SCQA-QCI-001-05

SUPPLIER CORRECTIVE ACTION RESPONSE REVIEW TRAINING

STELIA NORTH AMERICA

Introduction

- **Description**

This training will guide you through the process of evaluating a corrective action response. The training will discuss response content and criteria to ensure that you have the appropriate details provided in the response.

- **Time Required**

This course should take approximately 30 minutes to complete.

- **Prerequisites**

None.

- **Target Audience**

This course is intended for SNA SCQA representatives and suppliers to ensure they have effective corrective action communication.

STELIA NORTH AMERICA

Course Content

This training consists of 3 lessons:

Lesson 1: Immediate Correction

- Define three components of Immediate Containment: Contain, Correct, and Communicate
- Identify Immediate Correction plan to contain and correct the nonconformity and communicate awareness

Lesson 2: Immediate Action

- Identify the Direct Cause and develop an Immediate Action plan to prevent it from recurring

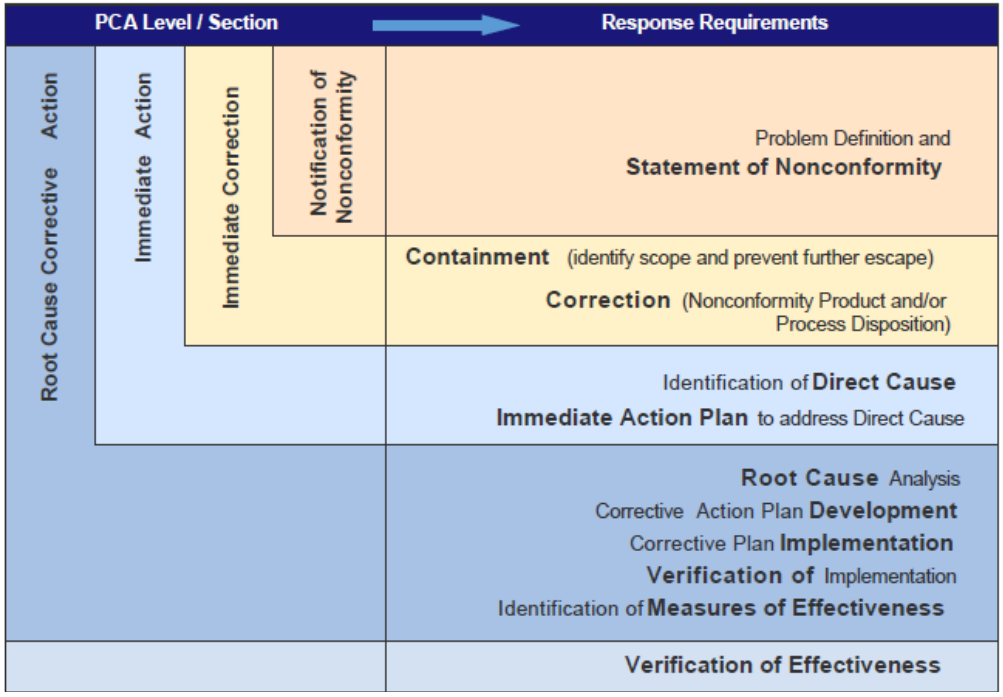
Lesson 3: Root Cause Corrective Action

- Root Cause Statement and Root Cause Analysis (RCA) tools
- Root Cause Corrective Action (RCCA) Plan Development
- Plan Implementation
- Verification of Implementation
- Verification of Effectiveness

STELIA NORTH AMERICA

Corrective Action Response Requirements

This guide will appear throughout the course, highlighting the applicable section being reviewed.



Examples:
"Is" and "Should be" conditions for product *Dimensional data, specification data, negative/unfulfilled* *of a requirement, etc*
Line/Stock check (reinspection), additional inspections, Notice of Escape to address other/similar product *Rejected unit(s)/requirement that has been corrected/addressed*
...The first "why" in a 5-why analysis *...C orrection of an issue in a process/operation that caused the defect to occur*
...The fifth "why(s)" in a 5-why analysis (no practical "why" follows it) *...Addressing the cause(s) that led to an issue in a process/operation* *5-why analysis, KNOT chart, brainstorming, fishbone, pareto charts*
Receiving inspection checks, in-process checks, data reviews

Lesson 1

Immediate Correction (IC)

