



for conformity assessment bodies

Developed to assist
new conformity assessment bodies
that wants to get accredited.



SANAS 2013 ©. All rights reserved.

CONTENTS

A	INTRODUCTION	03
B	TERMINOLOGY	08
C	ABOUT SANAS	11
D	ACCREDITATION BENEFITS	16
E	REQUIREMENTS	22
F	ACCREDITATION PROCESS	26
G	ACCREDITATION COSTS	36
H	MANAGEMENT SYSTEM MANUAL	38
I	KEY REQUIREMENTS	52
J	OPERATIONAL REQUIREMENTS	65
K	TECHNICAL REQUIREMENTS	68
	CONTACT DETAILS	99





INTRODUCTION

FOREWORD

When new conformity assessment bodies apply for accreditation or they are in the process of acquiring accreditation they often find it difficult to understand what is required for SANAS accreditation. The aim of the toolkit is to assist applicants by introducing them to accreditation and to explain some of the terminology that we use.

The toolkit serves as a general source of information. We take you through the whole accreditation process, i.e. explaining about where you start, the phases of the application process as well as tell you about the cost of accreditation.

You are also introduced to the SANAS procedures and forms. The toolkit provides you with tips on how to prepare a Quality Manual and tell you about the two approaches that can be used.

Your feedback on the usefulness of the toolkit and recommendations for improvements can be submitted to Dr Elsabe Steyn at elsabes@sanas.co.za.



HAVE YOU BEEN ASKED TO GET SANAS ACCREDITED BY A CLIENT OR A REGULATOR?

Do you want to know what accreditation is?

Do you want to know why you need to get accredited?

Do you want to know what the benefits are?

Do you want to know what the cost will be for accreditation?

Do you want to know what the process is to get accredited?



WHAT IS ACCREDITATION?

As the sole national accreditation body for South Africa responsible for carrying out accreditation in respect of conformity assessment, SANAS provides accreditation services for the accreditation fields shown in the table below.

- In general accreditation is a formal process of assessing and recognising whether a conformity assessment body that offers services is competent to provide such services.
- The recognition is provided by an Accreditation Body that is often formally recognised at a national level, in the case of SANAS it is recognised at both a national and international level. If the conformity assessment body is accredited it is recognised for its competence including knowledge, skills and ability to provide the service. The recognition is usually guided by minimum requirements outlined by relevant as well as accreditation requirements.
- The recognition by an Accreditation Body is used by the accredited conformity assessment bodies to illustrate to their clients, regulators and government that they are competent to provide the services as stated on the schedule of accreditation issued by the Accreditation Body.
- Clients of accredited conformity assessment bodies use the certificates and test reports issued by the accredited bodies to prove that their products or services were competently tested and comply with requirements of compulsory technical regulations or private specifications.

ACCREDITATION FIELDS	ACCREDITATION STANDARD USED
Laboratories (calibration and testing)	ISO/IEC 17025
Medical laboratories	ISO/IEC 17025 and/or ISO 15189 (the international standard specifically for medical laboratories)
Verification laboratories	SANS 10378 (the national standard)
Proficiency testing schemes	ISO/IEC 17043
Certified reference material	ISO Guide 34
Certification	
Quality Management System (QMS)	ISO/IEC 17021
Environmental Management System (EMS)	ISO/IEC 17021
GHG emission validation and verification	ISO/IEC 14063
Product certification systems Note: These include sector-specific industry schemes whose requirements are maintained by the industries themselves. Eurepgap, the British Retail Consortium (BRC) and the Global Food Safety Initiative (GFSI) are all examples of these.	ISO/IEC 17065
Personnel certification systems	ISO/IEC 17024
Inspection bodies	ISO/IEC 17020 and relevant national standards.
Good Clinical Practice Veterinary (GCPV)	ISO/IEC 17025 (compliance monitoring of veterinary laboratories conducting animal clinical trials)
Good Laboratory Practice (GLP)	According to the OECD's principles of GLP for facilities conducting non-clinical environmental health and safety studies
Broad-based Black Economic Empowerment (B-BBEE) accreditation of verification agencies	SANAS R47 and the B-BBEE Codes of Good Practice.

Disclaimer

This toolkit is intended only to serve as a guideline in pursuit of seeking accreditation and does not guarantee automatic qualification for accreditation. SANAS accepts no liability for the content of the toolkit, or for the consequences of any action(s) taken on the basis of the content of this toolkit.

WHAT'S THE DIFFERENCE BETWEEN ACCREDITATION AND CERTIFICATION?

- Accreditation and Certification are regularly wrongfully used interchangeably. However, in the conformity assessment industry both terms have very specific meanings. In layman's terms accreditation gives recognition of a conformity assessment body's competence to perform specific services. Whereas certification gives recognition to a companies compliance with requirements such as ISO9000 or ISO14000
- Certification Bodies, are accredited after they successfully undergo a process of assessment by an Accreditation body like SANAS, to ensure they meet international standards that among other things assess the bodies impartiality and competence.
- Certification is undertaken by Certification Bodies and is a process by which an independent third party certifies that a product, system or person, conforms to specific requirements.

Note! Not only certification bodies are accredited.





TERMINOLOGY

THE TERMINOLOGY USED IN THE WORLD OF ACCREDITATION

- Conformity Assessment Bodies (CAB)
- International Standards (ISO/IEC)
- Assessment
- South African National Standards (SANS)
- Accreditation Requirements

“Conformity Assessment Body (CAB)” means a conformity assessment body, which is a body that performs Conformity Assessments and that can be the object of Accreditation and includes an Applicant and/or accredited body, which shall in turn include calibration, testing and verification laboratories, certification bodies, inspection bodies, rating agencies and any other type of body that may be added to SANAS’ scope of activity;

“A Standard” is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

“Assessment” means a process undertaken by SANAS to assess the competence of a CAB, based on particular standard(s) and /or other normative documents and for a defined scope of accreditation; Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of the personnel, the validity of the conformity methodology and the validity of the conformity assessment results.

“Accreditation Requirements” means any and all requirements relating to Accreditation, including those specified in any accreditation standard, guide, regulation and/or any IAF/ILAC mandatory document which applies to a CAB, the Act and any policies, procedures and requirements of SANAS which applies to a CAB.



ABOUT SANAS

WHO IS SANAS?

- **SANAS is the South African National Accreditation System.** It is the only body in South Africa mandated by the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act No. 19 of 2006 to provide accreditation services to conformity assessment service providers in South Africa.
- In terms of the act SANAS's primary role is to serve the national and public interest by facilitating the provision of a reliable internationally recognised accreditation infrastructure to government, industry and the wider community.



WHO DOES SANAS ACCREDIT?

- Testing laboratories
- Calibration laboratories
- Certification bodies
- Inspection bodies
- Proficiency testing schemes
- Certified reference material



WHAT IS SANAS' RESPONSIBILITY?

SANAS assess factors relevant to a CAB's ability to produce precise, accurate test, calibration, certification, inspection results, including measurement, verification and validation data.

SANAS promotes the acceptance of such results nationally, regionally and internationally.

FACTORS TO BE ASSESSED

- Technical competency of staff;
- Validity and appropriateness of methods;
- Traceability of measurements to national and international standards;
- Suitability, calibration and maintenance of equipment;
- Suitable environmental conditions;
- Handling of test / inspection calibration and verification items;
- Quality assurance processes ; and
- Reporting of results.

Note! Not all of the above factors are applicable to certification bodies.



WHAT SANAS ACCREDITATION IS NOT?

