**ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES**

**CAB Accreditation Advisory Document**

**Document Title:** **Advisory Document on Transition to ISO 15189:2012**

**Document Number:** **ACCAB-CAB-AD-5.0**

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| Revision Number | Revision Date | Paragraph Number | Description of Revision | Revision Author |
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| **AD-5.1** | **Purpose:** |
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| AD-5.1.1 | To ensure that the ACCAB applicants and accredited Medical Laboratories get enough time to plan and implement the new requirements as published in the ISO 15189:2012 Version. |
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| **AD-5.2** | **Scope:** |
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| AD-5.2.1 | This advisory note is published for the informative use for the applicants and accredited Medical Laboratories who follow the ACCAB accreditation. |
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| **AD-5.3** | **Details:** |
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| AD-5.3.1 | ISO 15189:2012 has been published by ISO on 1st November 2012. |
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| AD-5.3.2 | International Laboratory Accreditation Co-operation (ILAC) has passed resolution to replace ISO 15189:2007 - Medical laboratories -- Particular requirements for quality and competence with ISO 15189:2012 – Medical laboratories -- Requirements for quality and competence.According to this resolution a three year transition period for the implementation of ISO 15189:2012 is agreed, therefore the three years transition period will conclude on 1st November 2015. |
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| AD-5.3.3 | ISO 15189:2012 incorporates following changes:<br><br>1. Clause 4.1.1.3 Ethical conduct;<br>2. Clause 4.1.2.6 Communication;<br>3. Clause 4.2 Quality management system;<br>4. Clause 4.14.4 Staff suggestions;<br>5. Clause 4.14.5 Risk management;<br>6. Clause 4.14.8 Reviews by external organizations;<br>7. Clause 5.1.7 Reviews of staff performance;<br>8. Clause 5.3 Laboratory equipment, reagents and consumables;<br>9. Clause 5.3.1.4 Equipment calibration and metrological traceability;<br>10. Clause 5.5.1.2 Verification of examination procedures;<br>11. Clause 5.9.2 Automated selection of results and reporting of results;<br>12. Clause 5.10 Laboratory information management. |
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| AD-5.3.4 | It may be noted that AD-2.3.3 of this document does not cover all the changes in the new edition of the standards ISO 15189:2012. It is the responsibility of the laboratory to ensure that it identifies and reviews the new edition against its current systems and addresses all issues to ensure its transition and implementation of the new revision in an effective manner. |
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| AD-5.3.5 | ACCAB may not accept any new application for accreditation to ISO 15189:2007 version after 1st November 2013. However, Medical Laboratories may choose to apply for accreditation to ISO 15189:2012 immediately. |
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| AD-5.3.6 | ACCAB will not issue any new accreditation to ISO 15189:2007version for the applications received after 1st November 2013. |
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| AD-5.3.7 | From 1st November 2013 all new applications will be assessed against ISO 15189:2012 |

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| AD-5.3.8 | From 1st November 2103 to 31st May 2014 all existing accredited laboratories will be assessed against the current ISO 15189:2007 Version of standard. |
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| AD-5.3.9 | All ACCAB surveillance/reassessments from 1st May 2014 will be carried out to ISO 15189:2012. |
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| AD-5.3.10 | ACCAB expects that all applicants and accredited Medical Laboratories should plan for the transition to ISO 15189:2012 as soon as possible that may require them to establish processes and systems including changes to processes, procedures, training and other arrangements. |
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| AD-5.3.11 | The action plan needs to demonstrate an analysis of the new standard and effective implementation such that the Medical Laboratory confirms it is operating to ISO 15189:2012 by 1st May 2014. |
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| AD-5.3.12 | ACCAB will review the following records during the surveillance/reassessment concerning implementation of ISO 15189:2012:<br><br>1. Analysis of impact on system and action plan;<br>2. Internal audit as per ISO 15189:2012;<br>3. Communication of changes to interested parties;<br>4. Implementation at all sites under the scope. |
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| AD-5.3.13 | The surveillance /ressaaseement schedule during 2014-215 may be arranged to ensure that all medical laboratories are verified for compliance to ISO 15189:2012 by 1st November 2015. |
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| AD-5.3.14 | ACCAB expects that the transition to ISO 15189:2012 will be complete by 1st November 2015. |
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| AD-5.3.15 | From 1st November 2015 accreditation certificates to ISO 15189:2007 will no longer be valid. |