

**PHILIPS HEALTHCARE**

<b>Trainee Name:</b>	
<b>Trainee Signature:</b>	
<b>Date:</b>	

<b>Course Title</b>	<b>Local Course Code</b>	<b>Revision</b>
PHNA Third Party Contractor Training Policy	5100-0171	C

By submitting this form, I agree that I have completed the required training for this course and understand the material and the impact on my job responsibility.

Signed by 3<sup>rd</sup> Party Contractor Training Representative:

\_\_\_\_\_ Date: \_\_\_\_\_

*\*\*This form is to be kept as a formal training record by the 3<sup>rd</sup> Party Contractor Agency\*\**

**PHILIPS PHNA**

**Document Number:** 5100-0171C  
**Title:** PHNA Third Party Contractor Training Policy  
**Effective Date:** See Matrix

<b>Approvals:</b>	<b>Title</b>	<b>Name</b>	<b>Date</b>
<b>Process Owner:</b>	Director, Quality and Regulatory	Lisa Garrett	See Matrix
<b>Designated User(s):</b>	Director , Regulatory Affairs (Canada)	Althea Lawrence	See Matrix
	Senior Director, Service Operations	Anne Papik	See Matrix
	Director, Strategic Relationships	Bud Reeves, Jr.	See Matrix

*Note: The Process Owner and Designated User names are here for reference only and may not be current. See Matrix for the current Process Owner and Designated User names.*

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<b>Rev</b>	<b>Major / Minor</b>	<b>Description</b>
C		Added Bud Reeves as designated user. Combined Philips 3 <sup>rd</sup> Party Program Manager/Philips Department Manager in Explanation of Key Terms section, Updated responsibilities in section 4.0 - Q&R, 3 <sup>rd</sup> Party Program Manager/Philips Department Manager & Philips TC.
A-B		See Matrix

## 1.0 PURPOSE AND SCOPE

The purpose of this document is to establish the requirements for identifying, establishing, implementing and monitoring training for Third (3<sup>rd</sup>) Party Contractors (including Manufacturer Representatives) in Philips Healthcare North America (PHNA) without access to the Philips Training Management System (TMS). This document was created to ensure that:

- PHNA 3<sup>rd</sup> Party Contractors are trained to adequately execute Philips quality system or business-related responsibilities they are performing
- Records of training are established and maintained
- Administration of training activities is defined
- Management and Contractor responsibilities are understood and clearly stated in any agreement with a 3<sup>rd</sup> Party Supplier and;
- PHNA quality and regulatory elements support and promote training per the U.S. Food and Drug Administration (FDA) Quality System Regulation (QSR) 21 Code of Federal Regulations (CFR) 820 and per PHNA corporate and business requirements.

This document applies to Philips-generated training required for 3<sup>rd</sup> Party Contractors in PHNA. This includes temporary workers, service providers, and manufacturers' representatives where a formal agreement has been executed between the 3<sup>rd</sup> party, and PHNA. It may also apply in cases where a global Philips entity holds the master service with the 3<sup>rd</sup> party, but the agreement provides for some level of operational control and responsibility of the supplier by PHNA when the supplier performs work in PHNA. This policy does not apply to 3<sup>rd</sup> Party Contractors with access to TMS. 3<sup>rd</sup> Party Contractors with access to TMS will be trained in accordance to the PHNA Training Policy (5100-0041).

The scope of this document applies to the PHNA's corporate headquarters and all PHNA sales and service affiliate offices in North America.

## 2.0 EXPLANATION OF KEY TERMS

### **Competency/Task/Role**

Groupings of one or more training requirements (courses) based on the tasks an employee or contractor is performing.

### **Courses**

Individual training event in the TMS system, also known as Learning.

### **Corporate Required Training**

Training required for all or a targeted segment of employees or contractors.

### **PHNA**

Philips Healthcare North America

### **On the Job Training (OJT)**

On the Job Training is learning completed by working alongside an individual that has already been trained and is performing the identified tasks with proven competence or experience.

### **Philips 3<sup>rd</sup> Party Program Manager/Philips Department Manager**

The Philips employee responsible for any program in which 3<sup>rd</sup> parties are used. Examples of programs include but are not limited to: Service, Sales, and Clinical Applications.

### **Third Party Contractor**

An individual employed by a third party agency or is an independent contractor working or performing tasks on behalf of Philips.

