1.0 Purpose

This document will cover the employee competence, awareness, and training policies and procedures for Product Resources. Special policies and procedures for product regulated under the ATEX Directive and the Medical Device Directive will be discussed as well.

2.0 Policy

Competence for job functions shall be established based on employees' **past experiences and any gap filled through training. Job descriptions shall be established. Employees shall be aware of the Quality system and shall be trained, at a minimum, to understand and fulfill the Quality Manual procedures that impact their functions so that the Quality system may operate as planned.**

Awareness training shall be given to all employees who interact with product controlled under the ATEX Directive.

Awareness training shall be given to all employees who interact with product controlled under the Medical Device Directive. In addition, for such product, product-specific training shall be given.

Job descriptions and training records shall be kept on file and organized to permit easy retrieval of the information.

3.0 Procedure - Competence

All personnel shall have a job description that covers all job functions including Quality functions that personnel are required to perform. Personnel shall show evidence of qualification for the job functions described either through formal education or past experience or otherwise training given at Product Resources or sponsored by Product Resources before being allowed to independently perform those functions. Employees are expected to work under the direct supervision of those qualified until the required training is obtained. See below for the assessment of training needs.

Competence for the assembly and test of product controlled under the Medical Device Directive shall be established by personnel having received product-specific training with that training recorded. Any given medical device product shall not be assembled or tested by personnel who have not yet received the product-specific training unless under the direct supervision of a trained employee. Note that the sign-off of an operation on a job order time sheet in the just-mentioned scenario shall be by the trained employee who is giving the direct supervision. Please see more below in the Training procedure for the nature of and responsibility for this training.

4.0 Procedure - Awareness

Employees shall be made aware of the company's **Quality system and ISO 9001. During orientation employees view a presentation about ISO 9001:2008 (TM-1015)**, and employees are given a copy of the company's **Quality Policy. Both are discussed.**

Human Resources determines the general orientation training needs for employees and also provides an Employee Manual (43-4391). Temporary employees shall be trained if they have continuous employement for at least 3 months, and within 6 months.

Participation in this orientation is recorded in the QT9 software by the provider of the training or Human Resources. See more below about recording training.

Employees who interact with ATEX-Directive-regulated product shall be made aware of the ATEX Directive and what it means to Product Resources to comply. This is facilitated by training material TM-1014 (Awareness/Overview of ATEX Directive, ISO 80079-34, and Product Resources' Implementation**) and by discussion. The QA Manager runs this training.**

Company management and other functional area leads who interact with Medical-Device-Directive-regulated product, medical devices, shall be made aware of the Medical Device Directive and what it means to Product Resources to comply. This is facilitated by training material TM-1016 (Awareness/Overview of Medical Device Directive, ISO 13485, and Product Resources' implementation**) and by discussion. The QA Manager runs this training. Production and Test personnel receive product-specific training; see Procedure - Training in the next section of this document.**

The Management Representative for ISO 13485 shall receive external training on the ISO 13485 standard to facilitate best awareness of its requirements and interpretation.

5.0 Procedure - Training

Assessment

Employees are assessed for training needs upon hire, during any probationary period, and at least annually, normally coincident with employees' reviews.

Human Resources shall initiate the training process upon hire by assigning the default and minimum-required training to the employee based on the employee role(s). These assignments are based on the Training Template.

The Training Template (43-2808) has been developed by Quality Assurance to assist Human Resources and department managers and supervisors in the assessment task. Reference document 43-2808. The Training Template describes the required training for a given job function (role). It gives the minimum training set for a job function. Department mangers and supervisors may use this Template to understand what training will be assessed by default for those employee in their area of responsibility and as the basis for instructing Human Resources that additional training is required.

