Procedure PR-PRO-009

Validation of Equipment

1. SUMMARY

1.1. The purpose of this procedure is to define how the company validates critical equipment tools and software programs prior to use.

1.2. The Directors are responsible for implementation and management of this procedure.

2. REVISION AND APPROVAL

Rev.	Date	Nature of Changes	Approved By
1	01/01/16	Original issue.	Kyle Devine
2	24/11/2021	Updated document number, formatting and references to relevant controlled document numbers added.	Kyle Devine

3. APPLICATION AND EXEMPTIONS

3.1. Application

3.1.1. This procedure applies to all business streams which require any equipment to undertake their duties.

3.2. Exemptions

3.2.1. Equipment solely used for supporting facilities is exempt from this procedure; this includes compressors, vehicles, air handling systems, lighting, etc.

3.2.2. All production equipment, tooling and software in use for at least six months prior to the release of the first version of this procedure in 01/01/16 is to be considered validated by way of previous use and history, and therefore is exempted from this procedure, unless otherwise marked as nonconforming (see rules below). However, if any significant change is made to legacy equipment, tooling or software, this may trigger a new validation requirement if the change could affect product quality.

4. VALIDATION PROCEDURES

4.1. Equipment and Tooling

4.1.1. In order to validate equipment and tooling, the items shall be built or installed and put through at least one trial operation; this usually means testing any new equipment in a controlled environment for correct operation.

4.1.2. If the results of the inspection show the item is not acceptable, the information shall be provided to the Director(s) for discussion with the supplier.

4.1.3. Where appropriate, it may become necessary to work with a device's manufacturer to assist in making the appropriate adjustment or repairs to get the equipment validated.

4.1.4. Equipment failing validation may not be used and must be marked visibly with appropriate signage indicating "DO NOT USE" or "AWAITING VALIDATION" or similar language.

4.1.5. Equipment and tooling may be considered to have been validated unless otherwise marked.

5. MAINTENANCE AND ONGOING VERIFICATION

5.1. Ongoing assessments of the validity of validated equipment, tooling and programs are done during internal auditing (see procedure *PR-PRO-014 Internal Auditing*), as well as ongoing inspection of parts during normal production.

5.2. Preventive maintenance programs are in place for critical equipment, to ensure proper functioning of such equipment, per the procedure *PR-PRO-018 Preventive Maintenance.*