ISSUE > 01 | 08/2016

Medical Technology Professionals NEWS

HPCSA
Health Professions Council of South Africa

Newsletter for Medical Technology Professional Board

CHAIRPERSON'S NOTE

It gives me great pleasure to welcome our new Board members for the term 2015 – 2020 and wish them well in this huge task that lies ahead of us. During the next five years of office, the Board will have achievements and challenges, but with the great team that we have, we will surely meet our goals and overcome any challenges.

One of the biggest challenges will be to successfully implement the Strategic Plan, which we will put together as a Board.

SUCCESSES:

The new Board was inaugurated in August 2015 and has achieved a lot in a very short space of time in terms of meeting its regulatory obligations, which include but not limited to registration of practitioners, developing guidelines (a task team was appointed to look into the issue of board examinations and successfully submitted a report on the matter).

1. The Board successfully put together the Strategic Planning objectives. Professional Board Medical Technology (PBMT) was the first Board to attend the Strat Plan of all twelve Boards);

2. The Board arranged and attended the Evaluator Training workshop, which was facilitated by the former chairperson of the Board, who is a Southern African National Accreditation System (SANAS) evaluator/ assessor with vast experience, Ms Roshini Bridgemohan; this is the first in a series of more workshops to be arranged as a continuous process;

3. The Board appointed a task team to look into the Board Examinations due to possible inconsistencies in the examination results, and a very comprehensive report was submitted to the Board for further action;

4. The Board had a successful meeting with one of our major stakeholders, the Society of Medical Laboratory Technologist of South Africa (SMLTSA) at their headquarters in Cape Town on 10 June 2016, among the matters discussed was the report by the Task Team on Board Examinations;

5. The Board is in the process of establishing a Task Team to deal with National Articulation and Recognition of Prior Learning (RPL) committee for the new 4 year degree, the BHSc-MLS, which is currently being offered only by two Universities of Technology (UoT's), namely the CPUT (Cape Peninsula University of Technology) in Cape Town and NMMU (Nelson Mandela Metropolitan University) in Port Elizabeth, Eastern Cape. Other UoT's are in the process of applying to offer the degree;

HIGHLIGHTS IN THIS ISSUE

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***MTB Board members: First row** – left to right :Ms M Baruth, Ms N Ramokoka, Mr E Chanza, Mr A M Louw, Dr B Mjamba, Mr H Nthunya, Ms V Gabashane, Ms A Vuma. **Back row** – Left to right : Ms M Mokoka, Ms J Hind, Ms J Chippa, Ms T Khoza, Ms L Ntsimane, Mr C Pieters, Mr T Mogano, Ms J Mthombeni, Ms N Mthembu*

6. Through our dedicated Secretariat, the Board is in the process of arranging a stakeholder meeting which took place in August 2016 in KZN. The purpose of the meeting is to converge as interest groups to engage and update each other on matters pertaining to the profession. The aim is to bring together as many stakeholders as possible.

7. The Board has done site evaluations of the following :

   a. Clinical Facilities:
      - Ampath, Nelspruit (Histology)
      - NHLS, Northdale, Pietermaritzburg.
      - NHLS, Addington Hospital Pathology Laboratory
      - Global Clinic and Virology Laboratory

   b. Institutions of Higher Learning (UoT's)
      - Tshwane University of Technology (TUT);
      - Durban University of Technology (DUT);
      - Mangosuthu University of Technology (MUT);
      - Nelson Mandela Metropolitan University (NMMU).

CHALLENGES:

Currently, the new Board is not faced with any serious challenges except completing certain tasks which were carried over from the previous Board:

Completion of outstanding evaluations of Clinical facilities, there is a huge number to still evaluate. The implementation of outstanding policies and regulations from previous years that have been promulgated into law by the Minister of Health. With the help of the Legal Department of the HPCSA, the Board will continue to update and finalise promulgation of policies that regulate our professions;

I am truly looking forward to working with this great team of dedicated practitioners and community representatives. I am confident that the targets that we have set for ourselves will be accomplished by the end of the current Board's term of office.

I would like to thank the Secretariat for their unwavering support that they give to our Board; it is really refreshing to have a dedicated team of professionals to implement the Board's resolutions.

The future looks GREAT!

Mr M Louw
Chairperson: Professional Board Medical Technology

COMPARISON OF QUALIFICATIONS ENCOUNTERED IN PATHOLOGY LABORATORY

By Jennifer Hind

A frequent question encountered in pathology laboratories is: where does my qualification fit in this environment? In order to clarify the situation, the National Qualifications Framework (NQF) has classified all qualifications into levels which explain, through Level Descriptors, the necessary competencies for each of the levels.