- With the now common and broad use of the term 'accreditation' and some long standing misconceptions of what SANAS accreditation involves, it is important that there is clarity about what SANAS accreditation is not.
- It is not merely a means of registering or listing of personnel or products and processes.
- It is not a management system assessment/audit dressed up with some scientific/technical elements.
- It is not the recognition of reputation/affiliation -these things change over time.
- It is not the recognition of future capabilities.
- It is not the recognition of an individual's qualifications.
- It is not broad approval of every activity that a CAB might do.





ACCREDITATION BENEFITS

WHAT ARE THE BENEFITS OF SANAS ACCREDITATION TO THE ACCREDITED CONFORMITY ASSESSMENT BODY?

Successful accreditation can reap many benefits for the conformity assessment bodies. The following is a list of typical benefits of bodies becoming accredited:

BENEFITS

- Improved management policies
- More effective and efficient operations
- Stronger risk management strategies
- Reduction in incidents
- Enhanced team awareness
- Credibility with government and customers
- Marketing edge (Competitive advantage)
- Greater customer trust (Customer intimacy)
- Professional self-respect
- International recognition

MORE BENEFITS

- Improved documentation
- Improved consistency
- Improved access to markets
- Improved supplier relations
- Improved productivity
- Improved employee morale
- Improved customer services
- Greater customer focus



WHAT ARE THE BENEFITS OF SANAS ACCREDITATION TO THE CLIENTS OF AN ACCREDITED CONFORMITY ASSESSMENT BODY?

Government bodies and regulators are constantly called upon to make decisions related to:

- Protecting the health and welfare of consumers and the public;
- Protecting the environment;
- Developing new regulations and requirements;
- Measuring compliance with regulatory and legal requirements; and
- Allocating technical and financial resources.



BENEFITS FOR GOVERNMENT BODIES AND REGULATORS

- In order to make informed decisions, Government bodies and regulators must have confidence in the results generated by conformity assessment bodies carrying out conformity assessments activities in these fields. Using an accredited conformity assessment body can help establish and assure this confidence.
- When a conformity assessment body is accredited by a recognised accreditation body, it has demonstrated that a prescribed level of technical competence to perform specific types of conformity assessment activities has been achieved.
- The result is assurance that the conformity assessment body is capable of producing results that are accurate, traceable and reproducible which is a critical component in governmental decision-making.



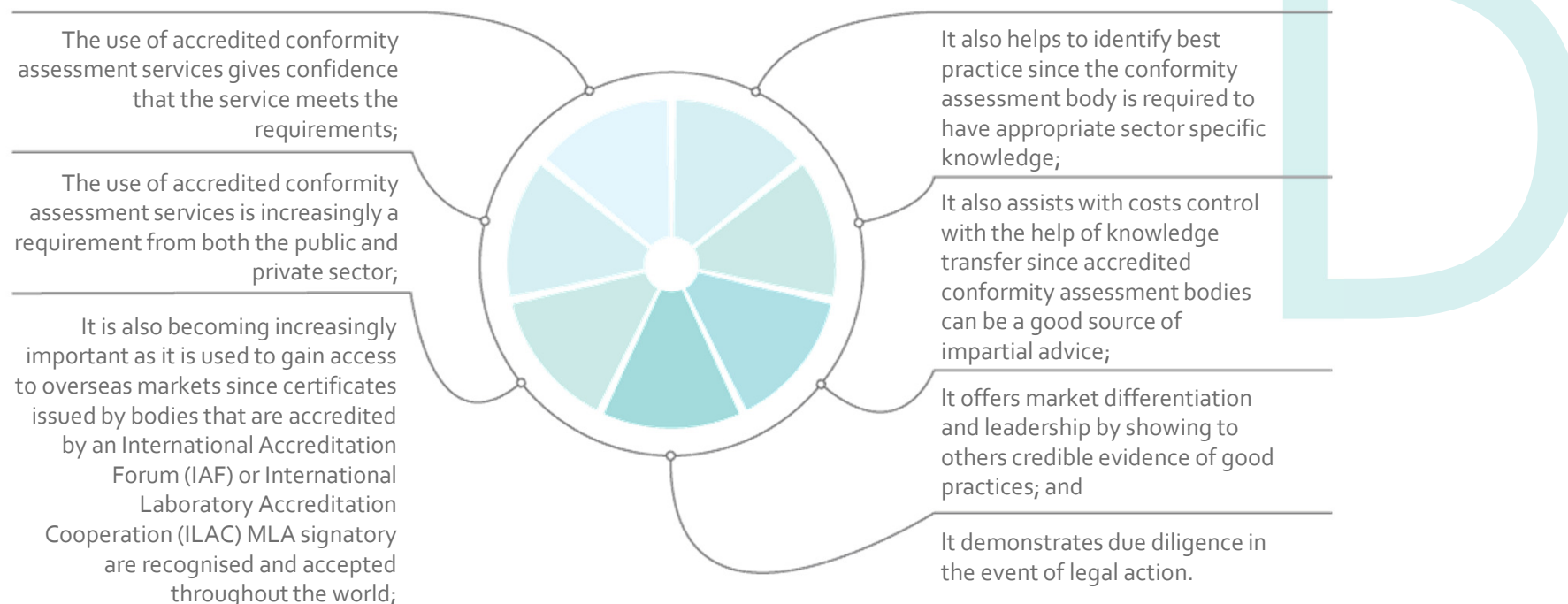
BENEFITS FOR CUSTOMERS IN THE PRIVATE SECTOR

Private sector are constantly called upon to comply with technical regulations or specifications when they provide a service or a product. These technical requirements include:

- Government regulations to protecting the health and welfare of consumers and the public;
- Government regulations to protecting the environment;
- Technical specifications required by the country that they export to; and
- Technical specification that the purchaser require



BENEFITS FOR CUSTOMERS IN THE PRIVATE SECTOR






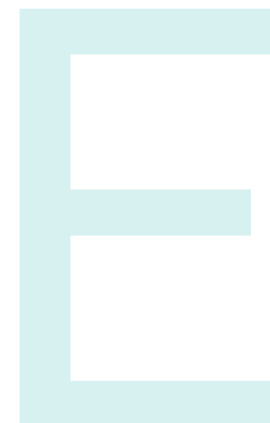
REQUIREMENTS

WHAT ARE THE REQUIREMENTS FOR ACCREDITATION?

- The requirements for accreditation is set out in:
 - International Standards also called ISO/IEC standards;
 - South Africa National Standards also called SANS; and
 - SANAS additional accreditation requirements.

- There are different standards for different conformity assessment bodies. 

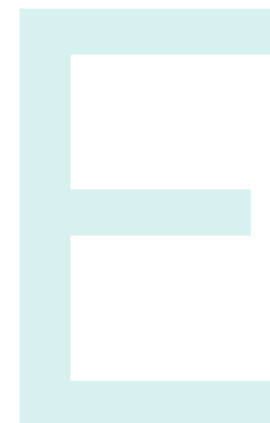
- The additional accreditation requirements as set by SANAS can be found on the SANAS website, **www.sanas.org.za**.



For example:
Ro3, Ro4, R51, TR81, TR54, etc.

SOME EXAMPLES OF ACCREDITATION STANDARDS

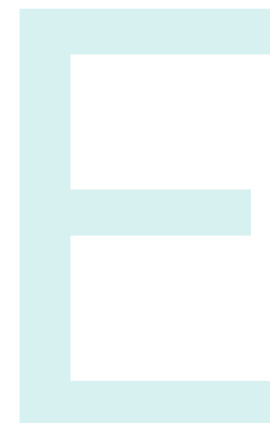
- If you set up Medical Laboratories the bodies will have to comply with ISO 15189 and/or ISO/IEC 17025.
- If you set up Certification bodies the bodies will have to comply with ISO/IEC 17021, or ISO/IEC 17024, or ISO/IEC 17065, or ISO/IEC 14065 (and the IAF interpretation thereof).
- If you set up Testing and Calibration laboratories the bodies will have to comply with ISO/IEC 17025.
- If you set up Inspection bodies the bodies will have to comply with ISO/IEC 17020 standards.
- GLP facilities are inspected for compliance to OECD GLP principles.
- If you set up Verification laboratories the bodies will have to comply with SANS 10375.
- If you provide Proficiency testing schemes your body will have to comply with ISO/IEC 17043.
- If you provide Certified reference material your body will have to comply with ISO Guide 34.



