



An Effective Regulator Assuring Engineering Excellence

Discipline-Specific Training Guide for Registration as a Professional Engineer in Biomedical Engineering and a Professional Engineer, Technologist, or Technician in Clinical Engineering

R-05-BCE-PE/PT/PN

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INTRODUCTION

All persons applying for registration as Professional Engineers, Technologists, and Technicians are expected to demonstrate the competencies specified in document **R-02-STA-PE/PT/PN** through work performed at the prescribed level of responsibility, irrespective of the Candidate's discipline.

The Training and Mentoring Guide for Professional Categories (document **R-04-T&M-GUIDE-PC**) provides key aspects of training, which are as follows:

- duration of training and length of time working at level required for registration
- principles of planning, training, and experience
- progression of training programme
- documenting training and experience
- demonstrating responsibility.

It is, therefore, important to standardise the framework for all engineering disciplines to ensure that all ECSA registration Categories are aligned.

This DSTG combines Biomedical Engineering and Clinical Engineering into a unified training guide that prepares Applicants from both streams. Applicants seeking professional registration in Biomedical Engineering are limited to the Engineer Category; however, Applicants seeking registration under Clinical Engineering may register under one of three Categories—Engineer, Technologist, or Technician—depending on their engineering qualifications.

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DEFINITIONS

Applicant: A person applying to the ECSA for registration in any of the Categories as per section 18 of the Engineering Professions Act, No. 46 of 2000.

Broadly defined engineering problems: Composed of many interrelated conditions and requiring underpinning methods, procedures, and technical judgement to create a solution within a set of originally broadly defined circumstances.

Candidate: A person registered with the ECSA in a Candidate Category of registration.

Clinical Engineering: A discipline that is primarily responsible for managing and maintaining medical devices and related systems.

Competency Assessment: A summative assessment of an Applicant's competence against the prescribed standard based on evidence from the Applicant's work and other assessments that include a Professional Review.

Competency Standard: Statement of competency required for a defined purpose.

Engineering problem: A problematic situation that is amenable to analysis and solution using engineering sciences and methods.

Engineering science: A body of knowledge based on the natural sciences that uses mathematical formulation where necessary and that extends knowledge and develops models and methods to support its application to solve problems and provide the knowledge base for engineering specialisations.

Health technology: The devices, drugs, and medical and surgical procedures, and the knowledge associated with these that are used in the prevention, diagnosis, and treatment of disease, in rehabilitation, and in the organisational and supportive systems within which care is provided (WHO, 1997).

Ill-posed problem: Problems for which the requirements are not fully defined or may be defined erroneously by the requesting party.

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Integrated performance: An overall satisfactory outcome of an activity requires several outcomes to be satisfactorily attained. For example, a design requires analysis, synthesis, analysis of impacts, checking of regulatory conformance, and judgement in decisions.

Level descriptor: A measure of performance demands at which outcomes must be demonstrated.

Medical devices: An article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose.

Mentor: A professionally Registered Person who guides the competency development of a Candidate in an appropriate Category.

Outcome: A statement of the performance that a person must demonstrate to be judged competent at the professional level.

Practice area: A generally recognised or distinctive area of knowledge and expertise developed by an Engineering Practitioner by virtue of the path of education, training, and experience followed.

Range statement: The required extent of or limitations on expected performance stated in terms of situations and circumstances in which outcomes are to be demonstrated.

Supervisor: A person who oversees and controls engineering work performed by a Candidate.

Well-defined engineering problems: Problems composed of interrelated conditions and requiring underpinning methods, procedures, and techniques to create a solution within a set of originally well-defined circumstances.

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ABBREVIATIONS

BEng	Bachelor of Engineering
BEng (Tech)	Bachelor of Engineering in Technology
BME	Biomedical Engineering
BSc Eng	Bachelor of Science in Engineering
BTech (Eng)	Bachelor of Technology in Engineering
CE	Clinical Engineering
CEASA	Clinical Engineering Association of South Africa
CoP	Code of Practice
CPD	Continuing Professional Development
D&D	Design and Development
DSTG	Discipline-Specific Training Guide
ECSA	Engineering Council of South Africa
HT	Healthcare technology
HTA	Healthcare technology assessment
HTM	Healthcare technology management
IoMT	Internet of Medical Things
IUSS	Infrastructure Unit Support System
MSc Eng	Master of Science in Engineering
MEng	Master of Engineering
OEM	Original equipment manufacturer
OHSC	Office of Health Standards Compliance
R&D	Research and development
SAFHE	South African Federation of Healthcare Engineering
SLA	Service level agreement

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BACKGROUND

The illustration below defines the documents that comprise the Engineering Council of South Africa (ECSA) system for registration in Professional Categories. The illustration also locates the current document.

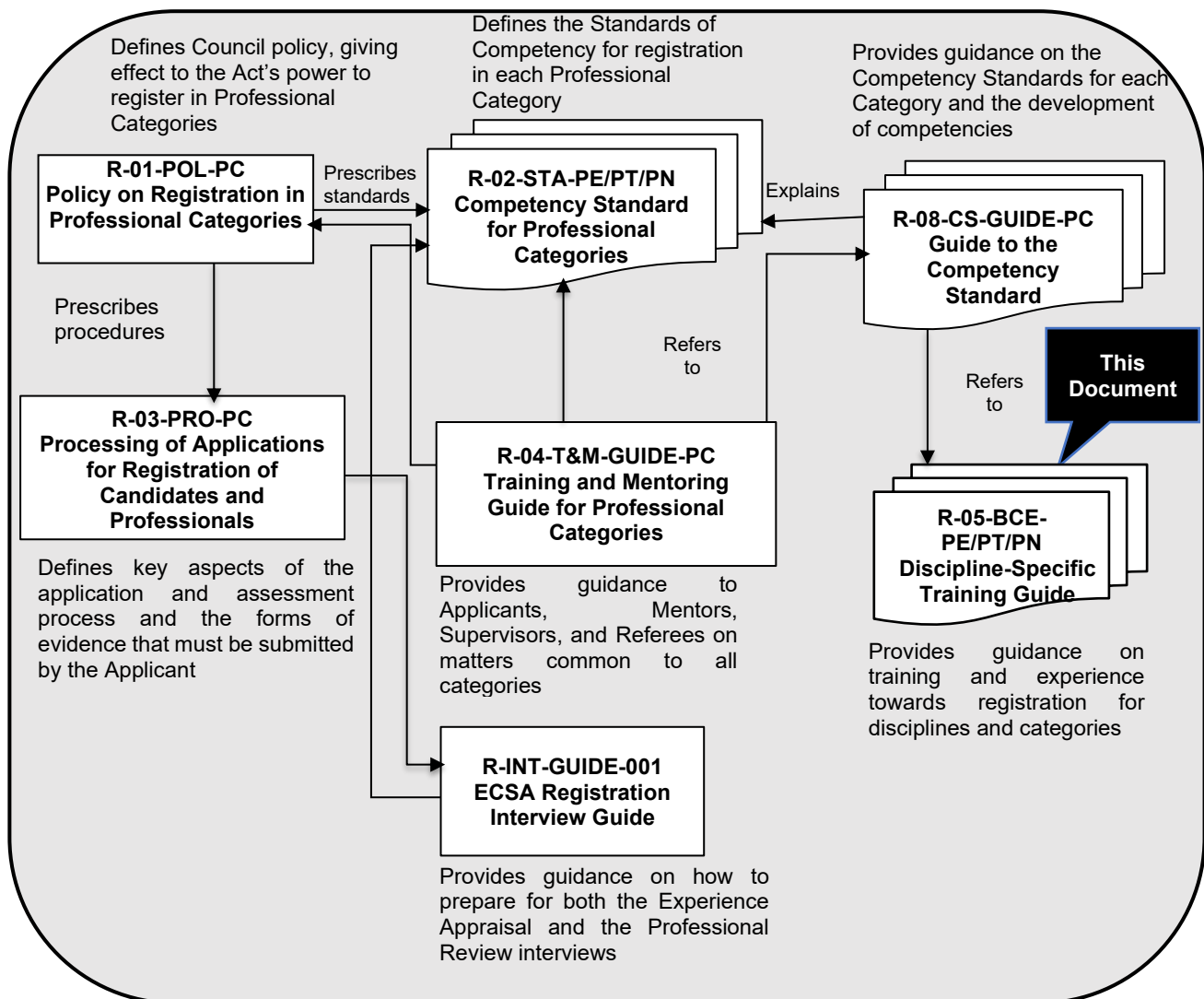


Figure 1: Documents defining the ECSA registration system

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1. PURPOSE OF THE DOCUMENT

All persons applying for registration as Engineering Professionals are expected to demonstrate the competencies specified in document **R-02-STA-PE/PT/PN** through work performed by the Applicant at the prescribed level of responsibility, irrespective of the trainee's discipline.

This document must be read in conjunction with the following:

- Policy on Registration in Professional Categories (document **R-01-POL-PC**)
- Processing of Applications for Registration of Candidates and Professionals (document **R-03-PRO-PC**)
- Training and Mentoring Guide for Professional Categories (document **R-04-TM-GUIDE-PC**).

2. AUDIENCE

This Discipline-Specific Training Guide (DSTG) is directed towards Applicants, Supervisors, and Mentors within the discipline of Biomedical and Clinical Engineering. It is intended to support a programme of training and experience incorporating elements of good practice.

The guide applies to persons who

- a. have registered with the ECSA as a Candidate Engineer, Technologist, or Technician
- b. hold an ECSA accredited qualification or acceptable combination of accredited qualifications prescribed for the Category:
 - i. Biomedical Engineering (BME) Applicants require a BEng, BSc Eng, or MSc Biomedical Engineering (or equivalent with an undergraduate qualification of a BSc or BEng) to be considered under the BME Category
 - ii. Clinical Engineering (CE) Applicants require a BEng or BSc Eng, an Advanced Diploma or Diploma (or equivalents as listed in the **R-02** documents) to be considered under the CE Categories
- c. have met the minimum educational requirement/s in a specific Category through an ECSA educational qualification evaluation or assessment

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- d. have qualifications accredited and/or recognised by international bodies where the ECSA is a signatory (i.e. Washington, Sydney, and Dublin Accords)
- e. hold a qualification or a combination of qualifications recognised under an international academic agreement relevant to the Category
- f. hold a qualification or combination of qualifications that have been determined by a case-by-case evaluation to satisfy the criteria for substantial equivalence to an accredited qualification for the Category by virtue of the following:
 - i. the qualifications being awarded in a jurisdiction or a quality assurance system by the ECSA, or
 - ii. an examination of detailed documentation on the qualifications reflecting substantial equivalence.

2.1 Persons registered as a Candidate with the ECSA

A Candidate Engineering Practitioner refers to a person registered with the ECSA after completing the relevant engineering undergraduate programme that is accredited or substantially assessed to be equivalent by the ECSA.

2.2 Persons not registered as a Candidate with the ECSA

Regardless of the training development path followed by any individual, all persons wishing to register with the ECSA must present the same evidence of having met the ECSA-prescribed Competency Standard when assessed.

A discipline-specific Voluntary Association (VA) recognised by the ECSA may be consulted to assist the trainee with an external Mentor. The Mentor must be familiar with all expected stages of the training development process and the ECSA's registration requirements.

It should be noted that this guide is intended to assist graduates who are still gaining work experience and knowledge towards professional registration. Experienced persons wishing to register as a professional may apply this guide retrospectively to identify possible gaps in their respective training and development and/or request a Mentor to act as an application adviser while preparing their professional registration.

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Document **R-08-CS-GUIDE-PE/PT/PN** adequately describes what is expected of individuals whose formative developments have not followed conventional paths, for example, academics, researchers, and specialists.

2.3 Persons registered with the ECSA in Professional Categories

Any person currently registered with the ECSA as a professional in another discipline but wishing to switch or change to BME or one of the CE Categories may apply this guide retrospectively to identify possible gaps before reapplying in the respective Category. This discipline-switch requires Applicants to reapply and be evaluated based on the new discipline's competency requirements, which may include extensive experience, training, and development. The discipline-switch requirement is also applicable to Registered Persons who wish to include BME or CE Categories in their dual-discipline registration, which may include a recognised combination of qualifications as an additional requirement.

Applications for these individuals are assessed on a case-by-case basis to satisfy the requirements of the new discipline. Applicants should be directed to ECSA's documents **R-01-POL-PC** and **R-03-PRO-PC** for the applicable process.

3. TYPE OF ENGINEERING WORK

Practitioners identify gaps in the healthcare clinical areas and design devices and systems to improve the service outcomes.

Practitioners use their specialised engineering knowledge in implementing healthcare technologies and strategies in hospitals and other healthcare settings. The selection, installation, and ongoing support of appropriate technologies and associated devices used by healthcare professionals are critical to the delivery of safe and effective healthcare.

Over the years, practitioners in this discipline have come from other disciplines such as Electrical/Electronic, Mechanical, Mechatronics, and Industrial Engineering. This was due to the slow introduction of BME and CE in the institutions of higher learning in the country. Therefore,

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Applicants from the above-mentioned disciplines with proven years of experience performing CE tasks will be considered.

Medical-device innovation is the primary focus of BME, which covers the full range of risk profiles and may include inhalers, face shields, splints, injectors, transcatheter heart valves, diagnostic imaging systems, and sterilising agents.

Table 1: Summarised differences between Biomedical Engineering and Clinical Engineering

Aspect	Biomedical Engineering	Clinical Engineering
Qualifications	▪ Pr Eng 4-year BEng / BSc Eng BME (NQF level 8) 4-year MSc BME (NQF level 9)	▪ Pr Eng 4-year BEng/BSc Eng (NQF level 8) ▪ Pr Eng Tech 4-year Advanced Dip (NQF level 7) ▪ Pr Eng Techni 3-year Diploma (NQF level 6)
Key Focus	▪ Design, development, and innovation	▪ Application, management, and maintenance
Work Environment	▪ Tech companies and research laboratories	▪ Vendor companies and healthcare facilities

3.1 Tasks of the Clinical Engineering Professional

Infrastructure projects

Infrastructure projects within the health sector refer to the construction of new health facilities or their refurbishment, renovation, and rehabilitation. Practitioners provide technical input during the planning, design, construction, and commissioning of projects. These include advising on technology services requirements, room setup, device location, and the technical specifications of the device.

The practitioners are responsible for furnishing and equipping completed healthcare facilities, healthcare technology (HT) acceptance testing, end-user training, compilation and consolidation of HT documentation (e.g. licences, certificates, services, and maintenance plans). Applicants must have extensive knowledge of the different standards and financial and project management.

