

OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

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GENERAL REQUIREMENTS FOR INFREQUENTLY PERFORMED TECHNIQUES

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GENERAL REQUIREMENTS FOR INFREQUENTLY PERFORMED TECHNIQUES

Scope

This document describes a practical approach to maintaining ISO/IEC 17025 compliance for techniques or tests which are performed infrequently (e.g. less than once a year). It covers situations where the Laboratory does not receive products to test for significant periods of time (e.g. over a year). The Laboratory shall demonstrate the ability to assure the veracity of test results in a timely manner when the technique is performed.

General requirements

The Laboratory shall identify the technique or product area and justify why accreditation or compliance shall be maintained in the absence of products to test. Interested parties shall be informed of the intention to adopt a *'low maintenance'* approach for retaining accreditation or compliance for the technique (e.g. National Accreditation body, Management, Quality Management unit, customers, subcontractors). Periodic reviews shall be undertaken to determine when it is no longer viable or necessary to perform the technique or test the product.

The Laboratory shall:

- Estimate the time required to reactivate the technique;
- Consider the consequences of failing to meet timescales for reporting test results;
- Ensure that the technique remains compliant with the standard and the Laboratory's Quality system;
- Ensure that Management and technical staff have the knowledge, expertise and authority to report results at short notice;
- Notify the Quality Management unit when the technique is to be performed and results are to be reported;
- Participate in internal audits, but not more often than the Laboratory is required to perform the technique;
- Regularly review the justification for a **'low maintenance'** approach.

Justification for the following 3 areas shall be documented:

1. Equipment

Ensure that equipment is identified, calibrated and qualified before a test is performed.

2. Staff competence

- Identify staff with the relevant training and competence for the technique;
- Consider the minimum reasonable period of time for trained staff to retain competence for the technique;
- Define criteria for maintaining competence, for example,
 - perform similar techniques regularly,
 - perform the technique periodically,
 - participate in Proficiency Testing Schemes (PTS), inter-laboratory comparisons.

3. Test performance

- Ensure that suitable reagents, kits, references and controls are available;
- Ensure that the Laboratory remains aware of changes a manufacturer may make to reagents or kits;
- Monitor the performance of references and controls to ensure that deterioration has not occurred and they remain fit for purpose.