NQF Levels 1, 2, 3 and 4 are the South Africa High School Grades with Level 1 designating Grade 9 up to Level 4 as Grade 12.

NQF Levels 4, 5, 6 and 7 cover **Technical qualifications** and College Diplomas and NQF Levels 7, 8, 9 and 10, the South Africa University qualifications / degrees.

The following table outlines where those qualification encountered in a pathology environment fall.

#and##: These are not recognised as Academic NQF Levels because the training involves practical training only. This training comes under the Health & Welfare Sector Education & Training Authority (HWSETA).

NQF LEVEL	DESIGNATION	# LABORATORY ASSISTANTS ## MEDICAL TECHNICIANS	MEDICAL TECHNOLOGIST	MEDICAL LABORATORY SCIENTIST (BHSc:MLS)	MEDICAL SCIENTIST	PATHOLOGIST
3	Grade 11					
4	Grade 12					
5	Certificates					
6	Diplomas and Advanced Certificates		National Diploma in Medical Technology 24 subjects			
7	Bachelor's Degree and Advanced Diplomas		B. Tech in Medical Technology Diplomate plus Professional Board Examination not previously recognised as an Academic Level		BSc Degree	Bachelor of Medicine (MB) Bachelor of Surgery (ChB), MBChB MBBCh(Wits)
8	Honours Degree, Post Graduate Diploma, Professional Degrees		B Tech plus Professional Board Examination not previously recognised as an Academic Level	BHSc:MLS All subjects have been updated to include international benchmarking as well as more application and understanding of concepts and critical thinking Includes Clinical Practice Training in the Pathology disciplines Includes Research project	BSc Hons Degree Missing specialist clinical subjects at HEI, Internship and specific Board examination for PBMT Registration	Credits pitch the two degrees at Level 8 but includes Internship and Community Service College of Medicine/Pathology – 42 months as Registrar Specialist degree conferred as a Fellowship Not recognised as an Academic Level
9	Master's Degree		M.Tech in Medical Technology. Department of Education has recently dropped this to a NQF Level 8	The Universities have, on instruction from DoE, standardised that the masters qualification for the BHSc:MLS will be a MSc and not MHSc Degree	MHSc Degree Degree for Medical Biological Scientists may be in a Clinical Pathology discipline but does NOT cover technology required on the Medical Laboratory Diagnostic Platform. RD orientated	M. Med
10	Doctoral Degree		PhD	PhD	PhD	PhD

CONCERNS AND LEGISLATION ON POINT OF CARE TESTING (POCT) IN SOUTH AFRICA

By Jennifer Hind

Concerns and legislation on Point of Care Testing (POCT) in South Africa or bedside testing is defined as medical diagnostic testing at or near the point of care—that is, at the time and place of patient care.

Is it the perfect solution in an imperfect world?

Two thirds of patient management decisions rely on laboratory medicine, with Point of Care *in vitro* diagnostic devices (IVDs) offering a perfect solution. The convenience of rapid 'point of care' or 'near patient' results, allows immediate implementation of treatment protocols.

However, medical professionals must be cognisant that they have, by way of ethics and medical law, a responsibility towards patients to deliver diagnoses and treatment of high standard and efficacy. Regulatory measures must be upheld precluding undesirable practice in laboratory medicine using POCT IVDs. Medical malpractice litigation is a reality in the United States and to differing extents throughout the rest of the world. Our media shows attempts in South Africa to bring such litigations as fraught with ineptitude and lack of service delivery of juristic bodies to uphold legislation. Cases take years to reach conclusion and settlement, notwithstanding unaffordable legal costs.

The country's population, at large, lacks knowledge of the significance of good laboratory practice and are not conversant with their legal rights regarding laboratory misdiagnoses. All *in vitro* diagnostic procedures are subject to legislation monitored by, amongst many others, the Department of Health appointed regulatory bodies. POCT should be undertaken by practitioners trained, evaluated and deemed competent by the Professional Board for Medical Technology (PBMT) in engagement with Pathologists to ensure that scope of profession and practice is upheld. There is a misconception that POCT devices are unregulated in South Africa. There are numerous regulations that may or may not be currently enforced and policed due to incompetence, ignorance and lack of reporting non-compliance and public knowledge.