### **Third Party Contractor Training Representative**

The employee of a 3<sup>rd</sup> party company/agency that has been given responsibility for accepting Philips-initiated training requirements on behalf of the 3<sup>rd</sup> party company/agency and for deploying that training to the appropriate employees of the 3<sup>rd</sup> party company/agency. It is the responsibility of the entity managing the relationship with the 3<sup>rd</sup> party company/agency to institute the Training Representative role within the 3<sup>rd</sup> party company/agency.

### **Training**

A formally planned activity, which has learning as its primary purpose. Training methods can include: Classroom, self-paced, On the Job (OJT), with the main goal being the acquisition of new skills and/or knowledge.

### **Training Management System (TMS)**

The internal training application utilized by Philips Healthcare to facilitate the deployment and recording of training to comply with this policy and process.

### **Training Record**

Documented objective evidence of training completion.

### **Training Completion Form**

A document which includes class title and/or training topic; training date(s); trainer(s); and some verification (for example names, initials, etc.) of who attended the training. A Training Completion Form (5110-0246) can also be used as evidence that the training requirement has been accepted by the 3<sup>rd</sup> Party Contractor Training Representative.

## **3.0 INSTRUCTIONS FOR USE**

### **Training Overview**

The Philips Training Management System (TMS) is the training system database that facilitates the Training Process by storing information regarding training. TMS allows the Training Process to work effectively by maintaining the linkage between training requirements and the training records. Intranet Web access for TMS is located on the PHNA homepage, under the Training section.

Required 3rd party self-paced training is identified to the Training Representative at each 3<sup>rd</sup> Party Company/ Agency through the use of roles/tasks/competencies. A role/task/competency is a grouping of one or more training requirements (courses) based on a person's responsibilities. A 3<sup>rd</sup> Party Contractor Training Representative may be linked/assigned to one or many competencies/tasks/roles based on the services their employees, the contractors, provide to Philips.

The relevant sections of the training system database are:

- Courses/Learnings
- Competency/Task/Role
- Training History

#### 4.0 ROLES AND RESPONSIBILITIES

Role	Responsibilities
<b>Quality and Regulatory Management</b>	PHNA Q&R Management is responsible for: <ul style="list-style-type: none"> <li>• Ensuring Process/Document owners and Philips 3<sup>rd</sup> Party Program Managers and Department Managers are conducting effective training through monitoring various measurements such as, customer feedback, quality/defect metrics, audits, and CAPA.</li> </ul>
<b>Philips 3<sup>rd</sup> Party Program Manager/Philips Department Manager</b>  <b>(The responsibilities in this role may be carried out by multiple people)</b>	Philips 3 <sup>rd</sup> Party Program Manager/Philips Department Managers are required to: <ul style="list-style-type: none"> <li>• Ensure that requirements in this document are clearly stated in any 3<sup>rd</sup> Party contract between Philips and the 3<sup>rd</sup> Party supplier.</li> <li>• Designate a Philips Training Coordinator and ensure the designated Philips Training Coordinator administers applicable training activities to Independent 3<sup>rd</sup> Party Contractors or 3<sup>rd</sup> Party Contractor Training Representatives.</li> <li>• Ensure that applicable training assignments are made for new contractors within 30 days of the date the contractor begins providing services to Philips.</li> <li>• Work with designated Philips Training Coordinator to determine the correct training for each Independent contractor or 3<sup>rd</sup> Party Contractor Training Representative.</li> <li>• Ensure training effectiveness - Training effectiveness will be monitored and reviewed annually by each manager, for their contractors. Philips Healthcare will monitor the systemic effectiveness of training through various measurements, including, but not limited to:               <ul style="list-style-type: none"> <li>○ Quality and/or Defect Metrics</li> <li>○ On-the-job observations</li> <li>○ Internal Audits</li> <li>○ Quizzes/Assessments</li> <li>○ Job Performance outputs</li> </ul> </li> </ul>
<b>Philips Training Coordinator</b>	The Philips Training Coordinator has the following responsibilities when working with 3 <sup>rd</sup> Party Contractors: <ul style="list-style-type: none"> <li>• Assign appropriate training plan with requirements for each contractor based on plan designated by Philips 3<sup>rd</sup> Party Program manager/Philips Department Manager.</li> <li>• Work with 3<sup>rd</sup> Party Contractor Training Representatives to administer training-related changes for 3<sup>rd</sup> Party Contractor personnel changes such as: hires, transfers, terminations and new contract assignments.</li> <li>• Manage and update training records for 3<sup>rd</sup> Party Contractor Training Representatives, where appropriate.</li> <li>• Provide training material to Independent Contractors or 3<sup>rd</sup> Party Contractor Training Representatives, where appropriate.</li> <li>• Monitor each 3<sup>rd</sup> Party Contractor Agency's training activities to ensure timely completion of training for each contractor and escalate training deficiencies to the Philips 3<sup>rd</sup> Party Program Manager.</li> </ul>
<b>3<sup>rd</sup> Party Contractor Training Representative</b>	A 3 <sup>rd</sup> Party Contractor Training Representative is a person that represents the 3 <sup>rd</sup> Party Company/ Agency to coordinate training activities between the Philips 3 <sup>rd</sup> Party Program Manager and/or Philips Training Coordinator. A Philips 3 <sup>rd</sup> Party Program Manager/Philips Department Manager or designated Philips Training Coordinator will work with the 3 <sup>rd</sup> Party Contractor Training Representative to assign training according to the responsibilities to be fulfilled by Contractor's employees.  3 <sup>rd</sup> Party Contractor Training Representative is responsible to: <ul style="list-style-type: none"> <li>• Ensure contractors understand their training requirements (plan), gaps, and completion dates.</li> <li>• Ensure that contractors are trained prior to independently performing the requested tasks.</li> <li>• Ensure that contractors are trained to applicable external mandatory</li> </ul>

