# Statutory regulations governing Medical Technology

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## Introduction:

This article serves to provide information regarding the statutory regulations governing the training, scope of practice and career paths of Medical Laboratory Personnel. It also provides an overview of the rules regarding confidentiality and continuous professional development.

### 1. Regulations governing Medical Technology personnel

Medical Technologists, Medical Technicians, Laboratory Assistants and Medical Scientists make up the core of the technical laboratory personnel in a medical laboratory.

The scope of practice (procedures that may or may not be performed within the category of registration) is regulated by the Health Professions Council of South Africa (HPCSA). This means that the profession operates within strict guidelines to ensure that the welfare of the patient is placed above all else.

### 1.1 About the HPCSA

The HPCSA is a statutory (legal) body established in terms of the Health Professions Act (Act No. 56 of 1974). There are 12 Professional Boards operating under it. The Professional Boards control the professions within their field.

The Main Objectives of Council and Professional Boards are to:

- Promote the health of the South African population
- Determine and uphold the standards of education and training
- Keep the Registers of each profession
- Determine and maintain standards of professional practice and conduct
- Advise the Minister of Health on matters pertaining to the Act

**1.2 Professional Ethics:**

Ethics can be defined as a set of standards of conduct and moral judgment and as a code of morals of a particular profession.
In medical Technology we are concerned with the code of morals of individuals as professionals.

**Code of ethics for Medical Technologists (applicable to all medical laboratory personnel):**

1. Being fully aware of my responsibility in the practice of Medical Technology, I commit to performing my duties with accuracy, thoughtfulness and care.

2. Realizing that the knowledge obtained concerning patients in the course of my work must be treated as confidential.

3. I will conduct myself at all times with integrity (honour) and uphold the dignity of my profession.

4. I pledge myself to practice Medical Technology strictly according to the principles, standards, traditions and regulations of the HPCSA and South African law.

5. I will always be aware that I have been entrusted with patient care through the practice of my Medical Technology duties.

6. It is my responsibility to strive constantly to increase my technical knowledge of Medical Technology and exchange knowledge with other competent practitioners of Medical Technology.

7. I pledge accuracy and reliability in the performance of tests and to seek competent professional assistance when in doubt of my own judgment or competence in a particular test or investigation.

8. As a further consideration for registration, I pledge myself to avoid dishonest, unethical or illegal compensation for such services as I shall render to the patient I'm serving.

9. I pledge myself to report the results of my findings free from all personal opinion to the attending physician. I shall not make or offer a diagnosis or interpretation except as the result of the report may of itself so indicated, or unless I am asked to by the physician taking care of the patient.

10. I will strive for increased efficiency and quality through organization.

11. I will be willing to accept responsibility for my own work and results

12. I will assume a professional manner, attire and conduct on a daily basis.

**1.3 Performance of Professional Acts**

Medical Technologists, technicians and Laboratory Assistants shall confine themselves to practicing in the specific discipline of medical technology in which they were educated, trained and registered.

Although Medical Technologists may conduct private practice if they have two years of postgraduate experience and prior written approval from the Board, Medical Technicians and Laboratory Assistants shall not conduct private practice.

Further to this, medical technicians shall only perform professional acts under the supervision of a medical practitioner or medical technologist registered in the relevant discipline.

According to the ethical rules published as Government Notice No R 717 of 4 August 2007, Medical scientists shall be involved with the development, evaluation and practice of scientific procedures which involve human or human biological material provided that such acts lead to or impact the treatment diagnosis and genetic counseling of humans.

Medical Technologists, medical technicians, laboratory assistants and their respective students/interns are registered with the Medical Technology Board of the HPCSA.

Medical Scientists and their interns are registered with the Medical and Dental Professions Board of the HPCSA.

## 2. Medical Technologist

### 2.1 Education and training requirements for Medical Technologists

The National Diploma in Biomedical Technology is obtained through three years of full time study at a University of Technology UoT (Accredited Higher Education Institution previously called Technikons).
During the last semester of study, the student technologist is given opportunity to spend 6 months in an approved (registered) training laboratory to integrate their academic theoretical education with the workings of a medical laboratory (experiential learning). This work integrated learning provides invaluable experience to the student on the scope of each medical technology discipline (chemical pathology, haematology, microbiology, histology and cytology). Blood transfusion, virology, cytogenetics and immunology are other disciplines in medical technology but are not routinely covered during experiential learning.

