Submission by the Laboratory Medicine Group on the Office of Health Standards Compliance, as proposed under the National Health Act (Chapter 10)

A. Introduction

The Laboratory Medicine Group (LMG) is a voluntary association representing all spheres of laboratory medicine, and employing over 18000 employees. The LMG consists of representatives from the NHLS, National Pathology Group (NPG), Southern African Laboratory Diagnostics Association (SALDA), Federation of South African Societies of Pathology (FSASP), The Society of Medical Laboratory Technologists of South Africa (SMLTSA), The South African Society of Clinical Cytologists (SASCC),The South African National Blood Service(SANBS),The BioMedical Scientists, Western Province Blood Transfusion Service and the College of Pathologists of South Africa.Further details regarding the Laboratory Medicine Group ("LMG") can be found in the Annexure.

Due to its wide representation, LMG hereby offers to the Portfolio Committee its assistance in any matter as the Committee may deem fit, insofar as it relates to the broader field of laboratory medicine, standards, accreditation and enforcement.

B. The importance of quality systems

The increasing awareness of the costly personal and economic impact of medical errors on patient safety has focused a spotlight on quality management in health care services. In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide laboratory services. Our historical perspective of quality control and quality assurance must be superseded by a more global view of internationally accepted quality activities applied to a laboratory's scope of work.

An integrated Quality Management System provides an opportunity to deliver consistent, high-quality, and cost-effective laboratory services.

Although some laboratories are working successfully at the level of a Quality Management System, in much of the world, many laboratories are operating at or below the stage of quality assurance. The need to upgrade to a Quality Management System approach has become evident from worldwide reports that describe medical errors in present-day health care systems and from reports of the cost of both good and poor quality on laboratory operations. The best contribution a laboratory can make to reducing errors that can or may cause harm is to understand and document its processes, train staff to competency in following those processes, identify problematic processes, and improve processes where problems exist.

The foundation of a Quality Management System provides a platform for continuous improvement and further transition up the quality hierarchy. With an integrated Quality Management System in place, the following outcomes can be greatly enhanced through the application of standards and benchmarking:

- Ability to reduce or eliminate error

- Meeting customer expectations
- Potential for successful governmental and accreditation assessments
- Sustainable attainment of quality objectives

Accreditation to a global standard, such as ISO 15189 provides a platform for recognizing quality and competency in laboratories.

C. Standards and standards bodies to be recognized by the OHSC

LMG is concerned that the reference made in the Amendment Bill No 24 of 2011, that the Minister will approve "quality assurance and quality management systems for the whole health system" (section 79(1)(f)), could lead to unnecessary duplication and unduly onerous provisions that will decrease the efficiency and cost-effectiveness of health services.

We recommend that, insofar as laboratory medicine is concerned, standards are aligned and that accreditation, and enforcement of the standards is harmonised between, for example, the system envisaged by the proposed medical device licensing regulation, the control of Hazardous Substances system and ISO accreditation, as well as the licensing system referred to in the HRH Strategy, 2011.

The system for alignment proposed by the Amendment Bill is not sufficiently clear to ensure legal certainty. Legal certainty is a key tenet of the constitutional principle of rule of law, entrenched in section 1(c) of the Constitution of 1996. The reference to the harmonisation by the OHSC of conflicting jurisdictions is not a sufficient mechanism to resolve this matter, as each law has its own mandate and each institution has to act within that legislative mandate.

This means that the following questions arise, viz: What happens if harmonisation cannot be achieved? And what is meant by the second criterion in clause 79(2)(e) that the agreement must ensure the "consistent application of the principles of the National Health Act"? Which principles are referred to, as the OHSC has a mandate only in terms of chapter 10, and not any other chapter in the Act? How could another regulatory body agree to ensure the consistent application of principles found in another Act that does not bind it? Etc.

The pieces of legislation (including provisions under the National Health Act itself) are potentially in conflict as giving mandates for the issuing and enforcement of various types of standards, include:

- Powers of the Medicines Control Council and the DG of Health in terms of the Medicines and Related Substances Control Act (i.e. standards development and enforcement towards manufacturers of medicine, wholesalers, pharmacies and dispensing doctors/nurses, etc), as well as standards set for clinical trials;
- Powers of the future South African Health Products Regulatory Authority (in terms of an Amendment Act to the Medicines Act), which will register medical devices and in vitro diagnostic products against quality, safety and performance standards, as well as set standards for manufacturers and importers;

- Powers of Radiation Control, a division of the National Department of Health in relation to standards setting and enforcement in terms of the Hazardous Substances Act, that applies to the manufacturers of large diagnostic/laboratory capital equipment;
- Standards set for healthcare professional conduct (behaviour) and scopes of practice (i.e. who can do what in a healthcare setting) in terms of the Nursing Act, Health Professions Act, Traditional Healers Act, Social Work Act, Pharmacy Act, Engineering etc. These bodies are also responsible to oversee the training and correct use of health technologies by professionals. These bodies also empower their respective professional groupings to be competent in certain areas, and to make pronouncement on, for example, what would be appropriate care or actions in certain circumstances.
- Training standards- and training facility standards set by the above bodies and entities such as the South African Quality Authority;
- Standards set by the South African Bureau of Standards (SABS) and the National Regulator for Compulsory Specifications (NRCS) for various types of equipment used in health facilities;
- Provisions in the Consumer Protection Act on safety, quality and purposefulness of services and goods;
- Compliance with standards in chapter 2 of the National Health Act (consent, confidentiality, duties of users and record-keeping standards);
- Procurement standards set by the Preferential Procurement Regulations of 2011, that came into operation on 7 December 2011, and that also apply to procurement by all public sector facilities, with accompanying guidelines issued by the National Treasury to ensure proper supply chain management (last-mentioned is, for example, included in the set of Core Standards presented to this Honourable Portfolio Committee in February as part of briefing it on the amendment Bill);
- Standards set by the Children's Act and regulations in relation to the provision of healthcare services to children;
- Etc.

