

## SOUTH AFRICAN QUALIFICATIONS AUTHORITY (SAQA)

In accordance with Regulation 24(c) of the National Standards Bodies Regulations of 28 March 1998, the Task Team for

## Medical Technology

registered by Organising Field 09 - Health Sciences and Social Services, publishes the following Qualification for public comment.

This notice contains the titles, fields, sub-fields, NQF levels, credits, and purpose of the Qualification. The full Qualification can be accessed via the SAQA web-site at www.saqa.org.za. Copies may also be obtained from the Directorate of Standards Setting and Development at the SAQA offices, SAQA House, 1067 Arcadia Street, Hatfield, Pretoria.

Comment on the Qualification should reach SAQA at the address below and no later than 29 January 2010. All correspondence should be marked Standards Setting - Task Team for Medical Technology and addressed to

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## SOUTH AFRICAN QUALIFICATIONS AUTHORITY

## QUALIFICATION: <br> Bachelor: Medical Laboratory Sciences

| SAQA QUAL ID | QUALIFICATION TITLE |  |  |
| :--- | :--- | :--- | :--- |
| 7TOB3 | Bachelor: Medical Laboratory Sciences |  |  |
| ORIGINATOR |  | PROVIDER |  |

New NQF Level: NQF Level 08
This qualification does not replace any other qualification and is not replaced by another qualification.

## PURPOSE AND RATIONALE OF THE QUALIFICATION

Purpose:
This Qualification is intended to develop the academic skills, values and attributes necessary to create a practitioner with solid ethical principles and a desire for life-long learning. It will enable successful learners to become medical laboratory scientists who are employed in laboratory diagnostic services and who are able to successfully undertake research.

This Qualification will lead the learner through six focus areas that contribute to the main objectives of the medical laboratory sciences and which are reflected in the Qualification, viz:

- Diagnostic techniques required for the diagnosis and subsequent treatment of patients.
- Keeping a breast of new trends in technology, equipment and diagnostic methodology to ensure continued professional development of the medical laboratory scientist and in turn, promote improved health services to society.
- Developing research potential to place South African medical services at the forefront of international patient care.
- Developing management and quality assurance skills required for effective, efficient and sustained delivery of quality laboratory services supporting the medical profession.
- Ethical and safety considerations required to underpin the profession.
- Empathy and communication skills required by practitioners to deliver relevant and accurate information to the different health care participants and sectors.

On completion of this qualification, the graduate will be able to:

- Integrate laboratory tests with pathophysiological conditions in a chosen field of specialisation in accordance with statutory and operational requirements.
- Critically evaluate current and new trends in technology to improve practices and to solve problems in a variety of contexts.
- Conduct research in the field of medical laboratory sciences, in compliance with legislated and ethical research principles.
- Apply management and entrepreneurship skills in the context of medical laboratory sciences.

Compliance with statutory requirements including quality, ethics and safety underpin all exit level outcomes.

Successful completion of this qualification will enable the graduate to register with the Health Professions Council of South Africa (HPCSA) as a Medical Laboratory Scientist.

Rationale:

The medical laboratory scientist plays an integral role in the healthcare of society. The health sector relies on the effective diagnosis and management of patient care, as well as the implementation and management of a legislative framework that protects people's rights to reliable and accurate healthcare services. Qualified medical laboratory scientists are specialised health professionals who provide vital information about a patient's state of health. Their input is necessary in the diagnosis, monitoring and treatment of disease. The analytical and diagnostic services provided by medical laboratory scientists require a strong scientific knowledge, as well as trained reasoning ability and empathy for humanity.

There is a critical shortage in South Africa of highly skilled and suitably qualified medical laboratory scientists as a health care resource. This Qualification has been structured to meet that need through the development of higher level competencies associated with a professional degree at NQF Level 8.

The acquisition of advanced competencies is required by the sector in order to meet the legislative and operational requirements of the Health Professions Council of South Africa (HPCSA). The flexibility of career pathing for medical laboratory scientists, both vertically and horizontally, is possible through personal growth and job advancement within and across the health sector. Therefore the qualification provides for learners with operational competencies as well as management skills, including supervision, mentoring and leadership.

A variety of organisations operate within the health care sector, including a number of national departments; provincial and local health authorities; private and public laboratory services; forensic laboratories; medical research laboratories; medical practitioners, inter alia doctors specialists, dentists; pharmaceutical companies; medical supply companies and the medical laboratory scientist plays a vital role in all of these areas.