Although you are awarded your National Diploma after 3 years of UoT full time study, you may only register and practice as a medical technologist after 12 months of internship and passing the Medical Technologist National Board Exam administered by the Society of Medical Laboratory Technologists of South Africa (SMLTSA).

Internship may be done in any of the disciplines listed above. Chemical pathology, haematology and microbiology may be combined in equal duration (4 months each) in the 12 month internship period and is called clinical pathology. At this point in your training, you are registered as an intern technologist (no longer a student technologist) and you will follow a syllabus that specifies the scope of tests that you must be trained on.

Important criteria that must be adhered to during internship:

- Internship is completed in an approved (registered) training laboratory (laboratory which has been accredited by the Professional Board for the training of intern medical technologists and/or student technicians).

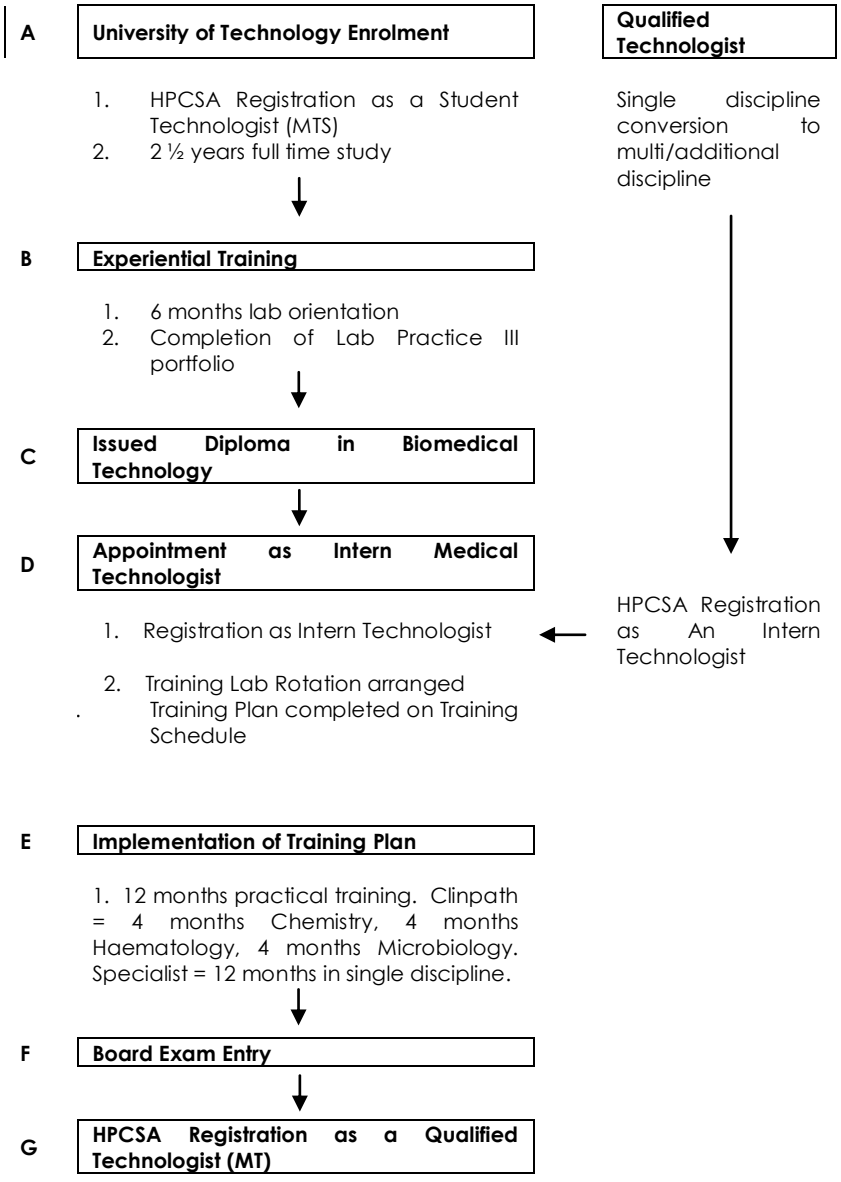
- The intern technologist registration must be done after the National Diploma has been completed and before internship commences.