	<p>standards/regulations and product specific requirements based on their assigned responsibilities. Example: Radiation Safety Training, Occupational Health and Safety requirements.</p> <ul style="list-style-type: none"> <li>• Submit one training completion form to the Philips Training Coordinator on behalf of the 3<sup>rd</sup> Party Company/Agency for each training requirement as affirmation that they understand the training requirement. By completing the training completion form, the 3<sup>rd</sup> Party Contractor Training Representative, confirms that they are aware of how product or service quality may be affected by improper job performance, and will ensure each contractor providing service on behalf of Philips is trained on the requirement.</li> <li>• Maintain Philips training completion forms for each individual contractor or maintain a training record in their own Training Management System.</li> <li>• Ensure training is assigned to employees providing services to Philips within 30 days of being assigned Philips tasks.</li> <li>• Within 2 business days of the request, provide the Philips Training Coordinator with evidence of training completion for identified employees</li> </ul>
<b>Contractor</b>	<p>A Contractor is an individual employed by a third party agency or is an independent contractor. Contractors are expected to:</p> <ul style="list-style-type: none"> <li>• Understand their training requirements (plan) and complete the assigned training within the indicated timeframe.</li> <li>• Advise the 3<sup>rd</sup> Party Contractor Training Representative if he/she has not completed training, is not properly trained or does not understand the training.</li> <li>• Perform self-assessment tests (or evaluations) if applicable.</li> <li>• Sign a training completion form or some other training record to indicate completion of self-lead training requirements.</li> <li>• Submit training completion form or training certificates to the 3<sup>rd</sup> Party Contractor Training Representative upon completion of training activities. If the Contractor is an Independent Contractor, not an employee of a 3<sup>rd</sup> party company or agency, he/she must be instructed to submit training completion forms or certificates to the Philips Training Coordinator.</li> <li>• By signing the training completion form or completing training at the Online Learning Center, the Contractor confirms that he/she is aware of how product or service quality may be affected by not executing the task as described in the training.</li> </ul>
<b>TMS PHNA Super User</b>	<p>The TMS PH NA Super User has the following responsibilities:</p> <ul style="list-style-type: none"> <li>• Train designated Philips Training Coordinators on their roles and responsibilities within the 3<sup>rd</sup> Party Contractor Training Policy</li> </ul>

## 5.0 Third Party Training Process

### Step 1 - Overview of the Training Requirements

There are two types of Training Requirements:

Quality System Training – Necessary to ensure the quality of Philips Healthcare’s products and services including:

- Quality System processes and procedures
- Product training
- External mandatory standards/regulations and product standards
  - Examples: Bloodborne Pathogen’s Training and Radiation Safety Training

Business System Training – To maintain or improve the performance of Philips’ business processes.

- Example: One Mobile

Philips 3<sup>rd</sup> Party Program Managers/Philips Department Managers should work with their designated Philips Training Coordinator to define training requirements applicable to each job task being executed by a 3<sup>rd</sup> Party Contractor.

