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| **TRANSITION REQUIREMENTS** |

**Transition of ISO 15189:2022 Medical laboratories – Requirements for quality and competence**

1. **Introduction and Scope**

The ISO 15189:2022 *Medical laboratories – Requirements for quality and competence* standard was published on 06 December 2022. This edition of ISO 15189 replaces ISO 15189:2012.

A transition period of 3 years has been agreed from the date of publication for accredited bodies to review the requirements and bring their operations and processes in line with the requirements of the new ISO 15189:2022. As a consequence, UKAS will require all of its accredited bodies operating under this standard to have demonstrated conformity and transitioned to the new standard by **06 December 2025**.

1. **Objective**

This document is aimed at providing all UKAS accredited bodies with details of the transition processes which will be implemented by UKAS and the information they will need to supply to assist this process.

1. **UKAS requirements for accredited bodies for the transition to ISO 15189:2022 Medical laboratories – Requirements for quality and competence**
2. Accredited laboratorieswho are currently accredited to ISO 15189:2012 are required to review the new standard, conduct a gap analysis and establish a transition plan to incorporate the required changes (where applicable) into their management system. Laboratories are required to document their gap analysis and transition plan, submitting a copy to UKAS one month before their assessment date, to the following email address; medlabscustomerservice@ukas.com. This information shall be submitted using the attached template (Annex 1) and shall be accompanied by any relevant supporting documentation (clearly indexed using the table in Annex 1).
3. The UKAS transition process will consist of the following assessment stages:
* Review of the Gap Analysis, plan and related documentation
* On-site assessment (to be conducted at time of an organisation’s annual surveillance or reassessment). Requests for an earlier visit will be considered subject to suitable resource availability.

**NOTE**: Additional time and effort may be required during the transition process, for example for the review of the Gap Analysis. Any additional time and effort will be quoted in advance of the activity taking place.

1. Mandatory Improvement Actions (IARs) which are raised against the new standard will need to be cleared prior to the grant of accreditation. Where verification of the effectiveness of the corrective actions is deemed necessary further on-site activity may be required.
2. If the accredited body fails to demonstrate conformity to ISO 15189:2022 and/or clear those improvements actions raised before the transition deadline, the body shall be suspended for a maximum of 6 months. If the body fails to address those actions required to complete the transition process within this timeframe, this will result in the withdrawal of accreditation for ISO 15189:2012.
3. **New Applications/Extensions to Scope:**
4. All new applications for accreditation received after 01 July 2023 shall be assessed against ISO 15189:2022.
5. For existing applicants, assessments which are scheduled to take place after 01 January 2024 shall be against ISO 15189:2022.
6. Extension to scope applications assessed before the accredited body has undergone its transition assessment will be to ISO 15189:2012. Extension to scope applications assessed concurrently with, or after, a transition assessment will be to ISO 15189:2022.
7. **Validity of ISO 15189:2012 Medical laboratories – Requirements for quality and competence**

ISO 15189:2012 Medical laboratories – Requirements for quality and competence ceases to be valid as of 06 December 2025.

1. **Projected Timetable**

**The following timetable is based on current knowledge with regard to the issue status of** ISO 15189:2022 Medical laboratories – Requirements for quality and competence**. Please note that should dates or actions change UKAS will provide updates via Technical Bulletins posted on the UKAS website** [www.ukas.com](http://www.ukas.com)

**Instructions for Using the Template**

**For Medical Laboratories:**

This template identifies the clauses of ISO 15189:2022 and provides UKAS’ opinion on the broad extent of any changes in requirements from ISO 15189:2012. Details of the actual changes are not provided and as such the Laboratory will need to use this template in conjunction with copies of ISO 15189:2022 and ISO 15189:2012.

It is the responsibility of the Laboratory to identify the changes between the standards, determine the impact of these on its systems, and then make and implement any required alterations as necessary. Details of alterations made to systems should be recorded in this template and the completed template provided to UKAS (as an MS Word document) at least 1 month prior to the transition assessment taking place. The submission of the template should be supported by documentation demonstrating how new or changed requirements are met. Effective implementation will be assessed at the site visit. If the Laboratory considers that it currently meets a changed requirement and does not need to make changes to its system, then this should be stated in the template.

