

**DOCUMENT REVIEW REPORT FOR INSPECTION BODIES - ISO/IEC 17020**

Initial Assessment       Scope Extension       Accreditation Renewal       Other

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| ORGANIZATION           |  |
| DOCUMENTATION RECEIVED |  |
| DOCUMENT REVIEW BY     |  |
| SIGNED                 |  |
| DATE                   |  |

**1. INTRODUCTION**

The supplied documentation (Quality Manual) was reviewed against the standard requirements and SADCAS requirements

*This is merely an example, change wording to suit your evaluation.*

**2. REVIEW AGAINST ISO/IEC 17020: REQUIREMENTS FOR INSPECTION BODIES**

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| <b>SECTION 4 : GENERAL REQUIREMENTS</b>   |
| 4.1 Impartiality and Independence         |
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| 4.2 Confidentiality                       |
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| <b>SECTION 5: STRUCTURAL REQUIREMENTS</b> |
| 5.1 Administrative requirements           |
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| 5.2 Organization and management           |
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| <b>SECTION 6: RESOURCE REQUIREMENTS</b>   |
| 6.1 Personnel                             |
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**6.2 Facilities and equipment**

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**6.3 Subcontracting**

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**SECTION 7: PROCESS REQUIREMENTS**

**7.1 Inspection methods and procedures**

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**7.2 Handling inspection items and samples**

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| 7.3 | Inspection records                             |
| 7.4 | Inspection reports and inspection certificates |
| 7.5 | Complaints and appeals                         |
| 7.6 | Complaints and appeals process                 |

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| <b>SECTION 8: MANAGEMENT SYSTEM REQUIREMENTS</b> |         |
| 8.1  | Options |

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| 8.2 Management system documentation (Option A) |
| 8.3 Control of documents (Option A)            |
| 8.4 Control of records (Option A)              |
| 8.5 Management review (Option A)               |
| 8.6 Internal audits (Option A)                 |

**8.7 Corrective actions (Option A)**

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**8.8 Preventive actions (Option A)**

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### 3. GENERAL COMMENTS

*Below are some examples of general comments for different situations encountered. Follow your instincts and use this general comments section to highlight areas you feel may require specific attention.*

**Example 1:** This could be where you notice from the application form or data on documents that the system has only been documented/ implemented for a short period of time. Or where it is clear that there is no clear direction given in the documentation, no “how” described.

Please note that for the initial assessment sufficient records generated by the system must be available to demonstrate the implementation of the system to give confidence that the facility can consistently ensure the quality of its results.

**Example 2:** Quality documentation is meant to be of benefit to a facility. The policies set by management give the overall direction of the facility. The objectives are always in line with the policies, usually measurable by some means, more specific to areas and may change. The procedures are the instruction manual defining how the facility operates to enable it to achieve the set objectives and thus continue moving in the planned direction as defined by the policies.

**Example 3:** Although the documentation submitted appeared to be written in accordance with the standard, there was very little direction given to the user thereof. Statements of fact were generally made but detail on how the facility was to achieve these requirements was lacking.

**Example 4:** The specific notes made during the evaluation are not necessarily non-compliances but sometimes areas of lack of clarity that could become obvious during the on-site assessment.

**Example 5:** The documentation submitted was deemed to be assessable and appeared to be in general compliance with the requirements of ISO/IEC 17020. Whether the facility’s actual operational procedures are reflected in the Quality documentation can only be determined on-site at the initial assessment.

**Example 6:** Use of terms that are open to interpretation, such as “where appropriate” and “if possible”, are not suitable as they do not give clear direction to the user to ensure consistency within the facility.

*Be wary of stating that the manual is excellent / in full compliance with the standards as this may cause problems when the site visit reveals weaknesses overlooked during the document review.*

### 1. RECOMMENDATION

**Example 1:** the deviations listed should be incorporated into the quality manual after an initial assessment of the facility may be arranged.

**Example 2:** The manual requires revision and re-submission for evaluation after which an initial assessment of the facility may be arranged.

**Example 3:** The deviations listed require a submission of additional documents or information to conclude the Document review process after which an Initial assessment may be arranged.

