

**§ 792.135**

**40 CFR Ch. I (7-1-12 Edition)**

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.

**§ 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 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]**

**Subpart J—Records and Reports**

**§ 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, 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, 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.

(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.

(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.

(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, 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.