

# **Using Mathmet**

## **Quality Assurance Tools to help meet requirements of standards for accrediting calibration and testing laboratories**

**This relates to  
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<b>11. Abstract</b> An outline is presented of how the Mathmet Quality Assurance Tools (QAT) could help meet the requirements of standards commonly used for the accreditation of calibration and testing laboratories, such as ISO/IEC 17025:2017 or ISO/IEC 17043:2023. Cross references between the QAT and these standards are listed.		
<b>12. Key words</b> Quality assurance tools, software, data, guidelines		

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0.1	11/05/2023	Keith Lines	INITIAL RELEASE.
0.2	14/05/2023	Keith Lines	Include review comments by WP2 partners.
0.3	16/05/2023	Keith Lines	Add further references.
0.4	25/05/2023	Keith Lines	Fix minor typos. Include review comments by Carlos Pires, IPQ.
0.5	13/05/2025	Keith Lines	Update for Mathmet quality assurance tools 1.0.0. Replace ISO/IEC 17043:2010 with ISO/IEC 17043:2023. Include review comments by Mathmet partners.

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## 1 INTRODUCTION

### 1.1 Purpose

This document outlines how the Mathmet quality assurance tools (QAT) [1] could help meet the requirements of standards commonly used for the accreditation of calibration and testing laboratories, such as ISO/IEC 17025:2017 [2] and ISO/IEC 17043:2023 [3].

The relationship between ISO/IEC 17025 and previous work on which the QAT is based is also described.

### 1.2 Background

Feedback from presentations of the QAT [4] and the training course held in March 2023 [5] made clear that there is interest in using the QAT to help achieve accreditation for calibration and testing laboratories. Mapping the QAT to the relevant standards is a first step in demonstrating how the QAT could help achieve this aim.

### 1.3 Document structure

The QAT consists of templates to help with quality assurance of data, software and guidelines. Section 2 of this document focuses on the guidelines templates.

The remainder of the document focuses on data and software. For each standard under consideration there is a table listing the mapping. These tables are followed by a section describing how earlier work, on which the QAT is based, related to ISO/IEC 17025.

The document ends with proposals for future developments of the QAT.

### 1.4 Version of QAT and standards

This document maps **QAT live version 1.0.0** to the ISO/IEC standards. The standard names include the version, e.g., ISO/IEC 17025:2017.

## 2 QAT FOR GUIDELINES

This document focuses on the features of QAT for data and software. The QAT also provides templates for accessing guidelines. These templates can help with developing checklists. Such checklists provide evidence of “commitment to the development and implementation of the management system” (ISO/IEC 17025:2017 subclause 8.2.3)

### 3 LINKS WITH ISO/IEC 17025:2017

The following section is an initial outline of how the QAT help meet the requirements of ISO/IEC 17025:2017, “General requirements for the competence of testing and calibration laboratories”.

ISO/IEC 17025:2017 Subclause	QAT for Data	QAT for Software
6.4.1 software	N/A	3. Software integrity level 4. User requirements 5. Functional requirements
6.4.13 a), d) If <b>location</b> is interpreted as including location of software and reference data, f) If <b>reference materials</b> is interpreted as including reference data.	Data QAT can provide documentation of reference data.	Q12.1 Configuration management
7.5.1	METROLOGICAL SOUNDNESS Q37 - How will the dataset's repeatability conditions be documented? Q38 - Is the dataset generation intended to be reproducible? Q39 - How will the dataset's reproducibility conditions be documented?	Software quality plan will help with <b>repetition of the laboratory activity under conditions as close as possible to the original</b> . E.g., version control will ensure same versions of software are used.
	QAT helps document the processes that lead to the development of software and datasets that are involved in measurement and measurement uncertainty evaluation. Therefore, QAT helps with repeatability.	