PCA Level / Section	Response Requirements	Examples:
Root Cause Corrective Action / Immediate Action / Immediate Correction / Notification of Nonconformity	Problem Definition and **Statement of Nonconformity**	*"Is" and "Should be" conditions for product* *Dimensional data, specification data, negative/unfulfilled* *of a requirement, etc*
	Containment (identify scope and prevent further escape) **Correction** (Nonconformity Product and/or Process Disposition)	*Line/Stock check (reinspection), additional inspections, Notice of Escape to address other/similar product* *Rejected unit(s)/requirement that has been corrected/addressed*
	Identification of **Direct Cause** **Immediate Action Plan** to address Direct Cause	*...The first "why" in a 5-why analysis* *...C orrection of an issue in a process/operation that caused the defect to occur*
	Root Cause Analysis Corrective Action Plan **Development** Corrective Plan **Implementation** **Verification of** Implementation Identification of **Measures of Effectiveness**	*...The fifth "why(s)" in a 5-why analysis (no practical "why" follows it)* *...Addressing the cause(s) that led to an issue in a process/operation* *5-why analysis, KNOT chart, brainstorming, fishbone, pareto charts*
	Verification of Effectiveness	*Receiving inspection checks, in-process checks, data reviews*

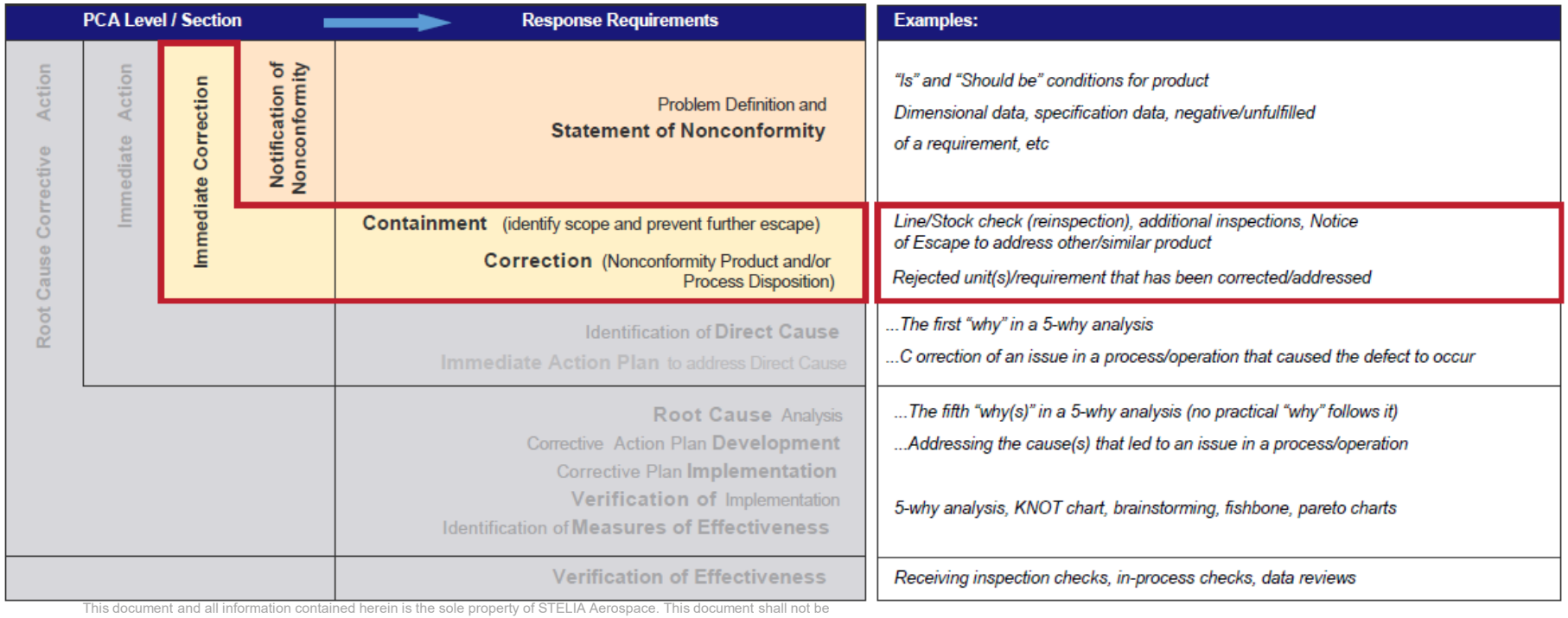
STELIA NORTH AMERICA

Immediate Correction

Contain: Identify and isolate all nonconforming products, system data, or any process to prevent the harmful effects of the nonconformity from continuing.

Correct: Fix a detected nonconformity. This may involve reworking or scrapping and replacing the product or correcting the paperwork.

Communicate the nature of the problem to all affected parties.



Immediate Correction

Overview of the Major Steps

Immediate Correction (IC) is the action you take to fix a detected nonconformity. This may involve reworking or scrapping and replacing the product. Paperwork may need to be corrected.

Immediate Correction consists of these major activities:

- Validate the problem.
- Contain, Correct, and Communicate the problem (included in a supplier response).

Containment – What is it and why do we do it

Containment is action(s) taken to:

- Determine the magnitude of a detected nonconformity or other undesirable situation.
- Prevent growth of the problem.
- Minimize the impact on
  - People
  - Hardware, work in process, and product.
  - Assets.