- No more than one months leave or 12 days of annual leave may be taken during internship. If this happens the internship period must be extended to compensate.

- The supervising technologist (trainer) must be registered for at least 2 years and practicing in the same category in which the intern is being trained. Their CPD (discussed in detail in criteria 4 below) must be up to date.

- The intern must qualify as a medical technologist within three years of registration as an intern technologist.

## Diagrammatic representation of Medical Technologist Qualification




Qualified, registered medical technologists can achieve a qualification in an additional discipline by following the procedure above from the point of registration as an intern technologist.

## 3. Medical Technicians:

### 3.1 Education and training requirements for Medical Technicians:

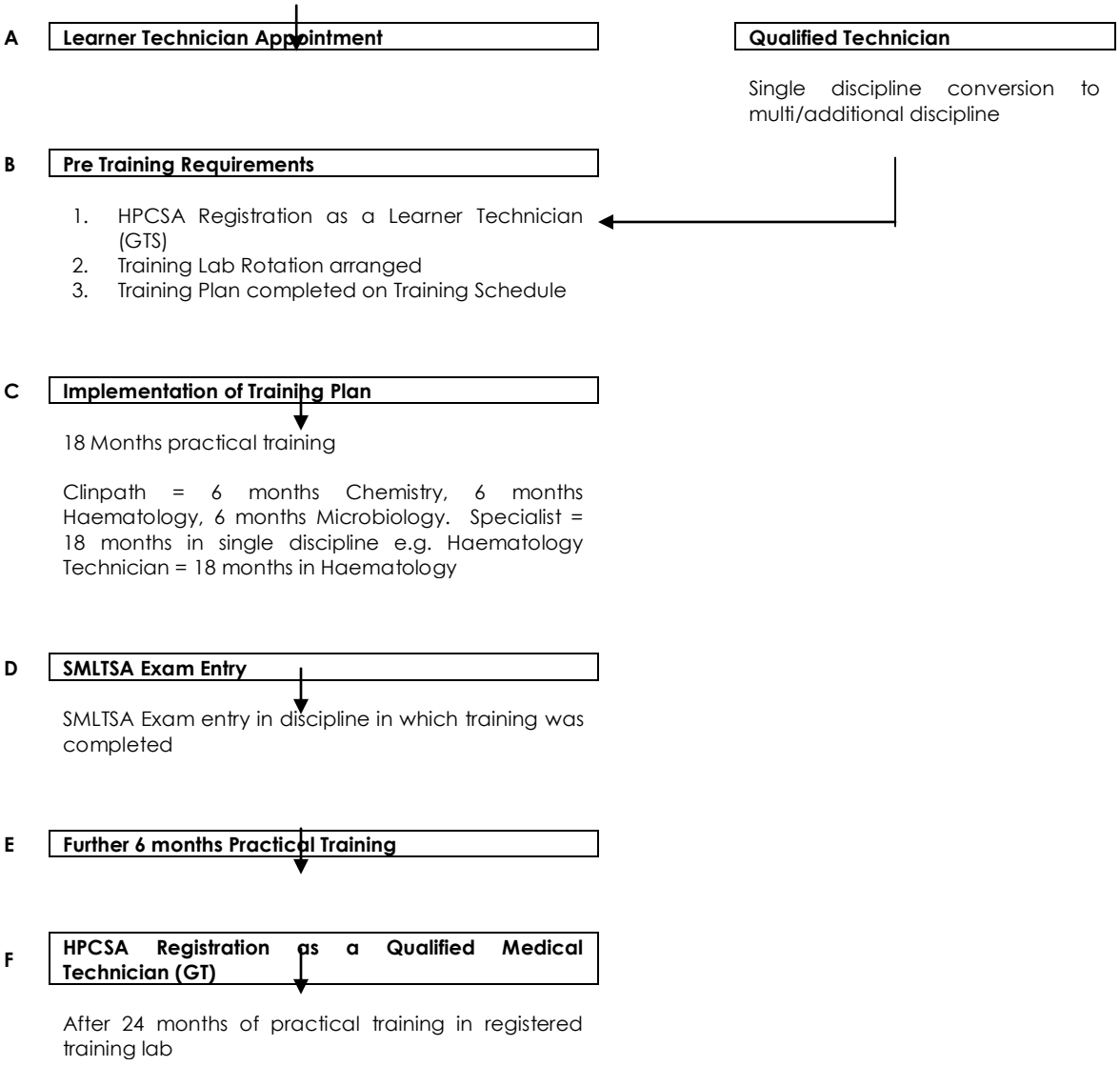
Medical Technicians qualify through on the job training in an approved training laboratory i.e. no prior academic training in an accredited Higher Education Institution is required.

