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APPLICATION FOR TECHNICAL SIGNATORY REQUIREMENTS



BY MARLAN PILLAY
Field Manager: General Testing

Facilities are reminded that, before applying to SANAS for persons to become Technical Signatories; the laboratory's senior management (Quality Manager and/or Technical Manager) needs to declare the person(s) competent as per the requirements of SANAS Nominated Representative and Signatories: Responsibilities, Qualifications and Approval (R03) document.

The signature of the technical signatory confers validity of the data on the test report. This means that the technical signatory accepts responsibility for the contents of the report and therefore confirms that amongst other ISO/IEC 17025 requirements, there is traceability to the raw data; the equipment used, calculations done and competency records of the person that did the test. The technical signatory is the one that confirms all the checks have been completed and therefore the result is fit to be sent to the customer.

The laboratory's senior management must prove that the applicant has been trained and has an understanding and knowledge of the method/s he/she is to be technical signatory for. This understanding must be commensurate to complexity of the testing activity.

The applicant must be able to analyse data, look for trends and take corrective action where needed.

Senior management must ensure that there is an appropriate checking criteria that a technical signatory must use before he/she signs off the test report which is in place.

Records must be available to indicate that the person has a full understanding of ISO/IEC 10725 requirements and a thorough knowledge of the relevant R documents (for example: R01, R03, R04, R05, TR025 & R51); any relevant field specific requirements and relevant field specific guidance documents.

Records must be available indicating that senior management has deemed the person competent to be a technical signatory and records must be available to show how competency was evaluated.

During assessment visits, non-conformances may be raised should it be found that the on-going competence of the Technical Signatory has not been maintained or if the Technical Signatory has failed to carry out his/her duties.

When assessors are completing an Application for Approval of Personnel - F18 application form, the recommendation shall detail the following as a minimum:

- The applicant's knowledge of the relevant SANAS R documents, ISO/IEC 17025 and the lab quality system;
- The applicant's understanding of the methods and its underlying scientific principles proportionate to complexity of the testing activity;
- The effectiveness of the training authorised by the laboratory's senior management for the applicant(s) to be a technical signatory;
- The assessor's expert recommendation, based on an evaluation conducted, on whether the applicant is competent to sign off test results;
- The specific test methods/activities the applicant is competent to sign for;
- The assessor's expert viewpoint based on what he/she has assessed regarding the frequency of checking and the checking criteria used by the laboratory.

NOTICE ON SUBMISSION OF THE PROFICIENCY TESTING ACTIVITY PLAN

The document on Proficiency Testing requirements for Testing Laboratories has been published as SANAS R80 and is available on the SANAS website under <http://www.sanas.co.za/manuals/index.php>. This document amplifies the ILAC, EA and SANAS requirements.

SANAS hereby requests that all accredited Testing Laboratories submit their Proficiency Testing activity plan in line with SANAS R80 requirements for the period 01 May 2009 to 01 May 2014 to Marlan Pillay via email marlanp@sanas.co.za by 06 July 2009. The SANAS



BY MARLAN PILLAY
Field Manager: General Testing

Assessors will be reviewing the plan and the evaluation of results from participation in Proficiency Testing at surveillance assessments using the F176 form.

CASE STUDIES FOR MEDICAL ASSESSMENTS



BY VIJAY PADAYACHEE
Field Manager: Medical Laboratories

During the recent Assessor Conclave and the SANAS Medical STC meeting, several issues were addressed, including:

1. The need to minimise assessor variability;
2. The need for on-going training of assessors;
3. The need for assessors to gain CPD points;

It was decided to investigate the creation of assessment situation case studies. Assessors will receive regular case studies which would describe a situation that had arisen during an assessment. These will be real situations but will be treated confidentially.

This would then give several alternative answers. Each case

study would carry a number of Continuing Professional Development (CPD) or Continuing Education Unit (CEU) points still to be decided.

The intention is to try and create a consensus answer, but it is envisaged that this type of exercise might involve considerable debate and discussions. This must be seen in a positive light, as sensible and informed debate can only lead to a better assessor pool, more able to handle debate and contentious issues during an assessment.

Assessors are requested to send potential case studies to Vijay Padayachee on vijayp@sanas.co.za. These can involve any aspect of an assessment and you can send in as many as you like.