Many South African POCT facilities exercise no regulatory quality control and assurance. These facilities have to accept that regulations relating to POCT IVD's must be conformed to; documentation on legislation regarding POCT is available for all those who are interested on the HPCSA website. The HPCSA statutory mandate is to protect the public and guide the professions. This sounds as soft cell but the HPCSA is, through the Health Professions Act 56 of 1974 plus all its amendments, a juristic entity and is guided by a formal regulatory framework which includes the Health Professions Act amongst many others.

The HPCSA has the power to institute disciplinary proceedings regarding any complaint, charge or allegation of unprofessional conduct - this includes allowing persons who are not registered and within scope of profession and practice to carry out professional procedures unlawfully. All individuals who practice any of the healthcare professions incorporated in the scope of the HPCSA are obliged by the Health Professions Act No 56 of 1974 to register with Council. Failure to comply constitutes as a criminal offense. Registration with the HPCSA offers healthcare professionals/practitioners conferral of professional status, inclusive of the right to practice the profession that they are qualified for; the assurance that no unqualified person may practise these professions and credibility as a competent practitioner who may command a reward for their services.

Here are some of the standards and regulations under which POCT falls:

It is important to recognise that IVD products are labelled "for *In Vitro* Diagnostic use only" by authorised healthcare professionals: i.e. HPCSA Board registered Medical Laboratory Scientists, Medical Technologists, Medical Technicians and Phlebotomists. This is based on the following:

ISO – INTERNATIONAL STANDARDISATION ORGANISATION

ISO - 15189:2012 used in conjunction with ISO - 22870:2006 requirements for POCT

This applies to hospitals, clinics and organisations providing ambulatory care. POCT or 'near patient' testing may benefit a patient and the healthcare facility provided the risk to the patient and to the facility can be managed by a well-designed, fully implemented quality management system that facilitates: 'evaluation of new or alternate POCT instruments and systems'. This is achieved by:

- Evaluation and approval of end-user proposals and protocols
- Purchase and installation of equipment
- Maintenance of consumable supplies and reagents
- Training, certification and recertification of POCT system operators
- Quality control and quality assurance (ISO 22870:2006. Point-of-Care Testing (POCT) – Requirements for quality and competence)

Reference: Review – Policies, Procedures and Guidelines for Point-of-care testing: RCPA Quality Assurance Programmes PTY LTD.

ISO 15189:2012 has four Quality Related Standards stemming from it:

Procurement / sample collection

- ISO 15190 – Safety
- ISO 22870 – POCT
- ISO 22367 – Risk
- ISO 17011 - Accreditation - accredited by the authorising body – SANAS.

Reference: Noble, M.A. Everything you want to know about ISO 15189:2012. Medical Laboratories; requirements for Quality and competence.

Take home messages regarding POCT

Four sources of POCT error:

1. Operator incompetence
2. Non-adherence to procedure
3. Uncontrolled reagents
4. Uncontrolled equipment

Three potential amplifies of POCT error

1. Incoherent regulation renders QC standards for safe performance among waived and moderate complexity POCT uncertain
2. Rapid results availability and immediate acceptance of results for definitive diagnoses without QC
3. Immediate therapeutic implications may increase risk of adverse events to the patient.

The modified KOST classification divides POCT into three phases, each with four steps.

PHASE 1: POCT errors arise from:
- Patient (mis-) ID
- Specimen (mis-) ID and poor quality
- Opacity of POCT analysis
- (mis- or non-) communication of POCT results

PHASE 2: anti-error prevention strategies:
- Operator training programme assessed and accepted by the PBMT/HPCSA
- Operator competence assessment – Board examination and registration with the PBMT/HPCSA

- Proficiency demonstration – practical training and CPD

PHASE 3: anti-error detection measures:
- Test order integrity
- Patient identification
- Specimen acceptability
- Report accuracy monitoring

PHASE 2 and 3 in accordance with ISO 15189:2012 and ISO 22870:2006

Reference: Meier, F.A. and Jones, B.A. (2005) Point of Care Testing Error. Arch. Pathol. Lab. Med. Vol. 129.