The information provided to UKAS should be more than just a reference to the documented procedure and should explain what has been changed and actions taken by the laboratory. Examples of expected level of information expected from the laboratory for major and minor changes are provided below:

| **ISO 15189:2012** | **ISO 15189:2022** | **EXTENT OF CHANGE** | **TO BE COMPLETED BY LABORATORY** | **TO BE COMPLETED BY UKAS ASSESSORS** |
| --- | --- | --- | --- | --- |
| **CLAUSE** | **RELATED CLAUSE(S)** | **CHANGES MADE & DOCUMENTATION SUPPLIED** | **COMMENTS ON COMPLIANCE & REF TO FINDINGS** |
| 5.1.5 | Training(example) | 6.2.2a8.1.3 | Personnel: competenceManagement system awareness | Minor | Policy and procedure to specify requirements for training and re-training covered in QM-1001 pages 6-7. Training requirements for each role are listed. Situations in which re-training is needed (e.g. post-maternity leave) are documented.All trainers and section managers have been made aware of and given an update on the changes (see document XYZ-001 attached) | Comments: |
| 4.14.5 | Internal audit  | 8.8.3 | Internal audits | Major | Service activities, recent NCs and complaints and last year’s audit schedule have been reviewed. New audit schedule written, taking into consideration risks, inc those affecting patients, identified during the review.Plan in place to update audit checklists to include ISO 15189:2022 clauses and appropriate questions.Audit schedule and recently completed audit provided as evidence (doc references XXX and YYY) |  |

**For UKAS Assessors:**

After reviewing the information and documentation supplied by the Laboratory and completing the assessment to confirm appropriate implementation, you should place your comments regarding the Laboratory’s conformity with the new requirements in this template, which forms the report for the transition. The level of comments provided should be similar to that provided in an assessment report. If any findings are raised relating to new or changed requirements these should be recorded in the IAR as normal but then cross-referenced in this template.

An Executive Summary and Recommendation on transition of accreditation to ISO 15189:2022 shall be included at the end of this template.

**Key - Extent of Change:**

* **Structural** – Requirement remains the same but is under a new clause number
* **Minor** – Wording of the requirement has changed but overall intent is consistent
* **Major** – Changes will require the CAB to implement new or change existing practice
* **New** – New requirement(s)/concept(s) not in previous version of the standard

**Annex 1**

**Gap Analysis and Transition Plan**

|  |  |
| --- | --- |
| **Name of Organisation** | Click here to enter text |
| **Accreditation Number** | Click here to enter text |
| **Date of Submission** | Select a date from the calendar |