STELIA NORTH AMERICA

Containment – The Objectives

The **1st objective** of Containment is:

- The proper identification, segregation and positive control of suspect product or undesirable condition.

The **2nd objective** of Containment is:

- To prevent the unintended use or installation of suspect product(s)

The **3rd objective** of Containment is:

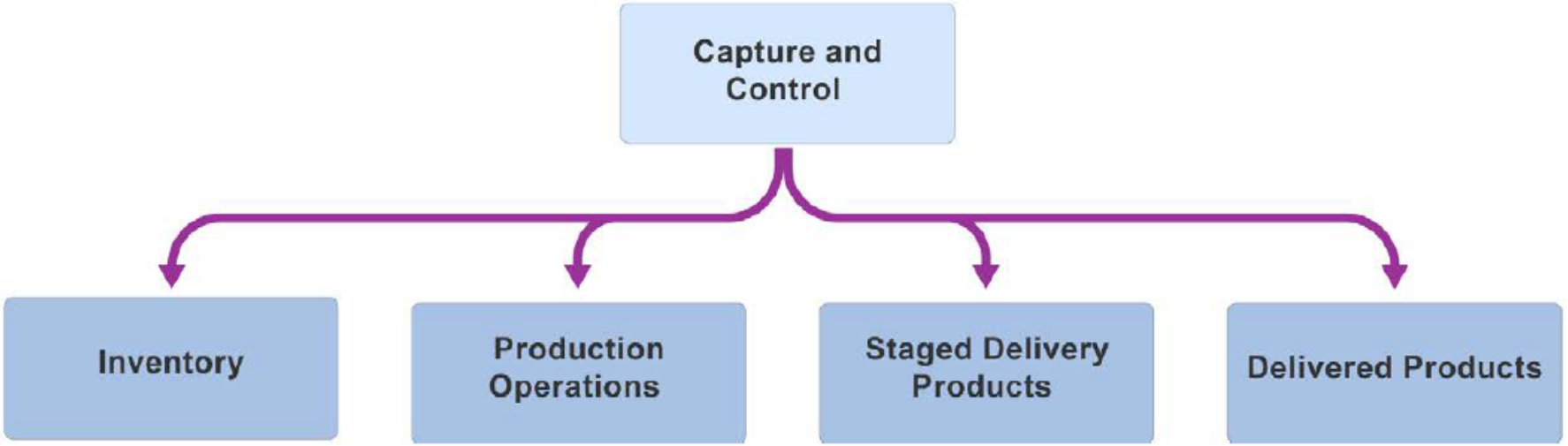
- The adequate communication of suspect conditions and products across the organization to ensure “like” items and “like” conditions do not impact other Programs or Operational areas.

Containment is a required element of both Product nonconformities AND Quality Management System nonconformities

STELIA NORTH AMERICA

Containment

Determine the extent of the nonconformity or undesirable condition and risk to similar product or processes.



Warehouse locations
- Internal
- External
- Spares Inventory

Nonconformity Exists?

Work In-Process Checked
- Upstream
- Downstream

Nonconformity Exists?

- Any pending deliveries checked

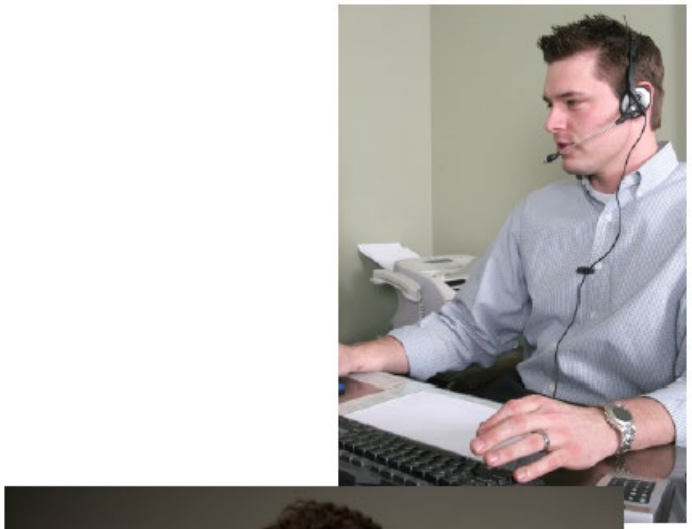
Nonconformity Exists?

