**Instructions for Using the Template**

**For Laboratories:** This template identifies the clauses of ISO 15189:2012 and provides UKAS’ opinion on the broad extent of any changes in requirements between the WHO laboratory manual for the examination and processing of human semen v5 (2010) and the updated manual (v6, 2021). Details of the actual changes are not provided and as such the Laboratory will need to use this template in conjunction with copies of the WHO 2010 and WHO 2021 manuals.

It is the responsibility of the Laboratory to identify the changes between the requirements of WHO 2010 and WHO 2021, 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 only) on or before 31st January 2023. The submission of the template shall be supported by documentation demonstrating how new or changed requirements are met. 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, and suitable evidence provided. Please note, all documentation shall be submitted together, in one batch. UKAS will not accept or request any additional documentation on the day of the assessment.

The information provided to UKAS shall include any relevant documents (e.g. SOP, patient information leaflet, EQA results reports) and an explanation of what has been changed and what actions the laboratory has taken. Please embed the documents in this form. If embedding documents makes the filesize too large to send via email, please send the documents as separate attachments, clearly labelled as to which document relates to which ISO 15189:2012 clause. An example of the expected level of information to be provided by the laboratory is provided below:

| ***ISO 15189:2012*** | ***WHO 2010*** | ***WHO 2021*** | **TO BE COMPLETED BY LABORATORY** | ***TO BE COMPLETED BY LABORATORY*** | ***TO BE COMPLETED BY UKAS ASSESSORS*** |
| --- | --- | --- | --- | --- | --- |
| ***CLAUSE*** | ***RELATED SECTION(S)*** | ***RELATED SECTION(S)*** | ***EXTENT OF CHANGE*** | ***CHANGES MADE & DOCUMENTATION SUPPLIED*** | ***COMMENTS ON COMPLIANCE & REF TO FINDINGS*** |
| *5.4.2* | *Information for patients and users* | *2.2.1* | *2.3.1* | *Major* | *Laboratory webpages have been updated to provide new information (hyperlink provided).**Patient information leaflet has been reviewed and updated to reflect changes A & B. Form (FORM-AND-001) provided as evidence (embedded here).* | *Comments:* |
| *Finding Ref:* |

Please return completed gap analysis to medlabscustomerservice@ukas.com on or before 31/01/2023, with the email subject line:

**Andrology WHO 2021 transition gap analysis, Customer number XXXX, Customer name XXXXXXX**

Failure to return the completed gap analysis and associated evidence by 31/01/2023 may put your accreditation at risk.

UKAS will acknowledge receipt of your email within 1 working day; if you don’t receive acknowledgement then please contact medlabscustomerservice@ukas.com

**For UKAS Assessors:**

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

An Executive Summary and Recommendation on transition of accreditation to WHO 2021 shall be included at the end of this template.

**Key - Extent of Change:**

This shall be completed by the laboratory. The extent will be different for each laboratory. E.g. Motility, some laboratories may already be reporting four grades of motility. Therefore the WHO 2021 requirement will be of lesser extent than a laboratory currently working to three grades of motility.

* **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

|  |  |  |
| --- | --- | --- |
| **TO BE COMPLETED BY LABORATORY** |  | **TO BE COMPLETED BY UKAS ASSESSORS** |
| **Organisation Name** |  |  | **Assessment Manager** |  |
| **UKAS Accreditation Number** |  |  | **Assessment Team Members & Roles** |  |
| **Completed by** |  |  | **Date(s) of review** |  |
| **Date of Completion** |  |  | **Issue Date** |  |

| **ISO 15189:2012** | **WHO 2010** | **WHO 2021** |  **TO BE COMPLETED BY LABORATORY** | **TO BE COMPLETED BY LABORATORY** | **TO BE COMPLETED BY UKAS ASSESSORS** |
| --- | --- | --- | --- | --- | --- |
| **CLAUSE** | **RELATED SECTION(S)** | **RELATED SECTION(S)** | **EXTENT OF CHANGE** | **CHANGES MADE & DOCUMENTATION SUPPLIED** | **COMMENTS ON COMPLIANCE & REF TO FINDINGS** |
| 5.1.5, 5.1.6 | Training and competence |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.4.2 | Information for patients and users | 2.2.1 | 2.3.1 |  |  | Comments: |
| Finding Ref(s): |
| 5.4.4 | Sample collection | 2.2.2 | 2.3.2 |  |  | Comments: |
| Finding Ref(s): |
| 5.4.5 | Sample transportation, delivery to laboratory | 2.2.5 |  |  |  | Comments: |
| Finding Ref(s): |
| 5.4.6 | Sample reception, pre-examination handling, preparation and storage | 2.3 | 2.3.3 |  |  | Comments: |
| Finding Ref(s): |
| 5.5.1 | Selection, verification and validation of examination procedures | 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 2.11, 2.12, 2.13, 2.14, 2.15, 2.17 | 2.4, 2.5 |  |  | Comments: |
| Finding Ref(s): |
| 5.5.2 | Biological reference intervals or clinical decision values | A1.1 | 3.1, 8.1 |  |  | Comments: |
| Finding Ref(s): |
| 5.6.2 | Quality control |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.6.3 | Interlaboratory comparisons |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.6.4 | Comparability of examination results |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.8.2 | Report attributes |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.8.3 | Report content |  |  |  |  | Comments: |
| Finding Ref(s): |
| 5.10.3 | Information system management |  |  |  |  | Comments: |
| Finding Ref(s): |

**Executive Summary:**

*Technical assessor:*

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

* *Key strengths and weaknesses identified*
* *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*
* *Comments on conformity with accreditation requirements*
* *Whether there is evidence that the quality management system has been updated to incorporate the new requirements (e.g have SOPs been updated, have processes been updated appropriately, etc)*
* *How effectively the results of quality assurance / quality control techniques such as proficiency testing, inter laboratory comparisons are used to reduce the risk of providing incorrect test/ calibration/ inspection/ certification results*

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

It is recommended that accreditation for fertility analysis on semen \*is/is not\* transitioned under ISO 15189:2012, incorporating the requirements of the sixth edition of the WHO Manual for the Laboratory Examination and Processing of Human Semen.

This recommendation is subject to:

* The agreement of an independent decision maker within UKAS
* \*Submission of electronic evidence on or before xx/xx/xxxx\* *1 month after the date of Recommendation*
* \*Satisfactory close out of all findings raised at this assessment classified as ‘M’ (action Mandatory)\*

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.

**References:**

ISO 15189:2012

WHO 6th Edition Laboratory Manual

**Appendices:\***

2023 Transition WHO 2021 - Improvement Action Report\*

*\*Delete as necessary\**

**REPORT END**