

SANAS Assessor Workshop March 2009

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AGENDA

- Introductions and welcome
- Opening Meeting-John Peart
- Issues from 2008 CONCLAVE
- Feedback from Assessment Packs:
- Completing the SANAS Forms (F48,F49,F15,F23)
- IMPLEMENTATION OF ISO 15189: 2007
- Assessment of Satellite labs without the LA

-Introductions and welcome

Thanked all for attending

New structure of the Medical Field which now includes Mponeng as the permanent Lead Assessor and the 2 new members of the team Praise Maja (praisem@sanas.co.za) who was not present and Shiela Moeketsi (shielam@sanas.co.za)

Praise and Sheila will be managing all medical pre and post assessment activities as of 01 April 2009.

The consequences when assessors confirm and then decline prior to the assessments. co-operation is required from all because the dates cannot be changed once it has been confirmed with the facility.

-Opening Meeting-John Peart

OPENING AGENDA

- **Plan for the assessment with the team prior to the pre-opening meeting.**
- **At the opening meeting be clear and concise which would set the platform and this would prevent any confusions during the day.**
- **Be clear that any findings(negative) raised would be graded together as a team at the pre-close out.**
- **Explain what would be regarded as a Major or Minor – very important.**
- **Discuss the significance of grading the NCs is to assist the team and the AC to make a recommendation at the end of the assessment process.**
- **Where satellites laboratories are being assessed only by the TA, the TA will now perform that duty.**
- **Training in the form of a workshop will be given to TAs, this date will be communicated once confirmed**



**Issues from 2008
CONCLAVE**

Issues from 2008 CONCLAVE

Two issues to be forwarded to STCs to develop guidance documents:

- guidelines for validation;
- guidelines for assessing persons that are authorizing results off site.

Suggest each technical assessor to complete their own matrix per assessment [F81 and F94].

Due to critical nature of the medical laboratories 25 days for completing non-conformances is acceptable

guidelines for validation

It was noted that due to the different terminology used by different facilities

The STC suggested that they would look at the CLI guidelines on validations.

suggestion from the assessors that maybe we should benchmark this issue.

David Rambau would obtain these documents and send them to the committee members to review at the next meeting (April 2009)

guidelines for assessing persons that are authorizing results off site.

The laboratory shall have clearly documented procedures for the release of results including details of who may release results and to whom.

The laboratory shall design internal quality systems that verify the achievement of the intended quality of results, the person authorizing results must have access to all QC results including outliers so that if there is a trend this can be picked up. There must be evidence that QC results are being reviewed by the person who is offsite.

Suggest each technical assessor to complete their own matrix per assessment [F81 and F94].

This has been piloted by some LAs using big teams and it has worked very well for the LA and for the TA.

Will be implemented on the 1st of April 2009. The TA will receive their own copy of the matrix which they would complete for the technical aspects, comments and concerns for next assessments must be noted incase there is a change of team.

I will email the ones for April and May 2009 to the specific TAs, look at what was done and you can prepare for the assessment. Please print for packs as some of the packs are already gone out to LAs.



Feedback from Assessment Packs:

Schedules

Please ensure that the facility dates and signs the schedule that you are working with as acknowledgement that the info on it is correct.

Mark off what was assessed

- Please do not add tests onto the scope at the time of assessment. Lab needs to forward a completed F14 for any extensions. If it is not in the pack ask the LA to contact SANAS or if they can provide proof.

F04

Version of the standard not stated on the F04
Assessment type not stated; ie :surveillance, re-assessment
Programme type must be indicated ie: Testing medical
Must indicate whether previous NC was cleared or not
Complete conclusion with regards to the effectiveness of the
organisation which must include positive and negative
feedback.

Comment on the Proficiency testing

Calculate the 25 working date correctly and note that it is 3
months for initial assessments

Management must sign the f04 before submitting

F03

Please do not tear NC that have been raised, write cancel on it and submit with the pack.

Write down the clause in the space : Area/Field of Organisation Assessed.

Reference number must be traceable to the vertical or witnessing,

Matrix

All: extent of assessment

LA: Management clauses and follow up for next assessment.

TA: Technical clauses

scope of tests assessed, very important to indicate
follow up should you not be the assessor next time.

