No. 408 11 May 2007

SOUTH AFRICAN QUALIFICATIONS AUTHORITY (SAQA)

In accordance with Regulation 24(c) of the National Standards Bodies Regulations of 28 March 1998, the Standards Generating Body (SGB) for

Engineering

registered by Organising Field 06 – Manufacturing, Engineering and Technology, 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 he accessed via the SAQA web-site at www.saqa.org.za. Copies may aiso 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*** 77 ***June 2007.*** All correspondence should be marked Standards Setting – Engineering and addressed to

The Director: Standards Setting and Development
SAQA
*Attention: Mr. **D.** Mphuthing*
Postnet Suite 248
Private Bag X06
Waterkloof
0145
or faxed to 012 – 431-5144
e-mail: dmphuthing@saqa.org.za

DR. S. BHIKHA
DIRECTOR: STANDARDS **SETTING** AND DEVELOPMENT

SOUTH AFRICAN QUALIFICATIONS AUTHORITY

QUALIFICATION:

National Certificate: Medical Equipment Maintenance

SAQA QUAL ID	QUALIFICATION TITLE		
58495	National Certificate Medical Equipment Maintenance		
SGB		PROVIDER	
SGB Engineering			
ETQA			
National Certificate	6 -Manufacturing, Engineering and Technology	Engineering and Related Design	
ABET BAND	MINIMUM CREDITS	NQF LEVEL	QUAL CLASS
Undefined	120	Level 5	Regular-ELOAC

PURPOSE AND RATIONALE OF THE QUALIFICATION
Purpose:

This qualification is aimed at people who work or intend to work within the medical industry or healthcare environment, and who seek recognition for essential skills in maintaining medical equipment.

Recipients of this qualification know about and are able to maintain medical equipment to contribute towards safe and correct functioning of this equipment.

The qualification is designed to be flexible and accessible so that people are able to demonstrate the competencies required to work to pertinent standards relating to medical equipment.

People credited with this qualification are able to:

- Apply problem solving skills in the workplace.
- Maintain medical equipment.
- Apply scientific and engineering skills in the workplace.
- Communicate technical, supervisory and management information.
- Apply basic management principles in maintaining medical equipment.
- Identify and comply with work ethics and good practice.

Rationale:

The Department of Health in South Africa has identified that medical equipment used in hospitals has serious consequences to the user and patient if not maintained correctly. It is envisaged that people who maintain this equipment will need to be registered by law in order to ensure the professional conduct of practitioners, and to hold them accountable for the work they conduct. This qualification provides a learner with all the skills and knowledge required *of* a medical equipment maintainer and may be seen as a pathway towards registration.

The majority of the candidates applying for this qualification are likely to be working in the medical equipment industry or healthcare environment in either the public or private sectors. This qualification will give them the opportunity to demonstrate the balance between their practical skills and the essential knowledge acquired to be registered as a medical equipment maintainer.

There is a critical need in the health sector to identify ana develop people who are able to conduct the essential operations associated with efficient and safe maintenance of medical equipment, This will lead to competence in the field of work and thereby add quality and value to the sector and improve the standards of healthcare in the country. It will also lead to learners understanding how the work they do fits into the greater engineering industry relevant to the healthcare sector.

RECOGNIZE PREVIOUS LEARNING?
Y

LEARNING ASSUMED TO BE IN PLACE
It is assumed that learners are already competent in:

- Communication and Mathematical Literacy at NQF level 4.
- Basic sciences at NQF level 4.
- Basic knowledge of electrical theory.
- Selecting, using and caring for engineering tools and equipment
- Reading and interpreting engineering drawings.

Recognition of Prior Learning:

This qualification can be achieved wholly or in part through recognition of prior learning in terms of the defined exit level outcomes. but assessors must take full responsibility for assessing the exit level outcomes.

Evidence can be presented in various ways, including international andlor previous local qualifications, products, reports, testimonials mentioning functions performed, work records, portfolios, videos of practice and performance records. All such evidence will be judged in accordance with the general principles of assessment described above and the requirements for integrated assessment.

Access to the Qualification:

Access to this qualification is open bearing in mind learning assumed to be in place.

EXIT LEVEL OUTCOMES
1. Apply problem solving skills in the workplace.

2. Maintain medical equipment.
- Range: Candidates will be assessed against at least one of the following categories, dependent on their area of work:
  - Mechanical equipment.
  - Electro-medical equipment.
  - Respiratory and anaesthesia equipment.
  - Medical imaging equipment.

