

4740.2089 STANDARDS, REAGENTS, AND BACTERIOLOGICAL MEDIA.

A. Reference standards that are used in the laboratory must be obtained, when available, from the National Institute of Standards and Technology (NIST), manufacturers that supply NIST standards or NIST traceable standards, or an international standard-setting organization.

B. A laboratory must retain records for all standards, reagents, and bacteriological media. The records must include:

- (1) identification of the manufacturer or vendor;
- (2) certificate of analysis or purity, if supplied;
- (3) lot number;
- (4) date of receipt or preparation;
- (5) preparer's initials, if applicable;
- (6) method of preparation, when prepared in the laboratory;
- (7) recommended storage conditions; and

(8) expiration date after which the material must not be used unless its reliability is verified by the laboratory.

C. All containers of reagents, standards, and bacteriological media must be assigned a unique identification linked to records containing the documentation required in this part.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

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