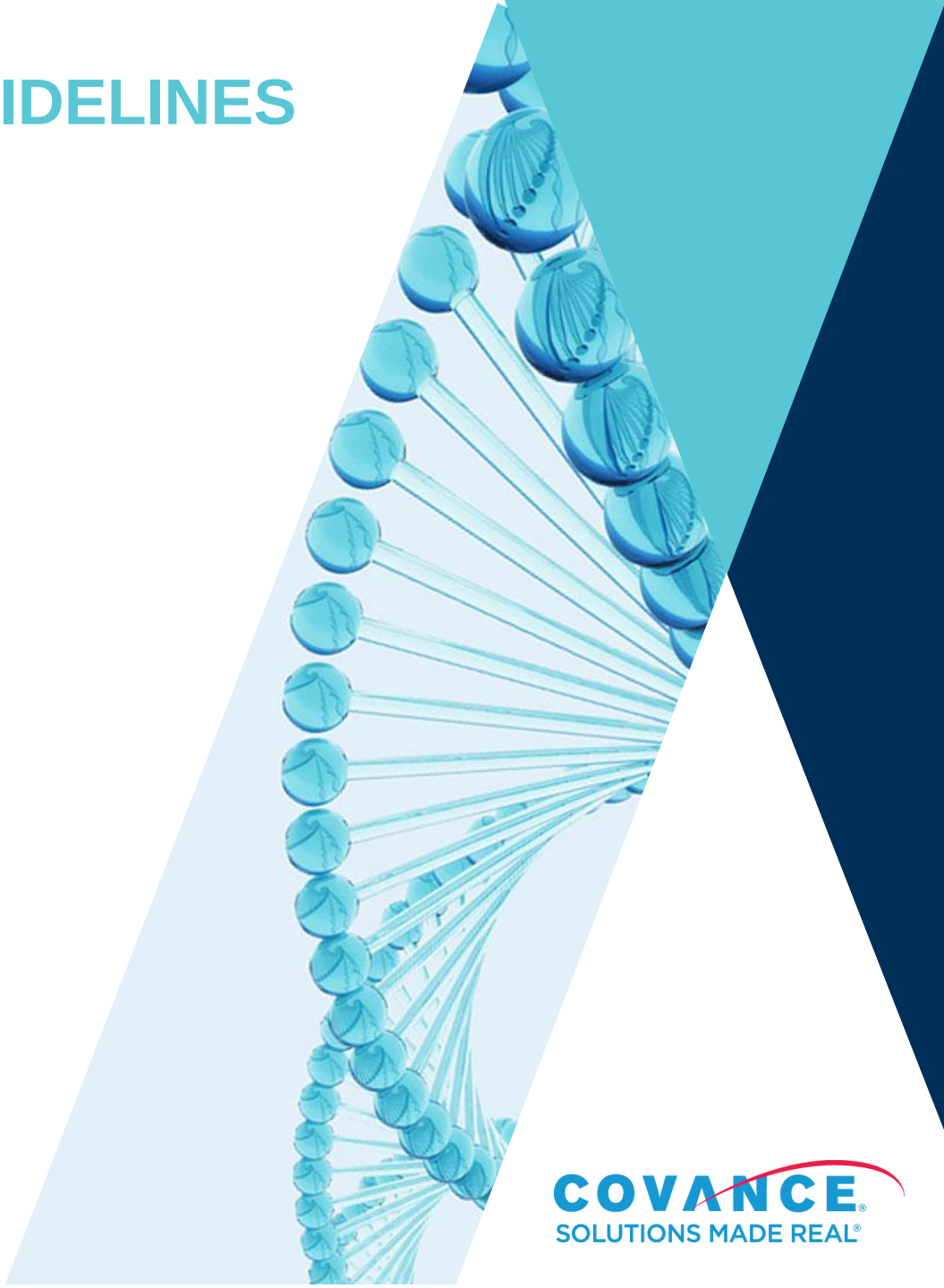
2015 AOAC ALACC GUIDELINES

Revision Summary



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Process

Chemistry

Microbiology

Pharma

Dietary Supplements
NEW

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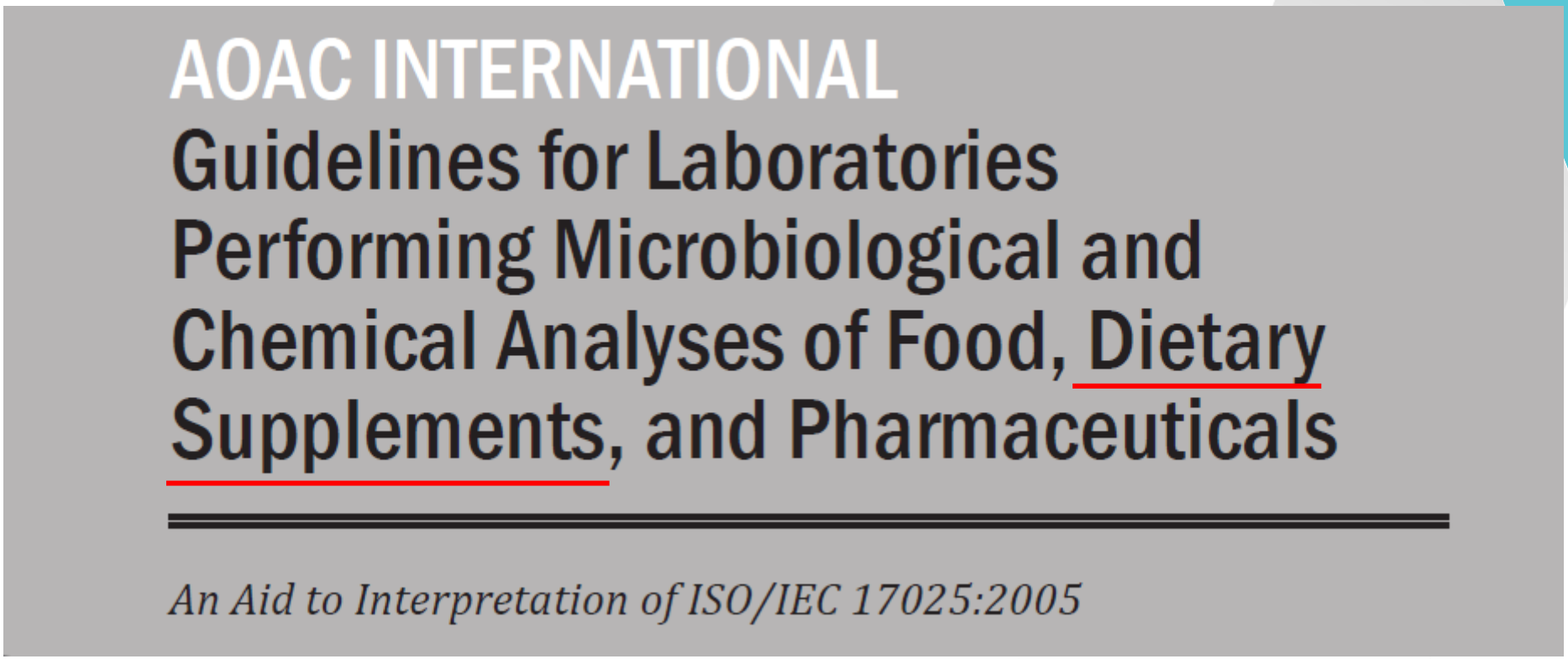
Title



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Section 1. Scope

1.1

This document is intended to provide guidance consistent with regulatory bodies having jurisdiction over dietary supplements such as FDA, Health Canada, and the Therapeutic Goods Administration (TGA).

1.5

Added reference to microbial and tissue disposal to bring microbiology on more equal footing

Section 3. Terms and Definitions

Removed references to document dates to minimize future updates

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4.1 Organization

4.1.5

(b) Removed requirement for **annual** attestation of commitment to avoiding conflict-of-interest in exchange for predetermined schedule.