3. Apply scientific and engineering skills in the workplace

4. Communicate technical, supervisory and management information.

5. Apply medical equipment maintenance principles

6. Identify and comply with work ethics and good practice.

This qualification addresses the following Critical Cross-Field Outcomes:

- Identifying and solving problems in which responses indicate that responsible decisions using critical and creative thinking have been made.
  - Evident in Exit Level Outcome/s 1, *2.*

- Working effectively with others as a member of a team, group, organisation or community
  - Evident in Exit Level Outcomels 2, 4, *5.*

- Organising and managing oneself and one's activities responsibly and effectively
  - Evident in Exit Level Outcomeis 6.

- Collecting, analysing, organising and critically evaluating information.
  - Evident in Exit Level Outcomeis 1, *2,* 6.

- Communicating effectively using visual, mathematical and/or language skills in the modes of oraliwritten persuasion.
  - Evident in Exit Level Outcomeis 4.

- Using science and technology effectively and critically, showing responsibility towards the environment and health of others.
  - Evident in Exit Level Outcomeis 2, 3.

- Demonstrating and understanding of the world as a set of related systems by recognising that problem-solving contexts do not exist in isolation.
  - Evident in Exit Level Outcomels 1, *5,* 6.

- Learning programmes directed towards this qualification will also contribute to the full personal development of each learner and the social and economic development of society at large, by making individuals aware of the importance of:

  - Reflecting on and exploring a variety of strategies to learn more effectively.
  - Participating as responsible citizens in the life of local, national and global communities.
  - Being culturally and aesthetically sensitive across a range of social contexts.
  - Exploring education and career opportunities; and developing entrepreneurial opportunities

ASSOCIATED ASSESSMENT CRITERIA

1.

- Variances from medical equipment specifications are identified in a methodical manner that includes all areas of performance.
- Causes of faults are identified and actions taken, to prevent similar problems in the future, are appropriate to the symptoms.
- Alternative solutions to problems are identified that provide similar results.
- Solutions identified are efficient in terms *of* cost, time and reliability.
- Logical procedures are followed to correct all identified variances.
- Variances are corrected in accordance with recognised clinical engineering procedures or codes of practice.

2.

- Application and operation of medical equipment are described in the clinical environment.
- Policies for maintenance work are sourced and confirmed for applicability with relevant sources.
- The work area is prepared for the relevant activities in accordance with workplace requirements.
- Defects are identified from user reports and test procedures.
- Tools and test equipment used are appropriate to the equipment.
- Faults are identified through logical fault finding procedures.
- Medical equipment is repaired, maintained and calibrated in accordance with manufacturer specifications and relevant policies.

- Equipment performance and safety inspecrions are completed according to relevant check lists and specifications before returning equipment *to* use.
- .Accurate equipment history is captured and recorded for future reference for a time period relevant to equipment type maintained and legal policies.

3.

- Work functions are explained in terms of quality in engineering practice.
- Engineering risks are identified in terms of the potential impact for each risk on safety and performance of medical equipment.
- Actions to improve work functions are identified and analysed in terms of available options.
- Maierials are explained in terms of their properties and uses.
- Facrication principles are explained in terms of functions and accuracy.
- Flow Characteristics are explained in terms of engineering principles.
  Measurements and related procedures are explained in engineering terms.

4.

- Work functions are explained in terms of quality in engineering practice.
  Engineering risks are identified in terms of the potential impact for each risk on safety and performance of medical equipment.
- Actions to improve work functions are idenrified and analysed in terms of available options.
- Materials are explained in terms of their properties and uses.
- Fabrication principles are explained in terms of functions and accuracy.
- Flow characteristics are explained in terms of engineering principles.
- Measurements and related procedures are explained in engineering terms.

5.

- Activities are planned in accordance with workplace requirements.
- Authorisation to conduct activities is obtained in accordance with workplace procedures.
- Potentially hazardous conditions are identified and reported in accordance with workplace requirements.
- Deviances from acceptable standards are identified and reported to the relevant stakeholder in accordance with statutory requirements and manufacturer specifications.
- The consequences of omitting procedures are explained in terms of potential risks and liability
- Work activities are completed within agreed timeframes. The importance of completing activities in these timeframes is explained in terms of customer *service* and work interruptions.

6.

- Professional conduct is explained in accordance with relevant acts, codes of conduct and practice.
- Work is conducted in accordance with relevant acts.
- Recognised clinical engineering principles are adhered to in order to preserve patient and public safety.
- Work is conducted in accordance with agreed economic and safety requirements.

Assessment Principles:

Assessment should be in accordance with the following general and specific principles:

- The initial assessment activities should focus on gathering evidence in terms of the main outcomes expressed to ensure assessment **is** integrated rather than fragmented. Where assessment at the broader level is unmanageable, then the assessment can focus on each assessment criterion, or groups of assessment criteria

- Evidence must be gathered across the entire range specified in each Exit Level Outcome, as applicable. Assessment activities should be as close *to* the real performance as possible, and where simulations or role-plays are used, there should be supporting evidence io prove that the candidate is able to perform in the real situation.

