COLLEGE of AMERICAN PATHOLOGISTS
Laboratory Quality Solutions

ISO 15189: 2022 –
Key Quality Management System Clauses

Processes
Pre-examination (7.2)
Examination (7.3)
Post-examination (7.4)
Result reporting (7.4.1)

Documents and document control (8.2, 8.3)

Risk Management (5. 6, 7.8, 8.5)

Improving Processes
Non-conforming work (7.5)
Improvement (8.6)
Corrective action (root cause analysis) (8.7)

Risk Management (5. 6, 7.8, 8.5)

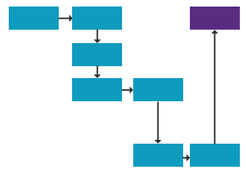
Monitoring Processes
Objectives and policies (5.5)
Complaints (7.7)
Evaluations (internal audits) (8.8)
Management reviews (8.9)

Risk Management (5. 6, 7.8, 8.5)

Resources and Infrastructure
Personnel (6.2)
Facilities (6.3)
Equipment (6.4, 6.5)
Reagents and consumables (6.6)
Externally provided products and services (6.8)
Control of data and information management (7.6)

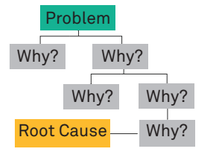
Risk Management (5. 6, 7.8, 8.5)

Frequent Areas of Nonconformance and Improvement Opportunities



Processes
- Not planning for risk when designing processes
- Not investigating how processes interact and the resulting risks
- Not involving the process users and not testing processes before official release

Risk Management
- Not using existing communication systems, eg, shift reports, as opportunities to identify risk
- Not mistake proofing processes
- Not monitoring the culture to make sure people feel able to speak up about risks



Corrective Action
- Shallow root cause analysis – eg, asking only one Why?
- Blaming people instead of analyzing processes for weaknesses
- Blaming learners instead of training

Internal Audit
- Checklist approach, versus a true process audit
- Poor selection and preparation of auditors
- Not considering risk when scheduling audits, eg, high risk areas, frequency of occurrences, new testing

Documents and Document Control
- Not keeping work aids and other secondary documents under control
- Creating difficult-to-follow procedures, eg, wall of words

Management Review
- Measuring things, but not doing anything about them; lack of follow up
- Not communicating outcomes to laboratory staff

Resources
- Not planning for gaps in staffing; not cross training staff
- Lack of standard process for inventory management and equipment maintenance
- Lack of evaluation of suppliers

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