(e) Removed prescriptive requirement for organizational **chart** in exchange for organizational description that could include charts.

4.1.6

New note

Note: Examples of communication processes are regularly scheduled meetings, distributing the annual management review to laboratory staff, effective leadership and supervision, etc.

4.6 Purchasing Services and Supplies

4.6.2 In some industries, such as dietary supplement or pharmaceutical, the use of specific reference materials (RMs) is mandated by the authoritative body, for example, the USP Reference Standards or the EP Certified Reference Standards. Reference Materials/Standards obtained from such authoritative sources are presumed to be suitable for their defined uses.

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4.8 Complaints

New requirement:

For dietary supplements and pharmaceuticals, a qualified person must review complaints for possible failures and investigate where needed.

4.9 Control of Nonconforming Testing and/or Calibration Work

New note for dietary supplement and pharmaceutical work.

Note: Specifications may be an important aspect of the laboratory's samples, therefore procedures for responding to out-of-specification (OOS) results should be considered. The degree to which OOS results are investigated can vary, so the laboratory is encouraged to design procedures that suit the industries they serve. Guidelines are available from organizations such as FDA and TGA.

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4.13 Control of Records

4.13.1 General

4.13.1.1

New Requirement: Labs must establish minimum record maintenance and security requirements.

4.13.2 Technical Records

4.13.2.1

New Requirement: Added (n) to require audit trail for proficiency test results

5.2 Personnel

5.2.1

Minor edits throughout for clarity and to remove extraneous verbiage.

New Requirement: 3rd paragraph adds explicit requirement to verify effectiveness of training.

New Requirement: Clear records when training on portions of procedures.

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5.2 Personnel (continued)

5.2.2

Moved content from 4.2.2 about regular training on roles and responsibilities within the management system and its maintenance.

5.3 Accommodation and Environmental Conditions

5.3.2

2010 Guidelines contained no guidance in this section.

Moved content from 5.4.1 on the topic of reagent grades to this more appropriate section and edited text for clarity.

New Requirement: Environmental monitoring for microbiology labs consistent with industry standards.

5.3.3

Minor edits

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5.3 Accommodation and Environmental Conditions (continued)

5.3.5

New Requirement: Documented cleaning and sanitization schedules for lab areas and equipment with performance recorded.

Discussion on consideration for sterile supplies in microbiology labs.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

Discussion moved to 5.3.2.

5.4.2 Selection of Methods

New Requirement: Must confirm performance of standard methods before use on routine samples (i.e., cannot verify concurrent to running client samples).

5.4.5 Validation of Methods

Two notes added to provide guidance on validation with published references.

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5.4 Test and Calibration Methods and Method Validation (continued)

5.4.5 Validation of Methods (continued)

5.4.5.3

Note edited to allow use of well characterized, homogenous, stable samples such as proficiency samples for accuracy - rather than just mentioning reference standards and spiking.

Removed discussion of use of incurred samples

Moved comment about estimating measurement uncertainty to 5.4.6.

5.4.6 Estimation of Measurement of Uncertainty

5.4.6.3

New Requirement: Identification of components of uncertainty.

Corrected and provided additional references to help labs calculate estimations.

Gives categories of uncertainty

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5.5 Equipment

New Requirements: Explicitly requires records for any calibrations, verifications, service, and maintenance. Discusses requirements around performance checks. Requires plans or procedures for calibration and verification of equipment in Appendix A, Table 1.

5.6 Measurement Traceability

Guidance added on how to establish measurement traceability. Indicated traceability may not be required for equipment/instruments with insignificant contributions.

5.6.3.1 Reference Standards

Minor edits for clarity.

5.6.3.2 Reference Materials

Changed “chemical Reference Material” to “Reference Material”. Added reference to assist labs.