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Healthcare facilities

Practitioners provide professional advice for procurement purposes in terms of technical specifications based on end-user needs, clinical protocols, and technology requirements. This includes installation and testing after procurement. Tasks include support and maintenance of medical devices and conducting continual training in the technical and operational aspects of the devices.

Industry service providers (vendor companies)

The practitioners in this environment are responsible for the support and maintenance of medical devices as per the recommendations and regulatory requirements of the original equipment manufacturer (OEM). Moreover, CE Professionals conduct device assembly and OEM-sanctioned refurbishment/upgrades.

3.2 Tasks of the Biomedical Engineering Professional

The various biomedical career paths can be broken down as follows:

- MD&I: Medical Devices and Instrumentation
- B&RE: Biomechanics and Rehabilitation Engineering
- BS&I: Biomedical Signals and Imaging
- TE&B: Tissue Engineering and Biomaterials

Career/Industry Matrix

Industry	MD&I	B&RE	BS&I	TE&B
Pharmaceuticals				x
Biotechnology		X		
Diagnostics	X		X	
Biomedical research tools	X	X	X	
Medical devices	X			x
Regenerative medicine		x		x
Digital health	X		x	

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Dominant Focus of Career Paths

Function	MD&I	B&RE	BS&I	TE&B
Design and development	X	X		
Research and development			X	X
Regulatory compliance	X			
Manufacturing readiness	X			
Life-cycle management	X			
Clinical trials		X		
Human factors		X		
Software validation			X	
Preclinical/clinical testing				X
Ethics				X

These skills may be applied to devices that are not yet regulated or classified as medical devices. Biomedical Engineers may also work on other areas within the medical sphere, including Computation Fluid Dynamics (CFD) models for the simulation of brain aneurysms or blood clots, imaging, and biomechanical modelling.

Biomedical Engineering Professionals research and develop manufactured materials and biomaterials that are derived from natural living tissue originating from hominine, porcine, bovine, ovine, crustacean, and selachian tissue.

Manufactured materials can range from metals and alloys to polymers and composites. Biomaterials comprise any materials used to interact with a biological system.

Research and development

This takes place in product-development centres (private companies) and at institutions of higher education. Practitioners undertake research and development (R&D) work that involves the review of existing medical devices, the design of new devices, product clinical trials, and in-depth application of various aspects of HT.

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4. DEVELOPING ENGINEERING COMPETENCIES: DOCUMENT

4.1 Training for registration as a Professional Biomedical Engineer

4.1.1 Outcome 1: Define, investigate, and analyse complex engineering problems

Outcome description

To perform engineering work, Applicants must be able to define complex problems. This involves defining the core issue in addition to any sub-issues and/or contributing factors.

Engineers investigate the problem by drawing on personal knowledge and skills and by consulting experts and stakeholders, researching related literature, reviewing existing technologies, and identifying current limitations. Common collaborators include the full spectrum of healthcare professionals in addition to researchers and patients.

Engineers analyse the problems by brainstorming different solutions based on pertinent skills and information. Thereafter, they evaluate the solutions based on feasibility and relevance and select the most appropriate solutions for further evaluation.

Complex engineering problems have the following characteristics:

- a. Require in-depth fundamental and specialised engineering knowledge, and one or more of the following:
 - Are ill-posed, under- or over-specified requiring identification and refinement
 - Are high-level problems including component parts or sub-problems
 - Are unfamiliar or involve infrequently encountered issues
- b. and one or more of the following:
 - Solutions are not obvious and require originality or analysis based on fundamentals
 - Are outside the scope of standards and codes
 - Require information from a variety of sources that is complex, abstract, or incomplete
 - Involve wide-ranging or conflicting issues: technical, engineering, and interested or affected parties

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c. and one or both of the following:

- Require judgement in decision-making in uncertain contexts
- Have significant consequences in a range of contexts

The problem may be a design requirement, an applied R&D requirement, or a problematic situation in an existing component, system, or process.

Typical tasks associated with the outcome:

- Ability to identify/recognise complex engineering problems in the health delivery system
- Conduct and use research or evidence-based methods for decision-making and advise on possible solutions
- Consult on policy development and infrastructure projects
- Apply risk management and failure mode analysis
- Analyse and report on complex medical devices using dedicated diagnostic tools

Competencies

Applicants should possess the following:

- A research background on clinically related matters
- A complete understanding of a wide range of medical devices and their life-cycle management
- A demonstrated ability to define the complex engineering problem by developing user needs, user requirements, and design inputs in accordance with applicable medical device design standards (ISO 13485 clauses 7.3.2–7.3.3, ISO 14971, IEC 62366-1).

4.1.2 Outcome 2: Design or develop solutions to complex engineering problems

Outcome description

Solutions to complex engineering problems often require significant time, money, materials, and skills. It is not uncommon during an engineering project to have unforeseen circumstances that may shift the resources required for project completion. It is, therefore, essential for Applicants to recognise the importance of planning and to anticipate changes that may affect the available resources and the final project outcome. Applicants must have effective planning skills to ensure

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that projects are delivered successfully against the defined scope and resources. In industrial BME practice (medical device development, manufacturing, regulatory environments), Applicants must demonstrate on-time, on-budget project delivery. In research and academic BME contexts, Applicants should demonstrate sound research governance, milestone-based progress reporting, and responsible stewardship of grant funding and institutional resources.

Solutions are developed predominantly through either research or design. Biomedical Engineers often perform at the forefront of modern medicine and commonly gain experience in both research and design at some point in their careers.

Research and development can be described as early-stage development that precedes design and development (D&D). The focus of R&D is to discover and innovate solutions and apply them to new products and services or to use them to improve existing ones; the research method usually results in a functional prototype. Research and development is predominantly handled by academic and research institutions, often in collaboration with healthcare professionals and industry. All solutions must meet safety and ethical standards.

Design and development translates solutions developed through research into regulation-compliant products. In the design of medical devices during D&D, the focus is on meeting users' needs while also meeting regulatory requirements. Medical devices are also designed for manufacturability, reliability, and cost-effectiveness. Once design specifications are frozen, prototypes are produced and iterated upon pending testing and validation results. All solutions in the design method must meet safety requirements and ethical standards; further standards must be met to allow the product or service to become marketable.

In summary, R&D and D&D can be paraphrased as follows:

a. R&D

- Early-stage development that precedes the D&D phase
- Development with a focus on exploration, feasibility, and innovation
- Involves researching previous data and literature, experimental testing, and proof of concept work

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b. D&D

- Turns concepts into functional, manufacturable, and market-ready products. Moreover, D&D is built upon R&D in addition to previous iterations of the product, should they exist.
- Involves design refinement, prototyping, and testing for compliance with standards.

Typical tasks associated with the outcome:

- Integrating new technologies such as artificial intelligence (AI), Internet of Medical Things (IoMT), robotics, and devices with machine learning
- Applying physiological principles to develop technological advances
- Designing new medical devices, prototyping, and manufacturing instruments with an emphasis on safety and reliability elements
- Designing and developing health systems to solve complex medical challenges or constraints in clinical areas

Competencies

Applicants should possess the following:

- A good understanding of biosensors, signal modelling, and simulation
- A basic knowledge of human biology and physiology
- Troubleshooting capabilities relating to software and digital health systems
- A comprehensive knowledge of circuit design and systems engineering
- A comprehensive knowledge of biomaterials, mechanical properties, and failure analysis as applied to the design, testing, and validation of medical devices, including understanding of fatigue, corrosion, tribology, and biocompatibility requirements (according to ISO 10993 and relevant device-specific standards)
- Proficiency in 3D parametric computer-aided design (CAD), including part modelling, freeform surface modelling, and top-down assembly design experience with rapid prototyping and additive manufacturing for functional design verification.

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4.1.3 Outcome 3: Comprehend and apply widely applied principles underpinning good practice specific to the jurisdiction in which the Engineer practises

Outcome description

This outcome requires Engineers to be able to comprehend and apply widely applied principles underpinning good practice that are specific to the jurisdiction in which the Engineer practises. For Professional Biomedical Engineers, this includes mandatory familiarity with internationally recognised medical device quality and risk management standards—specifically ISO 13485:2016 (Quality Management Systems for Medical Devices) and ISO 14971:2019 (Risk Management for Medical Devices)—that together define the foundational framework for compliant device development and commercialisation globally.

Typical tasks associated with the outcome:

- Attend training (theoretical and practical) to acquire competencies within the area of practice.
- Manage resources within legislative frameworks and budget.

Competencies

Applicants apply theoretical knowledge gained from completing their BEng, BSc or MSc in BME and in addition, demonstrate the ability to

- Comprehend and integrate clinical and engineering principles to achieve safe, effective, and sustainable healthcare solutions
- Understand not only their engineering standards and code of practice (CoP) but also have knowledge of applicable frameworks such as health regulations, legislation, medical protocols, and clinical practice
- Demonstrate a working knowledge of ISO 13485:2016 and ISO 14971:2019 and where applicable, of IEC 62304 and IEC 62366-1 as core good-practice frameworks governing medical device development in South Africa and internationally.

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4.1.4 Outcome 4: Manage part or all of one or more complex engineering activities

Outcome description

This outcome focuses on the capacity of the Professional Biomedical Engineer to manage complex engineering activities within the contexts of medical device development, R&D, and product life cycle. These activities require the Engineer to co-ordinate multi-disciplinary teams—spanning engineering, clinical, regulatory, and scientific functions—and to exercise leadership across individual project workstreams or entire product-development programmes.

Management in the BME context demands the ability to balance technical rigour with regulatory compliance, resource constraints, and the inherent uncertainty of translational research and device development. Applicants are expected to demonstrate both independent project management capability and the ability to lead or contribute to cross-functional teams working within structured design-control frameworks.

Typical tasks associated with the outcome:

- Manage part or all of a medical device D&D project, including design planning, stage-gate reviews, design verification and validation, and design transfer to manufacture
- Manage an R&D programme, including milestone planning, resource allocation, risk management, and reporting to project stakeholders or funding bodies
- Lead or co-ordinate a multi-disciplinary project team comprising Engineers, Clinicians, Scientists, and Regulatory Specialists
- Manage regulatory submission activities, including compilation of technical files, design dossiers, or submissions to SAHPRA, EU Notified Bodies, or equivalent authorities
- Manage vendor, supplier, or contract research organisation (CRO) relationships within a device-development or clinical-study context
- Oversee risk-management activities throughout the product life cycle in accordance with ISO 14971

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Competencies

Applicants are tested on the following:

- Demonstrated management of a complex engineering project with evidence of planning, execution, and delivery
- Application of a recognised design-control framework (e.g. ISO 13485 D&D process)
- Resource and budget management within a technical project environment
- Leadership of or meaningful contribution to a multi-disciplinary team
- Knowledge of regulatory project management requirements applicable to medical device development
- Identification and escalation of project risks and implementation of mitigation strategies.

4.1.5 Outcome 5: Communicate clearly using multiple media and collaborate inclusively with a broad range of stakeholders in the course of engineering activities

Outcome description

Engineers are expected to possess the communication skills that are required to communicate effectively with others during all engineering activities. This involves being able to speak and write or communicate in a way that is in the correct syntax and is appropriate to the context.

Engineers should be able to produce succinct and effective documents that are technically, legally, and editorially sound.

Engineers are also expected to have broad communication skills that will allow them to communicate the solution to a variety of different groups. These groups may comprise experts not involved in the solution, non-expert stakeholders, students, the community at large, and many other potential audiences. Communication can involve using visual aids to help provide context, language that is at an appropriate level for the audience (i.e. reduce the number of technical terms for non-Engineers), and presentations that provide enough information for the audience while also being comprehensible.

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Typical tasks associated with the outcome

Applicants are expected to

- make written reports and oral presentations using structure, style, language, and visual aids that are audience appropriate and fulfil the purpose
- collaborate with diverse stakeholders (clinicians, nurses, administrators, and other health professionals) during medical device procurement by translating technical data/specifications to language that is understandable within this interdisciplinary committee.

Competencies

Applicants must have the ability to write clear technical reports that are legally sound and easily translatable to different stakeholders.

4.1.6 Outcome 6: Recognise the reasonably foreseeable economic, social, cultural, and environmental effects of complex engineering activities seeking to achieve sustainability

Outcome description

In the healthcare sector where social and environmental considerations are primary, projects and/or engineering activities may require an impact assessment report.

Typical tasks associated with the outcome:

- Conduct socio-economic, cultural, and environmental impact assessments before complex engineering activities
- Consult multiple stakeholders

Competencies

Applicants should show knowledge of conducting impact assessments and reporting for consideration and should demonstrate the following:

- Competent assessment of social, cultural, and environmental effects

and answer the following:

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- Does the development, design, or use of a solution conflict with the values of any cultural groups?
- Is the solution appropriate in an applied social context?
- What are the effects of developing and testing on the environment?
- What are the effects caused by the manufacture and delivery of the device?
- What are the effects when in the consumer's possession (both during and between uses)?
- How does disposal affect the environment?

4.1.7 Outcome 7: Observe appropriate legal and regulatory requirements and take reasonable steps to protect the health and safety of persons during all complex engineering activities

Outcome description

This outcome not only requires Engineers to comply with engineering regulatory standards but also requires explicit alignment with healthcare/medical frameworks.

Applicants are expected to have a working knowledge of the following Acts, Regulations, and Standards and an understanding of how these affect their working environment:

- Engineering Profession Act, No. 46 of 2000
- Overarching Code of Practice for the Performance of Engineering Work, document **R-01-CoP**, Dec 2020
- Occupational Health and Safety Act, No. 85 of 1993
- Hazardous Substances Act, No. 15 of 1973
- Protection of Personal Information Act (POPIA) – Amended Regulations (2025)
- National Core Standards for Health Establishments in South Africa (Office of Health Standards Compliance [OHSC])
- Medicines and Related Substances Act, No. 101 of 1965 (as amended in 2008 and 2015)
- Medical Devices and In Vitro Diagnostics Guidelines (SAHPRA)
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 9001:2015 Quality Management Systems – Requirements

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- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO/TR 24971 Medical Devices – Guidance on the application of ISO 14971
- EU Medical Devices Regulation, No. 745 of 2017
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62304:2006+AMD1:2015 – Medical Device Software—Software Life-Cycle Processes
- IEC 62366-1:2015+AMD1:2020 – Medical Devices—Usability Engineering
- ISO 10993 Biological Evaluation of Medical Devices
- ISO 15223-1:2021/AMD 1:2025 – Symbols to be used with information supplied by the manufacturer – Part 1: General requirements
- FDA 21 CFR Part 820 – Quality System Regulation / Quality Management System Regulation (United States Food and Drug Administration)
- FDA Guidance Documents on Device Design Controls and Risk Management (21 CFR 820.30).

