissioner shall notify the testing facility and provide a copy of the order.		
Subpart K-- *Disqualification of Testing Facilities* **Sec. 58.210 Actions upon disqualification.** (a) Once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any ***nonclinical laboratory*** study conducted by the disqualified testing facility may be examined to determine whether such study was or would be essential to a decision. If it is determined that a study was or would be essential, the Food and Drug Administration shall also determine whether the study is acceptable, notwithstanding the disqualification of the facility. Any study done by a testing facility before or after disqualification may be presumed to be unacceptable, and the person relying on the study may be required to establish that the study was not affected by the circumstances that led to the disqualification, e.g., by submitting validating information. If the study is then determined to be unacceptable, such data will be eliminated from consideration in support of the application; and such elimination may serve as new information justifying the termination or withdrawal of approval of the application. (b) No ***nonclinical laboratory*** study begun by a testing facility after the date of the facility's disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated under Sec. 58.219. The determination that a	**No Comparable**	**No Comparable**

study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration. [43 FR 60013, Dec. 22, 1978, as amended at 59 FR 13200, Mar. 21, 1994]		
Subpart K-- *Disqualification of Testing Facilities* **Sec. 58.213 Public disclosure of information regarding disqualification.** (a) Upon issuance of a final order disqualifying a testing facility under Sec. 58.206(a), the Commissioner may notify all or any interested persons. Such notice may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the good laboratory practice regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under Sec. 58.206(a) and shall state that the disqualification constitutes a determination by the Food and Drug Administration that ***nonclinical laboratory*** studies performed by the facility will not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. If such notice is sent to another Federal Government agency, the Food and Drug Administration will recommend that the agency also consider whether or not it should accept ***nonclinical laboratory*** studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified. (b) A determination that a testing facility has been disqualified and the administrative record regarding such	**No Comparable**	**No Comparable**

determination are disclosable to the public under part 20 of this chapter.		
Subpart K-- *Disqualification of Testing Facilities* **Sec. 58.215 Alternative or additional actions to disqualification.** (a) Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a ***nonclinical laboratory*** study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate. (b) The Food and Drug Administration may refuse to consider any particular ***nonclinical laboratory*** study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.	**No Comparable**	**No Comparable**
Subpart K-- *Disqualification of Testing Facilities* **Sec. 58.217 Suspension or termination of a testing facility by a sponsor.** Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from	**No Comparable**	**No Comparable**

further participation in a **nonclinical laboratory** study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), it shall notify that Center in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration. [43 FR FR 60013, Dec. 22, 1978, as amended at 50 FR 8995, Mar. 6, 1985]		
Subpart K-- *Disqualification of Testing Facilities* **Sec. 58.219 Reinstatement of a disqualified testing facility** A testing facility that has been disqualified may be reinstated as an acceptable source of **nonclinical laboratory** studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future **nonclinical laboratory** studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under Sec.	**No Comparable**	**No Comparable**

58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under part 20 of this chapter.		