Each procedure in this Quality Manual shall appear in the Training Template. In addition, all procedures and training materials directly referred to by this Quality Manual shall appear in the Training Template. At a minimum, all Quality Manual procedures, next-tier procedures, and training materials for which understanding is required to perform a job function as planned shall be assigned to that job function in the Template. In addition, there shall be one each special role in the Template for employees interacting with ATEX-Directive-regulated product and Medical Device-Regulated product. These are separate from the balance of the roles in the Template because the need for this training is based on interaction with such product, and not everyone in a given, general role may interact with such product and therefore not everyone in a given, general role may require the associated training. Associated in the Template with the ATEX and Medical Device Directive special roles shall be required awareness training for each. The identities of these training materials are given above. Finally, the Template shall include entries for

ISO 9001 Quality system awareness and new employee orientation, which includes the Employee Manual.

An employee's supervisor or department manager **is responsible for assesses t**raining needs for the employee based on the employee's roles **and responsibilities that require training greater in scope than the default, minimum set given in the Template. This includes the employee being assigned to work on either product controlled under the ATEX Directive or the Medical Device Directive.**

Training Policy for the Assembly and Test of Product Controlled Under the Medical Device Directive

Any assembler or Production technician who is to work on an assembly that belongs to a medical device, or the final assembly / product itself, shall receive training specific to that assembly delivered by a member of Engineering or Quality Assurance familiar with that assembly and its requirements. Any Test technician who is to test and/or calibrate and/or configure a medical device or one of its assemblies shall be specifically instructed by Engineering or Quality Assurance on the given procedure; the instructor shall be familiar with the given procedure and its requirements. In these cases, the training material is the assembly drawing and/or the assembly procedure referenced in the Production operation(s) in the manufacturing routing for Production personnel or the procedure(s) referenced in the Test operation(s) in the manufacturing routing for Test personnel.

It is responsibility of the supervisor or manager to instruct Human Resources about these additional training requirements discussed in the above two paragraphs.

External training can supplement the internal training described above; examples are college classes, adult education, skill-based training, seminars, and webinars.

Based on external requirements, such as customer requirements or regulatory requirements not already covered in this procedure and not already known as of its release, additional training requirements may be put in place and completion required to work on certain products or projects.

Based on the corrective and preventive action process, additional training requirements may be put in place for a certain employee, for a group of employees, or for all employees.

Retraining

Also based on the corrective and preventive action process, a repeat of training may be required.

Any employee or their supervisor or manager may request a repeat of training if something is not understood or if it is thought that retraining would benefit an employee or Product Resources.

Revision of training materials triggers retraining. Training is revision-specific.

By default, once training is given, it does not expire, not counting the revision of training materials stated above.

Quality Assurance, the management of Product Resources, or the internal audit team may recommend that certain training have an expiration time interval, some given number of months or years following the last given training. This is done for the ATEX Directive and Medical Device Directive awareness training, and the interval is two years.

Recording Training

All employees' training rec**ords will be maintained using the QT9 QMS Web, a database application by QT9 Software, Inc. Human Resources creates and updates** employees' records in **QT9. A training record identifies the employee and list the training materials associated with the employee, those that are required for the employee to complete. For each listed training material, the trained status is identified: not trained, trained, and if trained as of what date.**

All department managers and area supervisors have access to QT9 to view employees' training records, or they may request training reports **from Human Resources.**

External training – see examples above – is to be recorded in the QT9 software as well. Department managers or area supervisors are to communicate to Human Resources that an employee has received external training, when, and the nature of the training. Human Resources is to record this in the QT9 software. Employees are asked to report all external training to their supervisors/managers or directly to Human Resources. A copy of any certificate received, if applicable, should be forwarded to Human Resources for storage in the employee's file.

The procedures of how to enter training (internal or external) is outlined under the "Help" tab in QT9. Both the "Help File" and "Training Academy" **carefully outline the procedure. The procedure may change slightly from time to time based on software upgrades. Additionally, the procedure for entering training is different depending on the details of the training (i.e. external**, internal, reoccurring, initiated by a "Training Profile", etc.**)**

The storage location and retention period for training records is given in 90-2000-4.2.4, Control of Records.