Washington State Department of Health
ELABORATIONS
News and Issues for Washington's Clinical Laboratories

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Top 10 deficiencies in 2019

The Washington State Department of Health, Laboratory Quality Assurance (LQA) team inspected 303 laboratories in 2019 under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited during 2019. The MTS Washington Administrative Code (WAC) citation appears after each item.

No. 1. No Remedial Action Taken {WAC 246-338-080(3)}: Document and maintain all remedial action in response to failures in quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigation. This deficiency is also cited when the laboratory fails to recognize that it has a failure and/or does not take effective action to correct the problem.

Compliance Tips:
- Establish an effective mechanism to recognize that problems exist, and document appropriate corrective action.
- Review documentation regularly and record that review.
- Document, document, and document.

No. 2. Proficiency Testing to include Proficiency Testing (PT) failures {WAC 246-338-050(1)(a)}: Participation in proficiency testing (PT) is required for all regulated analytes tested in your laboratory. The LQA website has information about PT requirements and a list of the regulated analytes under the "MTS Proficiency Testing" option on the left side of the screen. For non-regulated analytes, the laboratory can enroll in PT or use an alternative method (biannual verification) to comply with the regulation. PT is not required for waived tests, but is recommended as good laboratory practice.

Compliance Tips:
- Enroll in PT for all regulated analytes each year.
- Enroll in PT or develop a biannual verification (BV) policy for non-regulated analytes; test at least two samples per analyte twice per year.
- Check the attestation statements for signatures of the laboratory director (or designee per delegation policy) and the testing personnel.
- Rotate PT sample testing among all testing personnel.
- Ensure the PT samples are treated in the same manner as patient samples.
- Document the review of PT or BV results and any remedial action to correct problems including those results that are not graded by the PT company.

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the LQA website.

Acute Diarrhea
Anemia
ANA
Bioterrorism Event Mgmt
Bleeding Disorders
Chlamydia
Diabetes
Group A Strep Pharyngitis
Group B Streptococcus
Hepatitis
HIV
Infectious Diarrhea
Intestinal Parasites
Lipid Screening
PAP Smear Referral
Point-of-Care Testing
PSA
Rash Illness
Red Cell Transfusion
Renal Disease
STD
Thyroid
Tuberculosis
Urinalysis
Wellness

Top 10 deficiencies in 2019 (cont'd from page 1)

No. 3. Record Retention {WAC 246-338-070(8)}: The MTS must retain records, slides, and tissues as described in Table 070-1(see page 4), under storage conditions that ensure proper preservation.

Compliance Tips:

- Write and follow a record retention policy for your facility that meets or exceeds the requirements in Table 070-1.
- Records must be available during onsite inspections. If some records are stored offsite, be prepared to quickly retrieve records the inspector requests.

No. 4. Personnel Competency Evaluation {WAC 246-338-060(3)(b)(iv)}: The MTS director must evaluate, verify, and document the competency of technical personnel who perform test procedures and report test results.

Compliance Tips:

- Have a written policy defining personnel competency testing for your facility.
- Ensure your policy incorporates direct observation, review of records, performance of maintenance, assessment of test performance through testing previously analyzed samples, blind samples, or external proficiency testing samples, and problem-solving skills.
- Document the initial training of new testing personnel, assess competency at about six months and annually thereafter.
- Document remedial action for personnel failing the competency assessment.

No. 5. Preventative Maintenance Activities {246-338-090(2)(b)}: The MTS must establish criteria for, and maintain appropriate documentation of preventative maintenance activities.

Compliance Tips:

- Review necessary preventative maintenance required by the manufacturer for all instruments and/or methods.
- Establish a schedule for preventative maintenance activities as required by the manufacturer of instruments or methods.
- Review preventative maintenance logs, either electronically or manually, regularly to ensure that preventative maintenance is documented as per manufacturer requirements.
- Document remedial action when preventative maintenance activities are not performed as required by the manufacturer.

No. 6. Equipment Function Checks were not completed as required {WAC 246-338-090(2)(c)}: The laboratory must establish written criteria for, and maintain appropriate documentation for, equipment function checks.

Compliance Tips:

- Review all manufacturer product inserts and regulations to identify function checks required by the manufacturer or regulating organizations. Establish a schedule to perform these function checks and record that they have been performed.
- Review schedule for function checks when new tests, methods, or equipment are installed and put into use. Follow manufacturer product inserts and regulatory requirements.
- Rotate these function checks among all testing personnel who are responsible for instrument performance.
- Review documentation to validate that equipment functions checks are being performed as required.

