Quality Council for Trades & Occupations
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QUALIFICATION ASSESSMENT SPECIFICATIONS (QAS) DOCUMENT

QUALIFICATION	TYPE (NOMENCLATURE)	TITLE (DESCRIPTOR)	NQF LEVEL	CREDITS
	Occupational Higher Certificate	Health Products Regulatory Assistant	5	134
CURRICULUM CODE	242213-001-00-00			
PARTNER DETAILS	**ORGANISATION NAME**	**WEBSITE ADDRESS**	**TELEPHONE NUMBER**	**LOGO**
QUALITY PARTNER - DEVELOPMENT	CHIETA	www.chieta.org.za	011 628 7000	
QUALITY PARTNER – ASSESSMENT	CHIETA	www.chieta.org.za	011 628 7000	

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SECTION 1: ASSESSMENT STRATEGY

1.1 Internal Assessment

The curriculum document must be used for the assessment of learners in preparation for the EISA (External

Integrated Summative Assessment).

Internal Assessment is the responsibility of an accredited Skills Development Provider (SDP) and is conducted during the delivery of learning/training. The accredited Skills Development Provider (SDP) is responsible for internal assessment. To execute this responsibility, the SDP is required to:

- plan and develop
- conduct, administer and manage
- evaluate and analyse the results and outcomes
- moderate
- record and report

Internal Assessments must be in the form of (i) formative and (ii) summative assessments for all knowledge and practical modules, and the workplace/application statement of results recorded.

(i) Internal formative assessment is assessment of learning that must take place learning and includes a range of formal, non-formal, and informal assessment procedures that are used during the delivery of module(s) for the qualification to focus teaching and learning activities.

(ii) Internal summative assessment, is conducted at the end of each module to assess acquired outcomes (assessment criteria) and competencies, at the end of each module which may also be integrated. Results per module must be formally recorded.

The recorded internal summative assessment results are used to issue the learner with a Statement of Results (SoR). This SoR is an admission requirement for the (External Integrated Summative Assessment) EISA, and the template for this is available from the QP/NAMB.

1.2 External Integrated Summative Assessment (EISA)

1.2.1 Planning and Conduct and Quality Assurance of EISA

EISA is:

- planned and developed by the Quality Partner according to occupational assessment standards determined by industry
- conducted, administered and managed (evaluation, analysis of results and outcomes, moderation, recording and reporting) by a QCTO accredited Assessment Centre
- quality assured by the QCTO

EISA is a final assessment which integrates the knowledge and application to assess the competence of a learner against the stated Exit Level Outcomes (ELO) of the qualification.

1.2.2 Structure/model of EISA

<table>
<tr><td>FORMAT OF ASSESSMENT:

Written/Practical/Other</td><td colspan="5">Written and Technology Enhanced</td></tr>
<tr><td rowspan="3">COGNITIVE ABILITY:

For Applications for Medicine Registration

For Applications for Medical Device Establishment Licencing</td><td colspan="2">% KNOWLEDGE</td><td colspan="2">% APPLICATION</td><td>% CRITICAL THINKING</td></tr>
<tr><td colspan="2">3%</td><td colspan="2">27%</td><td>70%</td></tr>
<tr><td colspan="2">4.5%</td><td colspan="2">32%</td><td>58.5%</td></tr>
<tr><td rowspan="8">DURATION OF COMPONENT(S):</td><td>COMPONENT(S)</td><td colspan="4">HOURS</td></tr>
<tr><td>WRITTEN</td><td colspan="2">2 hrs and 50 minutes</td><td>TOTAL MARKS</td><td>155</td></tr>
<tr><td>PRACTICAL</td><td colspan="4">N/A</td></tr>
<tr><td>OTHER</td><td colspan="4">200 mins for Medicine Registration

60 minutes for Medical Device Establishment Licencing</td></tr>
<tr><td></td><td colspan="4"></td></tr>
<tr><td></td><td colspan="4"></td></tr>
<tr><td></td><td colspan="4"></td></tr>
<tr><td rowspan="4">TOTAL MARK OR COMPETENCY REQUIREMENT FOR EACH COMPONENT:</td><td>COMPONENT(S)</td><td colspan="4">MARK/COMPETENCY</td></tr>
<tr><td>WRITTEN</td><td colspan="4">155</td></tr>
<tr><td>PRACTICAL</td><td colspan="4"></td></tr>
<tr><td>OTHER</td><td colspan="4">145 for Medicine registration