Further recommended reading regarding regulatory bodies under which the uses of in vitro diagnostic devices are governed:

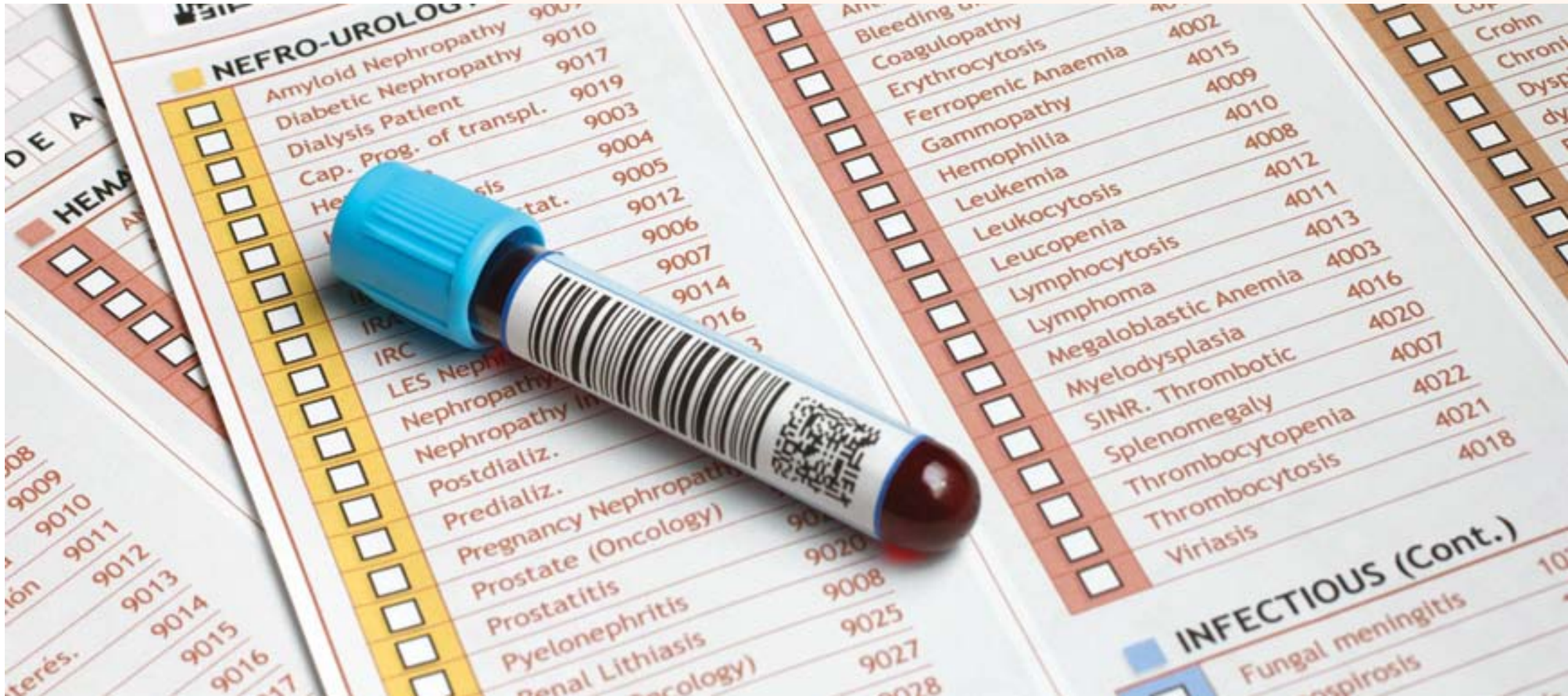
- South African National Accreditation System (SANAS): ISO 3485 for IVD Institutions and manufacturers
- The National Pathology Group (NPG): Constitution and Code of Conduct – NPG, Health Professions Act 56 of 1974; registration of private practice
- The Southern African Laboratory Diagnostics Association (SALDA): Marketing Code Authority 2014: The Code document refers to HPCSA Booklet 5 regarding good practice; item 3.6 and the Guidelines document Part C Clause 49.2 Note 1 round bullet 7 on Page 24
- ISO 13485: This is the Manufacturer's standard: This requires Post Market Vigilance for all products sold on the market
- ISO 15189:2012 – GLP Office of Health Standards Compliance: Improving the quality of healthcare in South Africa is an essential prerequisite for the National Health Insurance scheme (Private and Public)
- Hospitals accredited through Council for Health Service accreditation of Southern Africa (COHSASA): Hospitals are to comply with the international ISQua International accreditation programme (including the requirement for Clinical Laboratory accreditation)
- National Department of Health SA, Epidemiology and Surveillance for Notifiable Diseases: If any of the tests are on the list of notifiable diseases there needs to be mechanisms to report these to the authorities in accordance with the National Health Act, Act 61 of 2003, Notifiable Diseases
- The Health Act Chapter 9; National Health Research Committee and National Health Research Ethics Council: Permission needs to be obtained for all IVD Clinical Trials/ Investigations
- Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act 19 of 2006 compliance
- Criminal Procedure Act of 1977 as amended 23 January 2014: Tests for drugs of abuse need to be performed in accordance with the requirements of the Criminal Procedure Act of 1977 as amended 23 January 2014, since there are serious legal ramifications regarding a criminal offence
- Principles, outlined in Section 51 of the Electronic Communications and Transactions Act 2002 ('ECT Act') for the protection of personal information: The Protection of Personal Information (POPI) Act.
- National Environmental Management Waste Act 2008; OHSA Regulations for Hazardous Biological Agents – Department of Labour - plus Chapter 11 / 90 Regulations 90 (n) page 84 of the National Health Act 61 of 2003. Amended by the National Health Amendment Act 12 of 2013

Please note that FDA CLIA Waived assays and instruments are not yet recognised in South Africa.