Verticals and Witnessing

LAs: Please check that the TA's forms are well documented. Ticks and YES are not acceptable; constant monitoring of TAs during the day should give you an indication of how forms are being completed, ask to see forms during breaks. Make sure all documents are completed (dated and signed) Previous NC must be acknowledged as being checked, signature and date Ensure that the TA's NC are also clearly written and check that the correct clause number is indicated on the F03.

F15

Avoid statements like 'Person is competent'; 'Method is suitable'
How did you conclude that this person was competent ie:could interpret the results,the person was able to achieve an accurate and precise result as per the existing validation. He has demonstrated his competence to perform the method.

Avoid copying down the method:

Indicate what you observed the person doing, gives AC a better indication why you thought this person was competent.

Include brief description of activity assessed, reference to the method, outcome or conclusion of activity assessed.

Number your F15's if there are many

General

- ALWAYS remember YOU are SANAS,if you have issues then raise this with the FM/SM or use the F23.
- PLAN,PLAN and PLAN your assessment, include in your planning the clearance of NCs:suggestion start with clearance of NCs or put it in your plan next to the clauses.
- Do not allow management to complain about SANAS,stop it immediately state that you have limited time and all concerns must be addressed with SANAS.
- If a team member is unhappy don't entertain negativity within the team.
- Communicate as a team, Check or request the schedule from the LA regarding the assessment.
- Be prepared for the assessments, should you require SOPs request this from the LA.
- Keep your LA informed throughout the assessment of your progress and concerns.
- Manage your time, take the tea and lunch breaks, respect others.,

General

- LA must try plan to do the internal audit first to enable them to inform the TAs.
- Do not raise NC if it has been raised during their internal audits, however notify the LA who can request evidence that it has been completed within the agreed time frame. Must be noted on the F04.
- All forms will be issued in word format except the F03 and F04.
- The medical forms are being revised and these will be sent out, proposed date of implementation is 01 May 2009.
- Assessors are still experiencing difficulties whereby facilities do not have sufficient records on site-this must be requested prior to the assessment-state the month that is required and the facility shall provide this.

GENERAL

- Suggestion that if the facility is experiencing problems with retaining document then we should do more frequent visits.
- During an initial assessments where there are more than 1 discipline, the ALL or NO rule does not apply, eg one discipline can be recommended for accreditations and the other can be rejected.
- The facility has the choice to remove tests of their schedule even if it being done in the laboratory.
- A team can recommend that a test or tests be taken off the schedule due to the nature of NCs.
- Copies of how forms should be completed would be forwarded to the assessors once they have been converted to the word format.

GENERAL

Recommended that there shall be a TR document for Anatomical pathology.

Prof Bowen would be invited to the next STC meeting, get a working group together to start the process.

IMPLEMENTATION ISO 15189: 2007

As of 01 April 2009 all facilities will be converted to ISO 15189:2007

Assessment forms are revised and would be used as of 01 April 2009.

Comparison between ISO 15189: 2003 and ISO 15189: 2007

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F182 was completed by all facilities accredited to ISO 15189:2003 to convert them to ISO 15189:2007, this will be included in the pack of the HO.

All facilities must make mention of ISO 15189:2007 or ISO 15189 in their documents.

Very minor changes in the version, the documents are being revised and should be available for use on the 01st April 2009.

-Assessment of Satellite labs without the LA

SANAS is busy with a project whereby Satellite labs do not get assessed by LA and TA, only the TA would assess. The management of the satellite lab gets assessed during the annual visit of the HO/Regional
Labs are grouped and the HO/Regional with part of the grouped gets assessed every year.
This will enable the whole schedule to be covered over a cycle.

Assessment of Satellite labs using only the Ta

Send out the Assessment plan to the labs including the agenda

Opening meeting

Sign the register

Assessment of technical clauses

Pre-close out meeting if it is a big team

Ratify the SoA

Make a recommendation on the F04

Close out meeting

Sign register

Use F23 for feedback

Send pack to SANAS within 5 working days

Assessment of Head Offices- new project

assessment is very comprehensive minimum 2 days for the LA. nearly as comprehensive and has the function of a check of the compliance with all the accreditation criteria and of the coherence of the organizations' quality system.

Regional managers would be available for interviewing by LA,

The HO/Regional would have the following available, document control, internal audit records, management review, customer complaints, contract reviews for the LA.

questions