45 for Medical Device Establishment Licencing</td></tr>
<tr><td>CALCULATION OF FINAL RESULTS REQUIRED IN ORDER TO BE DECLARED COMPETENT:</td><td colspan="5">180 for Medicine registration

120 for Medical Device Establishment Licencing</td></tr>
</table>

REQUIREMENTS FOR AN ACCREDITED ASSESSMENT CENTRE:	**Written assessment** • QCTO accredited Assessment Centre. • Access to appropriate facilities where the theoretical learning can take place this implies lecture facilities, self study areas and/or computer-based learning hubs.
	• Compliance with occupational health, safety, and environmental protection regulations • The facilitator/learner ratio must not exceed 1/30 for theory and 1/15 for the technology-enhanced assessment. • Access controlled environment • Stationery • Examination hall/ room that is ventilated and illuminated • Furniture: chairs, tables, white board, and clock. • Strong rooms for storage of examination material • Signages to indicate directions to exam venues **Technology-enhanced** Computers, appropriate software, and electronic versions of documents for the various questions.
REQUIREMENTS FOR CANDIDATES TO BRING ALONG TO THE ASSESSMENT:	• Green bar-coded ID or Smart ID or Passport with a valid study visa • A copy of the Statement of Results (SOR) • Stationery (pens, pencils, rubbers and calculators).
OPEN OR CLOSED BOOK ASSESSMENT:	Closed
ACCESS TO EISA FOR CANDIDATES WITH SPECIAL NEEDS:	The assessments are done verbally and in writing. There are no limitations for physically handicapped learners as long as they were able to complete the required workplace components. Sign writers will be made available to assist persons with hearing impairments where applicable.

1.2.3 Competencies to be assessed in the EISA:

The assessment standards for the EISA are based on the Occupational Profile, the purpose of the qualification profile, the purpose of the qualification, the Exit Level outcomes, and is aligned to the SAQA NQF Level descriptors appropriate for the level of the qualification. The final EISA is based on all modules in the curriculum.

EXIT LEVEL OUTCOMES:	**WEIGHTING:**	**CRITICAL ASPECTS TO BE EXTERNALLY ASSESSED - CORE FOCUS OF WHAT WILL BE ASSESSED TO PROVE COMPETENCE**
		(encapsulating knowledge, skills and attitudes)**:**

Exit Level Outcome 1: Submit applications pertaining to licences of healthcare establishments and registration of health products	50%	**Associated Occupational Task 1** • Collate and assist with the submission of regulatory documentation for health and personal care products, under supervision, to the relevant authority, and **Associated Occupational Task 2** • Monitor the progress, lifecycle and compliance (amendments, variations etc.) of regulatory documentation submitted to the relevant authority **Occupational Responsibilities** • Check and collate information collected against requirements • Assist in compiling regulatory documentation according to requirements • Assist in submission of regulatory documentation according to specific formats and instruction • Liaise and communicate with relevant internal and external stakeholders • Identify industry experts and set-up appointments • Engage with peers and diverse audiences such as industry professionals and cross functional stakeholders • Participate in quality audits

		<u>and</u> • Follow-up on submissions made to the regulator (raising the alarm bell) • Perform change control • Follow-up variations **Associated Assessment Criteria for the ELO** • The regulatory body's online registration processes, guidelines and forms for all health products are obtained to ensure strict adherence in the application processes • The regulatory body's licensing processes, guidelines and forms for all health establishments are obtained to ensure strict adherence to the licensing process • Due diligence is performed on the file/s provided by a licence holder • Preparation of documentation for the various applications is completed by giving due consideration to the regulatory body's validation (screening) and evaluation processes for health products • All forms and supporting physical and electronic documentation required by regulator for the application are completed through adherence to regulatory body's requirements

		• The regulatory body's electronic system or appropriate submission procedure/ mechanism is utilised to

		complete submission of dossiers for registration of a health product or licensing of a health establishment
Exit Level Outcome 2 Submit applications pertaining to renewals, amendments/ variations and retentions	20%	This task is closely related to Task 1 above. Aspects to assess: • The regulatory body's processes, guidelines and forms for renewals, amendments/variations and retention of all health products are obtained to ensure strict adherence to the application processes • Due diligence is performed on the file/s provided by a licence holder • All forms and supporting physical and electronic documentation required by regulator for the applications are completed through adherence to regulatory body's requirements • The regulatory body's electronic system or appropriate submission procedure/mechanism is utilised to complete submission of applications for renewals, amendments/ variations and retentions