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5.5 Sampling

Minor edits for clarity

5.8 Handling of Test and Calibration Items

5.8.4

New Requirement:

Staff associated with administration of the sample handling system shall be properly trained, competent, and authorized. Minimum sample retention periods and storage conditions shall be documented in the management system and communicated to customers so that all parties are aware of how long the sample will be available for retesting or retrieval.

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5.9 Ensuring the Quality of Test Results

5.9.1

Section reorganized into two major categories:

Quality Control Samples

Quality control procedures shall be defined for both quantitative and qualitative methods. These procedures

Proficiency Test Samples

Proficiency testing (PT) is the determination of the testing performance of a laboratory against preestablished

New Requirement:

Laboratory On-going Competency: Laboratories shall participate in at least one PT event annually for each test, type of test/method, and/or technique on the scope of accreditation.

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5.9 Ensuring the Quality of Test Results (continued)

5.9.1

Section now clearly defines options for PT and adds option

- Participate in a round robin: interlaboratory test performed independently several times
- Testing of a blinded well-characterized laboratory control sample (LCS)
- Performance of an ILC with other accredited testing laboratories
- Performance of a comparison with another test method/technology
- Address the elements identified in ISO/IEC 17025 Section 5.9, including the evaluation criteria of the data

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5.9 Ensuring the Quality of Test Results (continued)

5.9.2

Acceptability criteria moved from 5.9.1

Quality Control Sample Acceptability

The laboratory shall have procedures that define the acceptability of quality control samples. A laboratory's

Proficiency Test Sample Acceptability

The laboratory shall evaluate PT results when they are received. Most external PT providers issue acceptability

Specific ratings for PT results removed.

Note added.

Note: Proficiency testing is only a part of the overall quality assurance of test results and should not be used as the only assessment of laboratory competency.

5.10 Reporting the Results

Edited for clarity

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Table 1

Appendix A: Equipment

Table 1. Calibration, verification, and service of equipment or systems

Equipment/system	Parameter	Frequency
Autoclaves	Accuracy of temperature sensing system	Calibrate at installation (or initial use)
		Verify annually
	Temperature and pressure	Verify each load
	Performance	Verify weekly with *Bacillus stearothermophilus* biological sterility indicator
	Uniformity and stability of temperature[A]	Conduct an initial mapping of the chamber and annually thereafter
	Service	As recommended by manufacturer or per laboratory procedure
Automated colony counters	Accuracy	Verify annually with manual count
Balances	Mass measurement	Verify daily when in use with internal calibration or with a working weight
		Calibrate annually[B]
Chromatographic systems (GC, IC, LC)	Detector response	Verify at a frequency established by the test

From old Appendix B

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Table 1

Chromatographic systems (GC, IC, LC)	Detector response	Verify at a frequency established by the test method or laboratory using multi-level standards that establish a correlation between analytical standard concentrations and instrument response[c]
		Verify with an analytical standard at mid-range concentration with each batch
DI systems	Conductivity	Weekly
Dispensing equipment and vial fillers used in microbiology	Mass measurement/volume	Verify at installation and daily when in use at each volume dispensed
Freeze-dryers, vacuum ovens	Ability to achieve and sustain vacuum; gauges calibrated or verified	Verify annually
Fume hoods	Service	Annually
Hydrometer, reference	Specific gravity	Calibrate every 2 years
Hydrometer, working	One point comparison to reference hydrometer	Verify annually
Microscope	Length	Calibrate stage micrometer at installation

NEW

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Table 1

Microscope	Length	Calibrate stage micrometer at installation
pH meters, ion selective, and related conductivity equipment	Reading with standard reference buffers[D]	Verify (bracketing range of use)
Safety cabinets and laminar airflow cabinets (if used for culture or sterility work)	Magnehelic gauge	Verify at installation and each day of use
	Open media control (sterility check)	During each use
	Service	As recommended by manufacturer
Temperature controlled chambers (refrigerators, freezers, ovens, furnaces, water baths)	Temperature	Monitor continuously with a validated system or check daily when in use
	Uniformity and stability of temperature[A]	Conduct an initial mapping of the chamber; verify annually and/or if the instrument has had maintenance repairs that would affect the inner chamber
Temperature controlled chambers used for incubation (incubators, water baths)	Temperature	Check daily am and pm when in use
	Uniformity and stability of temperature[A]	Conduct an initial mapping of the chamber; verify annually and/or if the instrument has had maintenance repairs that would affect the inner chamber[E]
Temperature sensing devices/systems (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.)	Temperature	Reference device: Calibrate annually
		Working device: Verify annually against reference device[F]

