Quality Assurance in Molecular diagnostic laboratory based on ISO15189 requirements

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Quality System Essentials
What Are Documents and Records?

Documents
• WRITTEN policies, process descriptions, procedures
• Blank forms
• Communicate information
• Need updating

Records
• Information captured on worksheets, forms, labels, and charts
• Permanent, do not change
Hierarchy of Documents

- **Policies**
  - "what to do"

- **Processes**
  - "how it happens"

- **Procedures / Work Instructions**
  - "how to do it" - (SOPs)
Document Preparation and Control Process

Preparation → Approval

Issue / Distribution ← Revision

Review
Organization

- Organogram
- Job description
- Responsibility and authority of each person
- Avoiding responsibilities’ overlaps
Process control

Pre-Analytic
- Personnel Competency
- Test Evaluations
- Sample Receipt and Accessioning
- Sample Transport

Post-Analytic
- Record Keeping
- Reporting

Analytic
- Quality Control Testing
- Data and Lab Management
- Safety
- Customer Service

• Patient/Client Prep
• Sample Collection
ISO 15189: 2012
Facilities & Physical lab

➢ Laboratory premises shall be maintained in a functional and reliable condition. Work areas shall be clean and well maintained.

➢ The laboratory shall monitor, control and record environmental conditions, where they may influence the quality of the sample, results, and/or the health of staff.
Laboratory Design Example

Figure 1. Recommended design for a molecular microbiology facility.
biosafety

The concomitant application of laboratory practices and procedures, laboratory facilities, and safety equipment when working with potentially infectious microorganisms
Biosafety Principles

- the existence of a responsible Supervisor
- Standards Operating Procedures
- the training of the personnel
  - aware of potential hazards
- Biosafety manual specific to different laboratories
Emergency Procedures

- Develop an emergency plan
  - Cuts, accidental punctures
  - Ingestion of chemicals/hazardous materials
  - Spills
  - Broken/leaking containers
  - Fire, and other natural disaster
  - MSDS: Material Safety Datasheet
ISO 15189: 2012

Staff competency

Job description

Training

Competency assessment

Continuing education

A routine reassessment

Job qualification

New instruments

New clinical programs and drugs

New tests

Technical competencies

Adherence to policies

Following safety rules

Communication skills

Skill refreshment

preliminary
Documenting Competency Assessment Program

- Have a written plan
  - New and existing staff
- Include in laboratory’s quality documents
- Periodically review
- Use for continual improvements
- Communicate the plans to the staff
<table>
<thead>
<tr>
<th>Method/Procedure</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Manuals</td>
<td></td>
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<tr>
<td>Direct Observation</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Safety policies followed</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Preparation of work area</td>
<td></td>
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<tr>
<td>Work area neat and organized</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Follows policies, procedures and rules pertaining to assignment</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Preparation/handling of specimen</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Preparation/handling of reagents</td>
<td></td>
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<tr>
<td>Preparation/handling of QC</td>
<td></td>
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</tr>
<tr>
<td>Preparation/handling of instrument and maintenance activities</td>
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<tr>
<td>Knowledge of criteria for acceptable specimen</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Knowledge of action if specimen is unacceptable</td>
<td></td>
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</tr>
</tbody>
</table>
Purchase, Inventory and Management of stocks

- Need for uninterrupted service
- More efficiency and service consistency
- Cost-effectiveness and avoiding waste
- Ensure that supplies and reagents are always available when needed
- Ensure that reagents and supplies are not lost to improper storage, expiration
Key points for Purchase, Inventory and Management of stocks

Minimum Inventory Level
• Amounts necessary to support normal operations until additional material can be supplied

Safety Stock
• Minimum to support emergency order

Lead-time
• Total time between placing order and receipt
• Include within-institution processing
Equipment

1. Organization
2. Selection and acquisition
3. Installation
4. Calibration / Validation (initial and ongoing)
5. Maintenance
6. Troubleshooting
7. Service and repair
Information management

Digital-based

Paper-based
Occurrence management

How are occurrences detected?