Competencies

Applicants must demonstrate a working knowledge of the Acts, Regulations, and Standards listed above as they apply to their area of practice in addition to a functional understanding of how the requirements of medical device quality management (ISO 13485:2016) and risk management (ISO 14971:2019) govern their engineering activities:

- Working knowledge of the applicable statutory and international regulatory framework and how it shapes the Applicant's working environment
- Application of a medical device quality management system (ISO 13485:2016) to govern engineering activities
- Application of a life-cycle risk management process (ISO 14971:2019, guided by ISO/TR 24971) to control risks to patients, users, and third parties
- Compliance with device-specific safety, performance, biocompatibility, and labelling standards (e.g. IEC 60601-1, IEC 62304, IEC 62366-1, ISO 10993, ISO 15223-1).

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4.1.8 Outcome 8: Conduct engineering activities ethically

Outcome description

The work performed by Biomedical Engineers focuses on individuals' well-being and, therefore, many decisions have immediate and/or lifelong implications. Biomedical Engineers are often in possession of highly sensitive patient data and are often involved in animal testing and the use of human cadavers, which are both high-value resources that have ethical implications of their own. As such, there is an uncompromising expectation of ethical behaviour from all Candidates.

Unethical behaviour could manifest as fraud, corruption, maladministration, and illegal activities.

Engineers are expected to conduct all engineering activities ethically, and this includes

- Avoiding intentional or unintentional plagiarism
- Not using or producing falsified data
- Ensuring all experiments are done ethically and, if necessary, obtain the required ethical approvals
- Not sharing confidential information such as patient data with unauthorised parties
- Ensuring all safety measures are followed for all project members, including the Applicant
- Adhering to all rules and regulations.

Applicants must understand that unethical conduct not only carries severe personal penalties but also damages the credibility and reputation of South African Biomedical Engineers, companies, academic institutions, and other institutions both locally and internationally.

Competencies

Applicants must have knowledge of the ECSA Code of Conduct and an understanding of how it relates to their area of practice.

4.1.9 Outcome 9: Exercise sound judgement by evaluating the outcomes, impacts, and alternatives in the course of complex engineering activities

Outcome description

Sound judgement in decision-making for complex engineering problems requires an integrated understanding of the solution by considering the interconnection with various factors:

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- Incorporating all pertinent regulatory policies and standards into projects
- Following internal company processes
- Considering the contexts of the solution and the nature and magnitude of any consequences
- Considering the needs of interested and affected parties
- Producing theoretical/conceptual models using engineering principles before creating and implementing a tangible product
- Analysing feasibility at various points in the project based upon new developments that may change the scope of the project and whether the current available resources are still sufficient.

Competencies

Applicants must demonstrate the ability to make sound decisions with incomplete information and competing interests in the course of complex engineering activities and to justify the outcomes, the impacts, and the alternatives that are being considered.

4.1.10 Outcome 10: Be responsible for making decisions on part or all of complex engineering activities

Outcome description

This outcome requires Applicants to make responsible decisions within their professional guidelines. Responsible decision-making in BME involves leaning into critical thinking and professional skills, following internal processes and procedures, and following standards and regulations.

Examples of responsible decision-making could include the following:

- ensuring that decisions relating to engineering activities conform with or do not violate standards or regulations
- making decisions that follow organisational procedures
- informing and discussing decisions with all stakeholders and/or collaborators before implementation

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- ensuring that decisions do not bring a project outside the scope of requirements and resources
- only making decisions within one's competence, function, and authority
- only performing project-related activities that conform with or do not violate any standards or regulations and that can be done safely with appropriate personal protective equipment (PPE), defined procedures, and training/certification
- ensuring that decisions are made based on the latest project developments—staying up to date with project developments could include the following:
 - checking recent reports or updates
 - reviewing recent documents
 - onsite inspections and meetings
 - interviewing stakeholders and/or collaborators
 - physical product inspections
 - responding to project-related emails, newsletters, and media releases
- ensuring that steady communication and collaboration are in place before implementing any decisions.

Competencies

Applicants must demonstrate how they were able to make decisions and take on responsibility for part of one or more complex engineering activities.

4.1.11 Outcome 11: Undertake sufficient professional development activities to maintain and extend competence and enhance the ability to adapt to emerging technologies and the ever-changing nature of work

Outcome description

This outcome requires Applicants to keep their personal knowledge up to date; this involves being aware of the latest technologies and changes in regulations and standards. Applicants should keep all relevant and necessary certifications up to date.

Applicant Engineers must register with relevant VAs to access pertinent training courses/conferences/seminars and other appropriate information:

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- Biomedical Engineering Society of South Africa (BESSA)
- South African Federation of Healthcare Engineering (SAFHE)
- Consulting Engineers South Africa (CESA).

Recommended training and courses include the following:

- ISO 13485:2016 training & certification
- ISO 9001 training & certification
- Healthcare & Biomedical Law: Compliance & Ethics Training Course in South Africa.

Conference attendance, employer-sponsored training, internships in the medical device industry, resources made available by international professional associations, multilateral organisations, and NGOs in addition to personal development opportunities should also be considered.

Conferences

- International Conference on Biophysical and Biomedical Engineering (ICBBE)
- International Conference on Biomedical and Health Sciences (ICBAHS)
- International Conference on Bioethics (ICB)

To maintain professional registration, non-retired Engineers are required to meet the Continuing Professional Development (CPD) requirements of the ECSA. Applicants should become familiar with and take part in ECSA CPD-approved programmes and courses.

Applicants must demonstrate that they are continuing to develop themselves and are required to provide proof of participation in courses, seminars/workshops, and conferences and/or evidence of furthering their studies.

4.2 Training for registration as a Professional Clinical Engineer

4.2.1 Outcome 1: Define, investigate, and analyse complex engineering problems

Outcome description

The ability to define or outline healthcare challenges involving medical equipment life-cycle management, patient safety, and service delivery is a must for this Category. A complex engineering problem may be defined as a developmental requirement to address challenges,

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improvement opportunities, or bottlenecks in healthcare delivery related to the use and/or performance of medical equipment.

The investigation and analysis of complex engineering problems in a healthcare setting involves clinical/technical data collection and interpretation and thereafter, requires specialised core engineering principles and related clinical systems with appropriate understanding of human physiology and anatomy.

Typical tasks associated with the outcome:

- Identify/recognise complex engineering problems in the medical equipment life cycle
- Conduct and use research or evidence-based methods for decision-making
- Consult on policy development, infrastructure projects, and the analysis of complex systems
- Apply risk management and failure mode analysis to improve reliability
- Analyse and report on complex medical devices using dedicated diagnostic tools

Competency

Applicants should be able to

- Conduct thorough research on related matters regarding the life cycle of medical equipment to improve it
- Advise on required improvements and provide direction on the life-cycle management of medical devices
- Formulate policies and organisational governance documents for effective life-cycle management of medical equipment.

4.2.2 Outcome 2: Design or develop solutions to complex engineering problems

Outcome description

This outcome is about resolving long outstanding engineering challenges or developing solutions to problems as and when they happen in the area of practice. The solution could relate to any stage of the life-cycle management of medical equipment or an engineering solution to improve

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clinical workflows through the integration with infrastructure, ICT, and health information systems. Every developed solution should be accompanied by more than one possible alternative.

Typical tasks associated with the outcome:

- Integrating new or existing technologies in clinical areas or support services
- Conducting any stage of the medical equipment life cycle as part of duties
- Using advanced diagnostic tools to conduct calibration and performance verification of complex devices

Competencies

Applicants should have

- Complete knowledge of the various life-cycle management stages of the medical equipment
- Capabilities regarding the integration of software and digital health systems
- Comprehensive knowledge of circuit design and troubleshooting
- Advanced knowledge of the various project stakeholder needs and integration with multiple role players to deliver on medical equipment requirements successfully as part of a project.

4.2.3 Outcome 3: Comprehend and apply widely applied principles underpinning good practice specific to the jurisdiction in which the Engineer practises

Outcome description

This outcome requires the Engineers to comprehend and apply widely applied principles underpinning good practice specific to the healthcare sector in which the Engineer practises. Engineers practising in the infrastructure environment may require a comprehensive understanding of Health Infrastructure Norms and Standards Guidelines. This may include general compliance with prescribed OHSC standards and inspection tools.

Typical tasks associated with the outcome:

- Attend training (theoretical and practical) to acquire competencies within the area of practice

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- Manage resources within legislative frameworks and budget

Competencies

Applicants should apply theoretical knowledge gained from completing their BEng / BSc(Eng) and in addition, demonstrate the ability to:

- Comprehend clinical and engineering principles to integrate safe, effective, and sustainable healthcare solutions
- Understand not only their engineering standards and CoP but also demonstrate knowledge of applicable frameworks such as health regulations, relevant aspects of the legislation pertaining to medical devices, and best-practice guidelines.

4.2.4 Outcome 4: Manage part or all of one or more complex engineering activities

Outcome description

This outcome focuses on Engineers' management capacity regarding complex engineering activities in the health sector. These activities involve working with other engineering disciplines and medical professionals. The complexity of activities is aggravated by the nature of the relationships that must be navigated to complete the work effectively and efficiently. It is not uncommon during an engineering project to have unforeseen circumstances that may shift the resources required for project completion. It is, therefore, essential for Applicants to recognise the importance of planning and to anticipate changes that may affect the available resources and the final project outcome. Applicants must have effective planning, organising, leading, and controlling skills to ensure projects are delivered effectively against the defined scope and the resources relating to the stages of the equipment life cycle.

Typical tasks associated with the outcome:

- Manage service level agreements (SLAs) / contracts for maintenance and placements of devices
- Develop and maintain Key Performance Indicators to ensure effective management of CE outputs
- Manage life cycle of complex medical devices (planning, procurement, commissioning, training, maintenance, and decommissioning)

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- Apply Healthcare Technology Assessment (HTA) methodology to guide technology adoption
- Manage part of a health facility infrastructure project.

Competencies

Applicants are tested on the following:

- Project management: Demonstrate a significant role played in a project
- Resource allocation and financial management
- Legislative frameworks
- Team leadership and conflict resolution
- Contract management

4.2.5 Outcome 5: Communicate clearly using multiple media and collaborate inclusively with a broad range of stakeholders in the course of engineering activities

Outcome description

Communication in engineering is the fundamental skill that is required for personnel to ensure safe environments and to verify that tasks are carried out correctly. This outcome requires Engineers to be able to explain complex technical documents and concepts to diverse audiences in the course of engineering activity and to maintain effective project collaborations within interdisciplinary teams. Providing clear, evidence-based reporting and documentation for regulatory submissions, inspection audits, and clinical use is another requirement for effective communication.

Typical tasks associated with the outcome:

- Make written reports and oral presentations using structure, style, language, and visual aids that are audience appropriate and fulfil the purpose
- Collaborate with diverse stakeholders (clinicians, nurses, administrators, and other health professionals) during medical device procurement by evaluating needs and aligning these to technical data/specifications within this interdisciplinary committee.

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Competencies

Applicants must possess the ability to analyse technical data and equipment performance and compile technical specifications and reports on equipment refurbishment / replacement assessments and adverse events, *inter alia*, that are factually correct, legally sound, and easily translatable to different stakeholders.

4.2.6 Outcome 6: Recognise the reasonably foreseeable economic, social, cultural, and environmental effects of complex engineering activities seeking to achieve sustainability

Outcome description

In the healthcare sector where social and environmental considerations are primary, there is a need to recognise and address sustainable HT acquisition, use, and disposal. This is best achieved through HT life-cycle optimisation, demonstrated through the application of appropriate HTA, healthcare technology management (HTM), and safe disposal practices.

Guiding end-users on effective cleaning and disinfection of medical equipment further ensures a safe patient environment that enables best clinical outcomes.

Typical tasks associated with the outcome:

- Conduct impact and stakeholder assessments as part of selecting and procuring complex HT to ensure fit-for-purpose and economic impact are met.
- Compile a medical devices cleaning/disinfection training programme as an individual or part of a multi-disciplinary team to ensure safe and effective patient care.
- Ensure safe disposal of ionising radiation devices.

Competencies

Applicants must demonstrate the following:

- Knowledge of HTAs and reporting
- Knowledge of correct disposal of ionising radiation or similar hazardous substance devices.

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4.2.7 Outcome 7: Meet all legal and regulatory requirements and protect the health and safety of persons during all complex engineering activities

Outcome description

This outcome not only requires Engineers to comply with engineering regulatory standards but also requires explicit alignment with healthcare/medical frameworks. All engineering work must be carried out in accordance with the norms and standards of the profession. Such norms and standards are generally derived locally or are internationally adopted for the specific industry. Applicants are expected to have, as a minimum, a working knowledge of the following regulations and Acts and an understanding of how this legislation affects their working environment. The most relevant and commonly used engineering- and healthcare-related regulating standards and Acts, Regulations, Standards, and Frameworks for CE practitioners in South Africa are listed below, and application will depend on the area of practice:

- Engineering Profession Act, No. 46 of 2000
- Overarching Code of Practice for the Performance of Engineering Work, document **R-01-CoP**, Dec 2020
- National Health Act, No. 61 of 2003
- National Health Insurance Act, No. 20 of 2023
- Occupational Health and Safety Act, No. 85 of 1993
- Medicines and Related Substances Act, No. 101 of 1965 (as amended in 2008 and 2015)
- Hazardous Substances Act, No. 15 of 1973
- National Environmental Management Act, No. 107 of 1998
- Employment Equity Act, No. 55 of 1998
- Protection of Personal Information Act (POPIA) – Amended Regulations (2025)
- Medical Devices and In Vitro Diagnostics Guidelines (SAHPRA)
- National Core Standards for Health Establishments in South Africa (OHSC)
- ISO 9001:2015 Quality Management Systems
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO/TR 24971 Medical Devices – Guidance on the application of ISO 14971

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- Infrastructure Unit Support System (IUSS) Guidelines
- Ideal Hospital Realisation and Maintenance Framework Manual (NDoH), 2018
- Ideal Hospital Framework, v2 (NDoH), 2025

Competencies

Because this outcome is Responsibility Level E, Applicants are required to demonstrate competence in their complex engineering activities by the following:

- Having a basic knowledge of the Acts applicable to activities within the area of practice
- Obtaining a functional understanding of provisions in their specific workplace
- Having extensive knowledge related to workplace safety and related regulations in engineering and healthcare, including licensing requirements of applicable equipment.