**GAP ANALYSIS**

| **CLAUSE** | **ISO 15189:2012** | **CLAUSE** | **ISO 15189:2022** | **EXTENT OF CHANGE** | **DETAILS OF CHANGES WITHIN YOUR MANAGEMENT SYSTEM WHICH HAVE/WILL BE TAKEN TO ADDRESS CHANGES** | **UKAS COMMENTS REGARDING INFORMATION SUPPLIED INCLUDING REFERENCE TO ANY IARS RAISED** |
| --- | --- | --- | --- | --- | --- | --- |
|  | Forward  |  | Forward  | N/A |  |  |
|  | Introduction  |  | Introduction  | N/A |  |  |
| 1. | Scope  | 1. | Scope  | Minor  |  |  |
| 2. | Normative references | 2. | Normative references  | Minor |  |  |
| 3. | Terms & Definitions | 3. | Terms & Definitions | Minor  |  |  |
| **4** | **Management Requirements** |  |  | N/A |  |  |
| 4.1 | Organisation and management responsibility |  |  | N/A |  |  |
| 4.1.1 | Organisation |  |  | N/A |  |  |
| 4.1.1.1 | General | 5.3.2 | Laboratory activities:Conformance with requirements | Structural |  |  |
| 4.1.1.2 | Legal entity | 5.1 | Legal Entity | Structural  |  |  |
| 4.1.1.3 | Ethical conduct | 4.1 | Impartiality | Minor  |  |  |
|  |  | 4.2 | Confidentiality | Structural  |  |  |
| 4.1.1.4 | Laboratory director | 5.2 | Laboratory director | Minor |  |  |
|  |  | 5.6b | Risk management | New |  |  |
| 4.1.1.4o | Contingency planning | 7.8 | Continuity and emergency preparedness planning | Minor |  |  |
|  |  | 7.6.4 | Control of data and information management: Downtime plans  | Minor |  |  |
| 4.1.2 | Management Responsibility |  |  | N/A |  |  |
| 4.1.2.1 | Management Commitment | 8.2.3 | Management system documentation: Evidence of commitment | Minor |  |  |
| 4.1.2.2 | Needs of users | 4.3 | Requirements for patients:  | New  |  |  |
| 4.1.2.3 | Quality Policy | 5.5 | Objectives and policies | Minor |  |  |
| 4.1.2.4 | Quality objectives | 5.5 | Objectives and policies | Minor |  |  |
|  |  | 8.1.3 | Management system awareness | New |  |  |
|  |  | 8.2.2 | Management system documentation: competence and quality | New |  |  |
| 4.1.2.5 | Responsibility, authority, interrelationships | 5.4 | Structure and authority | Minor |  |  |
| 4.1.2.6 | Communication | 5.4.1b | Structure and authority: General | Minor |  |  |
| 4.1.2.7 | Quality Manager | 5.4.2 | Quality management | Minor |  |  |
| 4.2 | Quality Management System | 8 | Management system requirements | N/A |  |  |
| 4.2.1 | General Requirements | 8.1 | General Requirements  | Minor unless using ISO 9001 certification to demonstrate QMS-compliance, in which case Major |  |  |
| 4.2.2 | Documentation Requirements | 8.2 | Management system documentation | N/A |  |  |
| 4.2.2.1 | General documentation | 8.2.1 | Management system documentation: general | Minor |  |  |
|  |  | 8.2.4 | Management system documentation: Documentation | Structural |  |  |
|  |  | 8.2.5 | Management system documentation: Personnel access | Minor |  |  |
| 4.2.2.2 | Quality Manual | 8.2.1 | Management system documentation: general | Minor |  |  |
|  |  | 8.2.4 | Management system documentation: Documentation | Structural |  |  |
| 4.3 | Document Control | 8.3  | Control of management system documents | Minor |  |  |
|  |  | 7.3.1c | Examination processes – General | Structural |  |  |
| 4.4 | Service agreements | 6.7 | Service agreements | Minor |  |  |
| 4.5 | Examination by referral laboratories | 6.8 | Externally provided products and services | Minor |  |  |
|  |  | 7.4.1.7c | Post-examination processes: Result reporting: Additional information | Minor |  |  |
| 4.6 | External services and supplies | 6.8 | Externally provided products and services | Structural |  |  |
|  |  | 7.6.5 | Control of data and information management: Offsite management | Structural |  |  |
| 4.7 | Advisory services | 5.3.3 | Advisory activities | Minor |  |  |
| 4.8 | Resolution of complaints | 7.7 | Complaints | Minor |  |  |
| 4.9 | Identification and control of NCNs | 7.5 | Nonconforming work | Major |  |  |
| 4.10 | Corrective action | 8.7 | Nonconformities and corrective actions | Major |  |  |
| 4.11 | Preventive action | 8.5 | Actions to address risks and opportunities | Major |  |  |
| 4.12 | Continual improvement | 8.6 | Improvement | Major |  |  |
| 4.13 | Control of records | 8.4 | Control of records | Minor |  |  |
| 4.14 | Evaluation and audit |  |  | N/A |  |  |
| 4.14.1 | General evaluation  | 8.8.1 | Evaluations: General | Minor |  |  |
| 4.14.2 | Periodic review of requests and suitability of procedures/samples | 7.2.4.1 | Primary sample collection and handling: General | Minor |  |  |
|  |  | 7.3.1e | 7.3 Examination processes: General  | Minor |  |  |
|  |  | 4.3c | Requirements regarding patients | Minor |  |  |
| 4.14.3 | Assessment of user feedback | 8.6.2 | Laboratory user and personnel feedback | Minor |  |  |