Exit Level Outcome 3 Conduct/perform code compliance activities on health products	15%	Associated Occupational Task Proof read marketing and promotional material and labelling for regulatory compliance Occupational Responsibilities • Proof read marketing and promotional material • Proof read labelling of health and personal care products

		• Keep records and update technical files • Package and label samples • Approve supplier information for packaging and printed material <u>Associated Assessment Criteria for the ELO</u> • The content and artwork of promotional and educational materials for a health product is checked for compliance to relevant codes and standard operating procedures (SoPs) • Promotional activities are checked for compliance with the relevant codes and SoPs and recommendations are made for activities that do not comply • Checks and corrections to promotional and educational materials and activities are completed and administrative records are appropriately filed/saved and updated as per regulatory requirements • Incoming and outgoing complaints pertaining to promotional and educational materials and activities are received and lodged, and escalated if required according to SoP • Unethical practices regarding promotional and educational materials and activities are handled and escalated if required according to SoP

Exit Level Outcome 4 Conduct / perform vigilance and post marketing surveillance to ensure the safe usage of health products	15%	Associated Occupational Task Handle the reports on post marketing surveillance in accordance with the requirements of the relevant authority Occupational Responsibilities • Collect and collate reports and submit on the system • Maintain a risk register Associated Assessment Criteria for the ELO • Concepts, definitions and terminology associated with vigilance are explained • Adverse reaction/event reporting forms are completed and submitted to the regulatory body through its appropriate submission procedure/mechanism • A health product recall assignment is implemented according to SoPs • A report on vigilance is prepared as per SoPs • Recall letters and media releases are prepared and sent to the industry

1.2.4 Planned assessment dates and candidate support

The Quality Partner for the qualification will publish:

- annual assessment dates and one exemplar (together with memoranda or marking guidelines) in order for the candidate(s) to see what can be expected in the EISA.
- final assessment guidelines and information in relation to queries, concerns and appeals.

For Occupational Trades, learners must register for the Practical EISA (Trade Test) at an Accredited Assessment Centre/Trade Test Centre. These Assessment Centres must notify the QCTO of these assessments that will be conducted, at least one month prior to the EISA.

1.2.5 Eligibility Requirements for the External Integrated Summative Assessment (EISA)

In order to qualify for the EISA:

- Accredited SDP, must upload learner information on the QCTO system within 21 days of learner being enrolled.
- Learners must have:
  - a copy of their ID (or alternative ID), and
  - a completed and signed Statement of Results (SoR).
  - Completed Statement of Work Experience template

Accredited Skills Development Providers must register their learners with the QCTO for an EISA at least 3 months prior to completion of the qualification.

EISA will be conducted according to dates scheduled by the Quality Partners.

SECTION 2: CRITERIA FOR SUBJECT MATTER EXPERTS (SME)

SME may be assigned as developers, markers/assessors and moderators. The criteria for SME are determined by industry, and contained in the QCTO Curriculum Document after each module.

The criteria for assessors/markers and moderators for the **development/moderation** of the EISA assessment instruments:

Each of the below categories must be determined by industry as required for each qualification; to be guided by the following criteria:

- Minimum three years' experience in industry for developers, markers or assessors; evidence thereof required.
- Minimum of five years' experience in industry for moderators; evidence thereof required.
- Occupational learning and development experience in related fields, evidence of active current practice, trained in assessment practice and recognised by the sector for experience and credibility.
- Active professional membership with professional designation is recommended.

(a) Requirements for the EISA Developers:

- Must be in possession of a NQF Level 6 health products regulatory or related qualification and/or
- Must have 3 years' experience working in the health products regulatory environment • Must have assessment experience

(b) Requirements for the EISA Markers/Assessors:

- Must be in possession of a NQF Level 6 health products regulatory or related qualification and/or
- Must have minimum 1 years' experience working in the health products regulatory environment

(c) Requirements for EISA Moderators (Pre and Post):

- Must be in possession of a NQF Level 6 health products regulatory or related qualification and/or
- Must have minimum 1 years' experience working in the health products regulatory environment
- Must have some moderation experience