4.2.8 Outcome 8: Conduct engineering activities ethically

Outcome description

Identifying ethical problems and addressing them without compromising integrity is critical, and Engineers are expected to conduct themselves in an ethical manner, always demonstrating professionalism during the course of the engineering activities.

Making mistakes that can cause delay or compromise safety can occur in complex engineering activities. Adherence to codes and rules of conduct is what separates ethical from unethical behaviour. Ethical behaviour ensures that Engineers report honestly and truthfully without consideration of the consequences.

Competencies

Applicants must have knowledge of the ECSA Code of Conduct and an understanding of how it relates to their area of practice. Furthermore, CE work should be performed while considering the following factors:

- Act with integrity and according to the general norms of professional conduct
- Strive to respect the interests of public health and safety.

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4.2.9 Outcome 9: Exercise sound judgement by evaluating the outcomes, impacts, and alternatives in the course of complex engineering activities

Outcome description

Complex engineering activities in the healthcare sector require sound judgement pertaining to financial priorities, technical requirements, and patient safety as relevant to the area of practice. Clinical Engineers must be able to use available and relevant frameworks to balance cost-effectiveness and safety while making decisions.

Competencies

Applicants must demonstrate the ability to make decisions with incomplete knowledge of the situation while there are competing interests during complex engineering activities.

4.2.10 Outcome 10: Be responsible for making decisions on part or all of complex engineering activities

Outcome description

This outcome requires Engineers not only to make decisions when needed but also to outline the process followed and the alternatives considered before making the final decision. This is called a responsible decision-making process. The process allows Engineers to gather all relevant information and compare data. The final decision could be based on the knowledge or experience of previous engineering activities.

If Engineers require further consultation or guidance from superiors, they need to provide all the gathered information to facilitate well-informed advice. However, Engineers must demonstrate the ability to make decisions on part or all of complex engineering activities based on Level E Degree of Responsibility.

Competencies

Applicants must demonstrate how they were able to make decisions and take on responsibility for part of one or more complex engineering activities.

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4.2.11 Outcome 11: Undertake sufficient professional development activities to maintain and extend competence and enhance the ability to adapt to emerging technologies and the ever-changing nature of work

Outcome description

This outcome requires Clinical Engineers to undertake sufficient professional development activities to extend their competence and to stay up to date with new medical technologies by completing relevant certifications and attending identified conferences. The outcome also requires enhancement of the ability to adapt to emerging technologies and the ever-changing nature of work with the advancement of AI, robotics, telemetry, wearables, and IoMT.

Continual development of Engineers in the healthcare setting includes an incremental understanding of the emerging and advancing technologies, integrating patient data with healthcare systems, and staying updated on the evolving standards associated with medical equipment and the risks related to cybersecurity, POPIA, etc. Continuing to develop oneself also means mastering available medical devices in terms of operation, application, and maintenance, as applicable to the specific jurisdiction.

Applicants should register with relevant VAs to access available seminars, conferences, and courses that carry CPD points to maintain professional registration status. Recommended VAs are listed below:

- Clinical Engineering Association of South Africa (CEASA)
- South African Federation of Healthcare Engineering (SAFHE)
- Consulting Engineers South Africa (CESA)

Recommended training and courses include the following:

- ISO 13485:2016 training & certification
- Medical Devices Regulatory Frameworks
- HTA

Conference attendance, employer-sponsored training, internships in the medical device industry, resources made available by international professional associations, multilateral organisations and NGOs, and personal development opportunities should also be considered.

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In most cases, available courses are not solely for CPD but are useful for Engineers to extend their level of competency. The following courses are by no means restricted to CPD-accredited providers; some employer-sponsored training for competency and personal development is included:

- Report writing – requirement to communicate with different stakeholders
- Public speaking – requirement for presentations and training junior Candidates and end-users
- Engineering finance – finance management in projects or maintenance budgets
- Dedicated medical device maintenance training at different levels
- Project and contract management
- ISO 13485:2016 training & certification
- Occupational health and safety in healthcare facilities and equipment handling.

Typical tasks related to this outcome:

- Attending and actively participating in relevant programmes, courses, seminars, webinars, and conferences.

Applicants must demonstrate that they continue to develop themselves. They are required to provide proof of courses, seminars/workshops, conferences and/or proof of furthering their studies.

Competencies

- Explain new technologies/systems that they have been exposed to within their jurisdiction and demonstrate a sound understanding of the application and benefits from a systems and stakeholder perspective.
- Demonstrate a sound understanding of the implications of POPIA risks concerning medical equipment together with the ability to collaborate with diverse stakeholders in developing suitable risk mitigation.

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4.3 Training for registration as a Professional Clinical Engineering Technologist

4.3.1 Outcome 1: Define, investigate, and analyse broadly defined engineering problems

Outcome description

The ability to define or outline the challenges affecting the overall life-cycle management of the equipment, patient safety, and service delivery is a must for this Category. Broadly defined engineering problems may be described as a developmental requirement and could include data analysis and/or research to investigate the challenges in equipment life-cycle management and/or the improvement of opportunities.

The investigation of broadly defined engineering problems in healthcare settings involves technical data collection and analysis and requires specialised core engineering principles and knowledge of related clinical use of devices with appropriate understanding of human physiology and anatomy.

Typical tasks related to this outcome:

- Conduct and use research or evidence-based methods for identification of broadly defined engineering problems in healthcare and the related decision-making. These could include adverse events involving medical devices and equipment reliability and performance.
- Present HT- and medical device-related contributions in policy development and broadly defined activities within infrastructure projects.
- Carry out performance testing and reporting on medical devices using dedicated diagnostic tools.
- Conduct a needs assessment and evaluation of medical equipment through trend analysis and stakeholder consultation.
- Determine equipment specifications in line with clinical needs to inform decision-making.

Competencies

Applicants should be able to

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- Conduct research on technology gaps in clinical-related areas to improve medical device/HT access and performance (including safety)
- Advise on improvements required for and/or provide direction for the life-cycle management of medical devices and related policies.

4.3.2 Outcome 2: Design or develop solutions to broadly defined engineering problems

Outcome description

This outcome should lead to effective contributions and improvement of the status quo, addressing equipment specifications, use and management of healthcare, improvement of hospital workflows, device performance/safety, and patient safety. Following the previous outcome of defining and investigating broadly defined engineering problems, the requirement to develop solutions is a necessity. Solutions must be based on advanced engineering principles while considering social and environmental impact.

Typical tasks related to this outcome:

- Develop and maintain device maintenance scheduling through a maintenance management system aligning with OEM recommendations.
- Apply technological advances to improve any stage of equipment life-cycle management.
- Refurbish devices and instruments with emphasis on safety and reliability.
- Develop and implement solutions to address systemic constraints, challenges, and inefficiencies.

Competencies

Applicants should be able to

- Demonstrate technical and analytical skills
- Demonstrate a systems-thinking approach to healthcare systems.

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4.3.3 Outcome 3: Comprehend and apply knowledge that is embodied in established engineering practices specific to the jurisdiction in which the Engineering Technologist practises

Outcome description

This outcome requires Technologists to apply widely applied principles underpinning good practice specific to the jurisdiction in which the Technologist practises. Technologists practising in the infrastructure environment may require a comprehensive understanding of Health Infrastructure Norms and Standards Guidelines. This may include general compliance with prescribed OHSC standards and inspection tools.

Typical tasks related to this outcome:

- Attend training (theoretical and practical) to acquire competencies within the area of practice.
- Manage resources within legislative frameworks and budget.
- Implement continual improvement processes as applicable to equipment life-cycle management elements such as equipment downtime/reliability, management of critical spares, and budget management.

Competencies

Applicants must apply theoretical knowledge gained from completing their **Advanced Diploma** and in addition, demonstrate the ability to

- comprehend clinical and engineering principles to evaluate trade-offs and integrate them to achieve safe, effective, and sustainable healthcare solutions
- not only understand the engineering standards and the CoP that is applicable to the Candidate's area of specialisation but also demonstrate knowledge of applicable frameworks such as health regulations (e.g. R158), relevant aspects of legislation on medical equipment such as POPIA, National Health Act, Hazardous Substances Act, and relevant best practices/guidelines.

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4.3.4 Outcome 4: Manage part or all of one or more broadly defined engineering activities

Outcome description

This outcome focuses on Technologists' management capacity regarding broadly defined engineering activities in the health sector. These activities involve working with other engineering disciplines and medical professionals.

Clinical Engineering Technologists manage maintenance workshops and related performance, including resourcing; staff-related matters; client-, supplier-, and service-provider engagement; financial management; reviews; and reporting. Applicants must have effective planning, organising, leading, and controlling skills to ensure projects are delivered effectively against the defined scope and resources relating to the stages of the equipment life cycle.

Typical tasks related to this outcome:

- Manage the life cycle of all medical devices from needs assessment to planning, budgeting, specification, procurement and commissioning, training, maintenance, cybersecurity, upgrades, refurbishment, replacement, decommissioning, and safe disposal.
- Assess different health technologies and their suitability for adoption in the current clinical settings.
- Manage contractor performance through inspecting the work carried out, accepting service documentation, and ensuring that applicable service-level agreement obligations are met.
- Develop and maintain key performance indicators to ensure effective management of CE outputs (e.g. compliance reports, rate of breakdown, adverse events).
- Where relevant, manage medical devices / HT as part of the infrastructure projects of the health facility (e.g. upgrades in hospital / new hospital).

Competencies

Applicants are tested on the following:

- Project management: Demonstrate a significant role played in a project
- Resource allocation and financial management

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- Legislative frameworks
- Teamwork
- Contract management, including SLAs.

4.3.5 Outcome 5: Communicate clearly using multiple media and collaborate inclusively with a broad range of stakeholders in the course of engineering activities

Outcome description

Communication in engineering is a fundamental skill that is required not only for personnel to ensure safe environments effectively but also for tasks to be carried out correctly. This outcome requires that Technologists are able to explain technical documents and concepts to diverse audiences in the course of carrying out broadly defined engineering activities and to maintain effective project collaborations within interdisciplinary teams. Providing clear, evidence-based reporting and documentation for regulatory submissions, inspection audits, and clinical use is one of the requirements of effective communication.

Typical tasks related to this outcome

Applicants are tested on their ability to

- make written reports and oral presentations using structure, style, language, and visual aids that are audience appropriate and fulfil the purpose
- collaborate with diverse stakeholders (clinicians, nurses, administrators, and other health professionals) during medical device procurement by evaluating the needs and aligning these with the technical data/specifications within this interdisciplinary committee.

Competencies

Applicants must have the ability to write clear reports analysing technical data, equipment performance, technical specifications, equipment replacement motivations, and adverse event reports involving medical equipment. These reports must be factually accurate, legally sound, and easily translatable to different stakeholders.

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4.3.6 Outcome 6: Recognise the reasonably foreseeable economic, social, cultural, and environmental effects of broadly defined engineering activities seeking to achieve sustainability

Outcome description

In the healthcare sector where social and environmental considerations are primary, there is a need to recognise and address sustainable HT acquisition, use, and disposal. This is best achieved through HT life-cycle optimisation, which is demonstrated through the application of appropriate HTA, HTM, and safe disposal practices.

Guiding end-users on effective cleaning and disinfection of medical equipment further ensures a safe patient environment that supports the achievement of desired health outcomes.

Typical tasks related to this outcome:

- Conduct impact and stakeholder assessments as part of the selection and procurement of HT to ensure adequate consideration of relevant economic impact and to ensure that fit-for-purpose is acquired. Where specific environmental impact has been identified, this is taken into consideration.
- Compile a medical devices cleaning/disinfection training programme as an individual or part of a multi-disciplinary team to ensure safe and effective patient care.
- Conduct impact and stakeholder assessments as part of the selection and procurement of complex HT to ensure fit-for-purpose and economic impact are met.
- Ensure safe disposal of medical equipment and related elements in compliance with relevant regulations.
- Ensure safe disposal of ionising radiation-emitting devices.

Competencies

Applicants must demonstrate knowledge of

- HTA assessments and reporting
- safe equipment-disposal practices.

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4.3.7 Outcome 7: Meet all legal and regulatory requirements and protect the health and safety of persons during all broadly defined engineering activities

Outcome description

This outcome requires Technologists to comply with engineering regulatory standards and ensure explicit alignment with healthcare/medical frameworks. All engineering work must be carried out according to the norms and standards of the profession. Such norms and standards are generally derived locally or are internationally adopted for the specific industry. The most relevant and commonly used engineering- and healthcare-related regulating Standards, Acts, Regulations, and Frameworks for CE practitioners in South Africa are listed below, and application depends on the area of practice.

Tier 1 (All practitioners):

- Engineering Profession Act, No. 46 of 2000
- Overarching Code of Practice for the Performance of Engineering Work, document **R-01-CoP**, Dec 2020
- National Health Act, No. 61 of 2003
- National Health Insurance Act, No. 20 of 2023
- Occupational Health and Safety Act, No. 85 of 1993
- Medicines and Related Substances Act, No. 101 of 1965 (as amended in 2008 and 2015)
- Hazardous Substances Act, No. 15 of 1973
- National Environmental Management Act, No. 107 of 1998
- Employment Equity Act, No. 55 of 1998
- Protection of Personal Information Act (POPIA) – Amended Regulations (2025)
- Medical Devices and In Vitro Diagnostics Guidelines (SAHPRA)
- National Core Standards for Health Establishments in South Africa (OHSC)
- ISO 9001:2015 Quality Management Systems

Tier 2 (Specific to area of practice):

- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices

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- ISO/TR 24971 Medical Devices – Guidance on the Application of ISO 14971
- IUSS Guidelines
- Ideal Hospital Realisation and Maintenance Framework Manual (NDoH), 2018
- Ideal Hospital Framework, v2 (NDoH), 2025

Competencies

Because this outcome is Responsibility Level E, Applicants are required to demonstrate competence in their broadly defined engineering activities by the following:

- Having basic knowledge of relevant Acts applicable to the activities within the area of practice
- Obtaining a functional understanding of provisions in their specific workplace
- Having extensive knowledge relating to workplace safety and related regulations in engineering and healthcare, including licensing requirements
- Ensuring POPIA requirements are adhered to.

Technologist's knowledge could, therefore, be tested on one or two of the regulating Standards and/or Acts listed above to prove competency.

