

4740.2065 STANDARD OPERATING PROCEDURES.

Subpart 1. **Written procedures required.** A laboratory must possess a written manual of standard operating procedures used by laboratory personnel for the analysis of samples. A laboratory must prepare written procedures for all laboratory activities including, but not limited to, sample analysis, operation of instrumentation, generation of data, and performance of corrective action.

Subp. 2. **Quality control.** Actual practice must conform to the written procedures. A laboratory must ensure that the applicable requirements in parts 4740.2080 to 4740.2120 are incorporated into each procedure. All quality control measures must be assessed and evaluated on an ongoing basis. Quality control acceptance criteria in the laboratory's quality assurance manual must be used to determine the validity of the data.

Subp. 3. **Manual requirements.** A standard operating procedures manual must contain:

- A. a table of contents;
- B. a unique identification of the manual, such as a serial number, an identification on each page to ensure that the page is recognized as a part of the manual, and a clear identification of the end of the manual;
- C. the laboratory's name. When several separate procedures are included in the manual, the name must appear on each procedure;
- D. a revision number; and
- E. a date indicating when the revision became effective.

Subp. 4. **Effective dates.** A laboratory must maintain a record of effective dates for all procedures. A copy of the procedure and the record of effective dates must be maintained for the same period of time that records of the data generated by those procedures are required to be maintained.

Subp. 5. **Availability.** A copy of a written procedure must be available to all personnel that engage in that particular activity.

Subp. 6. **Required use.** An analyst must use the laboratory's standard operating procedure beginning on the effective date for all laboratory activities for the analysis of samples for which certification is required.

Subp. 7. **Copy to commissioner.** A laboratory must submit a copy of its laboratory standard operating procedures manual to the commissioner at the time of application and within 30 days after the effective date of the revision. All changes to the standard operating procedures must be documented. The changes must be incorporated into the manual at least annually. All updated standard operating procedures must include the signature of the managing agent upon revision. The revised procedure manual must be forwarded to the commissioner in its entirety no later than 30 days after its effective date of revision.

Subp. 8. [Repealed, 44 SR 371]

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446; 44 SR 371*

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