| 4.14.4 | Staff suggestions | 8.6.2 | Laboratory user and personnel feedback | Minor |  |  |
| 4.14.5 | Internal audit  | 8.8.3 | Internal audits | Major  |  |  |
| 4.14.6 | Risk Management | 5.6 | Risk management | Major |  |  |
|  |  | 8.5 | Actions to address risks and opportunitiesfor improvement | Major |  |  |
|  |  | 7.1 | Process requirements: General | Major |  |  |
| 4.14.7 | Quality Indicators | 5.5 | Objectives and policies  | Minor |  |  |
|  |  | 8.8.2 | Quality indicators | Minor |  |  |
| 4.14.8 | Reviews by external organisations |  | No direct equivalent clause in 2022 | Minor |  |  |
| 4.15 | Management Review | 8.9 | Management Review | Minor |  |  |
| **5** | **Technical Requirements** |  |  | N/A |  |  |
| 5.1 | Personnel  | 6.1 | Resource requirements:General | Minor |  |  |
|  |  | 6.2.1 | Personnel: General | Minor |  |  |
| 5.1.1 | General |  | No direct equivalent clause in 2022 | N/A |  |  |
| 5.1.2 | Qualifications | 6.2.2a | Personnel: Competence requirements | Structural |  |  |
| 5.1.3 | Job descriptions | 6.2.5b |  | Minor |  |  |
| 5.1.4 | Personnel introduction to the organisational environment |  |  | Structural |  |  |
| 5.1.5 | Training | 6.2.2a | Personnel: Competence | Minor |  |  |
|  |  | 8.1.3 | Management System Awareness | New |  |  |
| 5.1.6 | Competence | 6.2.2 | Personnel: Competence | Minor |  |  |
|  |  | 6.2.3 | Personnel: Authorisation | Major |  |  |
| 5.1.7 | Appraisal |  | No direct equivalent clause in 2022 | N/A |  |  |
| 5.1.8 | CPD | 6.2.4 | Personnel: Continuing education and professional development | Minor |  |  |
| 5.1.9 | Personnel records | 6.2.5 | Personnel: Personnel records | Minor |  |  |
| 5.2 | Accommodation and Environment | 6.3 | Facilities and environmental conditions | N/A |  |  |
| 5.2.1 | General | 6.3.1 | General | Minor |  |  |
| 5.2.2 | Laboratory and Office Facilities | 6.3.2 | Facility controls | Minor |  |  |
| 5.2.3 | Storage Facilities | 6.3.3 | Storage facilities | Structural  |  |  |
| 5.2.4 | Staff facilities | 6.3.4 | Personnel facilities | Minor |  |  |
| 5.2.5 | Patient sample collection facilities | 6.3.5 | Sample collection facilities | Minor |  |  |
| 5.2.6 | Facility maintenance and environmental conditions | 6.3.1 | Facilities and environmental conditions: General | Structural |  |  |
|  |  | 6.3.2 b, c | Facilities and environmental conditions: Facility controls | Structural |  |  |
| 5.3 | Laboratory equipment, reagents and consumables | 6.4 | Equipment | Minor |  |  |
|  |  | 6.5 | Equipment calibration and metrological traceability | Minor |  |  |
| 5.3.2 | Reagents and consumables | 6.6 | Reagents and consumables | N/A |  |  |
| 5.3.2.1 | General | 6.6.1 | Reagents and consumables: General | Minor |  |  |
| 5.3.2.2 | Reagents and consumables - reception and storage | 6.6.2 | Reagents and consumables – Receiptand storage | Minor |  |  |
| 5.3.2.3 | Reagents and consumables - acceptance testing | 6.6.3 | Reagents and consumables – Acceptancetesting | Major |  |  |
| 5.3.2.4 | Reagents and consumables - inventory management | 6.6.4 | Reagents and consumables – Inventorymanagement | Structural |  |  |
| 5.3.2.5 | Reagents and consumables - instructions for use | 6.6.5 | Reagents and consumables – Instructions for use | Structural |  |  |
| 5.3.2.6 | Reagents and consumables - adverse incident reporting | 6.6.6 | Reagents and consumables – Adverseincident reporting | Minor |  |  |
| 5.3.2.7 | Reagents and consumables - records | 6.6.7 | Reagents and consumables – Records | Structural |  |  |
| 5.4 | Pre-examination processes | 7.2 | Pre-examination processes | N/A |  |  |
| 5.4.1 | General | 7.2.1 | Pre-examination processes - General | Minor |  |  |
| 5.4.2 | Information for patients and users | 7.2.2 | Pre-examination processes – Laboratory information for patients and users | Minor |  |  |
| 5.4.3 | Request form information | 7.2.3 | Pre-examination processes – Requests for providing laboratory examinations | Major |  |  |
| 5.4.4 | Primary sample collection and handling | 7.2.4 | Primary sample collection and handling | N/A |  |  |
| 5.4.4.1 | General | 7.2.4.1  | Primary sample collection and handling – General | Minor |  |  |
|  |  | 7.2.4.3 | Primary sample collection and handling – Patient consent | Minor |  |  |
| 5.4.4.2 | Instructions for pre-collection activities | 7.2.4.2 | Primary sample collection and handling - Information for pre-collection activities | Minor |  |  |
| 5.4.4.3 | Instructions for collection activities | 7.2.4.4 | Primary sample collection and handling – Instructions for collection activities | Minor |  |  |