## **Step 2 - Training Activity**

A training activity fulfills a training requirement and can take many forms:

- Classroom training – training which is facilitated by a trainer in a classroom or lab setting.
- Self-paced training – training which is completed by the learner. This could include: Computer Based Training (CBT), reading a document(s), online courses, etc.
- On-the-job training, hands-on training with a trained mentor.

Timing of the training:

- Training must be completed before the Contractor performs his/her job responsibilities independently.

### **Training will be required:**

1. When a new person is hired by a 3<sup>rd</sup> party company/agency to perform services on behalf of Philips.
2. Any time an existing training is updated or a new training is created.
3. Annually for certain critical processes.
  - Example: Customer Feedback Procedure.

### **Training Record**

A training record is documentation that a training activity has been successfully completed.

- The Philips Training Completion form for a specific self-paced training should be sent to the 3<sup>rd</sup> Party Contractor Training Representative.
- The 3<sup>rd</sup> Party Contractor Training Representative should complete and sign the training completion form, thereby confirming that they are aware of how product or service quality may be affected by not performing the task as indicated in the training, and will ensure each Contractor providing services on behalf of Philips receives the required training.
- 3<sup>rd</sup> Party Contractor Training Representative will return the completed training Completion form to the designated Philips Training Coordinator for each required course.
- The 3<sup>rd</sup> Party Contractor Training Representative for each Contract Agency will be responsible for maintaining training completion forms for each individual contractor or for maintaining some type of training record in their own company/agency Training System.
- If training was completed via the Philips Online Learning Center or through the Philips Healthcare Academy, Philips will automatically maintain electronic training records for these courses; however the 3<sup>rd</sup> Party Contractor Training Representative must also maintain a complete training record of all Philips-generated training activities for the contract employee.
- Philips may audit the 3<sup>rd</sup> Party Company/Agency or Individual Contractor's Training Records at anytime. Complete 3<sup>rd</sup> Party Company/Agency training records for individual employees must be provided to Philips as evidence of training completion within 2 business days of the request.

## **6.0 REFERENCED DOCUMENTS**

- 5100-0041, PHNA Training Policy
- 5110-0246, PHNA Training Completion Form (TCF)
- FDA Quality System Regulation 21 CFR Part 820



## 7.0 ADDENDA

### Corporate Required Training – Required for all 3<sup>rd</sup> Party Contractors

Includes, but is not limited to:

Course
PHNA Third Party Contractor Training Policy
Customer Feedback Training
Protected Health Information Policy

Training to be fulfilled by 3<sup>rd</sup> Party Contractor as needed:

Bloodborne Pathogens

Electrical Safety

Lockout/Tagout

Arch Flash Electrical Safety

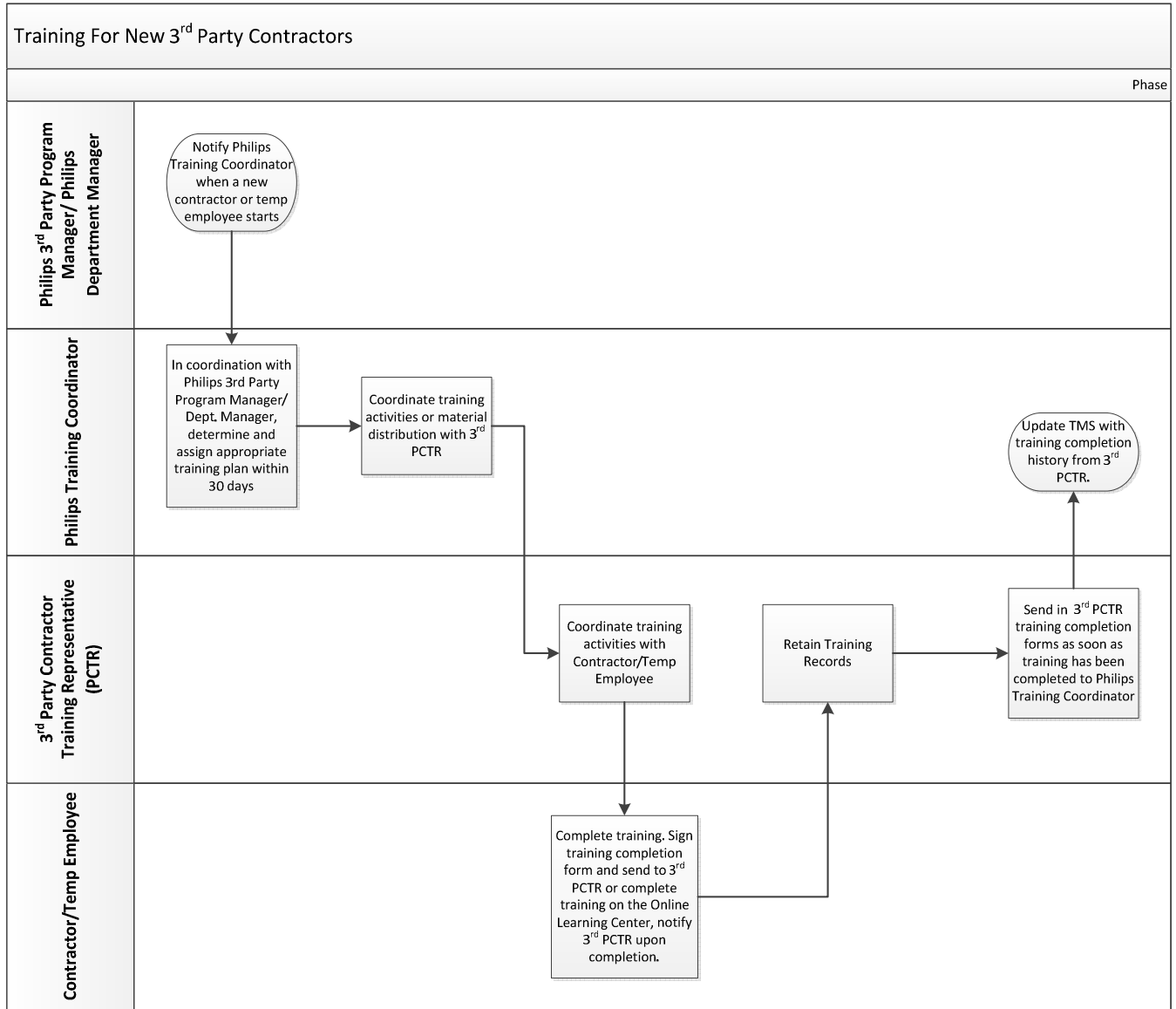
Ladder Safety

Hand and Power Tool Safety

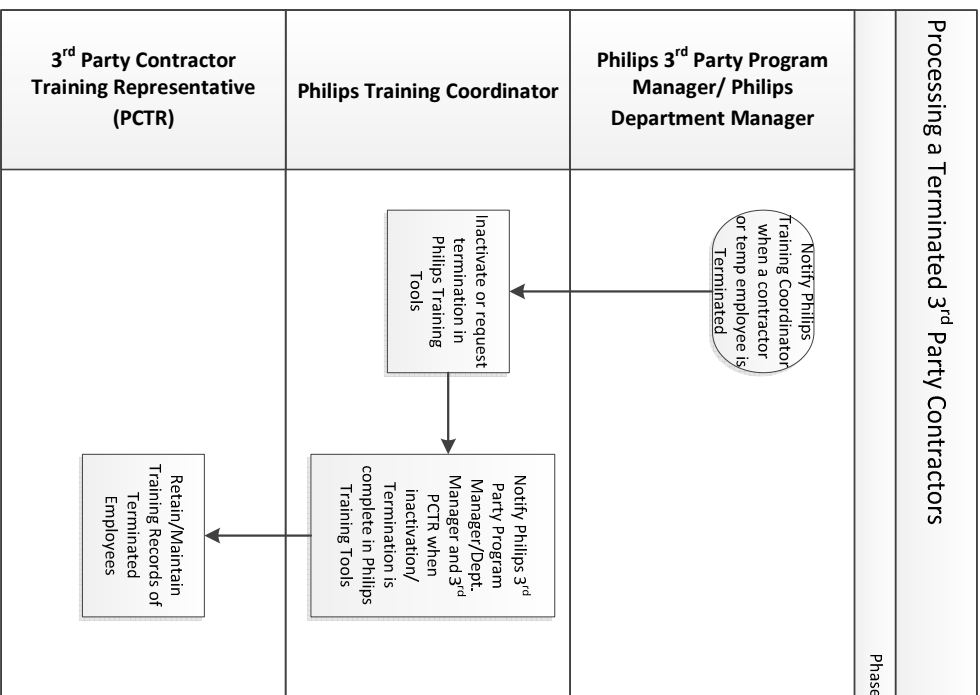
Personal Protective Equipment