4.3.8 Outcome 8: Conduct engineering activities ethically

Outcome description

Individuals are expected to conduct themselves in an ethical manner, always demonstrating professionalism during the course of the engineering activities. Identification of ethical problems and addressing them without compromising integrity and patient safety are critical.

In broadly defined engineering activities, making mistakes can cause delay or compromise safety. Adherence to codes and rules of conduct should be maintained. Ethical behaviour ensures Technologists report honestly and truthfully with consideration of accountability.

Competencies

Applicants must have knowledge of the ECSA Code of Conduct and an understanding of how it relates to their area of practice. The following factors should be considered when performing CE work:

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- Act with integrity and according to the general norms of professional conduct
- Strive to respect the interests of the public and health and safety.

4.3.9 Outcome 9: Exercise sound judgement by evaluating the outcomes, impacts, and alternatives in the course of broadly defined engineering activities

Outcome description

Broadly defined engineering activities in the healthcare sector require sound judgement concerning financial priorities, technical requirements, and patient safety as relevant to the area of practice. Clinical Engineering Technologists must have the ability to use available, relevant frameworks such as organisational policies and procedures to balance cost-effectiveness and safety while making decisions.

Competencies

Applicants must demonstrate the ability to make decisions in an incomplete knowledge situation with competing requirements in broadly defined engineering activities. Examples include the following areas of application:

- Planning, budgeting, and financing (focused on engineering assets)
- Needs Assessment and Technology Evaluation
- Operational Safety and Risk Management
- Trend Analysis.

4.3.10 Outcome 10: Be responsible for making decisions on part or all of broadly defined engineering activities

Outcome description

This outcome requires Technologists not only to make decisions when needed but also to outline the process that is being followed and the alternatives that are being considered before making the final decision. This is called a responsible decision-making process. The process allows Technologists to gather all relevant information and compare data. The final decision could be based on the knowledge or experience of previous engineering activities.

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If Technologists require further consultation or guidance from superiors, they need to provide all the gathered information to facilitate well-informed advice. However, Technologists must demonstrate the ability to make decisions on part or all of broadly defined engineering activities based on Level E Degree of Responsibility.

Competencies

Applicants must demonstrate how they were able to make decisions and assume responsibility.

4.3.11 Outcome 11: Undertake sufficient professional development activities to maintain and extend competence and enhance the ability to adapt to emerging technologies and the ever-changing nature of work

Outcome description

This outcome requires Technologists to undertake sufficient professional development activities and to extend their competence by completing relevant certifications and attending identified conferences to stay up to date with new medical technologies. The outcome also requires enhancement of the ability to adapt to emerging technologies and the ever-changing nature of work with the advancement of AI, robotics, telemetry, wearables, and IoMT.

Continual development of Technologists in the healthcare setting includes an incremental understanding of emerging and advancing technologies in addition to integrating patient data with healthcare systems and staying updated on evolving standards associated with medical equipment and risks related to cybersecurity, POPIA, etc. Continuing to develop oneself also means mastering available medical devices in terms of operation, application, and maintenance as applicable to one's specific jurisdiction.

Applicants should register with relevant VAs to access available seminars, conferences, and courses to enhance their knowledge and skills and to keep them abreast of technological and other developments in the industry. The recommended conferences and seminars should ideally carry CPD points to maintain professional registration status. Relevant VAs are listed below:

- Clinical Engineering Association of South Africa (CEASA)
- South African Federation of Healthcare Engineering (SAFHE)
- Consulting Engineers South Africa (CESA).

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Recommended training and courses include the following:

- Report writing: Requirement to communicate with different stakeholders
- Public speaking: Requirement for presentations and training junior Candidates and end-users
- Engineering finance: Finance management in projects or maintenance budgets
- Dedicated medical device maintenance training at different levels
- Project and contract management
- ISO 13485:2016 training and certification
- Occupational health and safety in healthcare facilities and equipment handling.

Employer-sponsored training, internships in the medical device industry, resources made available by international professional associations, multilateral organisations and NGOs, and personal development opportunities should also be considered.

Typical tasks related to this outcome:

- Attending and actively participating in relevant courses, seminars, webinars, and conferences.

Applicants must demonstrate that they continue to develop themselves. They are required to provide proof of courses, seminars/workshops, and conferences attended and/or proof of furthering their studies.

Competencies

- Detail the new technologies/systems to which they have been exposed within their jurisdiction and demonstrate a sound understanding of the application and benefits from a systems and stakeholder perspective.
- Demonstrate a sound understanding of the implications of POPIA risks concerning medical equipment together with the ability to collaborate with diverse stakeholders to develop suitable risk mitigation.

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4.4 Training for registration as a Professional Clinical Engineering Technician

4.4.1 Outcome 1: Define, investigate, and analyse well-defined engineering problems

Outcome description

The ability to define or outline challenges affecting equipment reliability, performance, total cost of ownership, and patient safety is a must for this Category. Well-defined engineering problems may be described as a developmental requirement to address day-to-day challenges and/or improvement opportunities related to effective performance and troubleshooting of medical equipment.

The investigation and analysis of well-defined engineering problems in a healthcare setting involves equipment end-user consultation, analysing clinical/technical information to support evidence-based methods for decision-making such as failure and root cause analysis, safety and quality assurance, and in-depth knowledge of medical equipment devices and related systems with appropriate understanding of related human physiology and anatomy.

Typical tasks related to this outcome:

- Use evidence-based methods to identify well-defined engineering problems in healthcare-related equipment reliability and performance.
- Analyse and report on medical device performance using dedicated diagnostic tools.
- Troubleshoot and maintain (preventive and corrective) medical devices and systems.
- Maintain related records and align with departmental and organisational information asset management systems.

Competencies

Applicants should be able to

- conduct equipment performance testing and analysis based on the above
- define/understand standard operating procedures (SOPs) regarding maintenance of different medical devices
- outline challenges and improvement opportunities experienced in equipment life-cycle management activities.

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4.4.2 Outcome 2: Design or develop solutions to well-defined engineering problems

Outcome description

Clinical Engineering Technicians are always at the forefront of medical devices that are in use or under maintenance. Therefore, these individuals contribute and participate in equipment specifications and in implementing related systems and processes to address the effective use and management of medical equipment with the aim of improving hospital workflows, device performance/safety, and patient safety. Following the previous outcome of defining and investigating well-defined engineering problems, the requirement to develop solutions is a necessity. The solution must be based on sound engineering principles.

Typical tasks related to this outcome:

- Implement maintenance management systems to develop device maintenance scheduling in alignment with OEM recommendations.
- Apply good-practice principles and technological knowledge to develop new workshop protocols and conduct medical-device diagnostic, testing/calibration, and maintenance procedures.
- Specify minimum requirements for medical equipment based on intended use, application, clinical location, and fit-for-purpose technology.
- Maintain a document management system for equipment-related records and align with departmental and organisational information asset-management systems and documentation retention requirements based on regulatory requirements and medico-legal impact.
- Implement end-user training mechanisms to address common errors with application and end-user maintenance effectively.

Competencies

Applicants should possess the following:

- technical and analytical skills
- a systems-thinking approach to health systems
- an understanding of the fundamentals of medical device hardware/software

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- an understanding of elements to consider when evaluating HT / medical equipment such as end-user requirements and technical requirements.

4.4.3 Outcome 3: Comprehend and apply knowledge that is embodied in established engineering practices that are specific to the jurisdiction in which the Engineering Technician practises

Outcome description

This outcome requires Technicians to be able to comprehend and apply principles underpinning good practice specific to the jurisdiction in which the Technician practises.

Typical tasks related to this outcome:

- Attend training (theoretical and practical) to acquire competencies within the area of practice.
- Interpret and apply OEM documentation to determine the effective maintenance protocols to be applied to medical equipment.
- Implement commissioning testing for new equipment to ensure it is safe for use and to provide a baseline against which to measure future performance.

Competencies

Applicants should apply the theoretical knowledge gained from completing their **Diploma** in addition to demonstrating the ability to

- comprehend clinical and engineering principles to determine and evaluate equipment specifications and integrate these requirements to achieve safe, effective, and sustainable healthcare solutions
- demonstrate knowledge of the frameworks applicable to the Candidate's area of specialisation such as health regulations (e.g. R158), relevant aspects of legislation on medical equipment such as POPIA, National Health Act, Hazardous Substances Act, and relevant best practices/guidelines.

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4.4.4 Outcome 4: Manage part or all of one or more well-defined engineering activities

Outcome description

This outcome focuses on Technicians' management capacity regarding well-defined engineering activities in the health sector. These activities involve working with other engineering disciplines and medical professionals. The complexity of activities and decision-making is aggravated by the nature of the relationships that have to be navigated to complete the work effectively and efficiently.

Clinical Engineering Technicians work with a broader team of role players that have an impact on the medical equipment life cycle; in this instance, the focus becomes managing different personalities to maximise output and better turnaround times.

Typical tasks related to this outcome:

- Contribute to the life-cycle management of medical devices, specifically tasks related to planning and procurement, ensuring compliance with specifications, commissioning, training, maintenance, OEM-compliant repair/refurbishment, and decommissioning of medical devices.
- Assess different health technologies against approved specifications to select fit-for-purpose devices.
- Manage and monitor device inventory and maintenance scheduling.
- Inspect and assess work carried out by vendors, including acceptance of service documentation and ensuring, where applicable, that service-level obligations/contractual obligations are met.
- Monitor key performance indicators and execute relevant tasks to ensure effective management of CE outputs in collaboration with affected stakeholders such as equipment end-users.
- Determine critical spares and stock requirements to minimise equipment downtime.

Competencies

Applicants should demonstrate acquired skills in the following areas:

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- Project management: Demonstrate planning, organising, leading, and controlling skills associated with allocated tasks.
- Resource allocation and financial management (e.g. spares required to minimise downtime / fit-for purpose equipment identification).
- Teamwork (e.g. influencing stakeholders to achieve the common goal).
- Contract management (e.g. SLAs).

4.4.5 Outcome 5: Communicate clearly using multiple media and collaborate inclusively with a broad range of stakeholders in the course of engineering activities

Outcome description

Communication in engineering is the fundamental skill that is required for Technicians not only to ensure safe environments effectively but also to ensure that well-defined tasks are carried out correctly. This outcome requires Technicians to be able to explain technical documents and concepts to diverse audiences in the course of carrying out well-defined engineering activities and to maintain effective project collaborations within interdisciplinary teams. Providing clear, evidence-based reporting and documentation for regulatory submissions, inspection audits, and clinical use are requirements for effective communication.

Typical tasks related to this outcome:

- Preparing written reports and oral presentations using structure, style, language, and visual aids that are audience appropriate and fulfil the intended purpose.
- Collaborating with diverse stakeholders (clinicians, nurses, administrators, and other health professionals) during medical device procurement by evaluating needs and aligning these with technical data/specifications within this interdisciplinary committee.

Competencies

Applicants must have the ability to analyse and interpret information (e.g. technical data and specifications, equipment performance, equipment replacement motivations, and adverse event reports involving medical equipment) in order to write clear reports that are factually accurate, legally sound, and easily translatable to different stakeholders.

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4.4.6 Outcome 6: Recognise the reasonably foreseeable economic, social, cultural, and environmental effects of well-defined engineering activities seeking to achieve sustainability

Outcome description

In the healthcare sector where social and environmental considerations are primary, there is a need to recognise and address sustainable HT acquisition, use, and disposal. This is best achieved through HT life-cycle optimisation demonstrated through application of appropriate HTA, HTM, and safe disposal practices.

Guiding end-users on effective cleaning and disinfection of medical equipment further ensures a safe patient environment that enables best clinical outcomes.

Typical tasks related to this outcome:

- Compile a medical devices cleaning/disinfection training programme as an individual or part of a multi-disciplinary team to ensure safe and effective patient care.
- Ensure safe disposal of ionising radiation devices and similar hazardous devices.

Competencies

Applicants must demonstrate knowledge of conducting impact assessments and reporting for consideration.

4.4.7 Outcome 7: Meet all legal and regulatory requirements and protect the health and safety of persons during all well-defined engineering activities

Outcome description

Applicants are expected to have at least a working knowledge of relevant legal and regulatory requirements and an understanding of how these affect their working environment. These requirements—within the context of healthcare and engineering environments—are contained in the following Acts, Regulations, Standards, and Frameworks; application will depend on the area of practice of the Technician.

Tier 1 (All practitioners):

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- Engineering Profession Act, No. 46 of 2000
- Overarching Code of Practice for the Performance of Engineering Work, document **R-01-CoP**, Dec 2020
- Occupational Health and Safety Act, No. 85 of 1993
- Hazardous Substances Act, No. 15 of 1973
- National Environmental Management Act, No. 107 of 1998
- Employment Equity Act, No. 55 of 1998
- Protection of Personal Information Act (POPIA) – Amended Regulations (2025)
- Medical Devices and In Vitro Diagnostics Guidelines (SAHPRA)
- National Core Standards for Health Establishments in South Africa (OHSC)
- ISO 9001:2015 Quality Management Systems

Tier 2 (Specific to area of practice):

- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO/TR 24971 Medical Devices – Guidance on the application of ISO 14971
- IUSS Guidelines
- Ideal Hospital Realisation and Maintenance Framework Manual (NDoH), 2018
- Ideal Hospital Framework, v2 (NDoH), 2025

Competencies

Because this outcome is Responsibility Level E, Applicants are required to demonstrate competence in their well-defined engineering activities by

- having a basic knowledge of relevant Acts applicable to activities within the area of practice
- obtaining a functional understanding of provisions in their specific workplace
- having extensive knowledge related to workplace safety and related regulations in engineering and healthcare, including licensing requirements of applicable medical equipment
- ensuring POPIA requirements are adhered to.

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Technicians' knowledge could, therefore, be tested on one or two of the regulating Standards and/or Acts listed above to prove competency.

4.4.8 Outcome 8: Conduct engineering activities ethically

Outcome description

Individuals are expected to conduct themselves in an ethical manner, always demonstrating professionalism during the course of the engineering activities. Identification of ethical problems and addressing them without compromising integrity and patient safety are critical.

Making mistakes in well-defined engineering activities can cause delay or compromise safety. Adherence to codes and rules of conduct is mandated. Ethical behaviour ensures that reporting is factual and correct, with accountability for consequences and acceptance of responsibility.

Competencies

Applicants must have knowledge of the ECSA Code of Conduct and an understanding of how it relates to their area of practice. In addition, the following factors should be considered when performing CE work:

- Act with integrity and in accordance with the general norms of professional conduct
- Strive to respect the interests of the public and health and safety.