WHERE DO I GET THE STANDARDS?

These ISO/IEC and SANS standards can be bought at the South African Bureau of Standards in Groenkloof, Brooklyn, Pretoria.

www.sabs.co.za






ACCREDITATION PROCESS

MY ORGANISATION WANTS TO BECOME ACCREDITED. WHERE DO WE START?

- The stages of the accreditation process is spelt out in the next slide.
- A detailed timeframe is available on the SANAS website, **www.sanas.co.za**.
- The timeframes indicates where SANAS controls the time and where you as the client controls the time.



Click on the button at the bottom of the home page that says “accreditation timeframes”.

Note! For more information, please see the SANAS document A03 on the SANAS website, **www.sanas.co.za**.

STAGES OF ACCREDITATION PROCESS

APPLICATION STAGE

The **first stage** of the accreditation process is for the CAB to complete and return their application, including relevant documentation requested within the application form, along with payment to SANAS.

DOCUMENT REVIEW STAGE

The **second stage** involves the Document Review where SANAS reviews the application documents against the relevant accreditation criteria and provides a report to the applicant. The next stage of assessment will not proceed until the documented systems meet requirements.

ASSESSMENT STAGE

The **third stage** involves the Assessment where SANAS selects an assessment team who undertake an on-site assessment at the applicant's offices. The assessment team also witnesses the applicant's team undertaking assessment activity at their client's premises. At the completion of the assessments the assessment team write a report of their findings along with recommendations.

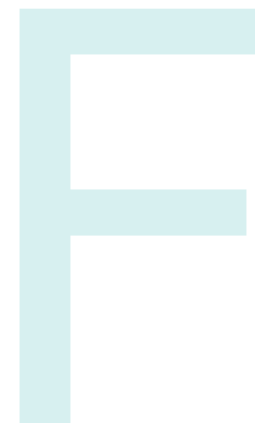
REVIEW OF THE ASSESSMENT

The **fourth stage** involves a Review of Assessment Report where SANAS forms an Accreditation Approval Advisory Committee (AAC). Members of this committee are individuals who have expertise in the scope of accreditation sought. The AAC reviews the report and makes a recommendation regarding accreditation to the CEO.

ACCREDITATION DECISION STAGE

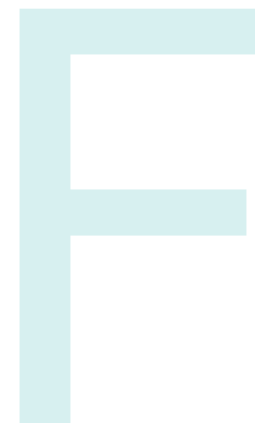
The **fifth stage** involves the Accreditation Decision where the CEO make a decision to approve or not approve accreditation based on the evaluation report of the AAC. If approval is granted a Certificate of Accreditation issued.

If accreditation is not approved, the applicant is advised of the reasons for the decision. A further application may be considered at a later date.



WHAT CAN YOU EXPECT FROM THE ACCREDITATION PROCESS AND THE ASSESSORS?

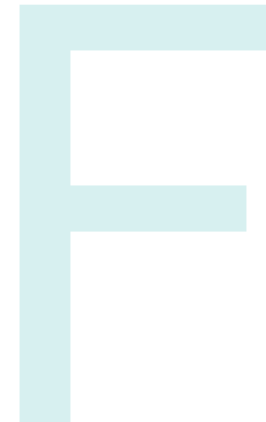
- The accreditation assessment team will come to your facility on the day of the assessment.
- They will meet as a team to prepare for the assessment in a room that you will make available.
- The lead assessor will have an opening meeting with the facility management staff with a view to brief them on how the process will unfold.
- The assessment will then take place and various staff members will participate in the assessment process.
- During the assessment assessors may record findings that facility staff will be required to acknowledge by signing.
- Once the assessment is completed the assessment team will meet to finalise the assessment conclusions on which they will base the recommendation concerning accreditation.
- The lead assessor will then have a closing meeting with the staff where the final recommendation will be presented to the facility management.
- After the assessment the lead assessor will submit a report to SANAS.
- An accreditation approval advisory committee will evaluate the assessment report and any corrective actions submitted by the facility to correct non-conformances records at the assessment. The accreditation approval advisory committee evaluates the report to see that the report documentation generated by the assessment team reflects the recommendation made by the team. The accreditation approval committee will make a recommendation to the CEO based on their evaluation.



WHAT WILL HAPPEN DURING AN ACCREDITATION ASSESSMENT?

The accreditation assessment have two main components namely:

- The assessment of the CAB's management system/quality manual.
- The assessment of the performance of the CAB activities (technical competence).



THE DOCUMENTAL ANALYSIS INCLUDES:

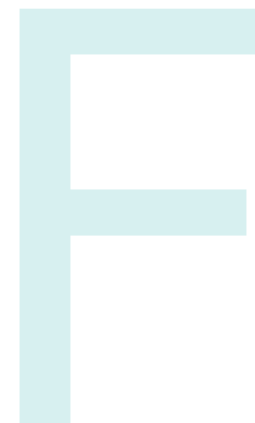
An assessment of the documentation of the CAB that specifies the criteria for the competence of personnel, including records for the conduct of competence analysis;

An assessment of specific procedures, guidelines, check-lists, instructions etc. addressing specific requirements for the different conformity assessment activities included in the accreditation scope (if any);

An assessment of the procedures followed and the personnel available for the contract reviews, the allocation of resources for the conformity assessment activities and reporting of results;

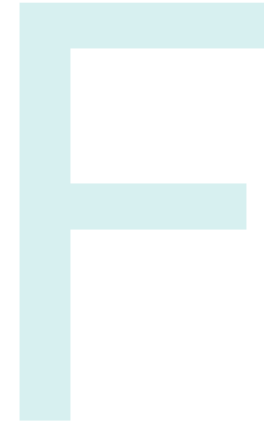
An assessment of records showing that the CAB has processes in place for the maintenance and review of the above criteria, on a periodic basis; and

An assessment of documented evidence supporting the CAB's personnel competence.



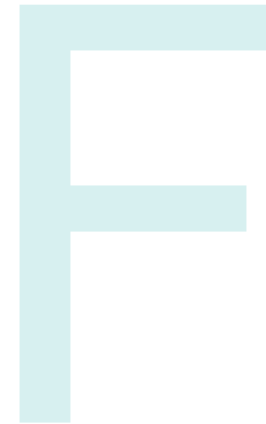
THE ASSESSMENT OF THE PERFORMANCE OF THE CAB'S ACTIVITIES:

- Confirm that the procedures and criteria established by the CAB for ensuring the competence of the personnel have been effectively and consistently implemented.
- Determine whether the required competence is actually demonstrated during the assessments, both in conducting CAB activities and in reporting the results.



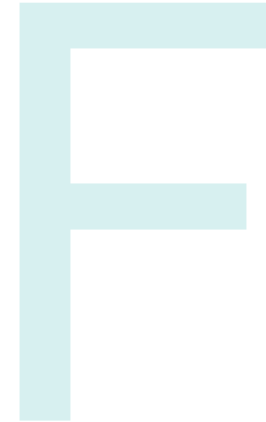
REGULAR VISITS AND RE-ASSESSMENTS

- Once accredited, regular visits are made to the CAB to assess on-going demonstration of competence and compliance with accreditation requirements
- SANAS also selects a sample of the CAB's personnel for witnessing of technical activities
- A re-assessment takes place when the accreditation cycle requires it.