In LMG's view each of these conflicts have to be considered prior to the adoption of any specific proposal in the amendment Bill, as the extent and nature of possible conflicts will determine the appropriate wording to deal with this. It may also mean that, in some cases, it would be more an issue of proper enforcement, rather than the development of new sets of standards.

LMG also proposes that the above bodies be approached in order to clarify the standards it sets in relation to persons, institutions, products and services and how those are enforced.

D. The structure and nature of the OHSC

LMG is not sure how exactly the independence of the OHSC is to be assured as the OHSC would be intrinsically linked to the office of the Honourable Minister of Health. Not only will the Minister finally approve quality systems and set standards and norms, s/he would also be the port of call for the Ombud in cases where the CEO of the OHSC fails to implement a recommendation of the office of the Ombud, and establish the members of

the Tribunal to adjudicate appeals against decisions of bodies under chapter 10 of the Act, as to be amended.

The LMG also feels that, in line with international benchmarks on quality assurance bodies, the OHSC should be truly independent from the Department of Health, as it would need to set standards without consideration as to where it has its offices, without contact with policy makers and without the possibility of it being instructed to change its reports or recommendations (as is possible under the current proposed clause on accountability of the OHSC and the CEO). The Minister also approves the organsiational structure of the OHSC.

Given the above, it is also unlikely that the OHSC would be allowed to retain its fees independent from the Department of Health. Subjecting the OHSC to the PFMA and stating that it is a juristic person does not ensure such independence, nor allows it, in terms of the PFMA to retain fees.

E. Fines by OHSC, powers of inspectors and matters that raise constitutional issues

The fines to be set by the OHSC without anyprovisions on the procedures to be followed in-between the issuing of a compliance notice and the alleged failure to implement a compliance order, could be problematic. The process to be followed in such circumstances should be spelt out in the Act, as the repercussion of a fine as high as R10m for any health establishment, including a state facility, is massive.

Provisions should be made for the OHSC to train inspectors and to ensure that inspectors are appropriately qualified and experienced in the areas that will be the subject-matters of their inspections.

The difference between environmental health investigations and other inspectors are not absolutely clear. The OHSC appears to only relate to standards of health establishments, but the powers of the environmental inspectors would go beyond investigating and inspecting health facilities?

F. Conclusion

The LMG supports endeavours to ensure that patients in South Africa have access to quality healthcare. Amongst the members of the LMG, expertise exists in many areas of standards compliance envisaged by the OHSC. The LMG hereby offers any assistance to the Honourable Portfolio Committee on this matter, as it may require.

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ANNEXURE: The Laboratory Medicine Group (LMG)

1. The Laboratory Medicine Group is a voluntary association and has no legal standing apart from the groups represented.

2. The Laboratory Medicine Group acknowledges the essential roles both private and public laboratories are playing and will continue to play in patient diagnosis, care and outcomes.

3. The objectives of the group are to promote the image and well beingof Laboratory Medicine, to assist in recruiting, training and retaining personnel in all aspects of Laboratory Medicine, as well as to improve the BEE component of this discipline, and to show that Laboratory Medicine is a cost saver and not a cost driver in medical care.

4. Laboratory Medicine is the core of all medicine. Where there is early and accurate diagnosis of disease, correct cost effective treatment can be instituted timeously and great savings are made in medical and absenteeism costs. In South Africa there are large numbers of cost effective In-vitro Diagnostic (IVD) tests available. Accurate, reliable results provided timeously to the requesting clinician ensures that the clinician can affect the correct treatment, therefore saving the health system from carrying costs of complications and saving the patient by helping them to return home or to work earlier and therefore to play an effective role in the economy. Failure to make an accurate diagnosis and treat properly can have extremely expensive and complex consequences, prolong inpatient stays, result in secondary disease or infections and increased morbidity and mortality.

5. For the above reasons it is imperative that rapid accurate pathology results are obtained. This requires trained staff in adequate numbers. Thus the LMG's desire is to utilise all cadres of this discipline to attain this outcome. The objectives of the LMG are to recruit, train and retain personnel in all aspects of Laboratory Medicine, to utilise both the Public and Private sector to optimise not only these objectives but also to maximally utilise the modern very accurate, rapid and cost effective laboratory equipment that is and will be available in the future in South Africa.

6. The advent of the NHI provides the impetus required to consolidate and harmonise the Laboratory Medicine resources of the country so as to utilise all its limited resources to serve all the people of South Africa. Like the rest of the world, South Africa is very short of trained personnel in Laboratory Medicine. So it is more important than ever to maximally utilise all the intellectual capital, facilitiesand equipment that are presently available in South Africa and to investigate Public Private Partnerships. The LMG includes the NHLS as a partner and needs to work closely with and the Department of Health to achieve these goals.