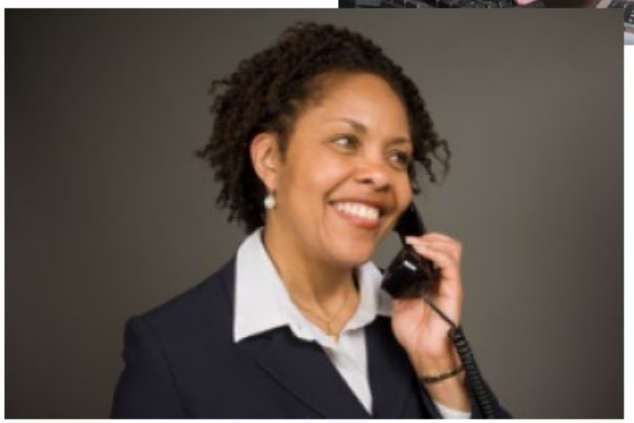
- Customer notified if NoE is determined
- Contracts Notified
- Legal Notified
- Program Management notified

Correction & Communication

Correction: As part of the Immediate Correction Plan, it must include information that ensures that the detected nonconformity has been corrected.

Communication: IC Plan should indicate how all affected and impacted parties have been notified of the nonconformity.





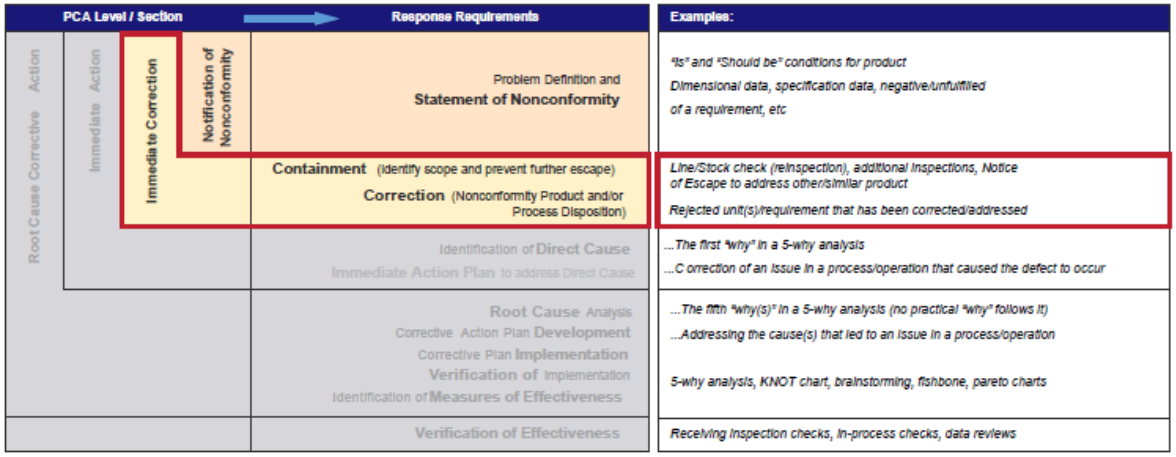
Immediate Correction

Correction

Immediate Correction (IC):

The action you take *to fix* a detected nonconformity

- Reworking
- Scrapping and replacing the product
- You may need to correct paperwork



Although Containment actions are documented within the IC section of the response, they continue to occur throughout all RCCA process steps

Immediate Correction Unacceptable

Containment? Correction? Communication?

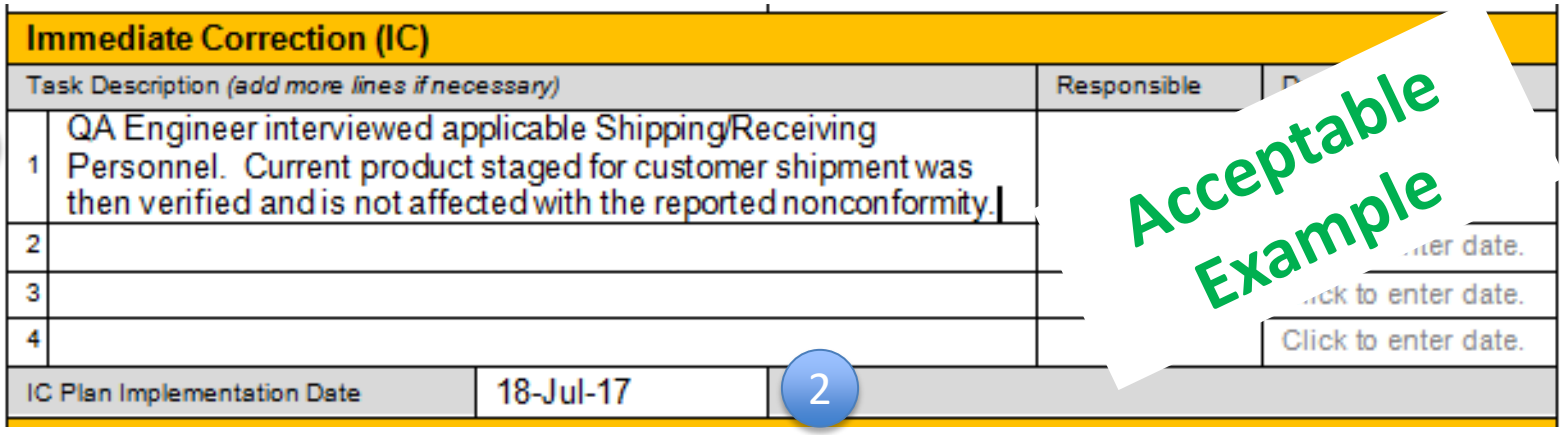
Immediate Correction (IC)			
Task Description *(add more lines if necessary)*		Responsible	Due D
1	NA		date.
2			ate.
3			er date.
4			ck to enter date.
IC Plan Implementation Date	18-Jul-17		

Unacceptable Example

"N/A" does not tell the story. Immediate Correction must be addressed. The reason why containment or correction was not necessary is to be provided.