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Laboratory Quality Assurance
Public Health Laboratories

Top 10 deficiencies in 2019 (cont'd from page 2)

No. 7. Temperature Records {WAC 246-338-090(2)(a)}: Establish written criteria for and maintain appropriate documentation of temperature-controlled spaces and equipment. Include the monitoring of room temperature for reagents stored at room temperature or if the manufacturer specifies a specific temperature range and percent humidity when specified by the test method or equipment. Temperature storage and ranges are found in the package insert and/or on the reagent box.

Compliance Tips:

- Establish acceptable temperature ranges. If the manufacturer recommends different ranges, the range used should be the most restrictive.
- Record temperatures on each day of business, including room temperature if specified for reagents, supplies, or equipment.
- Document corrective action taken when temperatures are outside acceptable limits.
- Re-record temperatures several hours after an adjustment to the thermostat.
- Ensure that the thermometers are calibrated and reading accurately.

No. 8. Personnel Education and Training {WAC 246-338-060(3)(b)(i)}: The MTS director must evaluate, verify, and document the education, experience, and training for all testing personnel. This deficiency will be cited if there is no documentation showing that the testing personnel are qualified to perform laboratory testing, or if there is no documentation of initial training for new testing personnel.

Compliance Tips:

- Establish a hiring protocol that includes documentation that testing personnel are qualified to perform moderate or high-complexity testing by having on-site copies of diplomas or transcripts with the date of graduation.
- Verify that current personnel have documentation on record that they are qualified to perform laboratory testing.
- Establish a protocol to have any qualification documentation that is in a foreign language translated into English so the surveyor will be able to read the qualifications.
- Foreign transcripts must be reviewed by an approved transcript evaluation agency to determine U.S. degree equivalency.
- Develop an initial testing personnel training document and complete that before performing patient testing.

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No. 9. Procedures {WAC 246-338-090(1)(a)}: The MTS must have written procedures and policies available in the work area for analytical methods used by the technical personnel.

Compliance Tips:

- Define "what" needs to be done in policies and "how" things are done in your procedures.
- Procedures should be written in Clinical Laboratory and Standards Institute (CLSI) format.
- Establish a timeline for annual review of procedures by the laboratory director.
- Document the review and approval of procedures by the laboratory director.
- Ensure that current procedures are available for analytical methods.
- Ensure that the most current product insert is available and signed by the MTS director if used as the primary procedure. Ensure that the staff adheres to written procedures and policies.
- Establish a mechanism to update procedures when there are changes in equipment or test methodology.
- Remove procedures no longer performed by the laboratory and place them in a file or separate notebook to be retained for two years.

No. 10. Quality Control {WAC 246-338-090(5)(b)}: Follow an equivalent quality testing procedure that meets federal CLIA regulations.

Compliance Tips:

- Establish an individualized quality control plan (IQCP) if you are performing two levels of external quality control less than each day of patient testing.
- IQCP is voluntary, but otherwise laboratories can achieve compliance by performing two external levels of QC each day of patient testing.
- Establish a separate IQCP for each qualifying test system.
- Ensure that all three components of an IQCP are addressed:
    - o Risk assessment
    - o Quality control plan
    - o Annual quality assessment
- Ensure that your risk assessment addresses the 5 following risk components in each phase of testing (pre-analytic, analytic, and post-analytic) :
    - o Specimen
    - o Environment
    - o Reagent
    - o Test system

table 070-1 Record/Slide/Tissue Retention Schedule

	Two Years	Five Years	Ten Years
(a) General Requirements for all Laboratory Specialities	• Test requisitions or equivalent; • Test records, including instrument printouts if applicable; • Test reports; • Quality control records; • Quality assurance records; • Proficiency testing records; • Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and • Discontinued procedures for all specialty areas		
(b) Transfusion Services		• Test requisitions or equivalent; • Test records; • Test reports; • Quality control records; • Quality assurance records	• Individual Product Records *
(c) Cytology		• All cytology slides, from date of examination of the slide	• All cytology reports
(d) Histopathology/Oral Pathology	• Specimen blocks, from date of examination		• All histopathology and oral pathology reports; • Stained slides, from date of examination of the slide
(e) Histopathology/Oral Pathology-Tissues	Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examinied and diagnosed		
(f) Instrument/method Validation Studies	For life of instrument/method plus two years		
*Must be retained for no less than ten years in accordance with 21 CFR 606.160(d)			

27th Annual Clinical Laboratory Conference
Virtual Event

November 9, 2020

Mark Your Calendars Now!!!

Calendar of Events

Training Classes:

2020 Northwest Medical Laboratory Symposium
October 15-16 Virtual Event

27th Annual Clinical Laboratory Conference
November 9, 2020 Virtual Event

2021 ASCLS-WA Spring Seminar
April 22-23 Virtual Event

2021 Northwest Medical Laboratory Symposium
October 7-9 Virtual Event

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD 1-800-833-6388).

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