

DOCUMENT NUMBER <b>91-8002</b>	REVISION <b>A</b>	TITLE <b>Competence, Awareness, Knowledge, and Training</b>	REV DATE <b>01/2018</b>	Page <b>1 of 4</b>
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## 1.0 Purpose of Procedure

This document will cover the employee competence, awareness, knowledge and training policies and procedures for Product Resources. Special policies and procedures for Explosive Atmosphere or Medical Device product will be discussed.

## 2.0 Scope of Process

The scope of this procedure is the competence, awareness, knowledge and training of employees at Product Resources.

## 3.0 Process Owner(s)

3.1 Human Resources Manager,

3.2 Quality Manager

## 4.0 Procedure

### 4.1 Competence, Awareness and Knowledge

Competency, Awareness and Knowledge for job functions is to be established based on employees' past experiences, training and education and the requirements of the job based on their job description. Employees will demonstrate competence and proficiency for their job function by working under direct supervision of those qualified, or they will be trained on the job at Product Resources or via outside training sponsored by Product Resources before being allowed to independently perform their described job functions.

Employees will be made aware of the Quality System and the Quality Policy and will 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.

Competency, Awareness and Knowledge for the assembly and test of Explosive Atmosphere and Medical Device product is to be established by employees having received product-specific training (see training requirements below). Any given explosive atmosphere or medical device product will not be assembled or tested by personnel who have not received the product-specific training unless under the direct supervision of a trained employee. Employees are expected to work under the direct supervision of those qualified until the required training is obtained and job proficiency is demonstrated to the satisfaction of their supervisor. Note that the sign-off of an operation on a job order time sheet in the just-mentioned scenario is to be by the trained employee who is giving the direct supervision.

Job performance competency is being assessed a few different ways. Informally, in day to day job functions, department supervisors are evaluating an employee's competence and skill of the required task. Formally, employees are evaluated by the department supervisor periodically (Employee Evaluations are maintained and stored in the Human Resource Department). The performance evaluation is an opportunity for the supervisor to document job performance, awareness and competency. Also, applicable changes to the quality system requirements are discussed.

As part of the Internal Audit process, an auditor should be evaluating the process and the employee's effectiveness of job competence, awareness knowledge and training as they perform their job function in that process. If a determination is made that an employee is not performing a job function as described and required, the Internal Auditor will notify the

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employee and their supervisor and require retraining. Also, the Internal Auditor may determine that it is necessary to perform additional auditing of a process or may require additional training of a group of employees depending on the severity.

## 4.2 Training

Human Resources determines the general orientation training needs for employees based on job title, job description and required skill set (see Training records in the QMS software). Employees are assessed for training needs upon hire, during any probationary period, and at least annually. Human Resources shall initiate the training process upon hire by assigning the default and minimum-required training to the employee based on the employee job description

All new employees receive company training that includes awareness of the quality procedures that pertain to their job, awareness of the Quality Policy and receive an Employee Manual (43-4391). Temporary employees shall be trained if they have continuous employment for at least 3 months, and within 6 months. Participation in this orientation is recorded in the QMS system software by Human Resources.

The Management Representative for ISO 9001 and ISO 13485 will receive external training on the standards to facilitate best awareness of its requirements and interpretation (they may be combined as a single program).

### 4.2.1 Training Policy for the Assembly and Test of Product Controlled Under the Explosive Atmosphere or Medical Device Directive

Any assembler or production technician who is to work on an assembly that belongs to an Explosive Atmosphere or 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 the Explosive Atmosphere and 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.

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.

Company management and other functional area leads who interact with Explosive Atmosphere or Medical Device Directive regulated product, shall be made aware of the appropriate Directive and what it means to Product

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Resources to comply. This is facilitated by training material TM-1014 (Awareness/Overview of Explosive Atmosphere Directive), 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;

#### **4.2.2 Training policy for employees participating in the Internal Audit process.**

The Lead Internal Auditor will receive external ISO 9001 and ISO 13485 training (they may be combined as a single program). External training or certification of assisting auditors is not required

All auditors will be familiar with the ISO 9001 standard and the ISO 19011 standard, which sets forth guidelines and guidance for auditing programs and the conducting of audits. As applicable, auditors will be familiar with other Quality standards being audited. For instance, the ISO 80079-34 extension to our Quality system for the manufacture of products used in explosive atmospheres and the ISO 13485 extension to our Quality system for medical device manufacturing.

All auditors will be given an orientation on ISO 9001, ISO 19011, ISO 13485, and the forms/templates and procedures currently used for internal audits. In addition, new auditors will receive training by means of internship during at least two internal audits, shadowing or participating with an existing auditor.

**Retraining.** Below are examples of when retraining may be required

- based on the results 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 Explosive Atmosphere and Medical Device Directive awareness training, and the interval is two years.

#### **Recording Training**

All employees' training records will be maintained using the QMS system software. Human Resources creates and updates employees' records in QMS system. 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 QMS system to view employees' training records, or they may request training reports from Human Resources.

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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 QMS system. 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.

**5.0 Control of Records**

The storage location and retention period for records referenced above are given in 91-6002, Control of Records.