SANAS will review the submissions to ensure that as many ISO 15189 and/or ISO/IEC 17025 requirements are covered.

We need a full description of the "finding", without names of people or labs. Let us know which section of the standard was infringed or potentially infringed, along with your response to that situation. Please send us difficult issues, one that will test other assessors and stimulate debate.

Your help and support in this exciting venture would be much appreciated.

SANAS APPROVAL COMMITTEE PROCESS



BY YOLANDA VINNICOMBE
Quality Manager

The SANAS Approval Committee process has recently undergone a review to align it with the international best practices. Changes have been incorporated into the P20-04 document "The Responsibilities and Duties of the SANAS Approval Committees". Please consult the SANAS website for this document, and familiarise yourself with the changes.

The main changes in the process are:

- Only assessment documentation of initial assessments, re-assessments and extensions of accredited facilities outside of the existing scope are submitted to the Approvals Committee;
- Assessment documentation of surveillance assessments will be reviewed by the relevant Field Manager, and not subjected to an Approval Committee, unless the assessment team has made a recommendation for suspension;
- Approval Committee meetings will be scheduled as a set calendar item;
- Approval Committee members evaluate whether a thorough assessment has been carried out and appropriately recorded.
- Monitoring of the Approval Committee Members, Approval Committee Process and Surveillance Review Process will be done on regular basis as part of SANAS internal control process.

ILAC / IAF / EA PUBLISHED DOCUMENTS RELEVANT TO THE ACCREDITED FACILITIES



BY YOLANDA VINNICOMBE
Quality Manager

ILAC G8:03/2009 Guidelines on the Reporting of Compliance with Specification

This document provides guidelines for testing and calibration laboratories (and their customers) in relation to the decision and reporting of non-compliance with specific requirements. Legal or regulatory requirements for the reporting of compliance override these requirements.

Please access the ILAC website <http://www.ilac.org> for more information on this document, and the list of other relevant publications.

IAF MD 5:2009 Duration of Quality Management Systems (QMS) and Environmental Management Systems (EMS) Audits

(Issue 1, issued on 01 February 2009; Application from 1 May 2009) This document provides mandatory provisions and guidance for Conformity Assessment Bodies (CABs) to determine the audit duration for stage 1 and stage 2 initial audits, surveillance audits and re-certification audits.

A simple methodology is used to determine the audit duration (stage 1 plus stage 2) from tables based on the effective number of client personnel. For EMS audits, the duration varies according to the complexity of the audit. Factors which could add to, or subtract from the time are applied and checks made to ensure specified caveats are applied and any reductions in time do not exceed requirements specified in this document. The justification for the calculated time is recorded for future audit by an accreditation body.

Please access the IAF website <http://www.iaf.nu> for more information on this document, and the list of other relevant publications.

EA-1/11 Food Safety Management System/Scope of Accreditation

Please access the EA website <http://www.european-accreditation.org> for further information on this document, and the list of other relevant publications.

CONGRATULATIONS AND WELCOME TO NEWLY QUALIFIED ASSESSORS



BY YOLANDA VINNICOMBE
Quality Manager

Congratulations and Welcome to our newly qualified Technical Assessors who are:

- Mr Reuben Heydenrych – Certification Field
- Dr Jan du Preez – Pharmaceutical Field
- Ms Leigh Johnson – Medical Field
- Ms Fierdouz Allie – Blood Transfusion Field
- Dr James Kitching – Veterinary Field

We are looking forward to a long and mutually beneficial relationship with you!

INTERNATIONAL ACCREDITATION DAY 9 JUNE 2009

09 June 2009 will mark International Accreditation Day, a global initiative jointly established by the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) to raise awareness of the importance of accreditation-related activities. The theme of the day this year is "competence", accreditation.

A joint message from ILAC and IAF Chairs, Daniel Pierre and Thomas Facklam is published on the websites under, http://www.ilac.org/jo_sta.html and <http://www.iaf.nu/>



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OUR MISSION

To create an impartial and transparent mechanism for organisations to independently demonstrate their competence and facilitate the beneficial exchange of goods, services and knowledge and provide a service that is recognised as equitable to best international practice while reflecting the demographics of South Africa in all that we do.

We issue our report monthly and if you would like to receive future copies, please forward your particulars to enable us to add your details to the distribution list.