Containment should also include reviewing all possible affected similar parts, work orders, Purchase Orders, etc. Determine the extent of the problem based on the Statement of Nonconformity without restricting focus on only the items already identified.

Immediate Correction Acceptable



Immediate Correction (IC)			
Task Description *(add more lines if necessary)*		Responsible	D
1	QA Engineer interviewed applicable Shipping/Receiving Personnel. Current product staged for customer shipment was then verified and is not affected with the reported nonconformity.		
2			ter date.
3			ck to enter date.
4			Click to enter date.
IC Plan Implementation Date	18-Jul-17		

1. The described actions must detail the action(s) that were taken to initiate containment and to immediately pursue correction.

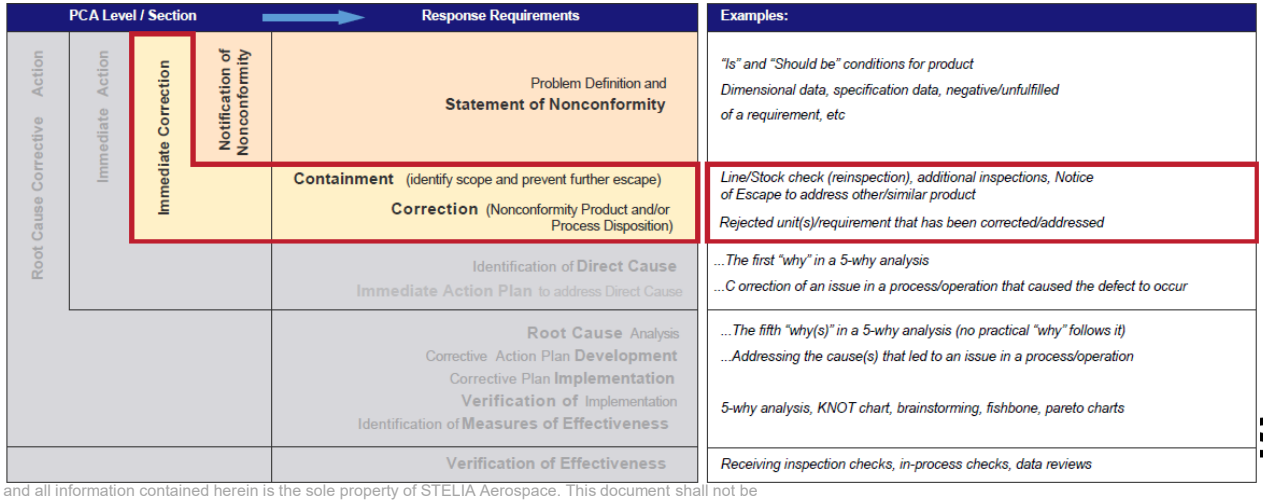
2. The IC Plan Implementation Date reflects the date that the supplier organization completed the task(s) as listed.

