### EXECUTIVE MANAGEMENT APPROVAL PAGE

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<th>Rev:</th>
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<td>90A0032</td>
<td>K</td>
<td>1 of 7</td>
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**Title:** Training Policy

**Author:** Gene Partin  
**Date:** 02/02/2017

**Approvals:**

<table>
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<tr>
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<tr>
<td>President</td>
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<tr>
<td>VP Eng</td>
<td>2/9/17</td>
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<tr>
<td>VP Operations</td>
<td>2/16/17</td>
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<tr>
<td>Director QA/RA</td>
<td>02-02-17</td>
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**Documentation Control:** Heather Marshall  
**Date Archived:** 2-10-17

### Electronic File info: (if applicable) If multiple files (such as multiple sheets of a drawing) list file info separately

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**Does the Release of / Change to this document affect QSR?**  
☑ Yes  ☐ No

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**ZOLL Form Number:** 90A0001-A04  
**Form REV Level:** N
# Training Policy

## Revision History Of Document

<table>
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<tr>
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<tr>
<td>FI</td>
<td>----</td>
<td>First Issue</td>
<td>L.F.</td>
<td>11/5/97</td>
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<tr>
<td>A</td>
<td>661</td>
<td>Added requirement for Quality Policy Training. Added requirement for ISO/FDA awareness training. Removed forms 90A0032-A01 &amp; A02 and all references to these forms. Added statement that format of training logs may vary from course to course but must include certain information.</td>
<td>G.P.</td>
<td>5/11/98</td>
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<tr>
<td>B</td>
<td>719</td>
<td>Major rewrite of procedure. Added section 8 to identify the required training and timeframe for training. Addressed supplemental and recurrent training requirements. Removed redundant statements. Added reference to 90E0004 - Maintenance of Quality Records SOP.</td>
<td>G.P.</td>
<td>10/9/98</td>
</tr>
<tr>
<td>C</td>
<td>1078</td>
<td>Added requirement for contract and temporary employees. Removed section on Outside Training and put it under Section 8.5 Other Job Specific Training. Shortened time requirements for training. Changed SOP trainer from manager to Author of SOP. Removed redundant statements.</td>
<td>L.F.</td>
<td>04-26-01</td>
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<tr>
<td>D</td>
<td>1627 / 1618</td>
<td>Changed title from &quot;Training SOP&quot; to &quot;Training Policy&quot;; small format change under &quot;INTRODUCTION&quot;, p. 1; added &quot;(or their designee)&quot; to section 7.2.3; moved end parenthesis in section 8 to now include &quot;and temporary&quot;; added HR to review training logs to section 3; added 90A0023 to &quot;Related Documents&quot; list;; removed &quot;in accordance with SOP 90E0004....&quot; from section 7.2.3.; section 3, line 11, replaced &quot;hiring&quot; with &quot;responsible&quot;; section 4, removed &quot;including full-time, part-time, temporary positions&quot;; section 7.1.1, replaced &quot;Company provides&quot; with &quot;requirements for&quot; and &quot;depending&quot; with &quot;depend&quot;; removed section 8.5.5. Added requirement for trainer to ensure training logs are completed properly.</td>
<td>L.F. / G.P.</td>
<td>02-03-03</td>
</tr>
<tr>
<td>E</td>
<td>1861</td>
<td>Add marketing to functional groups included in this policy; add new responsibility for dept. managers-- that they ensure job descriptions and training requirements are available for each position prior to filling it; add that training requirements also apply to those whose work affects the company's regulatory compliance; clarify section 7.2.2-- logs of technical training are not forwarded to HR; change timeframe for completion of &quot;Other Job Specific Training&quot; to 4 weeks; add to section 3 the option to extend timeframe through written justification; added section 8.5.5-- that all employees must keep training logs updated.</td>
<td>L.F.</td>
<td>10-31-03</td>
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**ZOLL Form Number:** 90A0001-A03  
**Form REV Level:** J
Title: Training Policy

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<td>F</td>
<td>2009</td>
<td>Revised time length for training to 30 days to accommodate employees that are located off-site.</td>
<td>G.P.</td>
<td>03-15-05</td>
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<tr>
<td>G</td>
<td>3040</td>
<td>Updated annual training requirements language to department-specific. Refined requirements for Defect Awareness training to those positions which could have impact on device quality; and aligned frequency of training to ISO &amp; FDA regulations. Updated language on how training is delivered to include the electronic delivery and storage of training Records.</td>
<td>S.M.</td>
<td>02-08-12</td>
</tr>
<tr>
<td>H</td>
<td>3641</td>
<td>Revised documentation to move from paper training logs to fully-online training logs. Removed specific naming of Required Training to accommodate multiple companies and positions and referred the training to the online database for review. Added language to identify the process for reviewing appropriateness of training to be provided on a regular basis. Updated sales personnel's deadlines to 60 days to meet business needs.</td>
<td>S.M.</td>
<td>06-24-14</td>
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<tr>
<td>J</td>
<td>4284</td>
<td>Added section 8.2: Orientation for Employees within Operations.</td>
<td>TEL</td>
<td>04-01-16</td>
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<tr>
<td>K</td>
<td>4443</td>
<td>Revised section 1 to explain role of ZLH in administering on-line training. Changed section 2 title from Policy to Scope and limited it to ZOLL Manufacturing. Removed references to Human Resources &amp; HR related orientation throughout document since that is a ZLH function and is summarized in section 1. Revised 7.2.1 &amp; 7.2.2 to reflect on-line training record retention. Added methods of competency assessments to 3.1.5. Added new 8.2 Course List By Job Training.</td>
<td>GP</td>
<td>2-10-17</td>
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1. **INTRODUCTION**

This procedure outlines the methods for providing training to all personnel performing activities relating to the development, design, production, inspection, or servicing of the company’s products. The responsibility for employee and contractor training ultimately resides with the department manager.

