

Title: Production and Service Provision - Validation

1.0 Purpose

- 1.1. This procedure defines the methods used to validate any special processes for production and service provision at **COMPANY**.

2.0 Responsibility

- 2.1. Production Control is responsible for this procedure.

3.0 Requirements

- 3.1. The Narrative contained in **6.0 Method** (Flowchart and/or Narrative) defines the system used at **COMPANY** for the control of validation of special processes.

Validation of special processes includes:

- a) defined criteria for review and approval of the processes
- b) approval of equipment and qualification of personnel
- c) use of specific methods and procedures
- d) requirements for records
- e) revalidation

Validation will demonstrate the ability of special processes to achieve planned results.

SAMPLE PAGE

4.0 Definitions

- 4.1. Special Processes – are processes where the resulting outputs cannot be verified by subsequent monitoring or measurement, to include any processes where deficiencies become apparent only after the product is in use or the service has been delivered.
- 4.2. Process Control Specifications – are formally documented specifications that define the conformity requirements of special processes.

5.0 Records

- 5.1. Quality Assurance maintains records of special processes validation.