NEW Names

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Table 1

Equipment/system	Parameter	Frequency
Timers and internal timing devices[G]	Time	Calibrate reference device annually if used
		Verify annually working device against reference or against NIST time clock[F]
UV/Vis spectrophotometer	Blank reading	Verify daily when in use
	Wavelength	Verify at installation by manufacturer and annually
Volumetric delivery devices: mechanical pipets, micropipettors, mechanical burets, and bottle-top dispensers	Accuracy and precision using mass of water or by spectrophotometric method	Verify every 6 months or at an increased frequency if required by regulation or test method
Volumetric delivery devices: positive displacement syringes used for volumetric delivery	Accuracy	Verify upon receipt; (manufacturer's Certificate of Accuracy may be accepted)
Volumetric glassware, non-class A—pipets, burets, and volumetric flasks	Accuracy and precision using mass of water or by spectrophotometric method	Verify upon receipt (manufacturer's Certificate Accuracy may be accepted)
Water activity meter	Water activity of known solutions	Verify daily when in use[D]
Weights, reference	Mass	Calibrate every 5 years[B]
Weights, working	Mass	Verify against reference weights annually

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Table 1

[A]	Uniformity and stability may not be needed for the following equipment: small chambered autoclaves, incubators, ovens, and refrigerators; circulating water baths; muffle furnaces; and freezers based on use or design. In these cases, the laboratory should have reasonable justification and document the justification for not determining uniformity and stability.
[B]	All weights and balances shall be calibrated traceable to recognized national or international calibration units [i.e., National Institute of Standards and Technology (NIST), Bureau International des Poids et Mesures (BIPM), Organisation Internationale de Métrologie Légale (OIML), or equivalent traceable weights]. Accrediting bodies may require calibration by an ISO 17025 accredited calibration laboratory.
[C]	Frequently, an instrument such as a gas chromatograph does not lend itself to calibration using a national or international standard. In these cases, adequate performance of the whole method involving the instrument is ensured by using a Certified Reference Material (CRM) or Reference Material (RM).
[D]	When pH and water activity are used to generate results reported to the customer, the traceability requirement is critical; hence, the reference material (e.g., buffer or water activity analytical standard) needs to be one that has the estimate of uncertainly available in the Calibration Certificate. In addition, the calibration must be done in a defined manner to take into account the measurement uncertainty. Accreditation bodies may require buffers obtained from a Guide 34 accredited manufacturer.
[E]	When determining mapping schedules, attention should be paid to extremes in laboratory ambient conditions (such as those brought on by seasonal changes) that can influence the performance of equipment.
[F]	Accrediting bodies may require initial calibration by an ISO 17025 accredited calibration laboratory.
[G]	Timers and internal timing devices only need to be verified when time is a critical factor in the test method. Time may not be a critical factor when time is not the reported result or a specific time requirement is not required for the test method.

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Appendix B: Microbiology

2. Media

2.1 Dehydrated Media Requirements and Records

2.1.1 **New Requirement:** Lot evaluated for suitability before use

2.1.3 Clarifies records to be kept

4. Sterilization

Autoclave verification requirements moved to Table 1

Sections 5 and 6 deleted

Too specific and covered by general sections.