4.4.9 Outcome 9: Exercise sound judgement by evaluating the outcomes, impacts, and alternatives in the course of well-defined engineering activities

Outcome description

Well-defined engineering activities in the healthcare sector require sound judgement concerning financial priorities, technical requirements, and patient safety as relevant to the area of practice. Clinical Engineering Technicians must have the ability to use sound judgement and available relevant frameworks such as organisational policies and procedures to balance cost-effectiveness and safety while making decisions.

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Competencies

Applicants must demonstrate the ability to make decisions in an incomplete knowledge situation with competing requirements in well-defined engineering activities (e.g. applying risk classification and assessment of required resources to determine sound asset management strategies, including frequency and execution of scheduled maintenance).

Applicants should demonstrate sound knowledge of the relevant requirements and asset life-cycle management criteria such as total cost of ownership and identification of critical spares to minimise downtime and ensure the safe performance of equipment.

4.4.10 Outcome 10: Be responsible for making decisions on part or all of well-defined engineering activities

Outcome description

This outcome requires Technicians not only to make decisions when needed but also to outline the process that is being followed and the alternatives that are being considered before making the final decision. This is called a responsible decision-making process. The process allows Technicians to gather all relevant information and compare data. The final decision could be based on knowledge or experience of previous engineering activities.

If Technicians require further consultation or guidance from superiors, they need to provide all the gathered information to facilitate well-informed advice. However, Technicians must demonstrate the ability to make decisions on part or all of well-defined engineering activities based on Level E Degree of Responsibility.

Competencies

Applicants must demonstrate how they were able to make decisions and take on responsibility for part of one or more well-defined engineering activities.

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4.4.11 Outcome 11: Undertake sufficient professional development activities to maintain and extend competence and enhance the ability to adapt to emerging technologies and the ever-changing nature of work

Outcome description

This outcome requires Technicians to undertake sufficient professional development activities and extend their competence to stay up to date with new developments in HT; these activities include supplier equipment introductions, attending relevant webinars and identified conferences, and completing relevant certifications/training records. The outcome also requires enhancing the ability to adapt to emerging technologies and the ever-changing nature of HT and the advancement of AI, digitisation and electronic medical records (EMRs), robotics, and telemetry.

Continual development of Technicians in the healthcare setting includes an incremental understanding of the emerging and advancing technologies regarding integrating patient data with healthcare information systems and staying updated on evolving standards associated with medical devices and risks related to interoperability, cybersecurity, POPIA, etc.

Continuing to develop oneself also includes understanding the criteria and factors enabling optimised needs assessment, specification, acquisition, commissioning, use, and maintenance of medical devices as applicable to the specific jurisdiction of the Technician.

Applicants should register with relevant VAs to access available seminars, conferences, and courses to enhance their knowledge and skills and to keep them abreast of technological and other developments in the industry. The recommended conferences and seminars should ideally carry CPD points to maintain professional registration status. Relevant VAs are listed below:

- Clinical Engineering Association of South Africa (CEASA)
- South African Federation of Healthcare Engineering (SAFHE)
- Consulting Engineers South Africa (CESA)

Recommended training and courses include

- ISO 13485:2016 training & certification

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Employer-sponsored training, internships in the medical device industry, resources made available by international professional associations, multilateral organisations, and NGOs. Personal development opportunities should also be considered.

Typical tasks related to this outcome:

- Attend and actively participate in relevant programmes, courses, seminars, webinars, and conferences, as appropriate and accessible.

Applicants must demonstrate that they continue to develop themselves. They are required to provide proof of webinars, training sessions, courses, seminars/workshops, conferences, and/or proof of furthering their studies.

5. FUNCTIONS PERFORMED

5.1 Degrees of Responsibility

Progression throughout the Candidacy period is presented in document **R-04-T&M-Guide-PC**.

Table 1 refers to the gradual increase in the Degree of Responsibility to which Candidate Engineers, Technologists, and Technicians are exposed during professional training. This progression is not standard for every Candidate because some start their responsibility at Level B. Considering the nature of work, specific examples and outcomes appropriate for training in BME and CE are given in Table 1 below.

Table 2: Progression throughout the Candidacy period

Degree of responsibility	Nature of work	Activities/duties to be undertaken during training
A: Being exposed	Candidate undergoes induction and observes processes and work of competent practitioners.	• Understand the business environment and the dynamics that shape the businesses and industries in which they operate. • Understand the business model, its key conversion processes, and critical outcomes. • Understand the value added by engineering practitioners and other professionals in the business.

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Degree of responsibility	Nature of work	Activities/duties to be undertaken during training
B: Assisting	Candidate performs specific processes under close supervision.	• Develop insight and understanding of the different processes and systems in transforming inputs into goods and services. • Develop an appreciation of the numerous resources at the disposal of Engineering practitioners. • Obtain experience in the day-to-day operations of the business to gain insight and understanding of the different processes and systems involved in transforming inputs into goods and services, with specific emphasis on productivity and quality measurements.
C: Participating	Candidate performs specific processes as directed and with limited supervision.	• Gain first-hand experience of a broad range of engineering activities (e.g. process design and re-engineering, planning and control, work study, value engineering, materials and information management, people management skills, logistics, specialists' inputs, tools and equipment, and quality assurance). • Note the problems and limitations of specific philosophies, methods, and techniques, with emphasis on cost/effort and relative benefit.
D: Contributing	Candidate performs specific work with detailed approval of work outputs.	• Be involved in activities such as the planning of production, the control of quality and costs of process study and work study, good material handling and workplace layout, activity-based costing, benchmarking, business cases, process re-engineering, maintenance practice and procedures, project management, and system specification. Of particular importance is the collective working of such activities in the economic use of people, materials, and machines. • Give specific attention to human aspects concerning communication, interpersonal relationships and teamwork, training and cost analysis, budget control, and profit accountability. These should proceed in parallel, applying engineering techniques and using computers in problem-solving.
E: Performing	Candidate works in a team without supervision, recommends work	• Assume escalating technical responsibility and increasingly co-ordinate the work of others.

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Degree of responsibility	Nature of work	Activities/duties to be undertaken during training
	outputs, and is responsible but not accountable.	● Gain exposure and develop skills in management areas such as labour relations, management accounting, technology management, and general business management. This is important for developing well-rounded engineering practitioners. ● Seek assignments that require judgement, even if full information is unavailable. This leads to a position of professional responsibility.

Special considerations in the discipline or specialty must be given to the competencies specified in the following groups:

- Knowledge-based problem solving (this should be a strong focus)
- Management and communication
- Identifying and mitigating the impacts of engineering activity
- Judgement and responsibility
- Independent learning

It is useful to measure the progression of a Candidate's competency using the Degree of Responsibility Scale, the Problem-Solving Scale, and the Engineering Activity Scale as specified in document **R-02-STA-PE/PT/PN**.

5.2 Candidates' training programmes

5.2.1 Leading practices

The DSTG assumptions must align with the Candidate programme, including completion of the Training and Experience Summary (TES), the Training and Experience Report (TER), and all other relevant application forms when changing programmes.

Candidate training is based on work assignments from the employer. Circumstantially, this means no prescribed structure for a training programme.

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5.2.2 Realities

The minimum prescribed experience required for ECSA registration in a Professional Category is three years after graduating with a recognised qualification. The time to gain the necessary experience is likely to be longer than the prescribed minimum due to availability of opportunities and exposure to the functions required for ECSA registration.

Regardless of the professional route taken, Applicants must demonstrate objective evidence of competence in the 11 outcomes described in document **R-08-CS-GUIDE-PE/PT/PN**.

5.2.3 Considerations for generalists, specialists, researchers, and academics

Researchers and Academics (BME): South Africa has a growing community of biomedical researchers—particularly in biomechanics, tissue engineering, and computational modelling—whose work falls squarely within the BME domain but who may not have followed a conventional engineering undergraduate degree pathway. Such Applicants who hold relevant master's or doctoral-level qualifications in biomedical-related fields (applied physics, physiology, materials science, computational science) and who have demonstrated engineering-equivalent competencies through research outputs and applied work may be considered under ECSA's substantial equivalence evaluation process as set out in **documents R-01-POL-PC and R-03-PRO-PC**. An ECSA-recognised VA may be consulted in all such equivalence evaluations.

Researchers and Academics (CE): Globally, CE researchers and academics provide evidence that demonstrates the contribution of CE—and related fields of HTA and HTM—in supporting achievement of improved health outcomes. The primary contribution of CE is helping to ensure access to fit-for-purpose, fit-for-service, safe, and sustainable medical devices as an essential component of healthcare coverage (and by extension, universal health coverage) in both well- and poorly resourced settings.

Generalists and specialists who are intent on professional registration must, at the minimum, possess knowledge that is equivalent to the required academic qualification and must demonstrate the ability to identify and create satisfactory solutions to complex engineering problems.

In addition to satisfying the academic qualification requirements, academic Candidates who need professional registration must be involved in engineering activities or activities requiring

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knowledge of and insights into engineering activities and the related competencies that are needed. Ideally, such activities should be done under the supervision of a relevant professional Engineering Practitioner and include the following:

Teaching/Lecturing/Facilitation

- Reading in applicable fields of knowledge
- Curriculum development
- Selection and development of teaching materials
- Compilation of lecture notes
- Compilation of examination papers
- Demonstration of application of theory in practice
- Service as Supervisor for student projects

Research or further studying

- Literature surveys
- Obtaining higher qualifications
- Advancement of the current state-of-the-art technology
- Theoretical research/development of analytical techniques
- Practical/experimental research
- Participation in international collaborative research
- Multi-Disciplinary Project exposure

Laboratory experimental activities

- Experimentation
- Design and building of laboratories
- Experimental equipment design/construction
- Experiment design
- Development of new manufacturing techniques

Conferences/Symposia/Seminars

- Publishing papers (peer-reviewed journals and international conferences)
- Public speaking

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Consulting (exposure recommended for academics)

- Consulting to industry in solving real problems encountered in engineering practice
- Design of products/structures/systems/components
- Supervise applied postgraduate and final-year projects

Multi-disciplinary exposure

Interface management among various disciplines needs to be formalised. Details of signed-off interface documents among different disciplines are essential.

Orientation requirements

- Introduction to company safety regulations
- Company code of conduct
- Company staff code and regulations
- Typical functions and activities in the company
- Hands-on experience and orientation in each of the major company divisions

Although there is no prescribed training method, various recommendations can be made that can improve the strength of an Applicant's Candidacy. These include successful completion of recommended professional development activities such as the recommended training and courses for the different Categories of BME and CE practitioners in this document.

6. CONCLUSION

To attain registration as professionals, Applicants must meet the educational requirements for the Category and demonstrate competency against the prescribed standards for the registration Category. Demonstrating competency is achieved by meeting the requirements for the 11 ECSA outcomes. Together with their Mentors, Applicants or persons willing to be registered as professionals must ensure that the training provided is geared towards achieving the ECSA Competency Outcomes. Focusing on one training aspect for the entire duration of training does not assist Applicants in achieving the necessary skills to demonstrate all the standard Competency Outcomes.

The development of training remains the Applicant's responsibility, and the Applicant must ensure that the provided training plan covers all aspects of the outcomes. In situations where a

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department or organisation is unable to provide training in certain areas, it is common practice that secondments are arranged with other departments or organisations so that the Applicant is able to develop all the competencies required for registration. These secondments are usually reciprocal in nature and benefit both the employee and the employer. Secondments between consultants and contractors in the medical device industry and between the public and private sectors should be possible to allow Applicants to acquire the necessary competencies.

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REVISION HISTORY

Revision number	Revision date	Revision details	Approved by
Rev. 0 Draft A	17 Nov 2025	The working group submitted the first draft	Working Group
Rev. 0 Draft B	22 Jan 2026	Draft submitted to Registration BU for comments	Registration BU
Rev. 0 Draft C	06 Feb 2026	The document was shared with stakeholders for inputs and comments	RID BU
Rev. 0 Draft D	16 Feb 2026	The RID BU hosted a webinar with industry stakeholders to solicit inputs and comments	RID BU & Working Group
Rev. 0 Draft E	9 Mar 2026	The RID BU and Working Group reviewed the comments received from stakeholders	RID BU & Working Group
Rev. 0 Draft F	25 Mar 2026	The RID BU and Working Group reviewed the comments received from stakeholders	RID BU & Working Group
Rev. 0 Draft G	17 Jun 2026	VA CEASA requested an extension for input on 24 April 2026 to provide input and comments which was granted.	RID BU
Rev. 0 Draft H	07 Jul 2026	The RID BU and Working Group reviewed the comments received from the VA	RID BU & Working Group
Rev. 0 Draft I	20 Jul 2026	Review and recommendation for Approval	Acting Executive RSIR
Rev. 0	05 Aug 2026	Approval	RPSC

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Revision 0 dated 05 August 2026 and consisting of 70 pages, has been reviewed for adequacy by the Business Unit Assistant Manager and is approved by the Acting Executive: Regulatory Services and International Relations (**ERSIR**).



 Business Unit Assistant Manager

13 October 2026

 Date



 Acting Executive: RSIR

13 October 2026

 Date

This definitive version of this policy is available on our website.

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APPENDIX A: TRAINING ELEMENTS

Synopsis: Applicants should achieve specific competencies at the prescribed level during their development towards professional registration and at the same time, accept progressively more responsibility as experience is gained. The outcomes achieved and established during the Candidacy phase should form the template for all engineering work performed after professional registration regardless of the level of responsibility at any specific stage of an engineering career:

1. Confirm understanding of instructions received and clarify if necessary.
2. Use theoretical training to develop possible solutions: select the best and present to the recipient.
3. Apply theoretical knowledge to justify decisions taken and processes used.
4. Understand role in the work team and plan and schedule work accordingly.
5. Issue complete and clear instructions and report comprehensively on work progress.
6. Be sensitive about the impact of the engineering activity and take action to mitigate this impact.
7. Consider and adhere to legislation applicable to the task and the associated risk identification and management.
8. Adhere strictly to high ethical behavioural standards and ECSA's Code of Conduct.
9. Display sound judgement by considering all factors, their interrelationship, consequences, and evaluation when all evidence is not available.
10. Accept responsibility for own work by using theory to support decisions, seeking advice when uncertain and evaluating shortcomings.
11. Become conversant with your employer's training and development programme and develop your own lifelong development programme within this framework.

Complex, broadly defined, and well-defined engineering work is usually characterised by the application of engineering deviating from standard procedures, codes and systems, deviations verified by research, modelling, and/or substantiated design calculations.

