

Top 10 Deficiencies in Laboratory Inspections

The Washington State Department of Health's Laboratory Quality Assurance (LQA) team inspects laboratories under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies the team cited during these inspections. 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 quality control failures, quality assurance, personnel, proficiency testing, and transfusion reaction investigations. Inspectors also cited this deficiency when the laboratory failed to recognize that it had a failure and did 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 the laboratory director's signature (or designee per delegation policy) and the testing personnel.
- Rotate PT sample testing among all testing personnel.
- Ensure the PT samples are treated the same as patient samples.
- Document the review of PT or BV results and any remedial action to correct problems, including those results that the PT company does not grade.

No. 3. Record Retention {WAC 246-338-070(8)}: The MTS must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.
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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	Lipid Screening
Anemia	PAP Smear Referral
ANA	Point-of-Care Testing
Bioterrorism Event Mgmt	PSA
Bleeding Disorders	Rash Illness
Chlamydia	Red Cell Transfusion
Diabetes	Renal Disease
Group A Strep Pharyngitis	STD
Group B Streptococcus	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Infectious Diarrhea	Wellness
Intestinal Parasites	

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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 on-site 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, records review, maintenance performance, test performance assessment 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-

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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 your preventative maintenance is documented as per manufacturer requirements.
- Document remedial action when the manufacturer does not perform preventative maintenance activities as required.

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 the manufacturer or regulating organization's required function checks. Establish a schedule to perform these function checks and record that you have performed them.
- Review schedule for equipment function checks when new tests, methods, or equipment are installed and put into use. Follow manufacturer product inserts and regulatory requirements.
- Rotate equipment function checks among all testing personnel responsible for instrument performance.
- Review documentation to validate that equipment function checks are being performed as required.

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 room temperature monitoring 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

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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. Inspectors will cite this deficiency 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 graduation date.
- 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.
- An approved transcript evaluation agency must review foreign transcripts to determine U.S. degree equivalency.
- Develop an initial testing personnel training document and complete that before performing patient testing.

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

Compliance Tips:

- Define "what" needs to be done in policies and "how" things are done in your procedures.
- Write procedures in Clinical Laboratory and Standards Institute (CLSI) format.
- Establish a timeline for the 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:
 - Risk assessment
 - Quality control plan
 - Annual quality assessment
- Ensure that your risk assessment addresses the five following risk components in each phase of testing (pre-analytic, analytic, and post-analytic):
 - Specimen
 - Environment
 - Reagent
 - Test system
 - Test personnel
- Ensure that your IQCP establishes a quality control frequency that is not less than what is required by the manufacturer or what other regulatory requirements establish.
- Ensure the laboratory director approves the IQCP and reassesses it annually.



Calendar of Events

Training Classes:

2022 Virtual Joint Spring Seminar
April 20-22
(VIRTUAL)

2022 NWMLS
October 12-14
(VIRTUAL)

2022 Clinical Laboratory Conference
November (date TBD)

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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