

DOCUMENT REVIEW REPORT FOR CERTIFICATION OF PERSONS (ISO/IEC 17024)

Initial Assessment Scope Extension Accreditation Renewal Other

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 17065:2012 CONFORMITY ASSESSMENT- REQUIREMENTS FOR BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES

4. GENERAL REQUIREMENTS

4.1 LEGAL MATTERS

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4.2 RESPONSIBILITY FOR DECISION ON CERTIFICATION

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4.3 MANAGEMENT OF IMPARTIALITY

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4.4 FINANCE AND LIABILITY

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5. STRUCTURAL REQUIREMENTS

5.1 MANAGEMENT AND ORGANIZATION STRUCTURE

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5.2 STRUCTURE OF THE CERTIFICATION BODY IN RELATION TO TRAINING

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6. RESOURCE REQUIREMENTS

6.1 GENERAL PERSONNEL REQUIREMENTS

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6.2 PERSONNEL INVOLVED IN THE CERTIFICATION ACTIVITIES

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6.3 OUTSOURCING

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6.4 OTHER RESOURCES

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7. RECORDS AND INFORMATION REQUIREMENTS

7.1 RECORDS OF APPLICANTS, CANDIDATES AND CERTIFIED PERSONS

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7.2 PUBLIC INFORMATION

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7.3 CONFIDENTIALITY

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7.4 SECURITY

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8. CERTIFICATION SCHEMES

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9. CERTIFICATION PROCESS REQUIREMENTS

9.1 APPLICATION PROCESS

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9.2 ASSESSMENT PROCESS

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9.3 EXAMINATION PROCESS

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9.4 DECISION ON CERTIFICATION

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9.5 SUSPENDING, WITHDRAWING OR REDUCING THE SCOPE OF CERTIFICATION

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9.6 RECERTIFICATION PROCESS

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9.7 USE OF CERTIFICATES, LOGOS AND MARKS

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9.8 APPEALS AGAINST DECISIONS ON CERTIFICATION

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9.9 COMPLAINTS

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10. MANAGEMENT SYSTEM REQUIREMENTS

10.1 GENERAL

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10.2 GENERAL MANAGEMENT SYSTEM REQUIREMENTS
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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 certification body can consistently operate in accordance with the relevant requirements.

Example 2: Quality documentation is meant to be of benefit to a certification body. The policies set by management give the overall direction of the certification body. 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 certification body 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 certification body 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 17065. Whether the certification body'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 laboratory.

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.

4. RECOMMENDATION

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

Example 2: The manual requires revision and re-submission for evaluation after which an initial assessment of the laboratory 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.

REVIEW OF ADDITIONAL DOCUMENTS

Comments on adequacy:

Reviewer Name: _____

Date: _____

Review Signature: _____