Monitoring complaints and satisfaction surveys

Management Review

Quality indicators
- Delayed reports
- Interpretation errors

Internal Audit
- Safety
- Quality

Process Monitoring
- Quality control
- L-J Charts

External Audit
- PT/EQA
- Accreditation
One example of an Occurrence Management Form

## Department of Laboratory Medicine and Pathology

### Laboratory Occurrence Management Form

**Effective Date:** mm/dd/yy

**PLEASE PRINT LEGIBLY**

### Step A: Fill out the following data completely:

- **Site of occurrence:** Hospital, OP LAB, Other: __________
- **Occurrence time (hr):** __________
- **Occurrence Date:** __________
  - (day/month/year)
- **Report Initiated by:** __________
  - Lab Dept (initiating the report): __________
  - Date of report: __________
- **Problem Identified by:** (Circle) LAB, NURSING, PHYSICIAN, Other: __________
  - Patient Location: __________
  - (if applicable)

### Step B: Indicate the problem and attach pertinent information if required (e.g., copy of requisition, report)

<table>
<thead>
<tr>
<th>Preambulatory (before testing) - circle UNIT/LAB as applicable</th>
<th>Analytical (testing phase)</th>
<th>Postanalytical (after testing)</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Specimen mislabeled/unlabeled by UNIT/LAB (computer codes here: __________)</td>
<td>[ ] Result discrepancies involving investigation</td>
<td>[ ] Critical result not phoned when required</td>
<td>[ ] LIS or IS problem</td>
</tr>
<tr>
<td>[ ] Specimen mix up/labeling error (computer codes here: __________)</td>
<td>[ ] Delay in testing/resulting (computer codes here: __________)</td>
<td>[ ] Patient Report sent to incorrect location/physician (e.g., copy to physician, ordering physician, FAX problems)</td>
<td>[ ] Equipment</td>
</tr>
<tr>
<td>[ ] Wrong tube type/container (computer codes here: __________)</td>
<td>[ ] Incomplete test run (circle one) REAGENT/INSTRUMENT/METHOD problem</td>
<td>[ ] Corrected reports required (complete Corrected Report Section below)</td>
<td>[ ] Purchasing</td>
</tr>
<tr>
<td>[ ] Delay in transport to laboratory (e.g., courier)</td>
<td>[ ] Invalid test run (QC failure)</td>
<td>[ ] Corrected Report Classification (circle one):</td>
<td>[ ] Receiving/Delivery</td>
</tr>
<tr>
<td>[ ] Tests missed at REI/wrong test ordered (computer codes here: __________)</td>
<td></td>
<td>B - Reporting error - corrected before release (near miss)</td>
<td>[ ] Vendor</td>
</tr>
<tr>
<td>[ ] Req missing UNIT/LAB</td>
<td></td>
<td>C - Minor report problem - e.g., revised format</td>
<td>[ ] Waste Management</td>
</tr>
<tr>
<td>[ ] Specimen lost (computer codes here: __________)</td>
<td></td>
<td></td>
<td>[ ] Environmental issue/Housekeeping</td>
</tr>
<tr>
<td>[ ] Specimen not handled/processed correctly (computer codes here: __________)</td>
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<td></td>
</tr>
<tr>
<td>[ ] Wrong episode selected at accessioning</td>
<td></td>
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</tr>
</tbody>
</table>
Step C: IMMEDIATE ACTION (Describe what happened and what was done)

Name of person providing immediate action ____________________________
(Investigation on reverse side)

Step D: Supervisor/Manager Investigation and Comments (optional): (How did this happen? Why did this happen? If appropriate, what changes have been made to prevent recurrence? Note: Have the necessary staff member review and sign.)

Supervisor Name: _______________ Date: _______________
Staff member reviewed (signature): _______________ Date: _______________
Assessment

- Important to monitor your laboratory for **compliance to quality practices**
- Both external and internal audits yield useful information
- Use information collected in the laboratory to identify problems
- Learn to find root causes of problems and take corrective action to fix
Assessment

Quality Improvement Plan

Corrective Action Plan

Monitoring & Evaluation
- Customer Satisfaction
- Quality Control
- PT
- Audits
Thanks for your attention