

4740.2097 RECORDS RETENTION AND RETRIEVAL.

A. The record-keeping system must allow historical reconstruction of all laboratory activities that produced the analytical data. This also applies to interlaboratory transfers of samples or extracts and the data resulting from the analysis of the samples or extracts.

B. Unless otherwise required by permit, program, or rule, all records must be retained for a minimum of five years after generation of the last entry in the record. All information required for the historical reconstruction of the data must be maintained by the laboratory. If records are retained only in electronic form, the hardware and software required for the retrieval of electronic records must be retained for the same time period as the records to be retrieved.

C. The records must include the identity of personnel designated by the laboratory as responsible for the task performed, as described in the person's job description. The laboratory must retain records of the signatures and initials of designated personnel.

D. All information relating to the laboratory facilities, equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, must be documented.

E. The record-keeping system must allow the retrieval of all working files and archived records for inspection and verification purposes, including but not limited to systematic naming of electronic files.

F. All records must be signed or initialed by personnel designated by the laboratory as responsible for the task performed. All changes must be clearly indicated in the records. The laboratory must have procedures for recording changes and identifying the personnel making the change.

G. All observations used to calculate the final result must be recorded immediately. If the record is handwritten, the record must be legible and in permanent ink.

H. Entries in records must not be obliterated by methods such as erasures, overwritten files, or markings. All corrections to records on paper must be made by one line marked through the error. The individual making the correction must sign or initial and date the handwritten or electronic correction.

I. A laboratory must maintain a record-keeping system that includes procedures for protecting the integrity and security of the data.

J. A laboratory must supply any documentation or data listed in parts 4740.2010 to 4740.2120 within 30 days of the date that the commissioner requests the information.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

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