After registration as a student technician with the HPCSA a syllabus which prescribes the scope of tests is followed during an 18 month training period. The following disciplines for qualification are available: Clinical pathology (6 month duration each of chemical pathology, haematology and microbiology), chemical pathology, haematology, microbiology, cytology, histology and blood transfusion.

The student is supervised by a medical technologist registered in the same discipline that the student is trained. The student registration is valid for a period of 4 years in which time the training and technicians exam must be successfully completed.

Once the examination is complete, a further 6 months of practical training must be completed for eligibility for registration as a qualified medical technician i.e. total 24 months of training required.

## Diagrammatic representation of Medical Technician Qualification:




Qualified, registered medical technicians can achieve qualification in an additional discipline by following the procedure as detailed above including registration as a student medical technician.

## 4. Laboratory Assistants

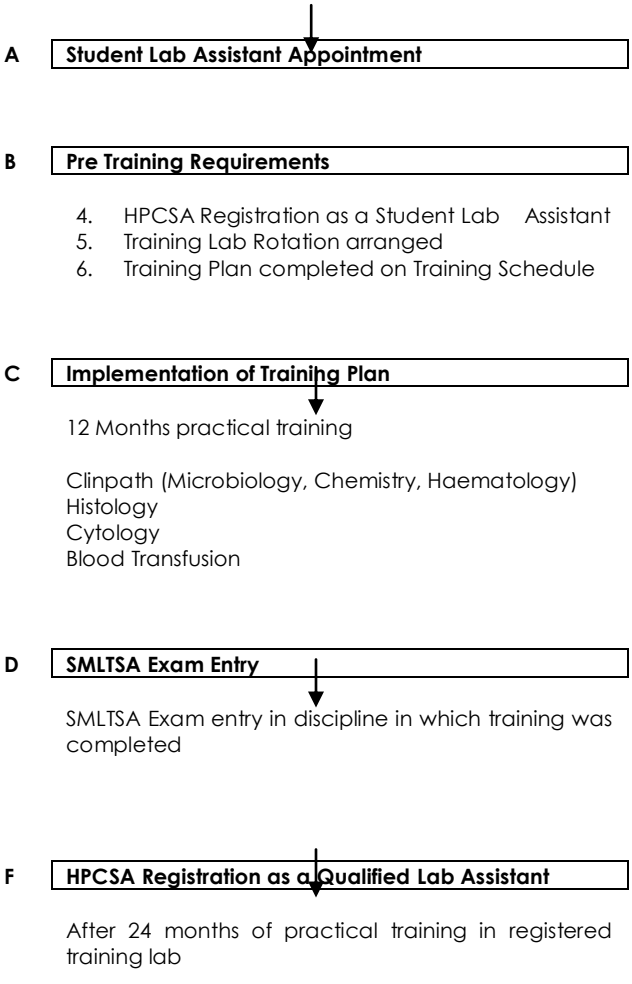
### 4.1 Education and training requirements for Laboratory Assistants:

In 2007 the Minister of Health made public the registration of Laboratory Assistants with the HPCSA. Under these regulations all persons involved with specimen handling for a period of five years or more were required to apply for registration as Supplementary Laboratory Assistants. This opportunity was available for a limited period only (31 December 2008).

Persons with less than 5 years specimen handling experience, who wished to register, are required to register as student lab assistants, complete 12 months of practical training prescribed by the syllabus.

Lab Assistants may qualify in clinical pathology (microbiology, haematology and chemical pathology), histology, cytology or blood transfusion. When the 12 month practical training is complete, you may enter for the National exam administered by the SMLTSA. When successfully completed, you may then register as a Laboratory Assistant with the HPCSA.

## Diagrammatic representation of Laboratory Assistant Qualification



## 5. Medical Technology Training Laboratories

A laboratory that wishes to train intern medical technologists and/or student technicians in a particular discipline must apply to the education committee of the Medical Technology Board of the HPCSA for training lab accreditation status.

