

Laboratory Quality System Document Review Form

Laboratory Name _____ Laboratory Number: _____

Rating Guide Item (A02)	Quality Manual cross reference	Other cross reference
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4 Management Requirements

4.1.1 Organisation - policy and procedures for:

- | | | |
|---|-------|-------|
| • Registration of laboratory | _____ | _____ |
| • Laboratory responsibility | _____ | _____ |
| • Scope of management system | _____ | _____ |
| • Conflict of interest | _____ | _____ |
| • Authority of personnel | _____ | _____ |
| • Freedom from undue pressure | _____ | _____ |
| • Customer confidentiality | _____ | _____ |
| • Operational integrity | _____ | _____ |
| • Organization Charts | _____ | _____ |
| • Responsibilities of staff | _____ | _____ |
| • Supervision of personnel | _____ | _____ |
| • Technical management | _____ | _____ |
| • Quality manager | _____ | _____ |
| • Managerial substitution | _____ | _____ |
| • Place of Staff in Organization Objectives | _____ | _____ |
| • Responsibility for Communication | _____ | _____ |

4.2 Quality System - policies and objectives

- | | | |
|----------------------------|-------|-------|
| • Quality documents | _____ | _____ |
| • Quality policy statement | _____ | _____ |
| • Supporting procedures | _____ | _____ |
| • Mgt and Quality Roles | _____ | _____ |
| • Planned Changes | _____ | _____ |

4.3 Document Control - policies and procedures for:

- | | | |
|---------------------------|-------|-------|
| • Approval and issue | _____ | _____ |
| • Identification | _____ | _____ |
| • Master list | _____ | _____ |
| • Availability | _____ | _____ |
| • Obsolete documents | _____ | _____ |
| • Document changes | _____ | _____ |
| • Altered and new texts | _____ | _____ |
| • Handwritten amendments | _____ | _____ |
| • Computerized amendments | _____ | _____ |

4.4 Review of requests, tenders and contracts - policies and procedures for:

- | | | |
|----------------------------|-------|-------|
| • Records of review | _____ | _____ |
| • Notification of customer | _____ | _____ |

4.5 Subcontracting - policies and procedures for:

- | | | |
|---------------------|-------|-------|
| • Competency | _____ | _____ |
| • Customer approval | _____ | _____ |

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4.6 Purchasing Services and Supplies - policies and procedures for: <ul style="list-style-type: none"> • Specifications • Approved suppliers 	_____ _____	_____ _____
4.7 Service to Customer - policies and procedures for: <ul style="list-style-type: none"> • Customer access for monitoring of work • Obtaining customer feedback 	_____ _____	_____ _____
4.8 Complaints - policies and procedures for: <ul style="list-style-type: none"> • Resolution and records 	_____	_____
4.9 Control of Nonconforming testing and/or Calibration Work - policies and procedures for: <ul style="list-style-type: none"> • Responsibilities and authorities • Non-conformance evaluation • Corrective Actions • Work recall - resumption 	_____ _____ _____	_____ _____ _____
4.10 Improvement - policies and procedures for: <ul style="list-style-type: none"> • Continual Improvement 	_____	_____
4.11 Corrective Action - policies and procedures for: <ul style="list-style-type: none"> • Cause analysis • Selection of corrective actions • Monitoring 	_____ _____ _____	_____ _____ _____
4.12 Preventive Action - policies and procedures for: <ul style="list-style-type: none"> • Identification • Action plans 	_____ _____	_____ _____
4.13 Control of Records - policies and procedures for: <ul style="list-style-type: none"> • Requirement to control • Record integrity • Technical records • Record information • Recording • Corrections 	_____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____
4.14 Internal Audits - policies and procedures for: <ul style="list-style-type: none"> • Requirements • Implementation 	_____ _____	_____ _____
4.15 Management Reviews - policies and procedures for: <ul style="list-style-type: none"> • Objectives • Contents of review • Action Taken • Records 	_____ _____ _____ _____	_____ _____ _____ _____

Rating Guide Item (A02)

**Quality Manual
cross reference**

**Other
cross reference**

5 Technical Requirements

5.2.1 Personnel – policies and procedures for:

- Qualifications _____
- Trainees _____
- Training Policy _____
- Evaluating Effectiveness of Training _____
- Employee Status _____
- Job descriptions _____
- Authorized personnel _____
- Records _____

5.3 Accommodation and Environmental Conditions – policies and procedures for:

- Facility _____
- Monitoring _____
- Termination _____
- Cross contamination _____
- Access _____
- Housekeeping _____

5.4 Test and Calibration Methods and Method Validation – policies and procedures for:

- Methods and procedures _____
- Equipment instructions _____
- Method deviations _____
- Method selection _____
- Non-specified method selection _____
- Inappropriate methods _____
- In-house methods _____
- Non-standard methods _____
- Method validation _____
- Range and accuracy _____
- Uncertainty of measurement _____
- Calculations and data transfer _____
- Computers _____
- Protection of data _____

5.5 Equipment – policies and procedures for:

- Operation _____
- Records _____
- Procedures _____
- Out of service _____
- Calibration status _____
- Return to service _____
- Adjustments _____

5.6 Measurement Traceability – policies and procedures for:

- Calibration program _____
- Traceability _____
- Reference standards and materials _____

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5.7 Sampling – policies and procedures for: <ul style="list-style-type: none"> • Procedures and plan • Deviations • Records 	_____ _____ _____	_____ _____ _____
5.8 Handling of Test and Calibration Items – policies and procedures for: <ul style="list-style-type: none"> • Procedures • Identification • Deficiencies • Facilities • Environmental conditions 	_____ _____ _____ _____ _____	_____ _____ _____ _____ _____
5.9 Assuring the quality of Test and Calibration Results – policies and procedures for: <ul style="list-style-type: none"> • Quality control • Analysis of QC Data 	_____ _____	_____ _____
5.10 Reporting the Results – policies and procedures for: <ul style="list-style-type: none"> • Test reports and Calibration certificates • Additional info for test results • Additional info for calibration results • Compliance data records • Statement of compliance • Repairs and adjustments • Calibration intervals • Opinions and interpretations • Amendments 	_____ _____ _____ _____ _____ _____ _____ _____ _____	_____ _____ _____ _____ _____ _____ _____ _____