| 5.4.5 | Sample transportation | 7.2.5 | Primary sample collection and handling – Sample transportation | Minor |  |  |
| 5.4.6 | Sample reception | 7.2.6 | Sample receipt | Minor |  |  |
| 5.4.7 | Pre-examination handling, preparation and storage | 7.2.7 | Pre-examination handling, preparation and storage | Minor |  |  |
| 5.5 | Examination processes | 7.3 | Examination processes | N/A |  |  |
| 5.5.1 | Selection, verification and validation of examination procedures |  |  | N/A |  |  |
| 5.5.1.1 | General | 7.3.1 | Examination processes: General | Major |  |  |
| 5.5.1.2 | Verification of examination procedures | 7.3.2 | Examination processes: Verification of examination methods | Major |  |  |
| 5.5.1.3 | Validation of examination procedures | 7.3.3 | Examination processes: Validation of examination methods | Major |  |  |
| 5.5.1.4 | Measurement uncertainty of measured quantity values | 7.3.4 | Examination processes: Evaluation of measurement uncertainty | Minor |  |  |
| 5.5.2 | Biological reference intervals and clinical decision values | 7.3.5 | Examination processes: Biological reference intervals andclinical decision limits | Minor |  |  |
| 5.5.3 | Documentation of examination procedures | 7.3.6 | Examination processes: Documentation of examination procedures | Minor |  |  |
| 5.6 | Ensuring quality of examination results | 7.3.7 | Ensuring the validity of examination results | N/A |  |  |
| 5.6.1 | General | 7.3.7.1 | Ensuring the validity of examination results: General | Structural |  |  |
| 5.6.2 | Quality control | 7.3.7.2 | Ensuring the validity of examination results: Internal quality control (IQC) | Major |  |  |
| 5.6.2.1 | General | As above | As above | As above |  |  |
| 5.6.2.2 | Quality control materials | As above | As above | As above |  |  |
| 5.6.2.3 | Quality control data | As above | As above | As above |  |  |
| 5.6.3 | Interlaboratory comparisons | 7.3.7.3 | Ensuring the validity of examination results: External quality assessment | Major |  |  |
| 5.6.3.1 | Participation | As above | As above | As above |  |  |
| 5.6.3.2 | Alternative approaches | As above | As above | As above |  |  |
| 5.6.3.3 | Analysis of interlaboratory comparison samples | As above | As above | As above |  |  |
| 5.6.3.4 | Evaluation of laboratory performance | As above | As above | As above |  |  |
| 5.6.4 | Comparability of examination results | 7.3.7.4 | Ensuring the validity of examination results: Comparability of examinationResults | Minor |  |  |
| 5.7 | Post-examination processes | 7.4 | Post-examination processes | N/A |  |  |
| 5.7.1 | Review of results | 7.4.1.2  | Post-examination processes: Result review and release | Minor |  |  |
|  |  | 7.4.1.3  | Post-examination processes: Critical result reports | Minor |  |  |
| 5.7.2 | Storage, retention and disposal of clinical samples | 7.4.2 | Post-examination handling of samples | Minor |  |  |
| 5.8 | Reporting of results | 7.4.1 | Result reporting | N/A |  |  |
| 5.8.1 | General | 7.4.1.1 | Result reporting: general | Minor |  |  |
|  |  | 7.6.3 d | Information systems management  | Minor |  |  |
|  |  | 7.4.1.4 | Result reporting: Special considerations for results | Minor |  |  |
| 5.8.2 | Report attributes |  |  | N/A |  |  |
| 5.8.3 | Report content | 7.4.1.6 | Result reporting: Requirements for reports | Minor |  |  |
|  |  | 7.4.1.7 | Result reporting: Additional information for reports | Minor |  |  |
| 5.9 | Release of results |  |  | N/A |  |  |
| 5.9.1 | General | 7.4.1.2 | Result reporting: Result review and release | Minor |  |  |
|  |  | 7.4.1.3 | Result reporting: Critical results reports | Minor |  |  |
| 5.9.2 | Automated selection and reporting of results | 7.4.1.5 | Result reporting: Automated selection, review, release and reporting of results | Minor |  |  |
| 5.9.3 | Revised reports | 7.4.1.8 | Result reporting: Amendments to reported results | Minor |  |  |
| 5.10 | Laboratory information management | 7.6 | Control of data and information management | N/A |  |  |
| 5.10.1 | General | 7.6.1 | Control of data and information management: General | Minor |  |  |
| 5.10.2 | Authorities and responsibilities | 7.6.2 | Control of data and information management: Authorities and responsibilities for information management | Minor |  |  |
| 5.10.3 | Information system management | 7.6.3 | Authorities and responsibilities for information management: Information systems management | Minor |  |  |
|  | No direct equivalent clause in 2012 | 4.3 | Requirements regarding patients | New clause |  |  |
|  | No direct equivalent clause in 2012 | 5.3.1 | Laboratory activities: General | New clause |  |  |
|   | ISO 22870:2016 |  |  | Minor |  |  |
|  |  |  |  |  |  |  |