The application is evaluated on the scope of tests performed on site compared to the relevant syllabus, the qualifications of the supervising personnel, availability of training resources such a space, training program alignment, reference material etc.

If the application is accepted, a site audit is conducted to evaluate the implementation of the proposed training program, the laboratories quality system and laboratory and personnel capacity to facilitate learning.

A laboratory accredited to train technologists may train technicians however a laboratory accredited for the training of technicians may only train technicians.

A laboratory accredited for the training of clinpath technologists could also train technicians in the categories chemical pathology, haematology and microbiology.

A laboratory approved for training may not employ more than five intern technologists and or student technicians and or qualified medical technicians in respect of every medical technologist registered in the specific discipline/category.

The board may during their audit decide to limit the number of interns/students that the lab can employ based on capacity to train.

Approved training laboratories are subject to annual audits by the Professional Board.

## 6 Medical Scientists

### 6.1 Education and training requirements of Intern Medical Scientists:

Bachelor of Science (BSc) honours graduates must within two years of completing their honours degree seek appointment in a laboratory accredited for Medical Scientist Training as an Intern Medical Scientist. The intern medical scientist registration is done with the Medical and Dental Professions Board of the HPCSA and is valid for 4 years. The intern process is 2 years.

The supervising scientist must be registered with Council in the same category for which the lab is accredited with at least 3 years of field experience.

The categories of lab accreditation:

- Medical Biological Sciences include the following disciplines of Pathology (Haematology, Anatomical Pathology, Chemical Pathology/Biochemistry, Microbiology/Virology, Immunology, Molecular Biology, Analytical Chemistry or Pharmacology).

- Laboratories may also be accredited in Medical Physicists, Genetic Counselling, Cell biology (Radiation Biology or Reproductive Biology) or Genetics.

A laboratory which seeks to be accredited as an Intern Medical Scientist Training Laboratory must meet the following criteria:

- A detailed intern training program showing the procedures, instruments and techniques, schedule of rotation for training and assessment, include academic training program for knowledge improvement and research projects that the intern will be involved in.

- An arrangement must be made with a collaborating university (that offers the same honours program in which the intern graduated) which undertakes to ensure that the training of the intern is in accordance with the program set out by the training lab.

The laboratory will make application to the Professional Board. If accepted the laboratory will undergo an audit process in which its training processes are evaluated.

Evaluation of whether the intern fulfilled the 2 yr internship criteria is determined by the sub committee of the Professional Board. Registration as a medical scientist is then recommended or remediation suggested.

**Summary of Intern Medical Scientist Training and Medical Scientist Lab Accreditation:**

| | |
|---|---|
| **1.** | Evaluate the need for Lab Accreditation |
| **2.** | Check compliance of having Supervising Medical Scientist and arrangement with collaborating university |
| **3.** | Complete application |
| **4.** | Application forwarded to Medical Scientist Board of HPCSA.<br>Audit date set. |
| **5.** | Laboratory is forwarded a checklist for completion. |
| **6.** | Completed checklist and details of intern training program to be submitted to Board 3 weeks before the audit. |
| **7.** | Audit performed on scheduled date. |
| **8.** | Training Accreditation awarded. |
| **9.** | Appoint BSc Honours graduate. |
| **10.** | Registration as an Intern Medical Scientist with the HPCSA. |

## 7. Procedure for BSc graduates and Foreign qualified employees to become Medical Technologists:

BSc graduates (no honours required) and foreign qualified Medical Technology graduates have the option of qualifying as Medical Technologists in South Africa.

Graduates must make application to a local University of Technology that offers the National Diploma in Biomedical Technology. Detailed documentation of the curriculum that the graduate completed must be submitted in the application for equivalence.

The UoT will recommend equivalence or recommend the completion of certain National Diploma subjects. If full equivalence is granted, the graduate may apply to the Medical Technology Board of the HPCSA for registration as an intern technologist, complete 2 years of internship (BSc graduate) or 1 years internship (Foreign qualified graduate), write the Technologist Board Exam and thereafter register as qualified medical technologist with the HPCSA. The BSc graduate will be allowed to write exams after 18 months of training however, 24 months of training is required before registration as a qualified.

**Apply the rules of confidentiality and ethical practice as prescribed by, HPCSA and the Patient Bill of Rights.**

"Health care provider or practitioner" is a term used to describe a person providing health services in terms of any law (doctors, nurses, technologists, technicians, pharmacists etc.). They are registered with a statutory council such as HPCSA or Nursing Council.

