ISO 15195:2018 (E)

Laboratory medicine — Requirements for the competence of calibration laboratories using reference measurement procedures

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

5 Structural requirements

6 Resource requirements

- 6.1 General
- 6.2 Personnel
- 6.3 Laboratory facilities and environmental conditions
- 6.4 Equipment
- 6.5 Metrological traceability
- 6.6 Reference materials
- 6.7 Externally provided products and services

7 Process requirements

- 7.1 Review of requests, tender and contracts
- 7.2 Reference measurement procedures
- 7.3 Handling of samples
- 7.4 Measurement records
- 7.5 Evaluation of measurement uncertainty
- 7.6 Ensuring the validity of measurement results
- 7.7 Reporting measurement results

8 Management requirements

- 8.1 General
- 8.2 Internal audits

Annex A (informative) Relationship to ISO/IEC 17025:2017

Page count: 8