SANAS FORMS THAT ARE IMPORTANT

- Terms and conditions of Accreditation F147.
- Terms and conditions of GLP/GCP Compliance F199.
- Application forms, programme specific F14's.




Forms are available on the SANAS website under publications.



ACCREDITATION COSTS

HOW MUCH WILL IT COST MY COMPANY TO BECOME SANAS ACCREDITED?

- Until we receive an application for accreditation which details the size of your operation it is very difficult to provide you with an accurate estimate as to what it will cost you to become SANAS accredited.
- However, the current fee can be found via this link **www.sanas.co.za**
- The fees include:
 - Application fees
 - Document review fees
 - Pre-assessment fees (if applicable)
 - Assessment fees
 - Annual fees



Click on Publications, View the Database Document No P14.

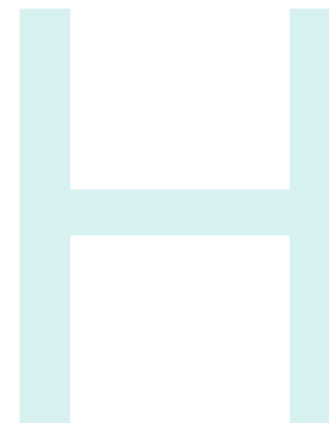


MANAGEMENT SYSTEM MANUAL

PREPARING MANAGEMENT SYSTEM DOCUMENTATION

This part of the toolkit can be used when you prepare your systems documentation which will help you to meet the management requirements of the appropriate standard on which your accreditation application is based, e.g. ISO/IEC 17025, ISO/IEC 17024, ISO/IEC 17020, ISO/IEC 17021.

Typically the system documentation consists of a **Policy Manual** (previously known as the Quality Manual) which gives direction from management and then supporting **Technical documentation**, procedures, instructions, method, etc. (the procedural aspects of the documentation manual).



WHEN PREPARING YOUR MANAGEMENT SYSTEM, TWO RECOMMENDED APPROACHES CAN BE USED:

You can start by first looking at your management requirements (see slides 39 - 50)



OR

You can start with your technical requirements (see slides 65 - 80)

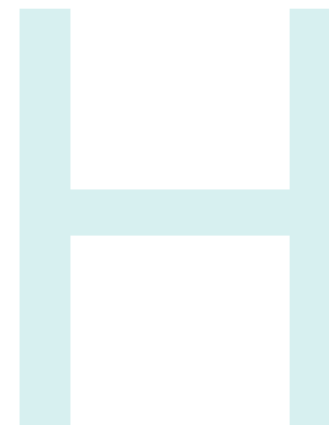


Management is required to take responsibility and control of the Management System.

If you start with the technical requirements it is an exercise to determine what you have or not have in place.

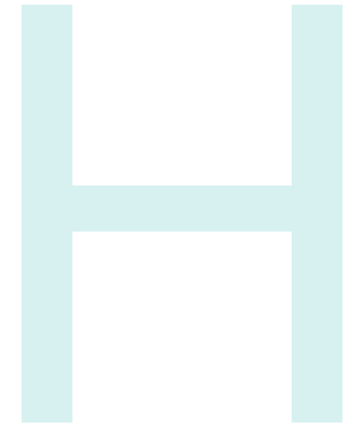
WHY DO YOU NEED A MANAGEMENT SYSTEM?

- Conformity assessment bodies that seek accreditation have to meet specific management and technical requirements as per the relevant standards on which accreditation is based.
- A management system is useful because it can be used by the management of the conformity assessment body to express its organisational structure, procedures, processes, documentation of methods and resources needed to perform the conformity assessment services. ➔
- The intention of a Policy Manual/Quality Manual is to give directives regarding an organisation's activities to employees in order to achieve effectiveness and efficiency within the organisation.



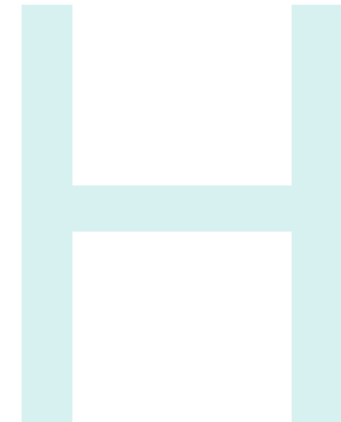
THE VALUE OF DOCUMENTING A MANAGEMENT SYSTEM ALSO CALLED YOUR QUALITY MANUAL IS TO:

- Ensure consistency of practices, activities, processes and systems;
- Clear transmission of information resulting from a minimal loss of information;
- Permanent, written and dependable information results in improved understanding, by:
 - Providing basic control;
 - Eliminating uncertainty and confusion;
 - Providing direction;
- Improved control and the management of changes prevents 'shortcuts'; and
- Improved analysis helps the writer to think more clearly.



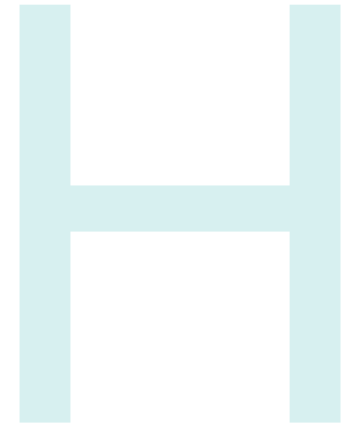
THE ELEMENTS OF A MANAGEMENT SYSTEM

- Organisational structure
- Responsibilities
- Methods
- Management of results
- Processes - including purchasing
- Resources - including natural resources and human capital
- Maintenance
- Sustainability - including efficient resource use and responsible environmental operations
- Internal audits
- Management reviews



TIPS FOR WRITING THE QUALITY MANUAL

- The systems documentation manual serves as a working document for the entire operation.
- Its application to day-to-day work results in uniformity and consistency. This will result in the meeting of specific requirement improvement in the operations of the body.
- This documentation gives clear direction on what must be done and how operations must be carried out.



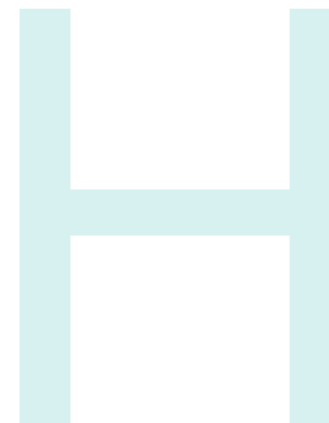
TIPS FOR WRITING THE QUALITY MANUAL

General guidelines

- The quality manual generally needs to be written by top management.
- It is better if the procedural manuals are written by the personnel performing the actual technical procedures, then edited/fine-tuned by those personnel delegated to review and approve the systems documentation.
- Write the manual in the present tense and do not use 'shall' or 'will' in the manual as to give direction on what must be done and how it must be done.
- Be cautious of copying content from the standard you have to comply with.
- Use simple and concise language aimed at the level of personnel for which the documentation is written.

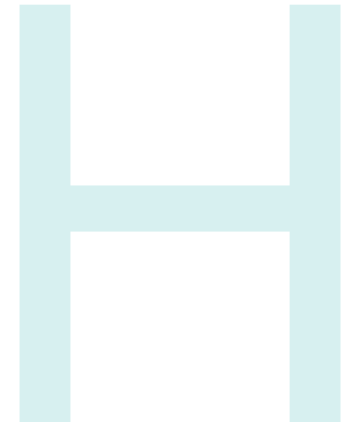
Get to the point of the clauses.