"Health care worker" refers to people in the medical field who render a service but are not required by law to register with a Statutory Health council e.g. admin staff and drivers in a hospital or laboratory.

"Health care personnel" is a term that refers to both health care providers and health care practitioners.

Both the statutory council and organization will define the access and distribution of confidential information by health care personnel.

Confidential information means all information, technology, know-how and trade secrets concerning or relating to the business or affairs of the company that are confidential and personal to the company.

### 2.1 What are the rules of confidentiality as prescribed by the Health Professions council of South Africa (HPCSA)?

Health care practitioners should:

a) Recognize that the patient has the right to expect that health care practitioners will not disclose any personal and confidential information they acquire in the course of their professional duties, unless the patient agrees to such disclosure, or unless health care practitioners have good and overriding reason for doing so (for example, if disclosure is not made, there is a likelihood of serious harm to an identifiable third party, or there is a public health emergency, or any overriding and ethically justified legal requirement).

b) Not breach confidentiality without sound reason and without the knowledge of their patients.

(Reference: HPCSA, Guidelines for good practice in the health care professions – Booklet 1 – General ethical guidelines for the health care professions – May 2008)

**What are the patients right to confidentiality?**

The National Health Act (Act No.61 of 2003) states that all patients have a right to confidentiality and this is consistent with the right to privacy in the South African Constitution Act (Act No. 108 of 1996)

Rule 13 of the Ethical Rules of the HPCSA states that a practitioner may divulge information regarding a patient only if this is done:

a) In terms of a Statutory (legal) provision,

b) At the instruction of a court,

c) In the public interest

d) With the express consent of the patient

e) With the written consent of a parent or guardian of a minor under the age of 12 years,

f) In the case of a deceased patient with the written consent of the next of kin or the executor of the deceased estate.

Disclosures in the public interest would include but not be limited to situations where the patient or other persons would be prone to harm as a result of risk related contact.

Patients have the right to expect that information about them be held in confidence by health care practitioners.

The National Act requires that health care providers and health care establishments are responsible for personal information about their patients and must make sure that such information is effectively protected against improper disclosure at all times.

(Reference: HPCSA, Guidelines for good practice in the health care professions. Booklet 11 Second Edition – Confidentiality: Protecting and providing information – 30th May 2007)

## 2.3 What are the ethical rights in practice with regards to HIV?

The South African constitution (Act 108 of 1996) and the law recognize the importance of maintaining the confidentiality of the HIV status of a patient.

The test results of HIV positive patients should be treated with the highest possible level of confidentiality.

Confidentiality regarding a patient's HIV status extends to other health care practitioners. Other health care professionals may not be informed of a patients HIV status without that patient's consent unless the disclosure is clinically indicated.

The decision to divulge information relating to the HIV status of a patient must always be done in consultation with the patient.

The report of HIV test results by a laboratory, as in the case with all laboratory test results should be considered confidential information. It is therefore essential that health care institutions, pathologists and health care practitioners formulate a clear policy as to how such laboratory results will be communicated and how confidentiality of the results will be maintained.

(Reference: HPCSA, Guidelines for good practice in the health care professions – Booklet 12 – Ethical Guidelines for good practice with regards to HIV – 30th May 2007)

The promotion of **Access to Information Act** states that a health care practitioner shall provide any person over the age of 16 years with direct access to his or her own records on request and provide them with a copy or abstract of such records.

Some laboratories have amended the application of this section allowing the patient to receive full benefit of the test result interpretation from their referring doctor. Patient results may only be given to the referring doctor. This rule is documented on the requisition form that the patient signs in which they consent for the collection of specimens for laboratory testing. Only on the request of the referring doctor may the test results be made available to a patient.

**Adhere to the Continuous Professional Development (CPD) guidelines as specified for the profession.**

### 3.1 What is CPD?

Section 26 of The Health Professions Act, 1974 (Act No 56 of 1974) prescribes that all registered practitioners with council undergo continuous education and training in order to retain their registration. Commitment to update and develop knowledge, skill and attitude is an ethical requirement for competent practice.

Continuous Professional Development (CPD) is a means for maintaining and updating professional competence to ensure that the public interest will always be promoted and protected as well as ensuring the best service to the community.

