AQUATIC TOXICITY TESTING IN SOUTH AFRICA: Guideline for the Accreditation of Routine Aquatic Toxicity Testing Laboratories

AA Chapman, EA Venter & H Pearson

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AQUATIC TOXICITY TESTING IN SOUTH AFRICA: GUIDELINE FOR THE ACCREDITATION OF ROUTINE AQUATIC TOXICITY TESTING LABORATORIES

Report to the
Water Research Commission

by

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AQUATIC TOXICITY TESTING IN SOUTH AFRICA: GUIDELINE FOR THE ACCREDITATION OF ROUTINE AQUATIC TOXICITY TESTING LABORATORIES (including a DVD with individual quality management documents)
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EXECUTIVE SUMMARY

The aims of this project were:

- To compile a quality assurance manual to guide South African aquatic toxicity testing laboratories;
- To develop an implementation plan for DWAF for routine toxicity testing; and
- To develop a guideline to promote a sustainable network between toxicity testing laboratories.

Volume 1 of this series of two volumes describes the research process undertaken, an overview of the international and national policy framework, a review of quality assurance and quality control, an assessment of toxicity testing in South Africa, and a draft implementation plan. The reader is encouraged to consult Volume 1 for a background to this volume and a glossary of common terms used.

A world-wide network of national accreditation bodies and many Multilateral Agreements (MLAs) have been established in an attempt to create a uniform level of confidence in the results of toxicity testing. Accreditation also has many other advantages for both the laboratory and the consumer, including improved business and legal defensibility of results.

This short document provides an overview of the procedure for applying for accreditation in South Africa. It also describes a four-tier quality management system and related documents. The accompanying DVD contains these latter documents (about 200), each in a separate file for convenience. They are in MS Word format to allow managers of toxicity laboratories to customise them to their requirements. Hyperlinks have been installed to access relevant information in other sections, e.g. a standard operating procedure or a blank form etc., and also to access information on the Internet.

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LIST OF ABBREVIATIONS

DEEEP	Direct Estimation of Ecological Effect Potential
DTI	Department of Trade and Industry
DWA	Department of Water Affairs
DWAF	Department of Water Affairs and Forestry
GLP	Good Laboratory Practice
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organisation
MLA	Multilateral Agreement
NTMP	National Toxicity Monitoring Programme
NWA	National Water Act
QA	Quality Assurance
QC	Quality Control
SABS	South African Bureau of Standards
SANAS	South African National Accreditation System
WRC	Water Research Commission

CHAPTER 1: INTRODUCTION

The reliability of analytical data goes hand in hand with the quality of such data, which, in turn, depends on the quality assurance (QA) and quality control (QC) practices applied by the test laboratory. According to the technical support document for toxics control (US EPA, 1991, cited in Slabbert *et al.,* 1998), precision and accuracy in the execution of the toxicity test affects variability of the test results. Quality systems must therefore be put in place to limit the variations that can be caused by, e.g. differences in individual test organisms, test conditions and laboratory personnel competence.

There is an increasing demand, driven either by legislation or regulatory requirements for QA and QC in biological tests (Hale, 1998). Toxicity tests used for regulatory compliance must provide the same results when applied for the same chemical in different laboratories as well as for tests performed in the same laboratories at different times of the year. If the South African Direct Estimation of Ecological Effect Potential (DEEEP) method (see Volume 1) is to be given legal standing to control and monitor point-source pollution in terms of licensing and setting licensing conditions, the toxicity tests which they are based on have to be legally justifiable. The scientific integrity of the method should therefore be indisputable: the method should be accepted as a "standard method" and the applicability of the method to provide the necessary information pertaining to the specific situation should be approved.

Only a small number of local laboratories are accredited according to ISO 17025 for one or more of the toxicity tests prescribed in the DEEEP document. The full scale implementation of the DEEEP and South African National Toxicity Monitoring Programme (NTMP) approaches to protect and conserve our country's water resources will require the accreditation of many more toxicity laboratories to satisfy the associated demand for toxicity testing.

CHAPTER 2: ACCREDITATION

2.1 BACKGROUND

Laboratory accreditation provides a means for third-party certification of the competence of laboratories to perform specified types of testing and calibration. These capabilities must be periodically evaluated (measured) according to the requirements contained in ISO/IEC 17025:2005. This serves to maintain confidence in the laboratory's ability to perform accurate and valid measurements and tests.