RESTORATION POLICY FOR THE PROFESSIONAL BOARD OF MEDICAL TECHNOLOGY

1. A health professional whose name was erased from the HPCSA register for a period of two(2) years or more and was not practicing his/her profession has to apply to restore his/her name to the register by complying with the following restoration procedures:
   - Complete Restoration Form 18.
   - Payment of restoration fees and any other fees outstanding.
   - The applicant will be restored in terms of supervised practice immediately on submission of the application form and payment of penalty fees;
   - The health professional will have to work under supervision of a registered Medical Technologist at an accredited laboratory, for a period of at least twelve (12) months;
   - The supervisor should on completion of the period of 12 months, submit a progress report with a recommendation as to the lifting of restrictions or a further period of supervised practice; and
   - The progress report will be considered by the Chairperson of the Professional Board or Education Committee.

2. A health professional whose name was erased from the register and has practiced their profession has to apply to restore his/her name to the register by complying with the following restoration procedures:
   - Duly completed application for restoration form (Form 18) and applicable restoration fee
   - Proof of practising their profession – CV or letter from the previous employer confirming employment with dates specified.
   - COS (Recent certificate of good status from the country where he/she has practised) not older than 3 months.
   - Proof of CPD attended to during preceding 24 months.



APPLICATION FOR APPROVAL TO CONDUCT A PRIVATE PRACTICE

In order to qualify to conduct a private practise, a practitioner needs to meet the following requirements;

1. Each application for approval to conduct a private practice has to be considered by the Professional Board.
2. In order to comply with the requirements, an applicant has to provide proof of at least two (2) years post registration experience in the particular category of registration.

The following ORIGINAL documentation must be submitted in support of the application for approval to conduct a private practice:

a. The enclosed application form (Form 133) duly completed;
b. An original letter from the practitioners' employer confirming at least two (2) years post registration experience in medical technology in the particular category;
c. An amount of R353.00 for a Certified Extract certificate from the register for registration purposes of a practice number at the Board of Healthcare Funders of South Africa. Also, the practitioner's MT registration number is required on the deposit slip.
d. Proof of payment of annual fee
e. HPCSA CEX certificate (copy)
f. Proof of compliance to CPD requirements

Banking details are as follows:

ABSA Bank Arcadia
Branch code: 334945
Account number: 061 00 00 169

INVITATION FOR CPD ACCREDITOR STATUS

By Melini Baruth

Continuing professional development (CPD) serves to maintain and enhance the knowledge, skills and ethical standards of practitioners so as to facilitate good quality of healthcare. CPD should meet an educational and developmental need and provide an effective learning experience for the participants.

Accreditors are groups or institutions appointed by a Professional Board on the basis that they meet the criteria set out by the HPCSA CPD Committee.

Potential Accreditors are invited to apply to the Professional Board of Medical Technology for registration as an Accreditor on Form CPD4.

The role of the Accreditor is

(a) to review applications for –
   i. Accreditation of accredited service providers if the function was delegated to them;
   ii. Applications for provision of Level 1 or 2 CPD activities by service providers according to the guidelines for service providers wishing to offer CPD activities;

(b) To monitor compliance with the guidelines;

(c) to revise continuing education units (CEUs) allocated where the provider failed to comply with the rules and regulations of the HPCSA CPD System;

(d) to review Accredited Service Providers and submit a report to the HPCSA CPD Committee noting whether the following was adhered to:
   - A list of all activities during the year was provided;
   - All ethical activities were mentioned;
   - Relevance of activities to the field of practice;
   - Has an activity been presented more than once to the same audience; and
   - Any problems experienced.

(e) To investigate complaints against Accredited Service Providers.

(f) To submit accredited CPD activities to the HPCSA for uploading on the website.

GENERAL INFORMATION

HPCSA
Health Professions Council of South Africa

For any information or assistance from the Council direct your enquiries to the Call Centre
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