STELIA NORTH AMERICA

Lesson 1 Summary

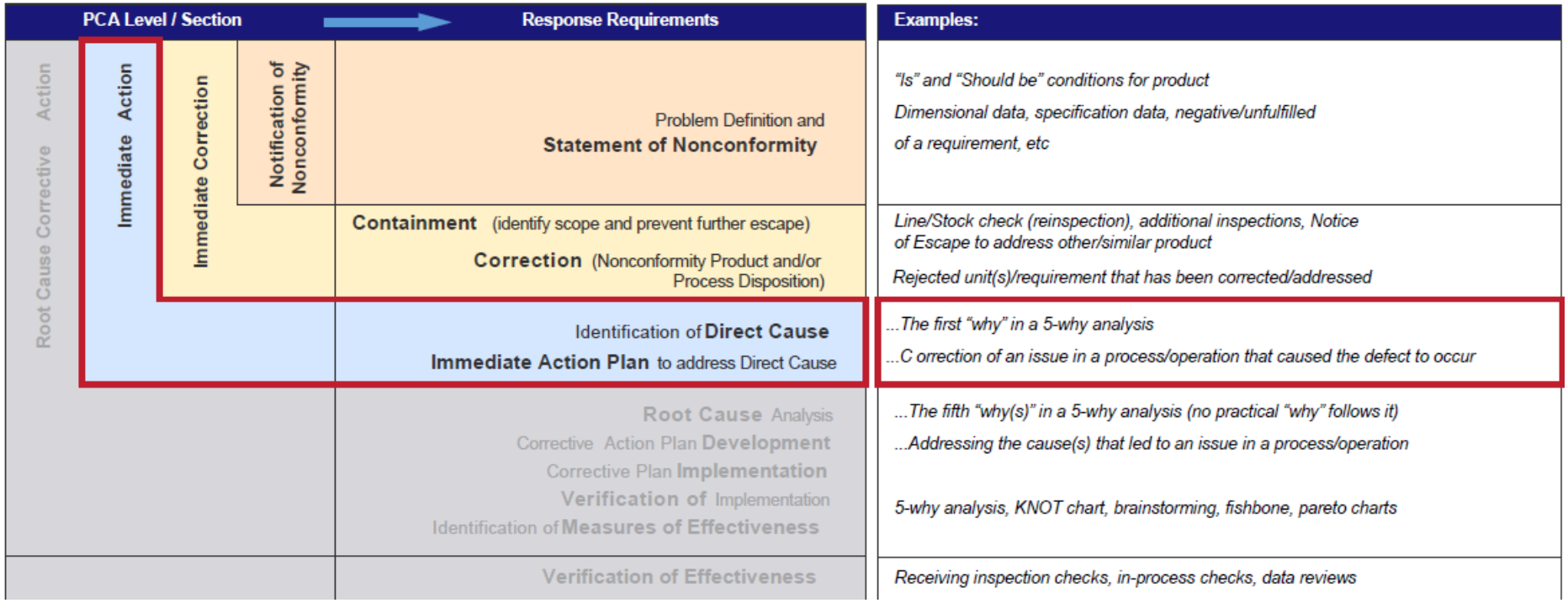
In this lesson you learned:

- The definition of Immediate Correction and its components:
  - > Contain
  - > Correct
  - > Communicate
- The importance of determining the extent and risk of a nonconformity.



Lesson 2

Immediate Action (IA)



Immediate Action

Overview of the Major Steps

Immediate Correction (IA) is the action you take to eliminate the cause(s) of a detected nonconformity or other undesirable condition.

Immediate Action consists of these major activities:

- Determine the Direct Cause
- Develop and implement the Immediate Action plan
- Develop and implement the Immediate Action verification plan
- Communicate to all stakeholders regarding delivery of next good product

Direct Cause is the event of action that immediately results in or proceeds the nonconformity.

STELIA NORTH AMERICA

Immediate Action - Identify the Direct Cause

Examine the nonconformity to identify the Direct Cause

Direct Cause:

The event or action that immediately results in or precedes the nonconformity

STELIA NORTH AMERICA

Immediate Action

When implementing a change to a process, the following actions should be taken:

- Document process changes (for example, instruction, job aid, or quality alert)
- Explain the reasons for the changes to all affected employees
- Inform affected employees how the changed process impacts their responsibilities

The Immediate Action must remain in effect until you have permanently incorporated the Root Cause Corrective Action (RCCA) into the system, and the action has been normalized and determined to be effective.

Immediate Action Acceptable

Immediate Action (IA)			
Direct Cause Statement			
Required paperwork was not included with parts shipment. 1			
2	Task Description *(add more lines if necessary)*	Responsible	Due
1	On June 15, 2015 the General Operators, Shipping/Receiving and Quality Manager's all met to discuss the corrective actions for the nonconformance reported. It was determined that no other like conditions exist or were delivered to the customer. It was determined that the shipping/receiving personnel did not fully understand the shipping requirements.		
2	The Shipping/Receiving Supervisor on June 15, 2015 held a learning moment during shift change to discuss the recent process failure. Shipping/Receiving business pro XXX-X was reviewed with all department personnel to ensure a common interpretation and understanding (O/R: Training form TFX)		enter date.
3	The Shipping/Receiving Supervisor and Quality Manager will jointly perform 1 spot audit per day in an effort to confirm short term implementation was effective from June 22 to June 26, 2015 of customer product being shipped to ensure all paperwork has been included with every shipment as required.		Click to enter date.
4			Click to enter date.
IA Implementation Date	15-Jun-15	Verification of Implementation Date	26-Jun-15 3

Acceptable Example

1. The Direct Cause Statement is short, concise, and without inconclusive statements.
2. The IA Plan Tasks address the actions that were necessary to address the Direct Cause.
3. The IA Plan Implementation and Verification Dates align with listed Task Descriptions.

