

## CONVERSION TO ISO 15189:2012 FOR MEDICAL LABORATORIES

During the General Assembly held on 11 October 2012, the ILAC Resolution GA 16.21 was adopted, and it was agreed that by 1 March 2016, all references to ISO 15189 in accreditation certificates (as defined and described in ISO/IEC 17011), shall refer to the ISO 15189:2012 edition. Compliance will be determined during normal

surveillance or reassessment activities or as a separate activity.

From 01st April 2014, SANAS accredited medical peripheral laboratories and initial assessments will be conducted in accordance to the ISO 15189:2012 requirements, and all other accredited medical laboratories will be assessed according to

these requirements from the beginning of January 2015. In preparation for this, laboratories are reminded to submit the policy manuals to SANAS for review as of 01st June 2014.

For more information, please contact medical field manager, Barbara Mokgethwa on [barbaram@sanas.co.za](mailto:barbaram@sanas.co.za)

ISSUED BY: *Christinah Leballo*

## NEWLY PUBLISHED / REVISED SANAS DOCUMENTS:

| Doc No. | Applicable Programmes | Title  | Date published | Comments  |
|---------|-----------------------|--|----------------|---|
| F 94    | Medical               | Assessment Cycle Matrix for Medical ISO 15189 Laboratories   | 2014/02/12     | Revised to the ISO 15189:2012 requirements            |
| F 209   | Medical               | ISO 15189:2012 Checklist for Medical Laboratories - Document Review                                      | 2014/02/13     | New Document  |
| R 72    | Medical               | Requirements for Relocation of SANAS Accredited Medical Laboratories                                     | 2014/03/06     | Revised – Refer to the Amendment List in the document |
| F 92    | Medical               | Application for Relocation of Medical Laboratory   | 2014/03/06     | Revised   |
| TG 38   | Certification         | Guidelines for Certification Body Accreditation in the field of Risk Based Inspection Management Systems | 2014/02/12     | New Document  |
| TR 03   | Certification         | Criteria for Certification Body Accreditation in the field of Risk based Inspection Management Systems   | 2014/02/12     | New Document  |
| TR 72   | Certification         | Technical Requirements for Certification Bodies in the Field of Energy Management Systems                | 2014/02/12     | New Document  |
| TR 71   | Inspection            | Department of Labour (DoL) and SANAS Technical Requirements for the application of                       | 2014/02/19     | Revised – Refer to the                                |

|         |         |  |            |  |
|---------|---------|--|------------|--|
|         |         | SANS/ISO/IEC 17020: 2012 in the Regulatory Assessment of Explosives Facilities, Processes and Equipment Installation Inspection Bodies |            | Amendment List in the document   |
| TR 26   | Testing | Criteria for Validation of Methods used by Chemical Laboratories in the Coal, Oil, Petroleum, Metals and Minerals Industry             | 2014/02/12 | Converted from a Technical Guidance document (TG 26) to a Technical Requirement document |
| P 26    | All     | Accreditation of Critical Foreign Locations  | 2014/02/12 | Revised – Refer to the Amendment List in the document                                    |
| TPAJ01  | All     | Guidelines for SADCAS/SANAS Joint Assessments under the Twinning Partnership Arrangement   | 2014/02/12 | Revised – Refer to the Amendment List in the document                                    |
| PM      | All     | SANAS Policy Manual  | 2014/02/13 | Revised – Refer to the Amendment List in the document                                    |
| P 20    | All     | The Responsibilities and Duties of the Approval Advisory Committees and Field Managers in the Approval and Decision on Accreditation   | 2014/02/14 | Revised – Refer to the Amendment List in the document                                    |
| R 04-09 | All     | Conditions for use of Accreditation Symbols, Reference to Accreditation and Combined Marks   | 2014/03/25 | Revised – Refer to the Amendment List in the document                                    |

### THE FOLLOWING DOCUMENTS HAVE BEEN MADE OBSOLETE

Please ensure that records of these are deleted and destroyed.

| Doc No. | Applicable Programmes | Title  | Date withdrawn | Comments                |
|---------|-----------------------|--|----------------|-------------------------|
| F 29    | Medical               | Management Requirements - ISO/IEC 17025:2005 for Medical Laboratories  | 2014/02/13     | F 48 to be used instead |
| F 47    | Medical               | Vertical Assessment Medical Laboratories   | 2014/02/13     | F 44 to be used instead |
| F 67    | Medical               | Assessment Plan – Medical  | 2014/02/13     | F 66 to be used instead |
| TG 26   | Testing               | Criteria for Validation of Methods used by Chemical Laboratories in the Coal, Oil, Petroleum, Metals and Minerals Industry | 2014/02/12     | Replaced by TR 26       |

### CONTACT INFORMATION

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