ISO/IEC 17025:2017 Subclause	QAT for Data	QAT for Software
<b>7.6</b>	METROLOGICAL SOUNDNESS Q40 - How will measurement uncertainty be expressed and evaluated?	4. User requirements 5. Functional requirements 8. Verification 9. Validation 10. Delivery, use and maintenance 13. Other Information: Mathematical area(s) and Metrology area(s)
<b>7.11.2</b>	QUALITY ASSURANCE Q25 - How will data quality be documented and made available for review? Q26 - How will the project team review data quality issues? Q27 - How will the customer or customer proxy review data quality issues? Q28 - How will the objectivity of the data quality issue review be ensured?	8. Verification 9. Validation Q11.4 Responsibilities for testing Q12.1 Configuration management
<b>7.11.2 NOTE 2</b>	N/A	Documented user and functional requirements will help verify that the commercial off-the-shelf package is being used within its designated application range.

ISO/IEC 17025:2017 Subclause	QAT for Data	QAT for Software
7.11.3 b), d), e)	QUALITY PLANNING Q21 - How will non-conformities in the dataset be reported? Q22 - How will corrective actions on non-conformities in the dataset be logged? Q23 - How will non-conformities in the dataset be prevented? Q24 - Who will oversee dealing with non-conformities in the dataset?	10. Delivery, use and maintenance Q11.6 Release rules
7.11.5	QAT can be used to help track the documentation regarding software, such as manuals, etc. to ensure that are available to the users	
7.11.6	N/A	8. Verification 9. Validation Q11.4 Responsibilities for testing
8.1.3 Option B	Data QAT complies with ISO 8000. Links to ISO 9001 are provided in the glossary.	Links to ISO 9001 are provided in the glossary.
8.2.3	Use of QAT provides evidence of commitment and continuous improvement	
8.4.1	Depends on what <b>legible records</b> consist of. E.g., versions of software in use, calibration of equipment, measurement results, customer certificates?	

ISO/IEC 17025:2017 Subclause	QAT for Data	QAT for Software
<b>Annex A Metrological traceability</b>	<p>METROLOGICAL SOUNDNESS</p> <p>Q33 - Will the dataset contain measurement data or data derived from measurements?</p> <p>Q34 - How will the main operations applied to the dataset be logged?</p> <p>Q35 - How will the operations applied to the dataset be logged?</p> <p>Q36 - Is the dataset generation intended to be repeatable?</p> <p>Q37 - How will the dataset's repeatability conditions be documented?</p> <p>Q38 - Is the dataset generation intended to be reproducible?</p> <p>Q39 - How will the dataset's reproducibility conditions be documented?</p> <p>Q40 - How will measurement uncertainty be expressed and evaluated?</p> <p>Q41 - How will confidence in the dataset generation process be demonstrated?</p>	<p>Q10.4 Traceability of output</p>



#### 4 LINKS WITH ISO/IEC 17043:2023

The following section is an initial outline of how the QAT help meet the requirements of ISO/IEC 17043:2023 “Conformity assessment — General requirements for the competence of proficiency testing providers”.

ISO/IEC 17043:2023 Subclause	QAT for Data	QAT for Software
7.2.1.3 j) o) p) q) s)	<p>DATA UNDERSTANDABILITY</p> <p>Q29 - How will the meaning of the data be formalised?</p> <p>Q30 - How will the structure of the dataset be documented?</p> <p>Q31 - How will the metadata be documented?</p> <p>Q32 - How will the customer know how to exploit the dataset?</p> <p>METROLOGICAL SOUNDNESS</p> <p>Q40 - How will measurement uncertainty be expressed and evaluated?</p>	<p>4 User requirements</p> <p>5. Functional requirements</p> <p>6. Design</p> <p>8. Verification</p> <p>9. Validation</p> <p>Q13.1 Mathematical area(s)</p> <p>Q13.2 Metrology area(s)</p>
7.2.2.2	N/A	As subclause 7.2.1.3
7.4.1.1	<p>QUALITY ASSURANCE</p> <p>Q25 - How will data quality be documented and made available for review?</p> <p>Q26 - How will the project team review data quality issues?</p> <p>Q27 - How will the customer or customer proxy review data quality issues?</p> <p>Q28 - How will the objectivity of the data quality issue review be ensured?</p>	As subclause 7.2.1.3