ZOLL LifeVest Holdings (ZLH) provides certain administrative services to ZOLL Manufacturing Corporation (ZMC) as it relates to training. These services include coordination of the orientation program covering corporate history, philosophy, policies, benefits and new employee files and documentation, coordinating the manager’s review and approval of training requirements for each job description, and the administration of the on-line training platform.

2. **SCOPE**

This procedure applies to training of ZMC personnel.

3. **RESPONSIBILITIES**

3.1 Department Managers

3.1.1 Department managers are responsible for ensuring suitable position descriptions and training requirements are available for each position (including contract positions) prior to filling it. These may be amended at any time.

3.1.2 Department managers are responsible for ensuring employees receive the required training identified on the *Course List By Job* attached to the job family, within the time frame specified in this procedure. Deviations from specified timeframes may be granted by filing a written justification for the extension, signed/dated by the appropriate departmental manager and Quality Assurance, in the employee’s file.

3.1.3 Department managers are responsible for periodically reviewing and approve the *Course List By Job* for a position to ensure that the training meets all performance and regulatory requirements. Records will be maintained in the on-line training platform in accordance with 90E0004.

3.1.4 Department managers are responsible for periodically reviewing training completion to ensure that those executing a procedure or task have been properly trained to do so.

3.1.5 Department managers are responsible for evaluating the effectiveness of the training provided (competency assessment) and ensuring that their personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Competency assessments may be accomplished by written and scored tests, the manager’s documented evaluation of the individuals work output, or by the manager’s documented interview with the individual.

3.1.6 Department managers are responsible for ensuring that any supplemental training is provided, as required.
3.2 Trainer

3.2.1 The person or manager of the department identified under “Who Trains” in section 8 of this document will:

- Determine the content, method of training and materials, in-line with the descriptions provided here for each course.
- Plan the course, including assigning the instructor and, if applicable, the content of the written test and correct answers.

3.2.2 The trainer is responsible for providing completed hardcopy training records to the manager or training coordinator.

4. APPLICABILITY

These requirements for training apply to all positions in the company whose work responsibilities affect the quality of a ZOLL product or the company's regulatory compliance.

5. RELATED DOCUMENTS

90E0021 Quality System Manual
90E0004 Maintenance of Quality Records
90A0023 Change Requests and Change Orders
90F0919 Specialized Processes Training Plan

6. DEFINITIONS

SOP Standard Operating Procedure

7. TRAINING REQUIREMENTS

7.1 Training Content

7.1.1 The requirements for job-specific training depend on the position or department of the employee. This is identified in the training record for each department, depending on the role or level of the individual.

7.1.2 The trainer identifies the content of the training, including the method of training and materials to be used. The trainer may use any materials or documented training plans as guidance during training.

7.2 Records of Training

7.2.1 Records of the required training identified on the Course List By Job shall be maintained in the on-line training platform.

7.2.2 Records of job specific training shall be maintained by the department manager or training coordinator.

7.3 Timing

7.3.1 Required training shall be completed within 30 days of (whichever is later):
- Employment/contract assignment,

Proprietary ZOLL
- Change of job assignment or responsibilities, or
- Implementation or revision of the training program

7.3.2 Task / Procedural Training
The timeframe for completing other task or procedure-specific training will be established during the first four weeks of employment or placement in a new position (whichever is later). This training shall be performed prior to the employee’s performing any relevant unsupervised work.

7.3.3 Recurrent training
Training identified as requiring annual re-training must be completed by the end of each calendar year.

8. REQUIRED TRAINING
The following training requirements apply to permanent (full and part-time) and temporary employees.

8.1 Orientation for Employees within Operations

8.1.1 The Operations orientation training familiarizes employees with Operations specific information and stresses the importance of proper job performance to ensure compliance to the established Quality System. It is suggested to perform this training prior to any Job Specific training.

8.1.2 Who Trains: Operations designated Training Coordinator

8.2 Course List By Job Training

8.2.1 The Course List By Job training trains employees to applicable standard operating procedures (SOPs) that support ZOLL’s quality system.

8.2.2 Who Trains: The author of the SOP or procedure or other qualified trainer designated by the department manager as responsible for the SOP or procedure. The trainer is responsible for developing the content of the written test and correct answers to be used in the on-line training platform.

8.3 Job Specific Training

8.3.1 Job specific training, required by the employee’s job description, shall familiarize the employee with the procedures and skills necessary for the proper performance and regulatory compliance through the execution of their job.

8.3.2 Who Trains: The author of the SOP or procedure or other qualified trainer designated by the department manager as responsible for the SOP or procedure.

8.4 Task / Procedural Training

8.4.1 Specific Tasks or procedures may require additional training as identified by the procedure or task owner. This training provides the learner with the necessary information and tools to enable them to meet performance requirements.
8.4.2 Who trains: The author of the procedure or other qualified trainer designated by the department manager as responsible for the procedure.

8.5 Supplemental Training

8.5.1 The need for supplemental training may be determined through performance reviews, quality audits, corrective action requests, analysis of quality data, and/or revisions of SOPs.

8.5.2 Who trains: Supplemental training may be provided by internal or external sources as deemed appropriate by the manager.