- All assessments should be conducted in accordance with the following universally accepted principles of assessment:

c Use appropriate, fair and manageable methods that are integrated into real work-related or learning situations.

c Judge evidence on the basis of its validity, currency, authenticity and sufficiency.

a Ensure assessment processes are systematic, open and consistent.

INTERNATIONAL COMPARABILITY

This qualification has been compared to qualifications within various countries and it has been found that South Africa and Japan are the only countries that have a legal requirement for certification of practitioners to maintain medical equipment. Many countries investigated were found to use the terms "Bio-medical engineer" and "Clinical engineer" as interchangeable, but these terms do not always mean the same thing. It should be noted that the word "engineer" is often used to describe a practitioner other than a registered engineer. Other countries have requirements for medical equipment maintainers, and the related qualifications for these practitioners have been compared to this qualification as follows:

USA:

Practitioners in America are required to achieve a two-year bio-medical qualification prior to being allowed to maintain medical equipment. That qualification includes electrical and computer engineering, as well as anatomy and physiology and is comparable to this qualification. America has progressive qualifications building on their two-year programme that lead to a diploma and degree in clinical engineering. Training in specific medical equipment is provided by equipment manufacturers, and practitioners are required to undergo specific training prior to being employed to work with or on specific equipment.

China:

There are no specific regulations for medical technicians in China, but in order for a person to be recognised as competent to work on medical equipment, they should have graduated from university with a three year engineering programme with elective subjects in clinical engineering. This equates to NQF level 6 and above, and is beyond the scope of this qualification. Medical companies are required to have a certain number of specialised technicians in order to obtain a trading license for dealing with medical equipment.

Europe:

Practitioners responsible for maintaining medical equipment have a range of qualifications that they may apply for in the UK. starting with EMME (Level 2) Safety Testing of Medical Electrical Equipment, then progressing to EMBC (Level 3) Biomedical Equipment Maintenance Practice, where after specialisation may be identified in one of ventilation equipment, anaesthetic equipment or defibrillator equipment. Training towards these qualifications is provided by workplace training institutes and higher education providers. The range of qualifications is more specific than the South African qualification and does not provide the same broad aspects covered in this qualification. Student exchange programmes between Europe and South Africa have identified equivalence at NQF level 6 and above in this field.

The European community is currently engaged in harmonising training programmes and regulations relating to health technology. This qualification can further be compared to the European standards once this is completed.

Australia:

80-95% of Australian medical equipment practitioners are at the associate or technician level. Generic engineering qualifications are obtained from various engineering training institutions

and candidates then migrate into the medical equipment maintenance field. Registration with a joint professional engineering body is on a voiuntary basis. The balance of medical equipment practitioners are at a higher level, and beyond the scope of this qualification.

Africa:

Kenya and Nigeria have training programmes equating to NQF level 5 that lead to qualifications in medical equipment maintenance. Ghana has a qualification in bio-medical engineering, which is beyond the scope of this qualification. SADC countries mostly send candidates to South Africa for training in medical equipment maintenance, and it is anticipated that this qualification will be adopted by them in its entirety.

ARTICULATION OPTIONS

This qualification articulates horizontally with the foliowing qualifications:

- National Certificate in Electrical Engineering: Light current, NQF level 5. (Under Construction)
- Nationai Certificate in Mechanical Engineering, NQF level 5. (Under Construction)
- ID 49746: National Certificate in Measurement, Control and Instrumentation, NQF level 5.

This qualification articulates vertically with the following qualifications:

- National Diploma in Electrical Engineering, NQF level 6. (Under Construction)
- National Diploma in Mechanical Engineering, NQF level 6. (Under Construction)

MODERATION OPTIONS

- Providers offering learning towards achievement of any of the outcomes that make up this qualification must be accredited through the Engineering Council of SA.

- Internal moderation of assessment must take place at the point of assessment with external moderation provided by the relevant ETQA in conjunction with the heaithcare sector, according to the moderation guidelines and the agreed ETQA procedures.

- Providers of programmes shall in the quality assurance process demonstrate that an effective moderation process exists to ensure that the assessment system is consistent and fair.

CRITERIA FOR THE REGISTRATION OF ASSESSORS

Registration of assessors is delegated by the Higher Education Quality Committee to the Higher Education providers responsible for delivering learning programmes. The following criteria are specified for assessors concerning the technical aspects of the qualification:

- Registration with ECSA and at least 5 years practical experience in a clinical engineering environment.
- Appropriate experience and understanding of assessment theory, processes and practices.
- Good interpersonal skills and ability to balance the conflicting requirements of the interests of the learner, the provider and the employer.

UNIT STANDARDS

This qualification is not based on Unit Standards.