- Address each clause/sub clause of the standard briefly in the quality manual. If you need to spell out too much detail, make a separate numbered document and refer to the document number in the quality manual.
- You may, if practical, also cross reference clause. For example, address the clause on impartiality and then cross reference that clause to the appropriate procedure.
- Avoid wordiness and unnecessary language.
- Make the manual user-friendly for the personnel who have to work with it.



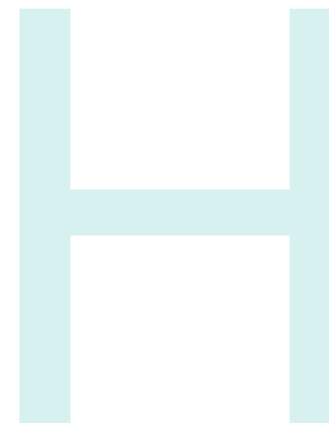
TIPS FOR WRITING THE QUALITY MANUAL

- Make a start. Do not get scared. Do not procrastinate.
- Go through the Standard.
- As you go through the standard, concentrate on, contemplate and comprehend each clause.
- Try to understand what the standard requires for your operation.
- If your body has been functioning for a while, some kind of quality system must already be in place.
- Perhaps some modification, some reorientation and some refinement is needed.
- Try to fine-tune the system that you already have.
- Document the procedures of what is already happening in your CAB.
- Do a gap analysis between the procedures and what the standard requires.
- Fill in the gaps.



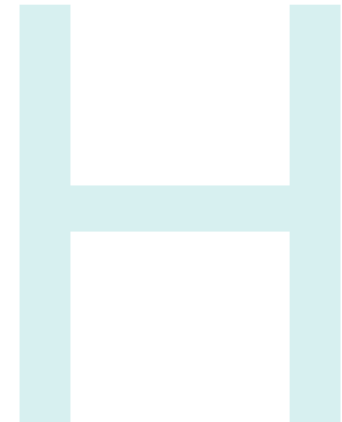
TYPICAL CONTENTS OF A QUALITY MANUAL

Typical contents of a Quality Manual:	Why:
<ul style="list-style-type: none">• Introduction / Foreword	<ul style="list-style-type: none">• This is not mandatory. To give personnel an insight on why the system is to be implemented and why the documentation is important.
<ul style="list-style-type: none">• Index for the Quality Manual	<ul style="list-style-type: none">• To provide ease of reference for the user.
<ul style="list-style-type: none">• Organisation Profile	<ul style="list-style-type: none">• To give an overview of the organisation's history and company profile.
<ul style="list-style-type: none">• Policy Statement and Organisational Objectives	<ul style="list-style-type: none">• A statement by top management to provide the organisation's overall intentions (objectives) and direction – what must be included in the management system documentation and how the system should be implemented.
<ul style="list-style-type: none">• Organisational Structure	<ul style="list-style-type: none">• To outline the organisation's reporting structures, responsibilities and authorities.
<ul style="list-style-type: none">• Policies addressing the requirements of the Standard	<ul style="list-style-type: none">• To provide an understanding of the organisation's guiding principles.



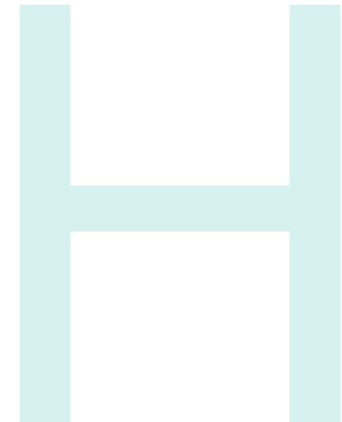
THE POLICY STATEMENT

- Your Policy Statement can be a fairly brief statement by management giving direction and the intent of implementing the applicable standard.
- This statement will include the policy of the facility e.g. management's commitment to the implementation of the appropriate standard and accreditation requirements and the objectives/goals to be achieved through implementing this system.
- From an accreditation point of view one of the main goals/objectives of management will be to supply customers/clients with consistently accurate results.
- Note: it is commonly accepted that goals are looked upon as long term and objectives short term. E.g. one of management's goals will be to meet customer requirements (that is long term and never change) but they will set objectives (maybe on a yearly basis) to ensure that they stay aligned to their goals.
- One of the goals can also be to meet the business objectives of the facility.



ORGANISATIONAL STRUCTURE

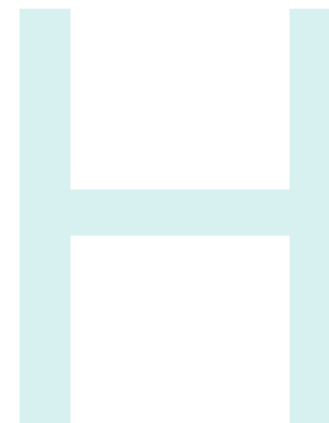
- Design and record your organisations organogram which illustrates clearly the structure of your organisation and the relationships in the organisation.
- If the facility is part of a larger organisation there is typically a 'Global' organogram indicating where the facility is situated in relation to the rest of the organisation and its relationship with the other departments and support services e.g. the purchasing function may be a department on it's own serving the whole of the organisation, not just the facility in question.
- A 'facility specific' organogram will show the management structure and the interrelationship of the personnel within the facility. This could also serve as an indication of authorities.



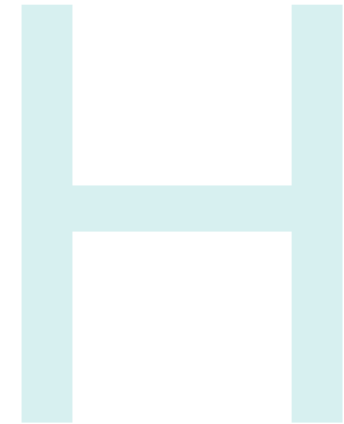
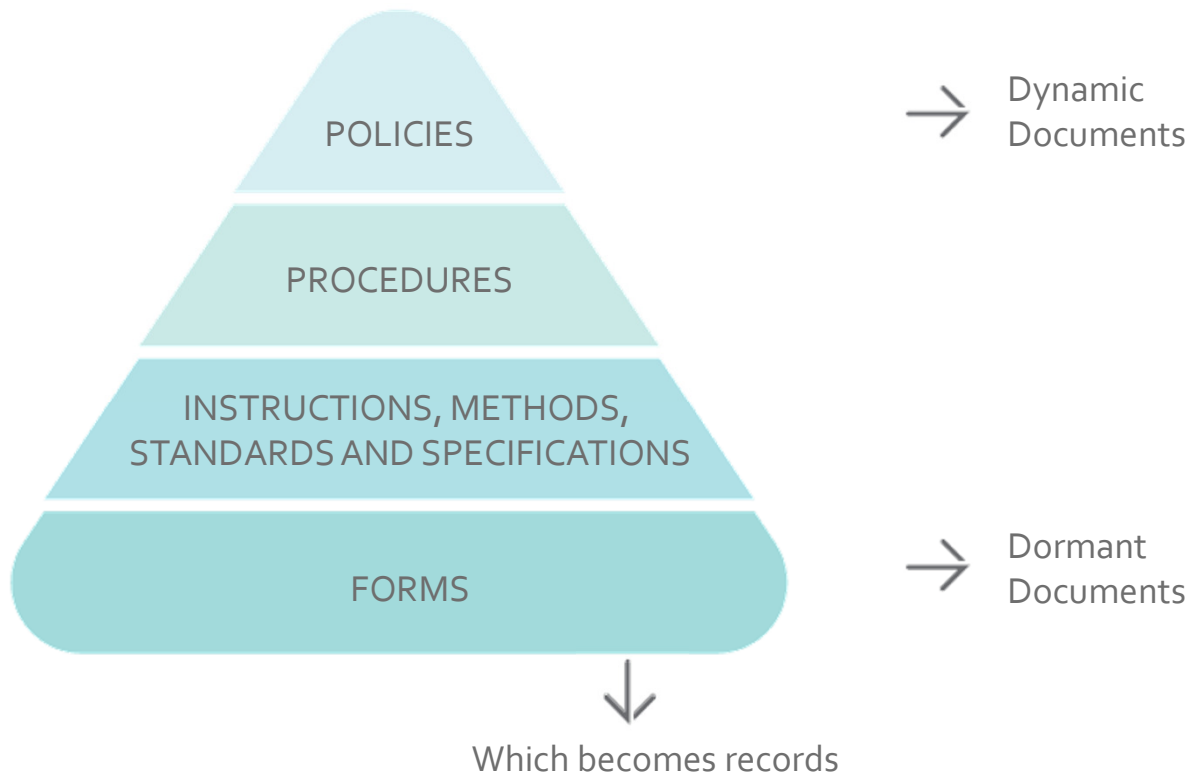
SYSTEM DOCUMENTATION STRUCTURE