The South African National Accreditation System (SANAS) is an independent body capable of assessing organisations and laboratories for compliance to the relevant international or national standards and verifying their competence for tasks undertaken within the scope of their activities. Laboratories receiving SANAS accreditation benefits from the impartial assessment of their performance by experts. SANAS has its office on the Department of Trade and Industry (DTI) Campus, Sunnyside, Pretoria, South Africa and is directed and legally represented by a Board of Directors whose members are appointed by the Minister of Trade and Industry. SANAS operates in accordance with the requirements, criteria, rules and regulations laid down in the following documents:

- The requirements of the international standard ISO/IEC 17011, the general requirements for bodies providing assessments and accreditation of conformity assessment bodies.
- The requirements as stipulated in the various Memorandums of Agreement with the international bodies and the national regulatory bodies.
- The Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006). "*To provide for an internationally recognised and effective accreditation and monitoring system for the Republic by establishing SANAS as a juristic person; to recognise SANAS as the only accreditation body in the Republic for the accreditation of conformity assessment and calibration and monitoring of good laboratory practice; and to provide for matters connected therewith*."

Note: SANAS documentation manuals, accreditation process, training courses and fees are available free of charge from the SANAS web site: www.sanas.co.za.

2.2 THE GLOBAL NEED FOR ACCREDITATION

Today modern transport systems and limited economic trade barriers allow the free movement of goods and interchange of services globally creating an international free market. To have trust in the products and services provided by a trading partner and to decide where best to source such products and services, internationally accepted quality criteria must be available for comparative purposes. These criteria must cover all aspects of product production, i.e. quality and environmental systems, personnel and product certification and inspection systems as well as the measurements and tests conducted. Accreditation of laboratories using common standards and practices satisfy those requirements. Major trading countries have established independent and internationally credible accreditation bodies. A world-wide network of national accreditation bodies and many Multilateral Agreements (MLAs) have been established. These will eventually ensure that the competence of certification bodies, inspection bodies and laboratories (testing and calibration) are assessed on the same principles, regardless of where in the world they are located. These assessments are based on the harmonised International Standards Organisation (ISO) standards. The world

accreditation network is headed by the International Laboratory Accreditation Cooperation (ILAC) (www.ilac.org) and the International Accreditation Forum (IAF) (www.iaf.nu.). SANAS is a member of both.

2.3 BENEFITS OF LABORATORY ACCREDITATION

SANAS accreditation gives formal recognition that laboratories, certification bodies, inspection bodies and good laboratory practice (GLP) test facilities are competent to carry out specific tasks. Organisations accredited by SANAS become a stakeholder in SANAS and are entitled to use the appropriate SANAS logo on the certificates they issue, their letterheads and promotional material.

Formal recognition of the competence of a laboratory by an accreditation body in accordance with international criteria has many advantages:

- Potential increase in business due to enhanced customer confidence and satisfaction in meeting their demands.
- Savings in terms of time and money due to reduction or elimination of the need for re-testing of products.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound quality assurance systems and are technically competent.
- Increase of confidence in testing data and personnel performing tasks.
- Customers can search for and identify the laboratories accredited by SANAS for their specific requirements from the SANAS website.
- Users of accredited laboratories will enjoy greater access to their products in both domestic and international markets when tested by accredited laboratories.

For aquatic toxicity testing laboratories there are added benefits:

- Increasing emphasis is currently being placed on the responsibility of manufactures for the environmental impacts of their products from “Cradle to Grave”. Consumers want to be assured that they are buying a product with a “small environmental footprint”. There will therefore be an increased demand from the manufacturer for reliable testing to, e.g. ensure effective treatment of effluents before discharge.
- The results will be legally defensible, e.g. in cases where accredited test methods are used to monitor point source pollution of environmental waters and setting license conditions.
- South Africa’s aquatic toxicity test results will be on par with results in countries like the USA and Canada that pioneered the application of aquatic toxicity tests to prevent pollution and protect the environment.

2.4 HOW TO APPLY FOR SANAS ACCREDITATION

The steps for applying for SANAS accreditation are shown in **Figure 2.1**. It also shows the timeframe from first approaching SANAS to enquire about accreditation to the final approval. The timeframe will depend on how quickly the client completes the required corrective actions. Fees are dependent on the number of assessors required. An additional assessor is required for every discipline provided the discipline can be assessed in 1 day. The base fee includes the cost of a lead assessor and a technical assessor for 1 day. Refer to the SANAS webpage for the fees.