### 3.2 Who needs to participate in CPD?

All persons registered with the HPCSA are required to participate in CPD in order to retain their council registration.

### 3.3. What are Continuous Education units (CEUs)?

Each activity has a certain amount of points allocated to it, called CEUs.

Units are accumulated by attending CPD registered activities.

Certificates of attendance and the amount of CEUs earned will be issued after each activity.

### 3.4 How many CEUs do I have to accumulate?

a) The HPCSA requires that all qualified and registered Medical Technologists and Scientists accumulate 30 CEUs per year or 60 CEUs over 2 years

b) Medical Technicians are to accumulate 15 CEUs per year or 30 CEUs over 2 years.

c) All registered Laboratory assistants must accumulate 10 CEUs per year or 20 CEUs over 2 years.

d) A total of 5 CEUs must be earned in the category of Ethics, Human Rights and /or Medical Law.

a) Each CEU is valid for 24 months.
   It is advised that practitioners accumulate an average of:
   - 2.5 CEUs – for Technologists and Scientists
   - 1.5 CEUs – for Medical and Phlebotomy Technicians and
   - 1.0 CEUs – for Lab Assistants

   per month to facilitate the process in order to meet the regulatory requirements.

### 3.5 How do I participate?

- Points may be accumulated by attending activities hosted by the company you work for or other organisations provided the activity has been accredited for CPD points by an Accredited Service provider or CPD Accreditor such as SMLTSA.

- Examples of activities and the levels under which they are categorised are listed below. Medmall articles are easily accessible through the internet to accumulate CEUs

- All required points may be accumulated in one level. It is compulsory to acquire five of the points in Ethics.

- All activities accredited for CPD points must contribute to uplifting/enhancing the competence of the practitioner in a particular HPCSA registered Profession.

- If a CPD activity has been accredited by an Accreditor for a specific Professional Board, all health care professionals may attend that

activity if it is relevant to their specific scope of practice (cross accreditation).

- No CPD points may be earned for training of undergraduates (interns and students) or postgraduates if this is part of your job description.

- If you are registered in two professions from two Professional Boards (e.g. Psychology and Medical Technology), you are required to obtain 30 CEUs per profession. The 5 ethics CEUs are credited to both professions.

- If you are registered in more than one category (e.g. Technician and Technologist), the higher CEU requirement is required i.e. 30 CEUs per year, 5 of which must be for ethics.

- Interns and students are not required to accumulate CEUs but are encouraged to participate as this will support the learning process.

**Level One Activity**

These activities do not have measurable outcomes i.e. no form of assessment is administered.

Examples of Level one activities:
Presentations, Case study discussions, formally organised special purpose lectures, conferences.

1 CEU per hour to a maximum of 8 CEUs per day.

Presenters may be allocated double CEUs (e.g. if activity was 1 hour in duration, attendee gets 1 CEU and presenter 2 CEUs). Please note that if the presenter repeats the lecture (presentation), to another group of attendees, the points cannot be re-earned.

**Level Two Activity**

These activities have measurable outcomes i.e. a form of assessment is administered (case study analysis, written test etc.)

Examples of Level Two activities:

a. Principle author of a peer reviewed publication or chapter in a book: 15 CEUs. Co-author: 5 CEUs

b. Principle presenter/author of a poster/paper at a congress/symposium: 10 CEUs. Co-presenter/co-author: 5 CEUs

c. Interactive skills workshop with an evaluation of the outcome: 5 CEUs. Please note that this is not a lecture or presentation. It involves a group of subject matter experts who come together to evaluate a particular methodology or procedure and culminates in a product or process for implementation.

d. All learning material (which could include DVD, CD, internet or e-mail activities) with multiple choice questions for evaluation with a pass rate of 70%: 3 per questionnaire.

e. Workshops, lectures, seminars on ethics (not including general presentations with a so called component of ethics): 2 per hour

f. Journal clubs: Participative discussion that occurs not less than 6 times per year in which clinical and laboratory findings, aetiology, method specificity and sensitivity etc. is discussed: 3 CEUs per meeting.

**Level Three Activity**

This level comprises structured learning in an accredited training institution, assessed by an accredited assessor and has measurable outcomes.

The postgraduate degree and diploma must be recognised as additional qualifications by the relevant Board.

