1.0 Purpose

This document discusses the validation of “special processes” (see below) for Production (or Service). It also covers the maintenance of production equipment and selection of tools including the instructions and the responsibilities.

2.0 Special Processes

The ISO 9001 standard requires that the organization validate any processes for Production (or Service) for which the resulting output cannot be verified by subsequent monitoring of measurement. We will call these “special processes”.

Product Resources does not currently run such special processes. Should Product Resources need to run a special process, it shall be the joint responsibility of Engineering and Quality Assurance to validate the process and thereby demonstrate the ability of the process to achieve planned results. It shall be the responsibility of Engineering to provide procedures for the process in the product routing. It shall be Manufacturing’s responsibility to maintain the process once put in place.

Should Product Resources begin to use special processes, this section of the Quality Manual will be augmented.

3.0 Specific Additional Requirements for Medical Devices

For ISO 13485, to which Product Resources’ Quality system applies when handling medical devices, there are specific requirements for the validation of sterilization processes.

Sterility is excluded from Product Resources’ scope for medical devices / for ISO 13485; see 90-2000-4.1. Should sterility be included in the future, the Quality Manual shall be amended with specific policies, procedures, and responsibilities to govern the validation of sterilization processes.

4.0 Production Equipment and Tools

4.1 Manufacturing is responsible for the selection, installation, and maintenance of production equipment. Engineering may be called on for assistance as needed.

4.2 Technical data sheets and maintenance manuals for production equipment, if provided, are kept by Manufacturing. Installation and maintenance are performed in accordance with the equipment manufacturer's recommendations.

4.3 Manufacturing maintains a database of all production equipment that requires periodic or preventive maintenance (PM) whether or not it is owned by the company. The database identifies a piece of equipment requiring maintenance by its part number, manufacturer, model, description, serial number, location, maintenance frequency, last maintenance date, next maintenance due date, maintenance provider (internal or external), and any related notes.

The database is updated as required and a PM record added the equipment history upon completion of PM.

QT9, Product Resources electronic QMS system, holds this database, and this process uses QT9's Calibration module.

See also 90-2000-4.2.4, Control of Records.

4.4 When it is important that a particular piece of production equipment or a particular tool be used for a production operation, Engineering shall include it by part number in the product's routing.