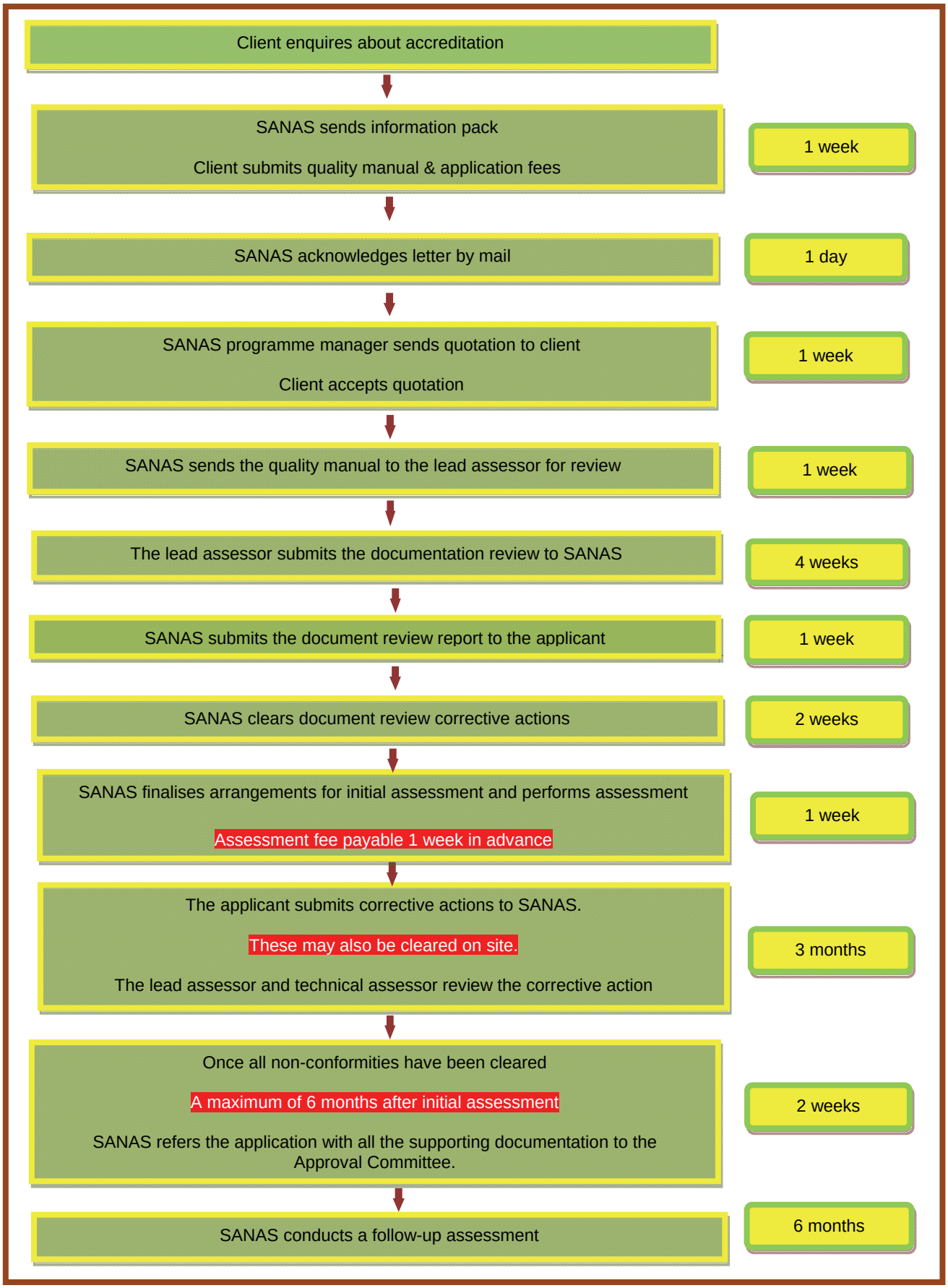

Figure 2.1. Application procedure and timeframe for SANAS accreditation

2.5 QUALITY MANAGEMENT SYSTEM DOCUMENTS

The documents in Sections 1 to 4 in **Figure 2.2** provide requirements and guidance on the establishment and management of a quality management system for environmental toxicity testing laboratories. This is based on the ISO/IEC 17025:2005 Standard and provides:

- Implementation clarification.
- Expectations and examples for compliance with requirements of the Standard.
- Requirements of SANAS.

These documents should be used in collaboration with the International Standard (ISO/IEC 17025:2005) and SANAS documentation manuals and must be customised to suit the requirements of the laboratory in question.

The purpose of the documents in Sections 1, 2 and 4 is to define, ensure and maintain adequate organisational structure to implement a quality system in the toxicity laboratory. The toxicity test methods in Section 3 provided in this manual serve only as examples and guidelines for the preparation of a laboratory's own methods manual outlining their own test methods. However, these standard methods were selected as they are currently used in most South African toxicity laboratories. They are "doable" and the turnaround time for tests is below the expected recommended frequency of sampling for rivers, i.e. fortnightly during the wet season and weekly during the dry season.