## RECOGNIZE PREVIOUS LEARNING?

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## LEARNING ASSUMED IN PLACE

It is assumed that learners accessing this qualification are competent in:

- Communication at NQF Level 4.
- Mathematics at NQF Level 4.
- Physical Sciences at NQF Level 4.
- Life Sciences at NQF Level 4.

Recognition of Prior Learning:
This Qualification may be achieved in part through the Recognition of Prior Learning. Evidence must be presented on application for recognition of prior learning and may take the form of verified testimonials, or other appropriate evidence, such as verified accounts of previous relevant work experiences or performance records.

All recognition of prior learning is carried out in accordance with the policies and procedures of the providing institution and in agreement with the relevance ETQA.

Access to the Qualification:
Learners accessing this Qualification will be expected to be in possession of a National Senior Certificate with Matriculation exemption, a relevant Further Education and Training Certificate, or equivalent NQF Level 4 qualification and comply with the selection policy of the relevant provider in agreement with the relevant Education and Training Quality Assurance body (ETQA).

It is recommended that applicants are fluent in English, as all major learning material is only available in that language medium.

## QUALIFICATION RULES

All the Exit Level Outcomes must be achieved for the learner to be awarded the Qualification.

## EXIT LEVEL OUTCOMES

1. Perform and integrate laboratory tests with pathophysiological conditions in a specific field of specialisation in accordance with statutory and operational requirements.

- Range of specialisations include: Medical Microbiology; Virology; Clinical Chemistry; Haematology; Clinical Pathology; Blood Transfusion Technology; Cytology; Histopathology; Cytogenetics; Immunology; Pharmacology; Forensic Medicine.

2. Evaluate current and new trends in technology to improve practices and to solve problems in a variety of contexts.

- Range of areas for evaluation include but are not limited to: Usefulness and practicality of equipment and methodologies in relation to laboratory constraints, integration with existing equipment, space, budgeting, standard operating procedures, laboratory safety procedures, infection control methods.

3. Conduct research in the field of medical laboratory sciences in compliance with legislated and ethical research principles.
4. Apply management and entrepreneurship skills in the context of medical laboratory sciences.

## Critical Cross-field Outcomes:

This Qualification addresses the following Critical Cross-field Outcomes, in the indicated Exit Level Outcomes.

- Identifying and solving problems is demonstrated in the process of performing laboratory tests, investigating new techniques and applying these in the workplace.
- Working effectively with others is demonstrated in the maintenance of laboratory etiquette and the adherence to ethical practices.
- Organising and managing oneself and one's activities responsibly and effectively is demonstrated in the presentation of a technically correct and valid research project.
- Collecting, analysing, organising and critically evaluating information is demonstrated in the application of the rules and principles of scientific investigation and supplying valid laboratory test results.
- Communicating effectively is demonstrated throughout all communication with stakeholders involved in health, laboratory functions and successful institutional management functions.
- Using science and technology effectively and critically is demonstrated in the preparation, analysis, investigation and reporting of findings of human tissue specimens.
- Demonstrating an understanding of the world as a set of related systems is demonstrated through the proper application of systems, policies and procedures related to laboratory work and practices within the functioning of the general health industry business processes.


## ASSOCIATED ASSESSMENT CRITERIA

## Associated Assessment Criteria for Exit Level Outcome 1:

1.1 Routine and specialised diagnostic techniques (including molecular biology techniques) in a specific field are selected, performed, interpreted and integrated in accordance with statutory requirements and situational standard operating procedures.
1.2 Laboratory results are evaluated through correlation of data in the context of the principles, techniques and instruments used.
1.3 Factors that affect procedures and test results are recognised and appropriate action is taken to nullify these.
1.4 Laboratory results are interpreted through correlation of data with physiological and pathophysiological conditions.
1.5 Findings are evaluated, interpreted and integrated through application of an in-depth knowledge of disease processes.
1.6 Equipment is monitored for efficient functioning and appropriate action is taken when necessary.
1.7 Laboratory safety procedures, including infection control, are described and applied throughout all operating procedures.
1.8 Quality assurance procedures are described and applied throughout all operating procedures.

## Associated Assessment Criteria for Exit Level Outcome 2:

2.1 The constraints within a given laboratory are analysed, synthesised and evaluated relative to the services required of the facility.
2.2 The use of new equipment is learned in depth to obtain the maximum use thereof.
2.3 Appropriate new techniques and methods are recommended on the basis of methodological scientific principles.
2.4 New techniques and methods which have been written up an/or presented formally are analysed, recommended with motivation and applied where applicable.

