



Approvals Committee



WELCOME TO SANAS KNOWLEDGE TRANSFER

Approvals Committee

- **Findings???? (+/-) Recorded by the Peer Evaluation**
- **We had to re-look at the SANAS procedure (one AC Member)**



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- **Back to what it used to be,
a meeting chaired by an FM or
other SANAS Technical Staffer.**



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- *Initial assessments, Re-assessments and extensions of accredited facilities outside of the existing scope, are the subject of the Approval Committee (AC) evaluation*



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- *Assessment documentation received after a surveillance assessment, with a recommendation of suspension of accreditation for partial or complete scope of existing accreditation status, will be subject to an AC meeting consisting of the relevant Field manager (FM) or delegate and a Senior Manager (SM).*



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- *Scheduling of AC Meetings*

The Senior Managers will meet at appropriate intervals to plan, schedule and review AC meetings as a standard calendar item set every 2 weeks



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- *The bi-monthly scheduled meeting will fulfil the eventuality that an AC meeting may be required for any of the programs for facility assessments requiring an AC decision.*



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- *For scheduled AC's within the Regulatory domain, the relevant FM will request the presence of at least one member representing the relevant regulatory authority,*



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- *Names of AC members will be published on the SANAS website so that facilities can object to AC members who may be assigned to evaluate that facilities assessment pack.*
- *Valid reasons must be submitted by the facility concerning any objections of an AC member they may have.*



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During the meeting:

Each AC member will give feedback on the packs they have evaluated, stating whether they support / reject the recommendations made by the assessment team, with reasons. This is also done to reach consensus amongst the AC members.

The report of the evaluation by the AC member will be recorded on the F 08 “Approval Committee Evaluation of Assessment Packs” form.



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The committee is tasked to evaluate whether the information submitted by the Lead Assessor was recorded on the appropriate assessment forms,

and

contained the necessary information to indicate if the competency and relevant system was appropriate and in place to support the technical competency for which the facility had applied for accreditation



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The committee would verify that the Technical Assessor had recorded, on the appropriate forms, the assessment of the technical aspects as per the schedule of accreditation.

The Committee member would, evaluate whether the comments made were sufficiently detailed and allowed for intelligent interpretation, and that the conclusion of the competencies and results or services provided by the accredited facility were reflected in the final recommendation



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- *The AC members must evaluate whether a thorough assessment has been carried out and appropriately recorded.*
- *The objective is not to try to re-assess the facility through the submitted Assessment pack. (The AC member must accept that the assessor(s) have been trained in assessment techniques and therefore competent to perform the assessment of that discipline.)*



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The AC must use the F 08 “Approval Committee Evaluation of Assessment Packs” form to inform the Chairperson of instances where insufficient information was available for them to make a judgment on the thoroughness of the assessment,

or

on any other issues of concern.

The Chairperson will pass on this information to the relevant FM who will then take up these “queries” with the relevant Lead Assessor



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The AC shall, where relevant, make recommendations to the relevant Chairperson regarding the performance of assessors and inspectors and whether they continue to meet SANAS requirements.

Any comments on the assessment team performance recorded on the F08 form and referred on the F182 shall be communicated to the assessment team by the relevant FM.



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AC Member will evaluate the pack to determine:

Was information available to indicate that the relevant disciplines shown on the applicant's application were covered in the assessment / GLP inspection performed by the SANAS assessors / GLP inspectors?

Was it evident that assessments / GLP inspections were performed against the documented Quality system or required OECD Principles of GLP?

Was it evident that the applicant had the capacity, capability and necessary expertise to certify organisations or perform calibrations, tests or GLP compliant studies competently?

and



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Was it evident that the applicant significantly complied with the requirements of the relevant ISO/IEC Guide, International Standard or OECD Principles of Good Laboratory Practice and relevant SANAS Requirement documents?

Was it evident that the applicant significantly complied with all the Accreditation Assessment and/or GLP Compliance Inspection requirements as contained in the relevant SANAS Procedural and Requirement documentation?

Have all outstanding Corrective Actions been closed out (within the agreed time period) to the satisfaction of SANAS?



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As discussed Yesterday the AC will also comment on situations concerning NC's root cause being evaluated

OR

If it appears that NC's have been signed off without the necessary objective evidence having been submitted.



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*Review of Surveillance Assessments,
Extensions in an already accredited
scope and Signatories*

by the Field Managers



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Training