Your policy manual indicates the structure that you have adopted for your documentation. This is for the understanding of personnel within the facility. The most popular structure is a four tier structure of:

- Policy documentation which gives direction from management of what they want the system to contain and how it should be implemented. This should include the main policy statement, the organograms (authorities and responsibilities), and the policies addressing the clauses of the relevant standard.
- Procedures which indicate what and how activities within the facility, other than the testing/inspection/verification activities, must be carried out.
- Instructions / Methods / Forms / Standards and Specifications which indicate how the CAB's technical activities must be carried out.
- Forms will be referred from various procedures or instructions on which information will be recorded and consequently become records.

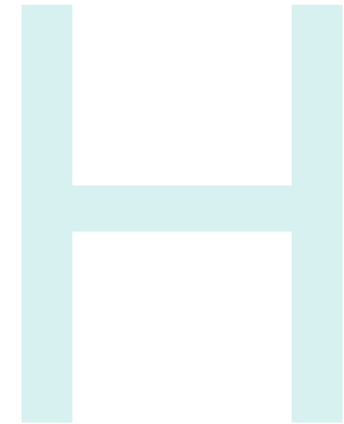


FOUR TIER STRUCTURE



KEEP THE FOLLOWING 6 BASIC QUESTIONS (THE SIX WISE MEN) IN MIND

- What is the policy / procedure?
- Why is it done?
- How will it be implemented (instruction / methods / standard specifications / ...etc)?
- Where will it be performed / recorded / kept (forms / records)?
- Who will be responsible (performing operator / authoriser...etc)?
- When will it be done?





KEY REQUIREMENTS

SOME OF THE KEY REQUIREMENTS THAT YOU NEED TO UNDERSTAND

- PRINCIPLES OF IMPARTIALITY
- SAFEGUARDING AND MANAGEMENT OF IMPARTIALITY
- ESTABLISHED UNDER NATIONAL LAW AND HAVE LEGAL PERSONALITY
- COMPETENT PERSONNEL
- MONITORING
- EQUIPMENT
- OUTSOURCING (SUBCONTRACTING)
- CONFIDENTIALITY

PRINCIPLES OF IMPARTIALITY

It is essential that a CAB's decisions results are based on objective evidence of conformity (or nonconformity) and that its decisions are not influenced by other interests or by other parties.

MANAGEMENT OF IMPARTIALITY

- All personnel have to formally commit themselves to the adherence of confidentiality as well as independence from commercial and other interests or relationships, arising from any existing or prior association with customers, that may result in a conflict of interest.
- A CAB shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.
- The impartiality of the CAB's top level management and assessment personnel shall be guaranteed.
- The remuneration of the CAB's top level management and assessment personnel shall not depend on the number of audits carried out or on the results of such audits.

This only applies to certification bodies.

ESTABLISHED AS A LEGAL ENTITY

- A body shall be established under national law and have legal personality.
- The body shall be a legal entity or a defined part of a legal entity such that it can be held legally responsible for all its activities and so that it can bear rights and obligations.

THE IMPORTANCE OF COMPETENCE AND SKILLS

Qualifications, training and on-going competence monitoring of staff of the conformity assessment body is important. The technical competency of the staff has to be relevant in terms of experience and sector expertise. The following elements are important:

- The staff's relevant educational levels and study specialisation;
- The staff's relevant work experience in the business sectors related to the scope;
- Staff is able to understand the characteristics of the relevant processes and products and applicable regulatory requirements; and
- The staff's ability to demonstrate knowledge and skills acquired through audit activities, as a complement or an alternative to direct work experience.

COMPETENT PERSONNEL

The CAB shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks.

The personnel responsible for carrying out the conformity assessment activities shall have the following:

- Sound technical and vocational training covering all the conformity assessment activities of the relevant scope;
- Satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;
- Appropriate knowledge and understanding of the requirements,
- The ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out, and
- Knowledge of the management system/quality manual.



MONITORING

- The CAB shall ensure the satisfactory performance of the conformity assessment activities including the review and attestation process by establishing, implementing and maintaining procedures for monitoring the performance and competence of the personnel involved.
- The body shall review the performance and competence of its personnel in order to identify training needs.
- Even if the standard does not mention monitoring it is often part of the internal mechanisms used by the CAB to supervise its activities and persons involved.
- The CAB shall conduct monitoring e.g. by on-site observations, or by using other techniques such as review of conformity assessment reports and feedback from customers to evaluate performance of conformity assessment personnel and to recommend appropriate follow-up actions to improve performance.
- The CAB shall maintain evidence that its personnel is continuing to perform competently.

EQUIPMENT

- The CAB shall have access to all necessary equipment or facilities.
- The equipment outside the permanent control of the CAB; they may use such equipment, provided that access to the equipment is assured, the equipment is fit for purpose and adequately calibrated and maintained.

This is not applicable to certification bodies.

OUTSOURCING (SUBCONTRACTING)

- Where the CAB subcontracts specific technical tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor is competent to carry out the subcontracted work or the subsidiary meets the requirements as described above.
- The CAB shall take full responsibility for the work performed by subcontractors.
- The CAB shall keep at the disposal of the assessors the relevant documents concerning the evaluation assessment of the qualifications of the subcontractor or subsidiary for the work carried out by them.
- The CAB may not under any circumstances subcontract evaluation of results and decision on conformity, as that would make the evaluation meaningless.
- For example, a CAB may subcontract tests while continuing to assess the results of the tests and in particular to validate the test report in order to evaluate whether the requirements of the relevant legislation are met.
- The CAB shall ensure that their subcontractors maintain the necessary competence.
- Subcontracting shall be part of contact review with the customer, carried out under be a contract.

CONFIDENTIALITY

- The personnel of the CAB shall be bound to observe professional secrecy with regard to all information gained in carrying out their tasks.
- Proprietary rights shall be protected.
- The confidentiality arrangements shall ensure that no results or other proprietary information are disclosed to any other party than the manufacturer or its authorised representative.
- Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.



OPERATIONAL REQUIREMENTS

APPEALS AND COMPLAINTS PROCESSES

A CAB needs to be able to demonstrate that:

- It has formal, robust and documented process(es) to receive analyse, manage and take independent decisions in relation to appeals against it.
- It communicates receipt of appeal, and the details of the formal process, appeals panel, status and progress of the appeal, and its outcome to the relevant client.
- It takes responsibility for all decisions at all levels of the appeals process.
- It ensures the process, outcome and consequences are non discriminatory.
- The people handling the appeal are independent of the relevant conformity assessment activity and engagement.
- It has a description of the appeals process that is publically available.
- It implements preventive and corrective actions and decisions.
- It has a similar process for handling complaints in relation to its conformity assessment activities, which in addition to the elements above also includes safeguarding the confidentiality of the complainant and what the complaint is about.