## Associated Assessment Criteria for Exit Level Outcome 3:

3.1 Research needs within the chosen specialisation in the field of medical laboratory sciences are appropriately identified, articulated and investigated.
3.2 Appropriate research methods are applied.
3.3 Applicable literature is reviewed and documented according to accepted scientific practices. 3.4 Data is accurately collected, analysed and interpreted using appropriate qualitative and/or quantitative techniques.
3.5 Research findings are evaluated and conclusions and recommendations, based on sound theoretical principles, are formulated.
3.6 A research report is produced and presented in accordance with the required institutional research guidelines.

## Associated assessment Criteria for Exit Level outcome 4:

4.1 Human, infrastructural, operational and financial resources are analysed and managed efficiently and effectively.
4.2 A business plan for a new medical laboratory service is developed, approved and implemented within a structured situation.
4.3 Principles of entrepreneurship skills are explained in terms of the proposed business model.
4.4 Current, relevant legislation is explained and applied where applicable, such as within the proposed business plan.
4.5 All clinical interactions and related activities are aligned with the provisions and rules of the relevant institution and the codes of ethics of the HPCSA and relevant professional associations. 4.6 All manner of communication, including appropriate use of electronic media and medical terminology, with patients, colleagues and other service providers, is clear, direct and accurate and delivered in terms of maintaining patient confidentially.

Integrated Assessment:
Formative and summative assessment strategies should be used throughout the qualification programme to ensure that exit level and cross critical outcomes are met.

Formative assessment may include:

- Tests.
- Written and practical assignments.
- Literature reviews.
- Case studies.
- Class presentations.
- Seminars.
- Peer evaluation.
- Simulations in structured learning environments.

Summative assessment may include:

- Written examinations.
- Oral examinations.
- Practical examinations.
- Supervisor reports where appropriate.
- Objective Simulated Clinical Evaluation Scenarios (OSCES).


## INTERNATIONAL COMPARABILITY

The challenge of selection for international comparability resides in the fact that direct comparison needs to consider a number of best practices internationally, while at the same time making provision for the diversity within the South African operating context. Internationally, qualifications in medical laboratory sciences e.g., Bachelor of Science in Biomedical Sciences, are not offered at the level of a diploma which strengthens the case for the South African Qualification to be upgraded to be in line with international practices. The context of South African legislation as it pertains to both the educational and health sectors supports the imperative for a professional qualification to be registered on the NQF.

## Australia:

The University of Technology Sydney (UTS) offers a Bachelor of Science in Biomedical Science as a three year full-time, or six year part-time degree. Alternately, learners can complete a four year full-time degree, with the successful completion of a diploma in Scientific Practice or 4 years full-time with Honours. This represents a fourth year and is required for full recognition to practice. Graduates with this qualification have professional recognition in overseas countries.

The UTS programme is not in an outcomes based format which makes it difficult to compare credit allocation. However, components of the course similar to those of the South African Qualification consist of Physiology, Pathophysiology, Immunology, Molecular Biology and clinical subjects such as Haematology and Microbiology. The overall credit points for this qualification is 144 credit points of which 24 credit points ( cp ) consist of electives that may be taken as a sub-major. This is a four year full-time study programme recognised by the Australian Institute of Medical Scientists (AIMS).

## Course Programme:

- Statistical Design and Analysis: 6 cp .
- Chemistry 1A: 6 cp .
- Cells, Genetics and Evolution: 6 cp .
- Medical Science I: 6 cp.
- Chemistry 2A: 6 cp.
- Physical Aspects of Nature: 6 cp.
- Biomolecules: Structure and Function: 6 cp .
- Medical Science 2: 6 cp .
- General Microbiology: 6 cp .
- Metabolic Biochemistry: 6 cp .
- Anatomical Pathology: 6 cp .
- Immunology I: 3 cp .
- Haematology I: 3 cp .
- Molecular Biology I: 6 cp .
- Analytical Biochemistry: 6 cp .
- Epidemiology and Public Health Microbiology: 6 cp .

The above make up the core modules.
Learners need to select 6 credit points from one of the following in their second year:

- Biotechnology: 6 cp .
- Physiological Systems: 6 cp .

In their third year learners need to select 24 credit points (12 credit points from group 1 and 12 credit points from group 2 , respectively) from one of the following electives.

Group 1:

- Cytopathology Part A.
- Clinical Bacteriology.
- Medical and Diagnostic Biochemistry.
- Haematology 2.
- Molecular Biology 2.
- Cytopathology.

