



**NPG SUBMISSION ON THE OFFICE OF HEALTH STANDARDS
COMPLAINT, TO BE CREATED BY AN AMENDMENT BILL (B24 – 2011)
TO THE NATIONAL HEALTH ACT NO 61 OF 2003**

1. Who the NPG represents

The National Pathology Group (NPG) is the official subgroup for pathology of the South African Medical Association. It has approximately 220 pathologist members who are predominantly in private practice. Members extend over all disciplines in pathology and are widely distributed in South Africa. Virtually all privately practising pathologists are members of our group.

The group promotes best practice standards and its members adhere to a Code of Ethical Conduct. Its objective is to inform medical practitioners about ongoing developments in pathology and updates practitioners about these developments. In so doing it promotes accurate diagnosis and quality care of patients. This results in appropriate and cost-effective therapy.

The NPG members have large numbers of centralized and peripheral branch laboratories and blood collection depots throughout South Africa, in both metropolitan and smaller urban areas and perform about 200000 individual tests daily. Through daily countrywide courier-services it additionally reaches virtually all of the remote and under-serviced areas, where the establishment of laboratories or depots are not feasible.

The test range extends over all pathology disciplines and includes an extensive range of chemistry and haematology testing and also the diagnosis of infectious diseases like tuberculosis and HIV and many others, as well as histopathology and cytology. Its services align with the prioritization of the National Department of Health to be responsive to the quadruple burden of disease (viz. HIV/Aids and TB, Maternal and Child Health, Non-Communicable Diseases and Injuries / violence).

Quality and coverage: contribution of NPG to access to laboratory services	
SANAS Accreditation	90% of all existing facilities
Courier km's travelled per month	3,431,000
Tests done per day	200,000+
Number of patients serviced per day	53,000+
Rural penetration of services	28% of all tests
Tests done in-hospital	44% of all tests

NPG members employ more than 10 000 staff and a large number of these are professional, either pathologists, medical technologists or technicians and nursing sisters.

Members are also actively involved in the tuition of pathology registrars and lecturing of medical students.

Professionals active in- and employed by NPG members	
Total number of employees	10,738 (excluding pathologists)
Total number of pathologists	235 (including part-time)
Breakdown of employees:	
Medical Laboratory technologists	1560 (+-)
Medical Laboratory technicians	868
Phlebotomy technicians	172
Medical Scientists	51 (+-)
Nursing Sisters	2390 (+-)

2. Comments on selected aspects of the OHS and the Bill that aims to establish it

The NPG welcomes the establishment of The Office of Health Standards Compliance (OHSC), as a necessary step towards a National Health Insurance system. It supports all efforts to ensure that quality healthcare is provided to all persons who utilize the health sector.

a. Independence of the OHSC

NPG welcomes the indications that the OHSC would be independent (memorandum to the Bill, par 1.1). The manner in which the draft legislation is worded in relation to this should be enhanced to ensure better protection of the OHSC as an independent. Only the independence of the Ombud is explicitly guaranteed (new section 81B) in the Bill.

The independence of the OHSC is **not guaranteed explicitly** in, for example, the amended section 77. NPG believes that the fact that the OHSC only advise the Honourable Minister of Health on standards, and that the actual standards would be issued by the Minister (amended sections 78(a), 79(a), 79(f), 79(3) and not the OHSC, could potentially erode the envisaged independence. The sense that the OHSC could become a mere advisory body is strengthened by the fact that the organisational structure has to be approved by the Minister (new section 79B(1)(c)) and that the CEO of OHSC tables his/her annual report to the Minister who tables it in Parliament (new section 79D(1) – (3)). It is strongly proposed that, as is the case with the Council for Medical Schemes, Medicines Control Council and other bodies working under the overarching auspices of the National department of Health, the OHSC and its CEO should be able to report to, and be called to account directly by Parliament and not via the Minister of Health.

Although the NPG does not doubt the integrity of the current staff involved with the OHSC, or that of the Minister, laws should be written in such a way that the key tenets are protected, irrespective of the comings and goings of cabinet members, CEOs and other staff. Relying in future on what everyone thought was agreed key principles (but not explicitly included in the law) might not be enough to protect this very important institution.

b. Certification of pathology health establishments (new section 79(1)(b))

The definition of health establishments in section 1 of the National Health Act includes all private practices. This also includes pathology practices that are the members of the NPG.

As noted in the introduction, over 90% of NPG member facilities are already SANAS¹ accredited. **SANAS certificates** and their accompanying schedules are a formal recognition that an organisation is competent to perform specific tasks. SANAS is responsible for the accreditation of Medical Laboratories to ISO 15189:2007, Certification bodies to ISO/IEC 17021:2006, ISO/IEC 17024:2003 and 65:1996 (and the IAF interpretation thereof), and laboratories (testing and calibration) to ISO/IEC 17025:2005. Inspection Bodies are accredited to ISO/IEC 17020:1998 standards. GLP facilities are inspected for compliance to OECD GLP principles. This means that NPG member facilities are competent to carry out specific laboratory analytical processes. SANAS also monitors laboratories regularly to ensure conformance. The NPG submits that the development of norms and standards for pathology services as rendered by SANAS accredited laboratories, are therefore not necessary.