INFORM THE ACCREDITATION BODY IMMEDIATELY OF CHANGES

Inform the Accreditation Body immediately of changes in any aspect of its status or operations that affects its:

- Legal, commercial or organisational status;
- Organisation and management, in particular key managerial staff;
- Policies or procedures, where relevant;
- Premises;
- Personnel, equipment, facilities, working environment or other resources, where significant; and
- Other matters that may affect the accredited Body's capability, or scope of accredited activities, or conformance with the accreditation requirements, or any other relevant criteria of competence specified by the Regulator or the Accreditation Body.

Note! An important SANAS document to take into account is F147. This is available on www.sanas.co.za.



TECHNICAL REQUIREMENTS

Applicable to laboratories, inspection bodies and verification bodies

ANOTHER WAY TO PREPARE FOR ACCREDITATION?

- The bottom up approach where you start with **Technical Requirements**
- The Technical Requirements are:



You may want to follow a bottom up approach i.e. to look at what you are already doing in your laboratory.

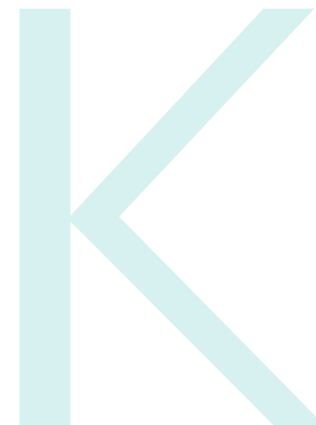
If this approach is followed it must be emphasised that this should be looked upon as an exercise to determine what you have or have not got in place (gap analysis) and from there management should set out their policies and necessary Management Requirements to give direction on the way forward with the system.

ARE YOU A LABORATORY THAT NEEDS TO PREPARE FOR ACCREDITATION?

You may want to follow a bottom up approach i.e. to look at what you are already doing in your laboratory.

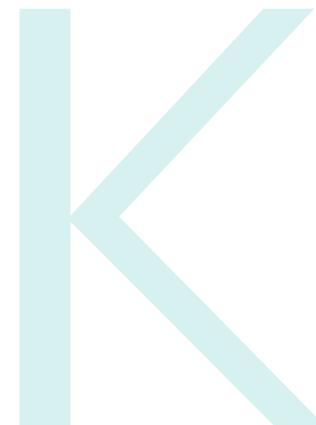
Ask yourself and your staff the following questions:

- What are you doing with your equipment?
- Which methods or work instructions are you using for your technical activities, e.g. testing/calibration/inspection?
- How do you calculate your uncertainty of measurement?
- How do you handle test, calibration, inspection/verification items?
- How do you manage the laboratory environment?
- What are the qualifications, experience and competence of your laboratory personnel?
- The next slides look at the above questions in more detail.



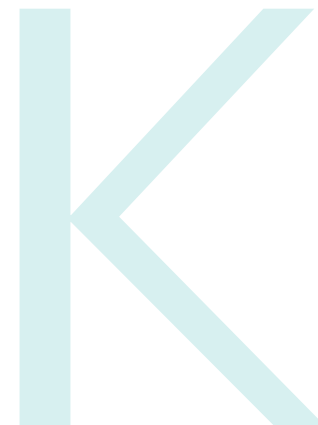
WHAT ARE YOU DOING WITH YOUR EQUIPMENT? YOU NEED TO CONSIDER THE FOLLOWING:

- How do you handle for transport, store, use and maintain your measuring equipment?
- How often do you check your equipment and what informs the intervals?
- Do you calibrate or verify your equipment, what are the intervals and what informs the intervals?
- Do you have equipment instructions, what are they and where are they available?
- Do you maintain your equipment, when and how and where are the records?
- Do you calibrate your equipment after repairs/ maintenance, where are the records and is the calibration status reflected on the equipment?
- Do you make sure that only authorised personnel use the equipment? How do you do it?
- How do you make sure that defective equipment is not used?
- How do you make sure that equipment is not adjusted without authorisation?
- How do you make sure that corrective factors are applied after calibration?



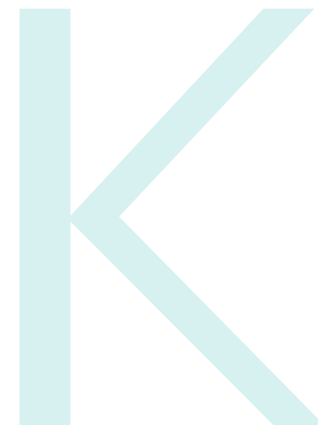
WHAT ARE YOU DOING WITH YOUR EQUIPMENT? AFTER CONSIDERING THE QUESTIONS IN THE PREVIOUS SLIDE YOU SHOULD MAKE SURE THAT THE FOLLOWING IS IN PLACE OR PUT IT IN PLACE :

- A procedure for the handling of transportation, storage, usage and maintenance of your measuring equipment.
- A procedure for the performance of intermediate check on the equipment.
- A justifiable calibration programme.
- Equipment instructions that is readily available.
- Records for the laboratory equipment including historical performance so that trends can be identified.
- Measurement traceability of equipment calibration.



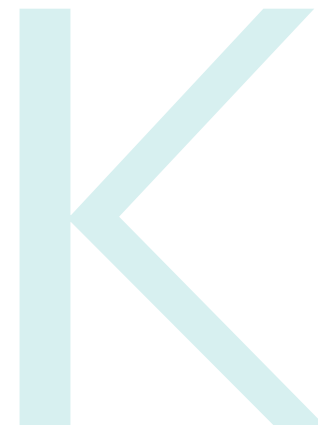
WHICH METHODS OR WORK INSTRUCTIONS ARE YOU USING? YOU NEED TO CONSIDER THE FOLLOWING:

- Which test/calibration methods, standards or laboratory methods are you using?
- Why do you use and how do you justify these methods?
- Why is the method fit for the intended purpose (validation)? Is the method capable for its intended use?
- Is the method repeatable and reproducible? Has the method demonstrated correct performance in terms of accuracy, precision, detection limits and robustness?
- When you perform a test how does it progress from start to finish? How do you ensure the method's continued capability?
- How do you determine the performance of the method?
- How do you make sure that the results of the test/calibration are valid?



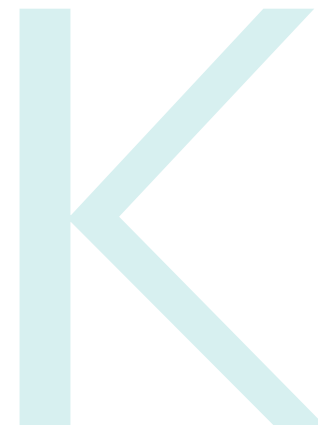
WHICH METHODS OR WORK INSTRUCTIONS ARE YOU USING?

- After considering the questions in the previous slide you should make sure that the following is in place or put in place:
- The published international, regional or national or other recognised method that contains enough information on how to perform the test/calibration used by the operating staff.
- If the above method is unclear a rewritten or supplement internal method can be used by the operating staff.
- Documentation for optional steps in the method or additional information.
- Contract reviews or training records that demonstrate the ability of the laboratory to select the appropriate method.
- Validation evidence i.e. calibration using reference standards or reference materials, comparisons results with other methods, inter-laboratory comparisons, systematic assessment of the factors influencing results and or assessments of uncertainty of measurements.