Group 2:

- Transfusion Science.
- Cytopathology Part B.
- Biochemistry, Genes and Disease.
- Parasitology.
- Immunology 2.

These competencies compare favourably with the competencies outlined in the South African professional degree. In addition, the South African professional degree emphasises competencies such as laboratory management, quality assurance and ethical conduct, which are not explicitly stated in the competencies outlined in the Bachelor of Science in Biomedical Science as offered by UTS.

## New Zealand:

The second qualification used for comparison is the Bachelor of Medical Laboratory Sciences (Level 7) 480 credits offered by Auckland University of Technology (AUT) which is also recognised in Australia by the Australian Institute of Medical Scientists (AIMS).

This is a four year full-time study programme with the following specialisations:

- Clinical Chemistry.
- Haematology.
- Histology.
- Immunology.
- Medical Cytology.
- Medical Microbiology.
- Transfusion Science.

The specialisations in the programme offered at Auckland University of Technology are similar to those of the South African Qualification. The South African Qualification includes the additional specialisations of Virology, Cytogenetics and Clinical Pathology. It also requires specialisation in the theory of four majors and intense specialised practical competence in one discipline in the fourth year.

The core competencies of the Bachelor of Medical Laboratory Science (Level 7) offered by Auckland University of Technology include:

- Scientific Communications.
- Statistical Models.
- Microbiology.
- Organic Chemistry.
- General Chemistry.
- Histological Techniques.
- Human Anatomy and Physiology.
- Biological Chemistry.
- Genetics.
- Clinical Chemistry.
- Haematology.
- Immunology and Virology.
- Transfusion Sciences.
- Molecular Genetics.
- Research.

Wales:
The University of Wales Institute, Cardiff offers the BSc. Honours programme in Biomedical Sciences (Applied Biomedical Sciences) that is recognised by the Welsh National Health Service. This is similar to the South African Qualification in that it is also designed to encourage, develop, integrate and apply scientific knowledge, understanding and skills into a multidisciplinary investigation of human diseases and disorders. The core and fundamental competencies are similar to those of the South African Qualification.

In the first year learners cover Fundamental Biochemistry, Cell Biology and Genetics, Immunology, Microbiology and Human Physiology. Molecular Biology of the Cell, Epidemiology, Data Analysis, Research Methods, Medical Biochemistry, Disorders of Cells and Tissues, Public Health and Medical Microbiology are covered in the second year. The third year covers Biology and Laboratory Investigation, Molecular and Genetic Analyses and Molecular and Clinical Immunology. In addition, the third year contains a strong research component to encourage independent enquiry and critical analysis. Integrated work-based training is undertaken in the Welsh NHS accredited clinical laboratories. On successful completion of the integrated workbased professional training undertaken in a NHS accredited clinical laboratory, the learner is awarded a "certificate of competence" which assists eligibility of graduates successfully completing this course in applying to become registered with the New Zealand Health Professions Council.

## Zimbabwe:

The University of Zimbabwe offers an internationally recognised degree namely, Bachelor of Medical Laboratory Sciences (Honours degree). The competencies required are equivalent to those of the proposed South African Qualification. The theory component of the course is covered in the first, second and fourth years of study ( 900 hours per year) while the third year is dedicated to working in accredited clinical laboratories. Within the first year $70 \%$ of the time is dedicated to lectures and tutorials, $15 \%$ to practicals and $15 \%$ to student-based learning i.e., assignments, projects, and self-study. For the second and fourth year the distribution is $75 \%: 15 \%: 10 \%$ and $70 \%: 10 \%: 20 \%$, respectively. The design of the Zimbabwe programme differs from the South African Qualification in terms of the intended practical work-based learning. The extra semester spent on developing practical competence in the South African Qualification is considered to give strength to the graduate as a potential practitioner.

Namibia:

Namibia offers a similar degree at the Polytechnic of Namibia. This qualification is called the Bachelor of Biomedical Sciences degree and is worth 500 credits at NQF Level 8.

## Course Programme:

Year $1:$

- Human Physiology (including Pathophysiology, Genetics and Cytology).
- Chemistry I.
- Biostatistics and Calculations.
- Medical Physics.
- Laboratory Principles I (including Computer Literacy).
- Communication Skills I.
- Basic Molecular Biology.
- Immunology.
- Biochemistry.
- Applied Laboratory Principles.


