Component Specification

Product and Process Validation

NFQ Level 5

5N3044

1. Component Details

Title	Product and Process Validation
Teideal as Gaeilge	Bailíochtú Táirge agus Proiseis
Award Class	Minor
Code	5N3044
Level	5
Credit Value	15
Purpose	The purpose of this award is to equip the learner with the relevant knowledge, skill and competence to complete product and process validations with limited supervision, in a wide variety of contexts to an auditable standard.
Learning Outcomes	Learners will be able to:

1   Explain the phases of a validation to include installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ)

2   Outline the requirements of relevant governing bodies such as Food and Drug Administration (FDA), International Standards Organisation (ISO), and Technischer Überwachungs-Verein (TUV)

3   Describe the positive benefits of pre validation runs and their influence on process stability and process windows

4   Explain the various validation rationales to include: grouping rationales for validation, lifecycle approach and retrospective validation

5	Summarise how a cleaning validation is completed
6	Utilise guidance documents such as ISO EN 13485 to apply the appropriate legislation as required
7	Use a validation flowchart to demonstrate the chronology of the documentation in a Master Validation Plan (MVP)
8	Analyse the results of either a design of experiments (DOE) or a failure mode effect analysis (FMEA) study
9	Illustrate by the use of examples or case studies how to construct validation protocols and reports
10	Design a complete complex validation protocol including IQ, OQ and PQ, providing all relevant documentation
11	Design a Master Validation Plan (MVP) for a given process, providing all relevant documentation.

Assessment

General Information

Details of FET assessment requirements are set out in
Assessment Guidelines for Providers.

All FET assessment is criterion referenced. Successful achievement of the award is based on learners attaining the required standards of knowledge, skill or competence.

The techniques set out below are considered the optimum approach to assessment for this component. In exceptional circumstances providers may identify alternative assessment techniques through the provider's application for programme validation which are **reliable** and **valid** but which are more appropriate to their context.

Assessment of a number of components may be integrated across programmes for delivery, provided that the learning outcomes of each minor award are assessed.

Group or team work may form part of the assessment, provided each learner's achievement is separately assessed.

All providers are required to submit an assessment plan as part of their application for programme validation. Assessment Plans will include information relating to scheduling and integration of assessment. See current FET validation guidelines at
www.qqi.ie.

Assessment Techniques	In order to demonstrate that they have reached the standards of knowledge, skill and competence identified in all the learning outcomes, learners are required to complete the assessment(s) below.

The assessor is responsible for devising assessment instruments (e.g. project and assignment briefs, examination papers), assessment criteria and mark sheets, consistent with the techniques identified below and FETAC's assessment requirements.

Programme validation will require providers to map each learning outcome to its associated assessment technique. See current FET validation guidelines at www.qqi.ie.

All learning outcomes **must** be assessed and achieved

Skills Demonstration	70%
Examination - Theory	30%

Description

Skills Demonstration

A skills demonstration is used to assess a wide range of practical based learning outcomes including practical skills and knowledge. A skills demonstration will require the learner to complete a task or series of tasks that demonstrate a range of skills.

The assessor will devise a skills demonstration based on learning outcomes 10 to 11.

Examination - Theory

An examination provides a means of assessing a learner's ability to recall and apply knowledge, skills and understanding within a set period of time and under clearly specified conditions.

A theory-based examination assesses the ability to recall, apply and understand specific theory and knowledge.

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The assessor will devise a theory based examination based on learning outcomes 1 to 9.

Recognition of Prior Learning (RPL)

Learners may be assessed on the basis of their prior knowledge and experience. Providers must be specifically quality assured to assess learners by this means. To do so they must complete B10, see Provider's Quality Assurance Guidelines and be included on the Register of RPL approved providers. See RPL

Guidelines at www.fetac.ie for further information and registration details.