ISO/IEC 17043: 2023 Subclause	QAT for Data	QAT for Software
7.4.1.2 to 7.4.1.5	N/A	As subclause 7.2.1.3
7.5.2.2	See QAT mapping for ISO/IEC 17025:2017 subclause 7.11.2	
7.5.2.2 NOTE 2	See QAT mapping for ISO/IEC 17025:2017 subclause 7.11.2 NOTE 2	
7.5.2.3 b), d), e)	See QAT mapping for ISO/IEC 17025:2017 subclause 7.11.3 b), d), e)	
8.4.2	N/A	Q11.5 Backup regime

## 5 PREVIOUS WORK

The Mathmet quality assurance tools (QAT) are based on quality management systems that have been in use in the development partner's organisations for over twenty-five years. The main innovation for the Mathmet QAT is the application of "integrity levels" to data as well as software.

In work related to the development of the systems, [6] [7], consideration was given to the relationship with standards such as ISO/IEC 17025:1999. It is interesting to compare ISO/IEC 17025:1999 and ISO/IEC 17025:2017 requirements for data and software. E.g.:

- The bottom paragraph of Page 7 of [6] notes that "the main emphasis is upon software developed by the user rather than the software embedded within an instrument or within standard packages". In contrast, ISO/IEC 17025:2017 makes no explicit mention of user-developed software.
- [7] notes that ISO/IEC 17025:1999 "appears to ignore software embedded within an instrument". ISO/IEC 17025:2017 at least states in subclause 6.4.13 "Records shall be retained for equipment which can influence laboratory activities. These records shall include... These the identity of equipment, including software and **firmware** version".
- Both ISO/IEC 17025:1999 and ISO/IEC 17025:2017 state that "Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated." (Subclause 5.4.7.2 in ISO/IEC 17025:1999 and subclause 7.11.2 in ISO/IEC 17025:2000). This statement is challenged in both [6] and [7]:  

"So the standard does not expect laboratories to validate MS Word (for example) but even standard software may go wrong when presented with data which the original design of the software did not anticipate."
- Following on from the above point, ISO/IEC/IEEE 24765:2017 [8] defines commercial off-the-shelf software as "product available for purchase and use without the need to conduct development activities". Does clause 7.11.2 of ISO/IEC 17025:2017 also apply to freeware?
- ISO/IEC 17025:2017 places as much emphasis on **information** (definition in [8] "knowledge that is exchangeable amongst users, about things, facts, concepts, and so on, in a universe of discourse") as **data** (definition in [8] "representation of facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by humans or by automatic means"). It also assumes the use of one or more Laboratory Information Management Systems (LIMS).

In contrast, ISO/IEC 17025:1999 only mentions data and makes no mention of LIMS.

[7] concluded "ISO/IEC 17025 was rather weak on software issues. It is necessary to have some guidance documents, such as the EA guidelines, to fill in gaps and ensure a uniform interpretation of the standard."

NOTE: The EA (1999) "Guidelines for the use of computers and computer systems in accredited laboratories" are no longer available from their website [9].

In 2006 Eurolab [10] published guidance for the management of computers and software in laboratories with reference to ISO/IEC 17025:2005 [11]. The guidance includes terms and definitions, risk analysis and mappings to ISO/IEC 17025 clauses. An update to the latest version of ISO/IEC 17025 would be very valuable.

## 6 FUTURE DEVELOPMENTS

There has been progress with guidance for data and software in ISO/IEC 17025 during the twenty-three years since [6] and [7] were both published. However, feedback from presentations of the QAT indicates a continued requirement for further guidance. Future developments of the QAT can take this requirement into account. More complete mappings to a wider range of standards and guidelines would be a good starting point.

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