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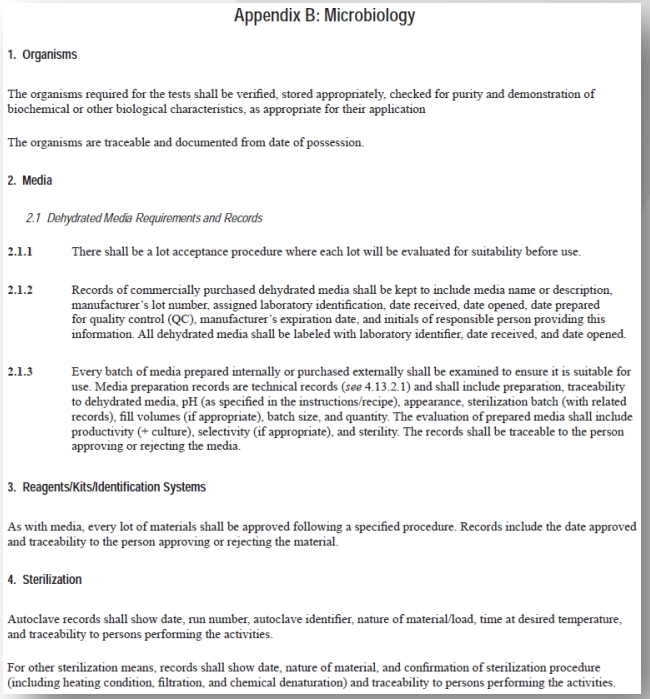

Appendix B: Microbiology

1. Organisms

The organisms required for the tests shall be verified, stored appropriately, checked for purity and demonstration of biochemical or other biological characteristics, as appropriate for their application

The organisms are traceable and documented from date of possession.

2. Media

2.1 Dehydrated Media Requirements and Records

2.1.1 There shall be a lot acceptance procedure where each lot will be evaluated for suitability before use.

2.1.2 Records of commercially purchased dehydrated media shall be kept to include media name or description, manufacturer's lot number, assigned laboratory identification, date received, date opened, date prepared for quality control (QC), manufacturer's expiration date, and initials of responsible person providing this information. All dehydrated media shall be labeled with laboratory identifier, date received, and date opened.

2.1.3 Every batch of media prepared internally or purchased externally shall be examined to ensure it is suitable for use. Media preparation records are technical records (*see* 4.13.2.1) and shall include preparation, traceability to dehydrated media, pH (as specified in the instructions/recipe), appearance, sterilization batch (with related records), fill volumes (if appropriate), batch size, and quantity. The evaluation of prepared media shall include productivity (+ culture), selectivity (if appropriate), and sterility. The records shall be traceable to the person approving or rejecting the media.

3. Reagents/Kits/Identification Systems

As with media, every lot of materials shall be approved following a specified procedure. Records include the date approved and traceability to the person approving or rejecting the material.

4. Sterilization

Autoclave records shall show date, run number, autoclave identifier, nature of material/load, time at desired temperature, and traceability to persons performing the activities.

For other sterilization means, records shall show date, nature of material, and confirmation of sterilization procedure (including heating condition, filtration, and chemical denaturation) and traceability to persons performing the activities.

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Appendix C: Chemistry ***NEW***

Appendix C: Chemistry

The laboratory shall define the acceptance criteria for each test method for the following items (when included in the test method): calibration curves, calibration checks, second source standards, quality control samples, blanks, spikes, matrix spikes, and duplicates.

The laboratory shall have a procedure or policy that provides guidance and/or criteria for the reprocessing and/or reintegrating of analytical data.

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Appendix D: Pharmaceutical Analysis and Legal Standards

Moved from C to D, but no edits

Appendix E: Legal Samples ***NEW***

Appendix E: Legal Samples

Legal samples are samples to be used in a court of justice or samples taken under the authority of a government agency for legal testing. All legal procedures prescribed by the agency or the body requiring the samples must be followed.

A chain of custody procedure must be applied for all samples and fully documented. Retain samples, if available or sufficient, for additional testing or to fulfill the right to access a second opinion or expertise must be kept according to the body requiring the sample.

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Questions