Grading	Pass	50% - 64%
	Merit	65% - 79%
	Distinction	80% - 100%

Specific Validation Requirements   There are no specific validation requirements

Supporting Documentation   None

Access   To access programmes leading to this award the learner should have reached the standards of knowledge, skill and competence associated with the preceding level of the National Framework of Qualifications. This may have been achieved through a formal qualification or through relevant life and work experience.sd

Transfer   Successful completion of this component award enables the learner to transfer to programmes leading to other certificates where this component is a mandatory or an elective requirement.

2. FET Award Standards

QQI award standards are determined within the National Framework of Qualifications (NFQ), http://www.nfq-qqi.com. QQI determines standards for the education and training awards that it makes itself and that are made by providers to whom it has delegated authority to make an award. Providers offering programmes leading to QQI awards **must** have their programme(s) validated in accordance with current validation policy (see www.qqi.ie).

Award standards are designed to be consistent with the NFQ's award classes i.e. major, special purpose, supplemental and minor awards. They are expressed in terms of **learning outcomes** i.e. concise statements of what the learner is expected to know or be able to do in order to achieve a particular award. Learning outcomes for FET awards are contained within the associated specifications:

AWARD CLASS	STANDARDS	AWARDS
Major Award	Certificate Specification	Certificate (Levels 1 to 5) Advanced Certificate (Level 6)
Supplemental Award	Supplemental Specification	Supplemental Certificate (Level 3 to 6)
Special Purpose	Specific Purpose Specification	Specific Purpose Certificate (Levels 3 to 6)

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Minor Award	Component Specification	Component Certificate (Levels 1 to 6)

Award standards are thresholds, they describe standards of knowledge, skill or competence to be acquired, and where appropriate, demonstrated, by a learner before an award may be made.

Award standards will be reviewed from time to time as necessary. Minor changes may be made by the QQI executive outside the review cycle where necessary. Changes to standards are published on QQI's website. Providers with validated programmes and providers with delegated authority to make awards are responsible for monitoring relevant standards and making necessary responses to changes.

3. FET Credit

Every FET certificate and component specification includes an FET credit value (Table 1). FET credit is quantified in multiples of 5 FET credits (up to 50 hours of learner effort). Learner effort is based on the time taken by typical learners at the level of the award to achieve the learning outcomes for the award. It includes all learning time involved including: guided learning hours, self-directed learning and assessment.

Table 1: FET Credit Values

NFQ Level	Major Awards Credit Values	Default Credit Values Minor Awards	Other Permitted Minor Award Credit Values	Special Purpose and Supplemental Award Credit Value Ranges
1	20	5	10	
2	30	5	10	
3	60	10	5,20	>5 and<60
4	90	10	5,15,20	>5 and<90
5	120	15	5,10,30	>5 and <120
6	120	15	5,10,30	>5 and <120

Guide to Level

Learning outcomes at this level include a broad range of skills that require some theoretical understanding. The outcomes may relate to engaging in a specific activity, with the capacity to use the instruments and techniques relating to an occupation. They are associated with work being undertaken independently, subject to general direction.

Strand	Sub-strand	Nature of learning
Knowledge	Breadth	Broad range of knowledge
	Kind	Some theoretical concepts and abstract thinking, with significant depth in some areas.
Know How & Skill	Range	Demonstrate a broad range of specialised skills and tools
	Selectivity	Evaluate and use information to plan and develop investigative strategies and to determine solutions to varied unfamiliar problems

Competence	Context	Act in a range of varied and specific contexts, taking responsibility for the nature and quality of outputs; identify and apply skill and knowledge to a wide variety of contexts
	Role	Exercise some initiative and independence in carrying out defined activities; join and function within multiple, complex and heterogeneous groups
	Learning to Learn	Learn to take responsibility for own learning within a managed environment
	Insight	Assume full responsibility for consistency of self- understanding and behaviour

Extract from 'Determinations for the Outline National Framework of Qualifications': NQAI