Radiation Safety

## 8.0 ADDENDA



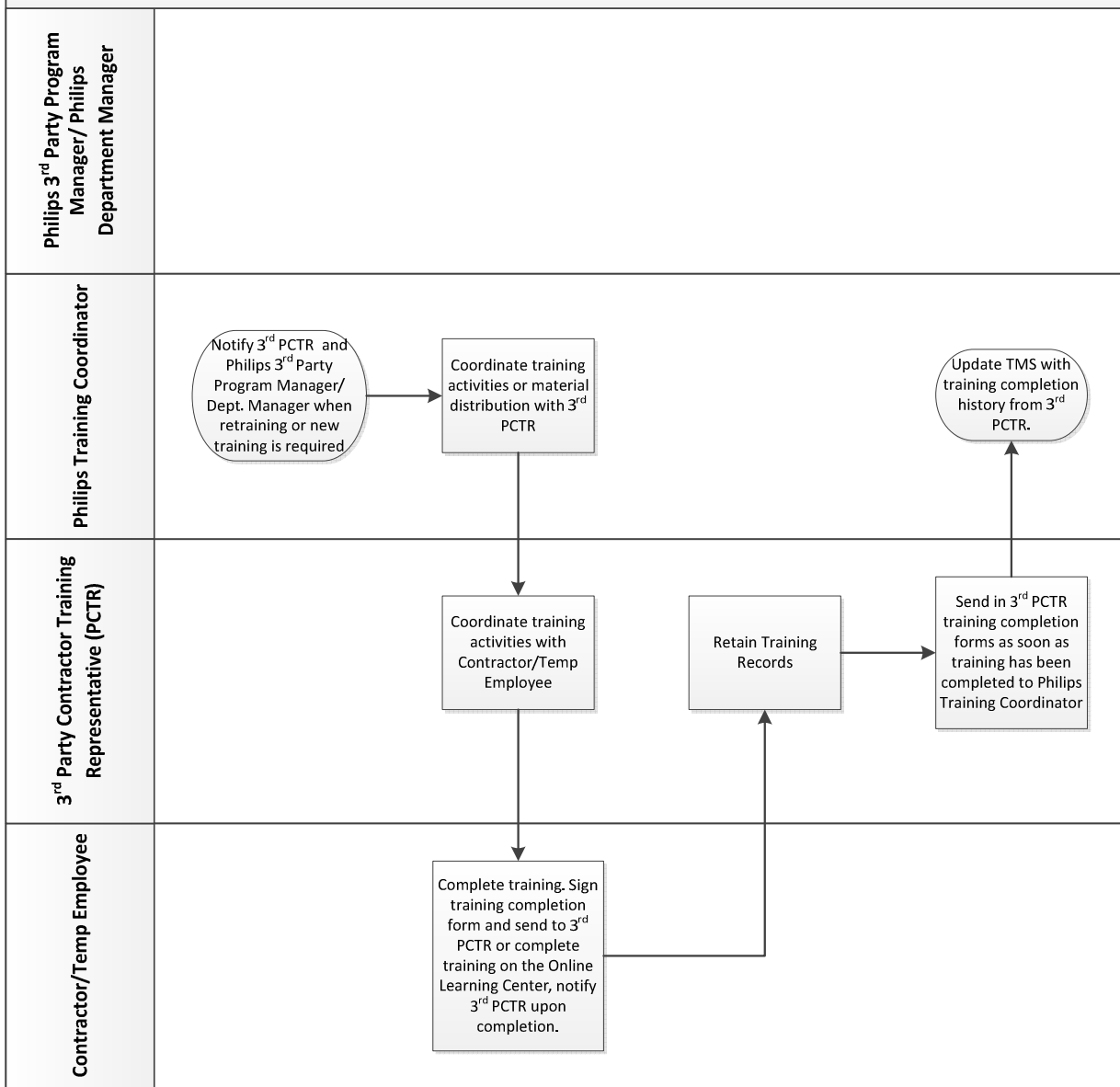
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Retraining or New Training Process For New 3<sup>rd</sup> Party Contractors

Phase



**\*\*\*END OF DOCUMENT\*\*\***