There is an existing system in place to ensure that tests are conducted in a manner that ensures quality and accuracy. It is also important to note that the manner in which pathology services are rendered are different to that rendered by other specialists practices – there are often very little or no contact with patients, and tests are conducted on samples provided by patients, and not on the patients themselves. An overlapping system of standard-setting over an above that set out above, is likely to only increase the cost of healthcare and increase inefficiencies in the system.

Reference in the amendment proposed to section 36 raises another concern to the NPG. Section 36 of the National Health Act contains the so-called “CON” – **Certificate of Need**. NPG is concerned that this means that the CON will be implemented sometime in the near future. NPG urges that, due to the contentious nature of the CON, an in-depth consultative process be embarked upon in relation to the timelines of such envisaged implementation, the exact nature of the implementation and, most importantly, the envisaged regulations that would accompany this implementation. As far as the OHSC is concerned, section 36(6)(a) - what exact information will be received by the DG from the OHSC in relation to

¹For more on Good Laboratory Practice and the role of SANAS, see http://www.sanas.co.za/accreditation_glp.php.

issuing a CON to a health establishment? And when would that information (i.e. non-compliance) lead to the withdrawal of a CON?

Unnecessary duplication of functions and vagueness in roles and mandates should be avoided at all costs, and in the NPG's view the mandate provided by the amended section 79(2)(e), where the CEO "may" negotiate co-operative agreements is too weak to prevent this from happening. This should be substituted by a "must" in cases "where another regulatory- or statutory body or another entity or unit within the Department of Health has similar responsibilities and/or duties in relation to the publication and/or enforcement of standards that are required to be fulfilled by health establishments".

c. Core Standards

The current document used by the National Department of Health entitled "Core Standards for health facilities" include standards that could potentially conflict with those set elsewhere, i.e. on equipment and on clinical governance.

Clinical governance refers to compliance with norms and treatment guidelines. These norms and standards relate to the manner- and timing at which patients are diagnosed and treated. NPG believes that these guidelines (also called treatment guidelines or protocols) have to be set by the professionals working in those specific fields, and authorized under the Health Professions Act to diagnose and treat specific conditions. This is one example where the OHSC would have to establish (refer new section 79B(3)) technical committees, as it would be impossible to employ experts from all possible fields. As far as pathology services are concerned, the NPG is willing to assist in this. Also included in clinical governance is the concept of peer review. Once again, only clinical peers would be able to evaluate whether a professional has acted in an appropriate manner. The NPG also wishes to draw attention to a body referred to in the Human Resource for Health (HRH) Strategy 2012 – 2017, the National Coordinating Centre for Clinical Excellence in Health and Health Care (**NCC for CE in H&HC**), which will, so it appears, also have rights to look into clinical governance matters. The way in which the OHSC will recognize the work undertaken by professional bodies and bodies such as this, would be critical.

The NPG believes that the appropriateness of care is to be determined by the professionals whose training and experience, coupled with the best available scientific evidence, place them in the best position to evaluate what the most appropriate care would be in particular settings. This is a key element of quality of care.

d. Issuing of Standards

The Amendment Bill does not provide for a process in terms of which standards will be issued, it merely states that it will be "prescribed" by the Minister, on the advice of the OHSC (amended section 79). It also does not create an effective and efficiency way for the publication of standards to prevent publication delays due to Government Gazette constraints.

It is submitted that, in order to ensure the required flexibility and efficiency, the OHSC

- Be permitted by the Amendment Bill to issue standards not as regulations (i.e. not 'as prescribed' but as OHSC Notices, similar to the Board notices of the HPCSA / SAPC, or the Circulars issued by the Council for Medical Schemes).
- Have to publish all proposed standards (not necessarily in the Government Gazette) for public comment and released specifically to other statutory bodies and structures affected by such standards, in order to ensure that possible contradictory provisions and jurisdictional overlaps could be identified early-on.

The inclusion of the above two provisions would serve as important safeguards to prevent challenges to the work of the OHSC based on administrative law principles.

3. Conclusion

The NPG feels strongly that scarce accreditation resources can be spared, as members have, voluntarily, submitted to SANAS accreditation and are supported by suppliers and others that provide service, maintenance and upgrade support. It also believes that efficiencies can be created by leveraging of the professions in ensuring good clinical governance, in line with the provisions of the Health Professions Act.

The NPG believes that the independence of the OHSC should be secured through explicit wording in the Amendment Bill, and that certain discretionary powers should be made mandatory (i.e. the publication of draft standards and the avoidance of duplicating and/or conflicting standards being set and/or enforced).

Certainty is required as a matter of urgency on the linkages between the OHSC and the envisaged CON.

As a well-organised, representative professional organisational structure, NPG remains committed to play a constructive role in the healthcare sector. We would gladly participate in, and contribute on, in particular, the issues outlined in this submission.

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