STELIA NORTH AMERICA

Immediate Action Unacceptable

Immediate Action (IA)			
Direct Cause Statement			
Shipping and receiving personnel failed to include the shipper during release of the shipment due to his/her bad attitude toward the company and has vowed to not follow company procedures because the company fails to recognize his/her value and not compensate them fairly.			
Task Description *(add more lines if necessary)*		Responsible	
1	The employee was cautioned		
2			
3			
4			Click to enter date.
IA Implementation Date	01-Jul-17	Verification of Implementation Date	02-Jul-17

1

2

3

Unacceptable Example

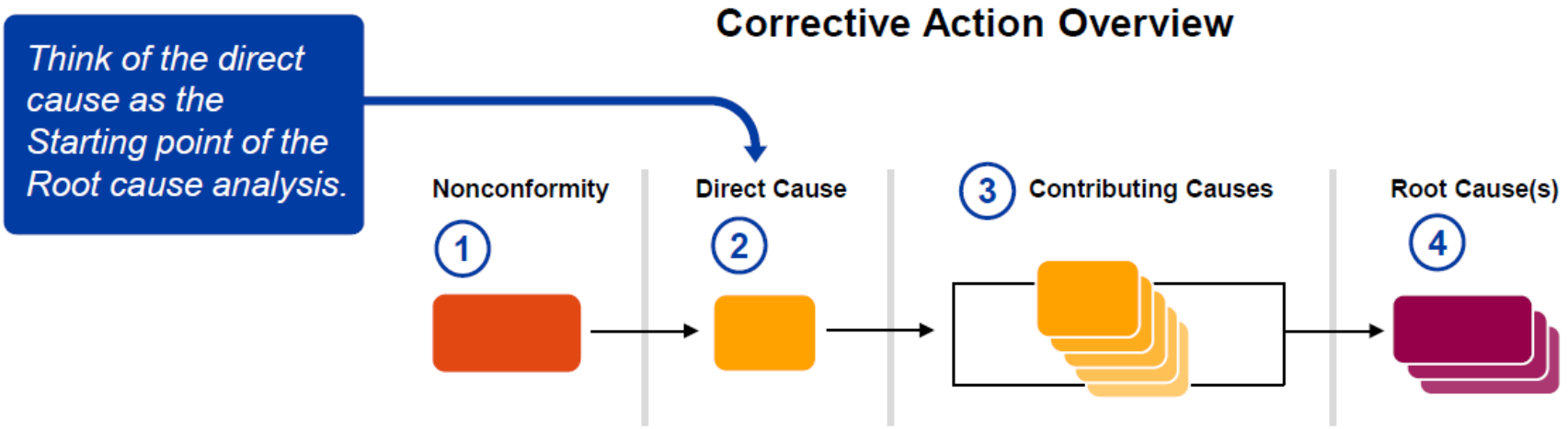
1. Direct Cause Statement is narrative and not representative of the true direct cause(s).
2. Immediate Action(s) does not address the issue(s) as they relate to the Direct Cause(s).
3. The IA Plan Implementation date and Verification of Implementation date are not consistent with ensuring a realistic timeline for effective action(s) for Direct Cause resolution.

STELIA NORTH AMERICA

Direct Cause vs. Root Cause

Direct Cause identifies the immediate issue and is used to prevent the issue from happening again in the short term; that is, you prevent the issue from impacting operations.

Root Cause takes you further by helping you identify the systemic issues that led to the direct cause. With this process you prevent recurrence in the long term.