Once a laboratory has selected the battery of tests to be used, original copies of the method should be obtained from the registered owner to comply with copyright requirements. International test methods are available at a cost from the International Organisation for Standards (www.iso.org) and national test methods from the South African Bureau of Standards (www.sabs.co.za). Should the laboratory develop new test methods, special attention must be given to the validation of such methods as per clause 5.4.5 of ISO/IEC 17025:2005.

A typical workflow of samples and test data in a laboratory along with the ISO/IEC 17025:2005 requirements pertaining to the individual steps from sample arrival to report production/storage (**Technical Requirements**) and the laboratory management (**Management Requirements**) is depicted in **Figure 2.3**. As shown in the Figure, **Management Requirements** are related to the operation and effectiveness of the quality management system within the laboratory. **Technical Requirements** address the competence of staff, testing methodology, equipment and quality and reporting of test results.

Figure 2.2. Four-tier quality management system

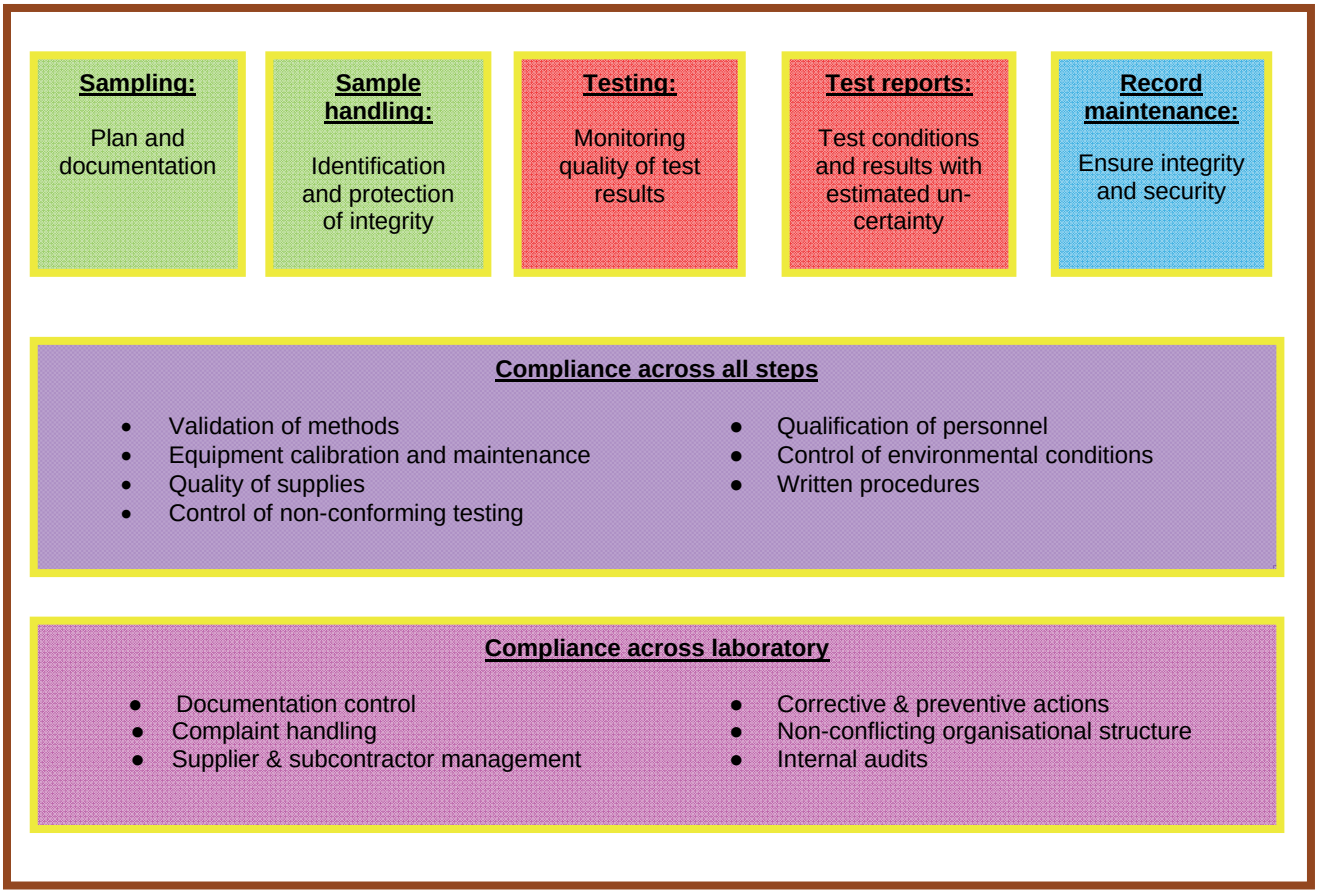

Figure 2.3. Typical workflow of samples and test data and ISO/IEC 17025:2005 requirements

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