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Guidelines for development of a Quality Manual for a testing laboratory

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Foreword

This Guide was drawn up by the ISO Committee on conformity assessment, ISO/CASCO, in response to a request arising from the International laboratory accreditation conference (ILAC 84) held in London in October 1984. It was approved by the ISO Council in September 1986 and by the IEC Council in October 1986.

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Section one : General

0 Introduction

0.1 This document constitutes guidelines intended to assist a laboratory which proposes to set forth, in a reasonably systematic way, the measures that it employs to implement its internal *Quality System*. It is intended as guidance to the laboratory in the development of its own Quality System, and in the preparation of a *Quality Manual* that describes the elements and functioning of that system.

0.2 It is expected that the Quality System actually used by the laboratory will be described in the laboratory's Quality Manual. It is *not* the intent of these guidelines to prescribe the methods by which a laboratory achieves its desired level of quality.

0.3 No Quality Manual, regardless of how well prepared, can serve a useful purpose unless the measures which it describes or refers to are actually followed on a day-to-day basis by the testing laboratory. It is not the existence of the Quality Manual that is of utmost importance, but rather the implementation of an effective Quality System. The Quality Manual simply describes the elements of the system and documents how they are implemented in the testing laboratory.

0.4 It is expected that the measures adopted to achieve a desired level of quality might be quite different from one laboratory to another, depending upon their size, field of activities, nature of work, etc.

0.5 The nature of the information[1] to be provided under each heading and subheading of the Quality Manual is critical to portraying a true and accurate picture of exactly how the Quality System works. Specifying how the information is made accessible to those needing it is a necessary part of the system's operation.

0.6 Experience shows that the order of presentation (format) of subjects covered in a Quality Manual for testing laboratories may vary from one laboratory to another depending upon such factors as, but not limited to, the needs, customs and field of competence of the laboratory.

0.7 It may be impractical for all subjects identified in these guidelines to be contained within a single document. It is, therefore, acceptable to produce separate documents. However, all these documents should be cross-referenced to a single document, generally called *Quality Manual*, which specifies their location and their up-dating and control procedures.

0.8 These guidelines supplement and expand upon the items relating to a Quality System identified in ISO/IEC Guide 25.

1 Scope and field of application

This document contains guidelines for the preparation of procedures and methods by which a testing laboratory describes those measures which it intends to employ to achieve its quality objective and give confidence to its work.

2 References

ISO/IEC Guide 2, *General terms and definitions concerning standardization and related activities.*

ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories.*

ISO/IEC Guide 38, *General requirements for the acceptance of testing laboratories.*

ISO/IEC Guide 43, *Development and operation of laboratory proficiency testing.*

ISO/IEC Guide 45, *Guidelines for the presentation of test results.*

ISO 8402, *Quality — Vocabulary.*

ISO 9004, *Quality management and quality system elements — Guidelines.*[2]

1) See annex C, which illustrates how an item of information might be conveyed in a laboratory's Quality Manual.

2) At present at the stage of draft.