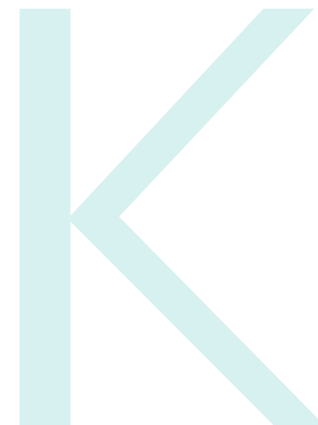
HOW DO YOU CALCULATE YOUR UNCERTAINTY OF MEASUREMENT? YOU NEED TO CONSIDER THE FOLLOWING:

- Do you perform your own calibrations?
- Do you identify components that contribute to the overall combined uncertainty of measurement e.g. mass, volume, temperature, inter-analysts, etc.?
- Do you decided on the approach for estimating each component's contribution to the overall uncertainty of measurement e.g. Empirical approach or Guide to Compression of Measurement Uncertainty (GUM)?



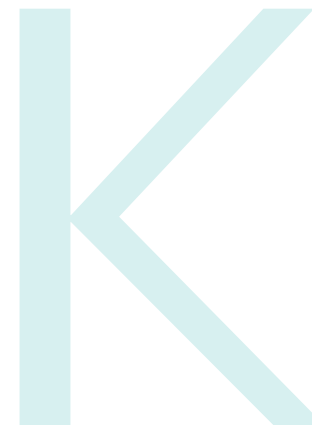
HOW DO YOU CALCULATE YOUR UNCERTAINTY OF MEASUREMENT?

- After considering the questions in the previous slide you should make sure that the following is in place or put it in place:
- A procedure for calculating the best measurement capabilities/uncertainty.
- Uncertainty budgets for all calibrations.
- Records of how uncertainty of measurement was estimated.



HOW DO YOU HANDLE TEST OR CALIBRATION ITEMS? YOU NEED TO CONSIDER THE FOLLOWING

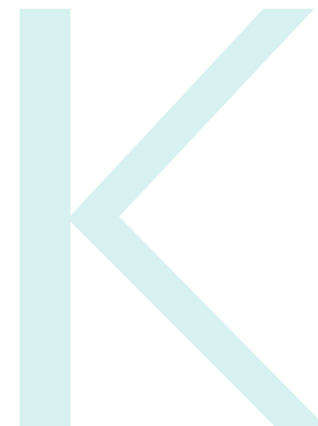
- How do you transport, receipt, handle, store, retain or dispose of items?
- How do you identify items?
- How do you inspect items condition on receipt?
- How do you protect the items from lost or deterioration?
- How do you store your items?
- How do you control access to items?
- What is the on-shelf stability of items prior and after analysis?
- Does the items identification protocol protect client details?



HOW DO YOU HANDLE TEST OR CALIBRATION SAMPLES?

After considering the questions in the previous slide you should make sure that the following is in place or put it in place:

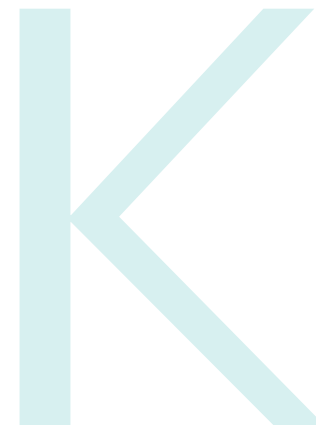
- A procedure for the transport, receipt, handle, store, retain or dispose of items.
- A documented chain of custody for receiving to disposal of items.
- An item procedure and plan.
- Records of all data influencing the quality of the results.
- Records of item delivery/waybill handover, item condition on receipt which should include seal intactness and evidence that packaging was not tampered with.
- Records of who received items and means of tracing back signatures e.g. signature specimen.



HOW DO YOU MANAGE THE CAB'S ACCOMMODATION AND ENVIRONMENT?

You need to consider the following:

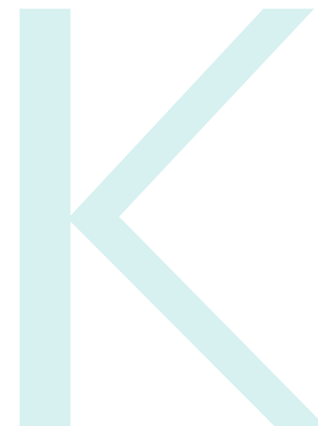
- Are the accommodation and environmental conditions conducive for laboratory work?
- Do the environmental conditions ensure valid results?
- Do you monitor and control the environmental conditions?
- Do you stop work if the environmental conditions may jeopardise the results?
- Do you manage access to the laboratory?
- Do you make sure that incompatible areas are effectively separated?
- Do you ensure good housekeeping?
- Do you identify critical conditions (e.g. humidity, temperature, vibrations) that could affect your results and do you keep control over the measures?
- Do you establish tolerance limits for the above critical conditions and how do you handle outliers?



HOW DO YOU MANAGE THE LABORATORY ENVIRONMENT?

After considering the questions in the previous slide you should make sure that the following is in place or put in place:

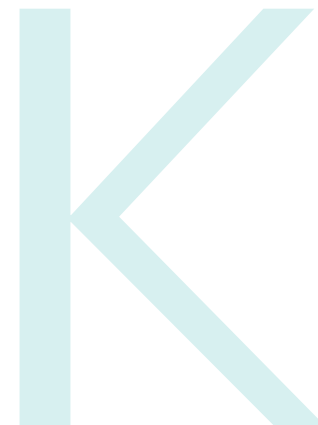
- Records of the environmental conditions that are controlled and monitored and how and when it was checked.
- A plan that indicates what actions will be taken when environmental conditions are outside the acceptable range (control charts).
- Access limitations posted clearly to prevent unauthorised access.
- Documentation on specific contamination or housekeeping controls.
- For housekeeping purposes keep the laboratory clean i.e. look under, behind, on top of equipment to keep it clean.



HOW DO YOU ENSURE THAT YOUR PERSONNEL ARE COMPETENT?

You need to consider the following:

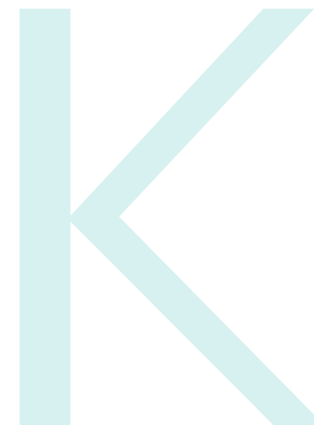
- Do you know what the requirements are for your personnel in terms of competency?
- Do you ensure that the relevant expert personnel have sufficient understanding of the relevant subjects and a realistic appreciation of limits of their own knowledge in the content of the opinions and interpretations reported?
- Can all the personnel demonstrate their competence to perform the task expected from them?
- Do you know what the training needs are?
- Do you supervise trainees and contracted personnel?



HOW DO YOU ENSURE THAT YOUR PERSONNEL ARE COMPETENT?

After considering the questions in the previous slide you should make sure that the following is in place or put in place:

- Job descriptions for managerial, technical and key support staff.
- Personnel records for education, training, technical knowledge and experience with evidence that they are qualified as per the requirements of the job descriptions.
- Policy and procedure to identify training needs.
- A training matrix for each position or area in the company and documented training.
- Signed training records.
- Evidence of successful outside training.
- Evidence of competency declaration on technical operations.
- A competency declaration mechanism appropriate for your technical objectives.
- A procedure for confirming continued competence of staff.
- Competency and authorisation records.



CONTACT DETAILS

Main Switchboard Number:

+27 (0) 12 394-3760

General Fax Number:

+27 (0) 12 394-0526

the dti Campus
77 Meintjies Street
Sunnyside
Pretoria, 0002
South Africa

