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

PART- QUALIFICATION	TYPE (NOMENCLATURE)	TITLE (DESCRIPTOR)	NQF LEVEL	CREDITS
	Occupational Certificate	Health Products Vigilance Officer (HPVO)	5	46
CURRICULUM CODE	242213-001-00-02			
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	

Contents

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</td></tr>
<tr><td rowspan="2">COGNITIVE ABILITY:</td><td colspan="2">% KNOWLEDGE</td><td colspan="2">% APPLICATION</td><td>% CRITICAL THINKING</td></tr>
<tr><td colspan="2">11%</td><td colspan="2">71%</td><td>18%</td></tr>
<tr><td rowspan="4">DURATION OF COMPONENT(S):</td><td>COMPONENT(S)</td><td colspan="4">HOURS</td></tr>
<tr><td>WRITTEN</td><td>Yes</td><td>TOTAL MARKS</td><td colspan="2">80</td></tr>
<tr><td>PRACTICAL</td><td colspan="4">N/A</td></tr>
<tr><td>OTHER</td><td colspan="4">N/A</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">80</td></tr>
<tr><td>PRACTICAL</td><td colspan="4">N/A</td></tr>
<tr><td>OTHER</td><td colspan="4">N/A</td></tr>
<tr><td>CALCULATION OF FINAL RESULTS REQUIRED IN ORDER TO BE DECLARED COMPETENT:</td><td colspan="5">Must obtain 60% = 48 marks</td></tr>
</table>

REQUIREMENTS FOR AN ACCREDITED ASSESSMENT CENTRE:	• Access to appropriate facilities where the theoretical learning can take place this implies lecture facilities, selfstudy areas and/or computer-based learning hubs. • Compliance with occupational health, safety, and environmental protection regulations • The invigilator/candidate ratio must not exceed 1:20 for the written. • 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
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)
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. 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 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:

- Developer must have 3 years' experience working in the health product sector and/or
- Developer must be in possession of a NQF Level 6 health product or related qualification

(b) Requirements for the EISA Markers/Assessors:

- Assessor must have 2 years' experience working in the health product sector and/or
- Assessor must be in possession of a NQF Level 6 health product or related qualification

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

- Moderator must have moderation experience
- Moderator must be in possession of a NQF Level 6 health product or related qualification