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Competency Standards for Registration as a Professional Engineer, Technologist, and Technician	Explanation and Responsibility Level
1. Purpose This standard defines the competence required for registration as a Professional Engineer, Technologist, and Technician . Definitions of terms having a specific meaning within this standard is given in the text of the relevant section.	The DSTGs give context to the purpose of the Competency Standards. The Engineer, Technologist, and Technician operate within the 12 disciplines that the ECSA recognises. Each discipline can be further divided into sub-disciplines and finally, into specific workplaces, as indicated in section 4 of the specific DSTG. The <u>DSTGs are used to facilitate experiential development towards ECSA registration and assist in compiling the required portfolio of evidence (specifically the Engineering Report in the application form).</u> NOTE: The training period must be used to develop the trainee's competence towards achieving the standards below at a Responsibility Level E (i.e. Performing). Refer to the specific DSTG.
2. Demonstration of competence Competence must be demonstrated within complex, broadly defined, and well-defined <i>engineering activities</i> (detailed below) by integrated performance of the outcomes specified at the level defined for each outcome. Required contexts and functions may be specified in the applicable DSTG. Level Descriptor: Complex engineering activities (CEA), broadly defined engineering activities (BDEA), and well-defined engineering activities (WDEA) have several of the following characteristics: a. Scope of practice area is linked to the technologies used and changes due to adoption of new technology into current practice.	Engineering activities can be approximately divided into the following: 5% Complex (Professional Engineers) 5% Broadly Defined (Professional Engineering Technologists) 10% Well-Defined (Professional Engineering Technicians) 15% Narrowly Well-Defined (Registered Specified Categories) 20% Skilled Workman (Engineering Artisan) 55% Unskilled Workman (Artisan Assistant) Activities can be in-house or contracted out; evidence of integrated performance can be submitted irrespective of the situation. Level Descriptor: CEA, BDEA, and WDEA in the various disciplines are characterised by several or all of the following: Scope of practice area does not cover the entire field of the discipline (exposure limited to the sub-discipline and specific workplace). Some technologies used are well established, and adoption of new technologies needs investigation and evaluation.

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b. Practice area is located within a wider, complex context, requires teamwork, and has interfaces with other parties and disciplines. c. Involves a variety of resources, including people, money, equipment, materials, and technologies. d. Requires resolution of occasional problems arising from interactions between wide-ranging or conflicting technical, engineering, or other issues. e. Are constrained by available technology, time, finance, infrastructure, resources, facilities, standards and codes, and applicable laws. f. Have significant risks and consequences in the practice area and related areas.	Practice area varies substantially with unlimited location possibilities and an additional responsibility to identify the need for advice on complex, broadly defined, and well-defined engineering activities and problems. Complex, broadly defined, and well-defined activities in the sub-discipline need interfacing with Professional Engineers, Professional Technicians, artisans, architects, financial staff, etc. as part of the team. The bulk of the work involves a familiar, defined range of resources, including people, money, equipment, and materials, but new technologies are investigated and implemented. Most of the impacts in the sub-discipline are on wider issues but some arise from conflicting technical and engineering issues that have to be addressed by the application of broadly defined, non-standard engineering principles. The work packages and associated parameters are constrained by operational context with variations limited to different locations only (cannot be covered by standards and codes). Even locally important minor risks can have far-reaching consequences.
Activities include design; planning; investigation and problem resolution; improvement of materials, components, systems, or processes; manufacture or construction; engineering operations; maintenance; project management; research; development; and commercialisation.	Activities include design; planning; investigation and problem resolution; improvement of materials, components, systems or processes; engineering operations; maintenance; and project management. For Engineers, Technologists, and Technicians , research, development, and commercialisation happen more frequently in some disciplines but are seldom encountered in others.
3. Outcomes to be satisfied	Explanation and Responsibility Level
Group A: Engineering Problem Solving	
Outcome 1: Define, investigate, and analyse <i>complex, broadly defined</i> and <i>well-defined</i> , engineering problems	Responsibility Level E Analysis of an engineering problem means the 'separation into parts possibly with comment and judgement'. <i>Complex, broadly, well-defined</i> means 'not minute or detailed' and 'not kept within narrow limits'.

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Complex, broadly defined, and well-defined engineering problems have the following characteristics:

- They require coherent and detailed engineering knowledge, underpinning the technology area.
and one or more of the following:
- Are ill-posed, are under- or over-specified, require identification and interpretation in the technology area.
- Encompass systems within complex engineering systems.
- Belong to families of problems that are solved in well-accepted but innovative ways.
and one or more of the following:
- Can be solved by structured analysis techniques.
- May be partially outside standards and codes—justification to operate outside must be provided.
- Require information from practice area and sources interfacing with practice area that are complex and incomplete.
- Involve a variety of issues that may impose conflicting constraints: technical, engineering, and interested or affected parties.
and one or both of the following:
- Require judgement in decision-making in the practice area, considering interfaces to other areas.
- Have significant consequences that are important in the practice area but may extend more widely.

- Coherent and detailed engineering knowledge for the **Engineer, Technologist, and Technician** means the problem encountered cannot be solved without the combination of all the relevant details, including engineering principles applicable to the situation.
- The nature of the problem is not immediately obvious, and further investigation to identify and interpret the real nature of the problem is necessary.
- The problem is not easily recognised as part of the larger engineering task, project, or operation and may be obscured by the complexity of the larger system.
- It is recognised that the problem can be classified as falling within a typical solution requiring innovative adaptation to meet the specific situation.
- Solving the problem needs a step-by-step approach adhering to proven logic.
- The standards, codes, and documented procedures must be analysed to determine to what extent they are applicable to solve the problem, and justification must be given to operate outside these.
- The responsibility lies with the **Engineer, Technologist, and Technician** to verify that some information received as part of the encountered problem may remain incomplete, and solutions to problems may need justified assumptions.
- The problems handled by the **Engineer, Technologist, and Technician** may be solved by alternatives that are unaffordable, detrimental to the environment, socially unacceptable, not maintainable, not sustainable, etc; the **Engineer, Technologist, and Technician** will have to justify their recommendations.
- Practical solutions to problems include knowledge and judgement of the roles displayed by the multi-disciplinary team and impact of own work in the interactive environment.
- Engineers, Technologists, and Technicians** must realise that their actions might seem to be of local importance only but may develop into significant consequences extending beyond their own ability and practice area.

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Assessment criteria: A structured analysis of broadly defined problems typified by the following performances is expected: 1.1 Performed or contributed to defining engineering problems leading to an agreed definition of the problems to be solved. 1.2 Performed or contributed to investigating engineering problems including collecting, organising, and evaluating information. 1.3 Performed or contributed to the analysis of engineering problems using conceptualisation, justified assumptions, limitations, and evaluation of results.	To perform an engineering task, the Engineer, Technologist, and Technician typically receive an instruction from a senior person (customer) to do a specific task, and they must 1.1 Ensure the instruction is complete, clear, and within their capability and that the person who issued the instruction agrees with their interpretation. 1.2 Ensure the engineering problem and related information are segregated from the bulk of the investigated and evaluated information. 1.3 Ensure that the instruction and information to do the work is fully understood and complete, including the acceptance criteria and the engineering theory needed to understand the task and to carry out and/or check calculations. If needed, supplementary information must be gathered, studied, and understood. Concepts and assumptions must be justified by engineering theory and calculations, if applicable.
3. Outcomes to be satisfied:	Explanation and Responsibility Level
Range statement: The problem may be a design requirement, an applied research and development requirement or a problematic situation in an existing component, system or process. The problem is one amenable to solution by technologies known to the Candidate. This outcome is concerned with the understanding of a problem: Outcome 2 is concerned with the solution.	Please refer to section 4 of the specific DSTG.
Outcome 2: Design or develop solutions to complex, broadly defined, and well-defined engineering problems	Responsibility Level E Design means 'drawing or outline from which something can be made'. Develop means 'come or bring into a state in which it is active or visible'.
Assessment criteria: This outcome is normally demonstrated after a problem analysis as defined in Outcome 1. Working systematically to synthesise a solution to a broadly defined problem typified by the following performances is expected:	After the received task is fully understood and interpreted, a solution to the posed problem can be developed (designed). The synthesis of a solution is 'the combination of separate parts, elements, substances, etc. into a whole or into a system' by the following:

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2.1 Designed or developed solutions to complex, broadly defined, and well-defined engineering problems. 2.2 Systematically synthesised solutions and alternative solutions or approaches to the problem by analysing designs against requirements, including costs and impacts on outside parameters (requirements). 2.3 Drawing up detailed specification requirements and design documentation for implementation to the satisfaction of the client.	2.1 The development (design) of more than one way to solve an engineering task or problem should always be done, including a costing and impact assessment for each alternative. All the alternatives must meet the requirements set out by the received instruction, and the theoretical calculations to support each alternative must be done and submitted as an attachment. 2.2 The Engineer, Technologist, or Technician will, in some cases, be unable to support proposals with the complete theoretical calculation to substantiate every aspect and must, in these cases, refer his/her alternatives to an Engineer for scrutiny and support. The alternatives and the recommended alternative must be convincingly detailed to win customer support for the alternative that is recommended. Selection of alternatives might be based on tenders submitted with alternatives deviating from those specified. 2.3 The best selected complete and final solution must be followed up with a detailed technical specification, supporting drawings, bill of quantities, etc. for the execution of the work to meet customer requirements.
Range Statement: Solutions are those enabled by the technologies in the Candidate's practice area.	Applying theory to conduct complex, broadly defined, and well-defined engineering work is mostly done in a way that has been used before, probably developed by Engineers in the past and documented in written procedures, specifications, drawings, models, examples, etc. The Engineer, Technologist, and Technician must seek approval for any deviation from these established methods but must also initiate and/or participate in the development and revision of these norms.
Outcome 3: Comprehend and apply the knowledge embodied in widely accepted and applied engineering procedures, processes, systems, or methodologies and those specific to the jurisdiction in which he/she practises	Responsibility Level E Comprehend means 'to understand fully'. The jurisdiction in which an Engineer, Technologist, and Technician practises is given in section 4 of the specific DSTG.
Assessment criteria: This outcome is normally demonstrated in the course of design, investigation, or operations.	Design work for the Engineer, Technologist, and Technician is based on MSc (BME), BEng, Advanced Dip, and Dip theory and mainly comprises the use and configuration of manufactured components and selected materials and associated novel engineering. The Engineer, Technologist, and Technician develop and apply

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3.1 Apply engineering principles, practices, technologies, including the application of MSc (BME), B Eng, Advanced Dip and Dip theory in the practice area. 3.2 Indicate working knowledge of areas of practice that interact with practice area to underpin teamwork. 3.3 Apply related knowledge of finance, statutory, safety and management.	codes and procedures in their design work. Investigation would be on broadly defined incidents and condition monitoring and operations mostly on developing and improving engineering systems and operations: 3.1 Calculations at MSc (BME), BEng, Advanced Dip, and/or Dip theoretical level confirming the correct application and use of equipment, materials, and systems listed in section 4 of the specific DSTG must be done on relevant Category-level activities. 3.2 The understanding of complex, broadly defined, and well-defined procedures and techniques must be based on fundamental mathematical, scientific, and engineering knowledge as part of personal contribution within the engineering team. 3.3 The ability to manage the resources within legal and financial constraints must be evident.
Range Statement: Applicable knowledge includes the following: a. Technological knowledge that is well established and applicable to the practice area, irrespective of location, and supplemented by locally relevant knowledge, for example, established properties of local materials. Emerging technologies are adopted from formulations of others. b. A working knowledge of interacting disciplines (engineering and healthcare) to underpin teamwork. c. Jurisdictional knowledge includes legal and regulatory requirements in addition to locally relevant codes of practice as required for the practice area—a selection of laws of contract regarding health and safety, environmental sustainability, intellectual property, contract administration, quality management, risk management, maintenance-management regulation, and project and construction management.	a. The specific location of the task to be executed is the most important determining factor in the layout design and use of equipment. A combination of educational knowledge and practical experience must be used to substantiate decisions taken, including a comprehensive study of systems, materials, components, and projected customer requirements and expectations. New ideas, materials, components, and systems must be investigated, evaluated, and applied and be accompanied by complex theoretical motivation. b. Despite having a working knowledge of interacting disciplines, the Engineer, Technologist, and Technician take responsibility for the multi-disciplinary team of clinicians, nurses, administrators, SCM practitioners, etc. c. Jurisdictional in this instance means ‘having the authority’, and the Engineer, Technologist, and Technician must be aware of and decide on the relevant requirements that are applicable to each specific project for which they are responsible. They are usually appointed as the ‘Responsible Person’ for specific projects in terms of the Occupational Health and Safety (OHS) Act.

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Group B: Managing Engineering Activities	Explanation and Responsibility Level
Outcome 4: Manage part or all of one or more complex, broadly defined, and well-defined engineering activities	Responsibility Level E Manage means 'control'.
Assessment criteria: The Candidate is expected to display personal and work-process management abilities: 4.1 Managed self, people, work priorities, processes, and resources in broadly defined engineering work. 4.2 Role in planning, organising, leading, and controlling broadly defined engineering activities evident. 4.3 Knowledge of conditions and operation of contractors and the ability.	In engineering operations, the Engineer, Technologist, and Technician are typically given the responsibility to carry out projects: 4.1 Resources are usually subdivided based on availability and controlled by a work breakdown structure and scheduling to meet deadlines. Quality, safety, and environmental management are important aspects. 4.2 The basic elements of management must be applied to broadly defined engineering work. 4.3 Depending on the project, the Engineer, Technologist, or Technician can be the team leader or a team member or he/she can supervise appointed contractors. To achieve this, maintenance of relationships is important and must be demonstrated.
Outcome 5: Communicate clearly with others in the course of his/her broadly defined engineering activities	Responsibility Level E
Assessment criteria: Demonstrates effective communication by the following: 5.1 Ability to write clear, concise, and effective technical, legal, and editorially correct reports shown. 5.2 Ability to issue clear instructions to stakeholders using appropriate language and communication skills evident. 5.3 Oral presentations made using structure, style, language, and visual aids	Refer to Range Statement for outcomes 4 and 5 below. Presentation of point of view mostly occurs in meetings and discussions with immediate supervisor.