At the end of each year of study, 30 CEUs may be claimed upon submitting an academic report on progress. An additional 30 CEUs may be claimed on successful completion of the qualification.

### 3.6 How do I record evidence of accumulating CEUs?

Practitioners are personally responsible for accumulating the required CEUs, keeping records of attendance and submission of CEUs to HPCSA as required.

Portfolios of proof of progress should be kept in your personnel file at the site of work.

Each portfolio should consist of the following:

- CPD individual activity record sheet
- Original certificate/copies of attendance in the case of Level 1 and/or 2 activities attended.
- Certified certificates of qualifications in the case of Level 3 activities completed.
- Medmall certificate representing the electronic activities completed
- Documents prior to the current cycle must be kept for a minimum of two years.

### 3.7 Will the HPCSA check that I have accumulated my CEUs?

The HPCSA conduct audits every 2 months. Should a practitioner be randomly selected in the audit, he/she will be expected to submit the portfolio within 21 day of receiving the audit call.

A paper copy of the Practitioners CPD Activity Record may be submitted to:
The CPD Officer
HPCSA
P.O Box 205
Pretoria
0001

Alternately, an electronic copy of the Practitioners CPD Activity record may be submitted to: cpd@hpcsa.co.za

### 3.8 What happens if I do not have enough CEUs?

a) The council will request reasons for non-compliance.
b) Should your reasons be accepted, you will have 6 months to comply and submit your portfolio to the HPCSA CPD committee.
c) In the event that your reasons for non-compliance are not accepted, your case will be handed to a Preliminary Enquiry committee where your past records will be reviewed.
d) If past record proves to be satisfactory, you will have 6 months to comply and submit your portfolio to the HPCSA CPD committee.
e) If past records are unsatisfactory, the council may require you to:

- Work under supervision

- Be suspended from practice for a time period determined by the HPCSA's Medical Technology Board.
- Follow a program of continuing education and training recommended by the board (i.e. rewrite the board examination, etc.)

**3.9 What will happen when I will not be able to accumulate CEUs?**

Practitioners may request from the SMLTSA a deferment from accruing CEUs for up to 3 years. The application should be strongly motivated with appropriate evidence/documentation. All applications will be reviewed on an ad hoc basis.

Deferment may be granted in the following cases:

- Non-practicing
- Have has long term illness
- Practitioners who are employed outside of South Africa and not practicing his/her profession.
- Practitioners who are practicing outside South Africa in a country where formal continuing professional development does not take place.
- Practitioners who are registered for an additional qualification but is of the view that she/he will not meet the outcome within two years and thus will not be able to claim CEUs.

**Reference:**


1. Education and training requirements in Medical Technology in South Africa, Professional Board for Medical Technology
2. Policy regarding intern Medical Technologists and Training Medical technologist, Form 160-MT
3. Regulation relating to Intern Medical Technologists and Registration of intern Medical Technologist,2002
4. www.hpcsa.co.za

Questions:

1. Your HPCSA Intern Medical Technologist registrations expires after

a) 4 years
b) 3 years
c) 5 years
d) 10 years

2. A Haematology qualified Technologist can only work in a

a) Haematology department
b) Clin Path department
c) Microbiology
d) Chemical Pathology
e) All of the above

3. The following is a requirement to qualify as a Medical Technologist

a) N. Diploma in Medical Technology
b) N.Diploma in Biomedical technology
c) N.Diploma in Biotechnology
d) BSC Honors

4. The following body administers the Technologist Board Exam

a) SMLTSA
b) HPCSA
c) HPCSA Medical Technology Board

5. The discipline of clinical pathology is made up of:

a) Microbiology, Haematology, cytology
b) Cytology, Histology, virology
c) Microbiology, Haematology, Chemical Pathology

6. An intern technologist registration is required for the period of experiential learning (sixth semester of technikon studies)

a) True
b) False

7. If you are registered in more than one category (e.g. Technician and Technologist), the higher CEU requirement is required

a)True
b)False

8. Patients have the right to expect that information about them be held in confidence by health care practitioners

a) True
b) False

9. The training status for the laboratory after accreditation by HPCSA is valid for four years.

a)True
b) False

10. The purpose of CPD is to:

a) Provide opportunity for all practitioners to have exposure to all clinical disciplines
b) Keep current their professional knowledge and skills
c) Provide opportunity to network with other health professionals at seminars and congresses.