**TRANSITION PLAN**

\**Please detail in the table below the actions taken, or to be taken (with timescales) to complete the transition to this new standard/scheme within your organisation*

|  |  |  |
| --- | --- | --- |
| **ACTION** | **TIMESCALE** | **OWNER** |
| Example: develop training plan, update documentation, complete internal audit, notify customers, complete assessments  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**DOCUMENTATION**

**\****Please index in the table below the documentation supplied in support of your transition with this Gap Analysis and Transition Plan.*

|  |  |  |
| --- | --- | --- |
| **DOCUMENT REFERENCE** | **DOCUMENT NAME** | **VERSION NUMBER**  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Executive Summary:**

*Lead Assessor:*

*Please comment on the following, and delete this prompt in the final report:*

* *What evidence has been seen to demonstrate that the management system and technical processes have been updated to conform with ISO 15189:2022 requirements*
* *Effectiveness of the gap analysis for identifying and implementing required changes to documentation and process*
* *Key strengths and weaknesses identified, with regard to compliance with ISO 15189:2022*
* *Significant risks (if there are any) to the accredited organisation’s business based on assessment evidence*
* *Comments on the extent of competence of the assessed CAB*

**Recommendation (date xx/xx/xxxx\*):**

It is recommended that accreditation is transitioned to ISO 15189:2022 for the scope shown on UKAS schedule vXXX\*

This recommendation is subject to:

* The agreement of an independent decision maker within UKAS
* Submission of electronic evidence on or before xx/xx/xxxx\*\*
* Satisfactory close out of all findings raised at this assessment classified as ‘M’ (action Mandatory)
* Clearance of any mandatory findings raised at the associated surveillance/reassessment visit (where applicable)

Findings raised at this assessment classified as ‘R’ (Recommendation), where provided, identify opportunities for improvement or potential nonconformities. It is recommended that appropriate action is taken to resolve these, but the customer is not required to agree improvement actions (although it may be in the interests of the customer to do so) or to provide evidence of such improvement actions.

See also the assessment report and improvement action report for the associated annual assessment, project number xxxxxx-xx\*\*\*

*\*replace XXX with the current published version number*

*\*\*1 month after the date of Recommendation*

*\*\*\* replace xxxxxx-xx with the project number of the associated SU/RA*

**References:**

ISO 15189:2022 Medical laboratories – Requirements for quality and competence

**Appendices:\***

Improvement Action Report\*

*\*Delete as necessary\**