## Year 2:

- Medical Microbiology 1.
- Cellular Pathology I.
- Haematology 1.
- Clinical Chemistry
- Biology of diseases.
- Medical Microbiology II.
- Haematology II.
- Cellular Pathology II.
- Clinical Chemistry II.
- Immunohaematology 1.


## Year 3:

- Medical Microbiology III (Pathophysiology integrated).
- Haematology III (Pathophysiology integrated).
- Clinical Chemistry III (Pathophysiology integrated).
- Cellular Pathology III (Pathophysiology integrated).
- Research Methodology (including higher level of Biostatistics).
- Laboratory Management.
- Integrated Clinical Pathology.
- Integrated Cellular Pathology.

Year 4:

- Integrated Clinical Pathology (at workplace).
- Research Project.

In terms of the credits, the Namibian qualification equates to 50 credits at NQF Level 5,75 credits at NQF Level 6, 235 credits at Level 7 and 140 credits at Level 8 . The total number of credits is 500 . In the South Africa Qualification the credit values are as follows: 76 credits at NQF Level 5, 114 credits at NQF Level 6, 158 credits at NQF Level 7 and 154 credits at NQF Level 8 . The total number of credits is 502 . There has been close collaboration between Namibian and South African professionals in the development of the Namibian qualification.

Conclusion:
The South African Qualification compares well with the Bachelor of Science in Biomedical Science as offered by the University of Technology: Sydney; Bachelor of Medical Laboratory Sciences (Level 7) 480 credits offered by Auckland University of Technology; the BSc. (Honours): Biomedical Sciences offered by University of Wales Institute, Cardiff's; the Bachelor of Medical Laboratory Sciences (Honours) offered by the University of Zimbabwe and the Bachelor of Biomedical Sciences degree offered by the Polytechnic of Namibia. The comparison is particularly strong with regard to the core operational areas of medical laboratory sciences. All the qualifications used for comparison are 4 year qualifications that require professional recognition before the graduates can practice.

In the qualifications selected for comparison a similarity of competencies is clearly identifiable, and in some instances, in order to meet the South African requirements in the field of medical laboratory sciences, the South African Qualification provides a broader scope of choice of specialisation. These requirements are catered for by the intended learning time in the work place, research competencies and the national standards set for the integrated exit level. assessment.

In contrast to all international qualifications investigated, assessment in the South African Qualification is strengthened by incorporation of the professional body requirements into the final summative examination. In addition, the South African Qualification is further strengthened over all the international qualifications used for caparison through the incorporation of a substantial research project to be undertaken by learners.

It is clear from the comparison of qualifications that a similar approach is followed with different focus areas to provide for South Africa's unique requirements. The main areas of competence shared amongst the qualifications are certainly equal to internationāl best practice.

## ARTICULATION OPTIONS

This qualification articulates horizontally with:

- ID 72371: Bachelor of Technology: Biomedical Technology, New NQF Level 8.

This qualification articulates vertically with:

- ID 74039: Master in Biomedical Technology, New NQF Level 9.


## MODERATION OPTIONS

- Anyone assessing or moderating assessment of a learner, against this Qualification must be registered as an assessor or moderator with the relevant ETQA, or with an ETQA that has a Memorandum of Understanding with the relevant ETQA.
- Assessment and moderation of assessments may be overseen by the relevant ETQA according to the policies and guidelines for assessment and moderation of that ETQA or relevant ETQA that has a Memorandum of Understanding with the ETQA.
- Any institution offering the Bachelor degree in Medical Laboratory Sciences must be accredited as a provider with the relevant ETQA, or with an ETQA that has a Memorandum of Understanding with the relevant ETQA and HPCSA.


## CRITERIA FOR THE REGISTRATION OF ASSESSORS

- Assessors must be registered in terms of the requirements of the relevant ETQA.
- Assessors and moderators must be used in a manner that fits into the quality management system of the provider and in accordance with the institutional tuition and assessment policies. This must also apply to the appointment of outside assessors and/or moderators.


## NOTES

On completion of this qualification, a graduate wanting to practice as a medical laboratory scientist will be required to register with the HPCSA. Unregistered medical laboratory scientists may only work in non-diagnostic laboratories.

The HPCSA requires a medical laboratory scientist to have an additional 2 years postregistration laboratory experience before full registration as a professional medical laboratory scientist with the HPCSA can be obtained.

UNIT STANDARDS
This qualification is not based on Unit Standards.

LEARNING PROGRAMMES RECORDED AGAINST THIS QUALIFICATION None