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Range Statement for Outcome 4 and Outcome 5: Management and communication in complex, broadly defined, and well-defined engineering involves the following: a. Planning complex, broadly defined, and well-defined activities b. Organising complex, broadly defined, and well-defined activities c. Leading complex, broadly defined, and well-defined activities d. Controlling complex, broadly defined, and well-defined activities.	a. Planning means 'the arrangement for doing or using something, considered in advance' b. Organising means 'put into working order, arrange in a system, make preparations for' c. Leading means to 'guide the actions and opinions of, to influence, to persuade' d. Controlling means the 'means of regulating, restraining, keeping in order, checking' The Engineer, Technologist, and Technician write specifications for the purchase of materials and/or work to be done, make recommendations on tenders received, place orders and variation orders, write work instructions, report on work done, draw, correct and revise drawings, compile test reports, use operation and maintenance manuals to write work procedures, write inspection and audit reports, write commissioning reports, prepare and present motivations for new projects, compile budget reports, report on studies done and calculations carried out, report on customer requirements, report on safety incidents and risk analysis, report on equipment failure, report on proposed system improvement and new techniques, report on cost control, etc.
Group C: Impacts of Engineering Activity	Explanation and Responsibility Level
Outcome 6: Recognise the foreseeable social, cultural, and environmental effects of complex, broadly defined, and well-defined engineering activities generally	Responsibility level E Social means 'people living in communities; relations between persons and communities'. Cultural means 'all the arts, beliefs, social institutions, etc. characteristic of a community'. Environmental means 'surroundings, circumstances, influences'.
Assessment criteria: This outcome is normally displayed in the course of the analysis and solution of problems. The Candidate typically shows:	

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6.1 Ability to identify interested and affected parties and their expectations regarding interactions between technical, social, cultural, and environmental considerations shown. 6.2 Measures taken to mitigate the negative effects of engineering activities evident.	6.1 Engineering has a significant impact on the environment (e.g. equipment disposal, ionising radiation-emitting devices, borrow pits, dust, obstruction, power dips and interruptions, visual and noise pollution, malfunctions, oil and other leaks, electrocution of human beings, dangerous rotating and other machines, and demolishing of structures). 6.2 Mitigating measures taken may include environmental impact studies, environmental impact management, community involvement and communication, barricading and warning signs, temporary crossings, alternative supplies (ring feeders and bypass roads), press releases, and compensation paid.
Outcome 7: Meet all legal and regulatory requirements and protect the health and safety of persons in the course of his/her broadly defined engineering activities	Responsibility Level E
Assessment criteria: 7.1 Identified applicable legal and regulatory requirements, including health and safety requirements for the engineering activity. 7.2 Circumstances stated where Applicant assisted in or demonstrated awareness of the selection of safe and sustainable materials, components, and systems and identified risk and applied risk management strategies.	7.1 The OHS Act is supplemented by a variety of parliamentary Acts, regulations, local authority by-laws, standards, and codes of practice. Places of work might have standard procedures, instructions, drawings, and operation and maintenance manuals available. Depending on the situation (emergency, breakdown, etc.), these documents are consulted before work is commenced and during the activity. 7.2 It is essential to attend a Risk Management (Assessment) course and to investigate and study the materials, components, and systems used in the workplace. The Engineer, Technologist, and Technician seek advice from knowledgeable and experienced specialists if the slightest doubt exists that safety and sustainability cannot be guaranteed.
Range Statement for Outcome 6 and Outcome 7: Impacts and regulatory requirements include the following: a. Requirements include both explicit regulated factors and those that arise in the course of specific work.	a. The impacts will vary substantially with the location of the task (e.g. the impact of laying a cable or pipe in the main street of town will be entirely different to the impact of construction in a rural area). The methods, techniques, or procedures will differ accordingly and may be complex. These are identified and studied by the Engineer, Technologist, and Technician before starting the work.

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b. Impacts that are considered extend over the life cycle of the project and include the consequences of the technologies that are applied. c. Effects to be considered include the direct and indirect and the immediate and long-term effects related to the technology used. d. Safe and sustainable materials, components, and systems. e. Regulatory requirements are explicit for the context in general.	b. The Safety Officer and/or the Responsible Person appointed in accordance with the OHS Act usually confirms or checks that the instructions are in line with regulations. The Engineer, Technologist, and Technician are responsible for verifying that this is done, and if not, establishing which regulations apply and ensuring that they are adhered to. Usually, the people working on site are strictly controlled w.r.t. health and safety, but the Engineer, Technologist, and Technician check that this is done and may authorise unavoidable deviation after setting conditions for such deviations. Projects are mostly carried out where contact with the public cannot be avoided, and safety measures such as barricading and warning signs must be used and maintained. c. Effects associated with risk management are mostly well known if not obvious, and methods used to address these are clearly defined. Risks are mostly associated with elevated structures, subsidence of soil, electrocution of human beings, and moving parts on machinery. The Engineer, Technologist, and Technician need to identify, analyse, and manage any long-term risks and develop strategies to solve these by using alternative technologies. d. Safe and sustainable materials, components, and systems must be selected and prescribed by the Engineer, Technologist, and Technician. Alternatively, other professional specialists must be consulted. It is the responsibility of the Engineer, Technologist, and Technician to use their knowledge and experience to confirm that prescriptions by others are correct and safe. e. Application of regulations associated with the particular aspects of the project must be carefully identified and controlled by the Engineer, Technologist, and Technician.
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Group D: Exercise judgement, take responsibility, and act ethically	Explanation and Responsibility Level
Outcome 8: Conduct engineering activities ethically	Responsibility Level E Ethically means 'science of morals; moral soundness'. Moral means 'moral habits; standards of behaviour; principles of right and wrong'.
Assessment Criteria: Sensitivity to ethical issues and the adoption of a systematic approach to resolving these issues is expected and typified by the following: 8.1 Conversance and operation in compliance with ECSA's Rules of Conduct for Registered Persons confirmed. 8.2 How ethical problems and affected parties were identified and how the best solution to resolve the problem was selected is demonstrated.	Systematic means 'methodical; based on a system'. 8.1 The ECSA's Code of Conduct, as per the ECSA's website, is known and adhered to. 8.2 Ethical problems that can occur include tender fraud, payment bribery, alcohol abuse, sexual harassment, absenteeism, favouritism, defamation, fraudulent overtime claims, fraudulent expenses claimed, fraudulent qualifications, and misrepresentation of facts.
Outcome 9: Exercise sound judgement in the course of complex, broadly defined, and well-defined engineering activities	Responsibility level E Judgement means 'good sense: ability to judge'.
Assessment criteria: Judgement is displayed by the following performance: 9.1 Judgement exercised in arriving at a conclusion within the application of technologies and their interrelationship with other disciplines and technologies.	9.1 The extent of a project given to a junior Engineer, Technologist, and Technician is characterised by several broadly defined and a few well-defined factors and their resulting interdependence. They will seek advice if educational and/or experiential limitations are exceeded.

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9.2 Factors taken into consideration given while bearing in mind risk and consequences for affected parties in technology application.	9.2 Risky decisions will lead to equipment failure, excessive installation and maintenance costs, damage to persons and property, etc. Evaluation includes engineering calculations to substantiate the decisions taken and the assumptions made.
Range Statement for Outcome 8 and Outcome 9: Judgement in decision-making involves the following: a. taking several risk factors into account; or b. significant consequences in technology application and related contexts; or c. ranges of interested and affected parties with widely varying needs.	In Engineering, about 5% of engineering activities can be classified as broadly defined. For these, the Engineer, Technologist, and Technician use standard procedures, codes of practice, specifications, etc, but develop variations and completely unique standards when needed. Judgement must be displayed to identify any activity falling inside the broadly defined range, as defined above: a. Getting the work done despite numerous risk factors needs good judgement and substantiated decision-making. b. Consequences are part of the project (e.g. extra cost due to unforeseen conditions, incompetent contractors, and long-term environmental damage). c. Interested and affected parties with defined needs that may be in conflict (e.g. the need for a service irrespective of environmental damage, local traditions, preferences, etc. needs sound management and judgement).
Outcome 10: Be responsible for making decisions on part or all of all of one or more complex, broadly defined, and well-defined engineering activities	Responsibility Level E Responsible means 'legally or morally liable for carrying out a duty; for the care of something or somebody in a position where one may be held accountable for loss, failure, etc.'.
Assessment criteria: Responsibility is displayed by the following performance: 10.1 Engineering, social, environmental, and sustainable development taken into consideration in discharging responsibilities for significant parts of one or more activities. 10.2 Advice sought from a responsible authority on matters outside practitioner's area of competence.	10.1 Considering all interrelated factors is indicative of professional responsibility being accepted when working on broadly defined activities. 10.2 The Engineer, Technologist, and Technician do not operate on tasks at a higher level than complex, broadly defined, and well defined, respectively, and consult professionals at Engineer level if elements of the project to be done are beyond their education and experience (e.g. power system stability).

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10.3 Academic knowledge of at least MSc (BME), BEng, Advanced Dip, and Dip level combined with past experience used in formulating decisions.	10.3 Continual self-evaluation is conducted to ascertain that the task given is done correctly, on time and within budget. Continual feedback to the originator of the task instruction and corrective action, if necessary, forms an important element. The calculations, for example, fault levels, load calculations, and losses are done to ensure that the correct material and components are used.
Range Statement: Responsibility must be discharged for significant parts of one or more complex, broadly defined, and well-defined engineering activities.	The responsibility is mostly allocated within a team environment, with an increasing designation as experience is gathered.
Note 1: Demonstrating responsibility is under the supervision of a competent Engineering Practitioner, but he/she is expected to perform as if in a responsible position.	
Group E: Initial Professional Development (IPD)	Explanation and Responsibility Level
Outcome 11: Undertake independent learning activities sufficient to maintain and extend his or her competence	Responsibility Level E
Assessment criteria: Self-development managed typically by the following: 11.1 Strategy independently adopted to enhance professional development evident. 11.2 Awareness of philosophy of employer regarding professional development evident.	11.1 If possible, a specific field of the sub-discipline is chosen, available developmental alternatives are established, a programme is drawn up (in consultation with employer if costs are involved), and options open to expand knowledge into additional fields are investigated. 11.2 Record-keeping must not be left to the employer or anybody else. Trainees must manage their own training independently, taking initiative and being in charge of experiential development towards professional registration.
Range Statement: Professional development involves the following: a. Planning own professional development strategy	a. In most places of work, training is seldom organised by a training department. It is the responsibility of the Engineer, Technologist, and Technician to manage their own experiential development. Engineers, Technologists, and Technicians frequently end up in a 'dead-end street', being left behind doing repetitive work. If self-development is not driven by oneself, success is unlikely.

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b. Selecting appropriate professional development activities	b. Preference must be given to engineering development rather than the development of soft skills.
c. Recording professional development strategy and activities, while displaying independent learning ability.	c. Developing a learning culture in the workplace environment of the Engineer, Technologist, and Technician is vital to their success.

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APPENDIX B: TRAINING ELEMENTS

1	Introduction
1.1	<i>Induction programme (typically 1–5 days)</i>
1.1.1	Company structure
1.1.2	Company policies
1.1.3	Company Code of Conduct
1.1.4	Company safety regulations
1.1.5	Company staff code
1.1.6	Company regulations
1.2	<i>Exposure to Practical Aspects of Engineering (typically 6–12 months) and covers how things are: (Responsibility Levels A–B)</i>
Experience in one or more of these sectors but not all:	
1.2.1	Manufacturing
1.2.2	
1.2.3	
1.2.4	Field installation
1.2.5	Testing
1.2.6	Commissioning
1.2.7	Operation
1.2.8	Maintenance
1.2.9	Fault location
1.2.10	Problem investigation
2	Design or develop solution
2.1	<i>Experience in design and application of design knowledge (typically 12–18 months). Focus is on planning, design, and application (Responsibility Levels C–D)</i>
Experience in one or more of the sectors below:	
2.1.1	Analysis of data and systems
2.1.2	Planning of networks and systems
2.1.3	System modelling and integration

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2.1.4	System design
2.1.5	Network / circuit design
2.1.6	Component / product design
2.1.7	Software design
2.1.8	Research and investigation
2.1.9	Preparation of specifications and associated documentation
2.1.10	Preparation of contract documents and associated documentation
2.1.11	Development of standards
2.1.12	Application of quality systems
2.1.13	Configuration Management
3	Engineering tasks
3.1	<i>Experience in the execution of engineering tasks (remainder of training period). Focus should be on projects and project management (Responsibility Level E)</i>
	Working in one or more of these sectors but not all:
3.1.1.	Design or develop solution
3.1.2	Manufacture
3.1.3	Construction
3.1.4	Erection
3.1.5	Installation
3.1.6	Commissioning
3.1.7	Maintenance
3.1.8	Modifications
3.2	<i>Organising for implementation of 3.1 (Responsibility Level E)</i>
3.2.1	Manage resources
3.2.2	Optimisation of resources and processes
3.3	<i>Controlling for implementation or operation of 3.1 (Responsibility Level E)</i>
3.3.1	Monitor progress and delivery
3.3.2	Monitor quality
3.4	<i>Completion of 3.1 (Responsibility Level E)</i>
3.4.1	Commissioning completion

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3.4.2	Documentation completion
3.4.3	Documentation handover
3.5	<i>Maintenance and repair of 3.1 (Responsibility Level E)</i>
3.5.1	Planning and scheduling maintenance
3.5.2	Monitoring quality
3.5.3	Overseeing maintenance and repair
4	Risk and impact mitigation
4.1	<i>Impact and risk assessments (Responsibility Level E)</i>
4.1.1	Risk assessments
4.2	<i>Regulatory compliance (Responsibility Level E)</i>
4.2.1	Health and safety
4.2.2	Codes and standards
4.2.3	Legal and regulatory
5	Managing engineering activities
5.1	<i>Self-management (Responsibility Levels C–D)</i>
5.1.1	Manages own activities
5.1.2	Communicates effectively
5.2	<i>Team environment (Responsibility Levels C–D)</i>
5.2.1	Participates in and contributes to team planning activities
5.2.2	Manages people
5.3	<i>Professional communication and relationships (networking) (Responsibility Levels C–D)</i>
5.3.1	Establishes and maintains professional and business relationships
5.3.2	Communicates effectively
5.4	<i>Exercising judgement and taking responsibility (Responsibility Level E)</i>
5.4.1	Ethical practices
5.4.2	Code of Conduct
5.4.3	Exercises sound judgement in the course of complex engineering activities
5.4.4	Is responsible for decision-making in some or all engineering activities
5.5	<i>Competency development (Responsibility Level D)</i>
5.5.1	Plans own development programme

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5.5.2 Constructs initial professional development record

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