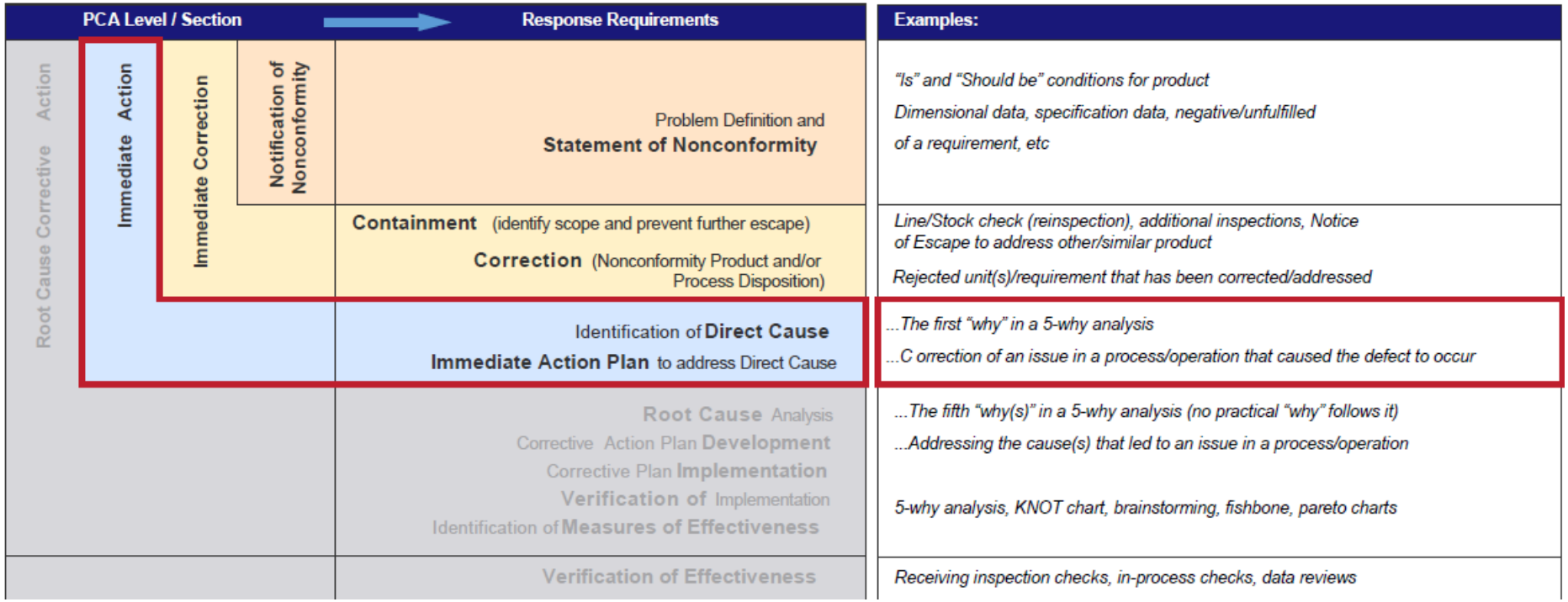


It is not always practical to shut down operations while you search for a root cause. Most issues will take some time for you to investigate and identify a root cause. **By implementing Immediate Action, you allow operations to continue and prevent the nonconformity from recurring in the short term.**

Lesson 2 Summary

In this lesson you learned:

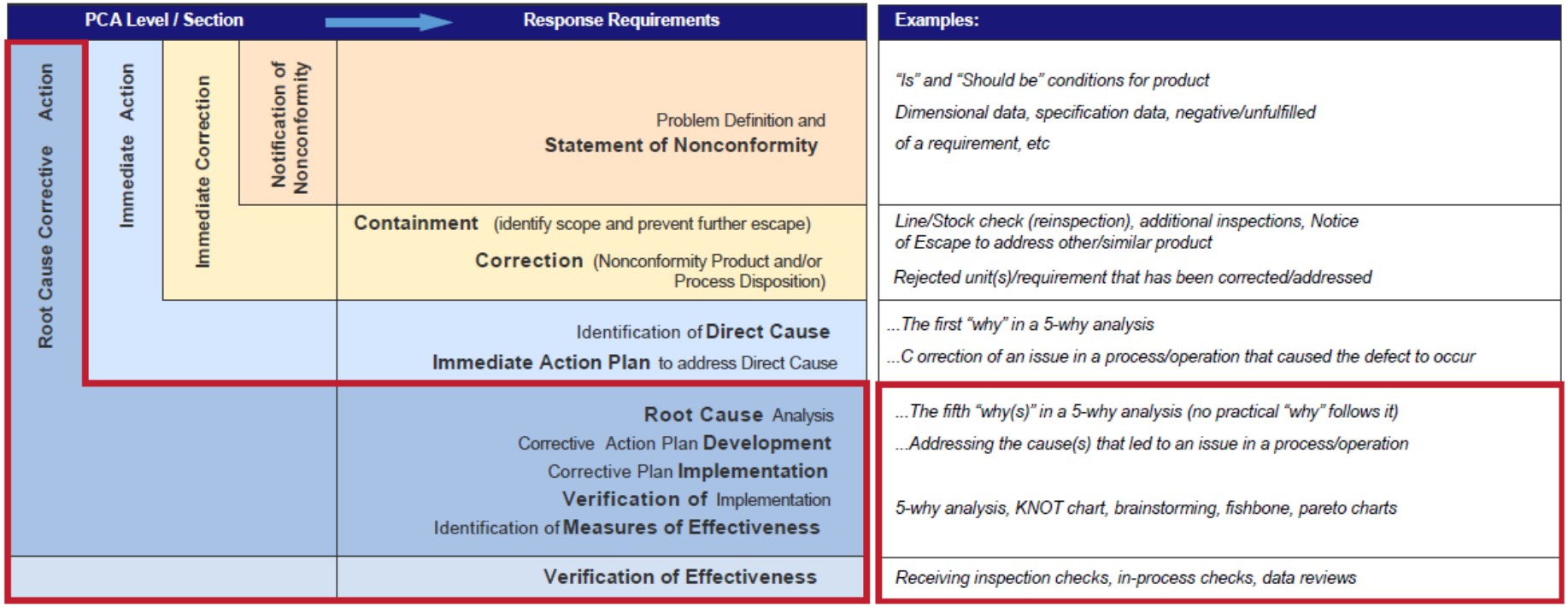
- The definition of Direct Cause
- How to develop an Immediate Action Plan.



STELIA NORTH AMERICA

Lesson 3

Root Cause Corrective Action (RCCA)



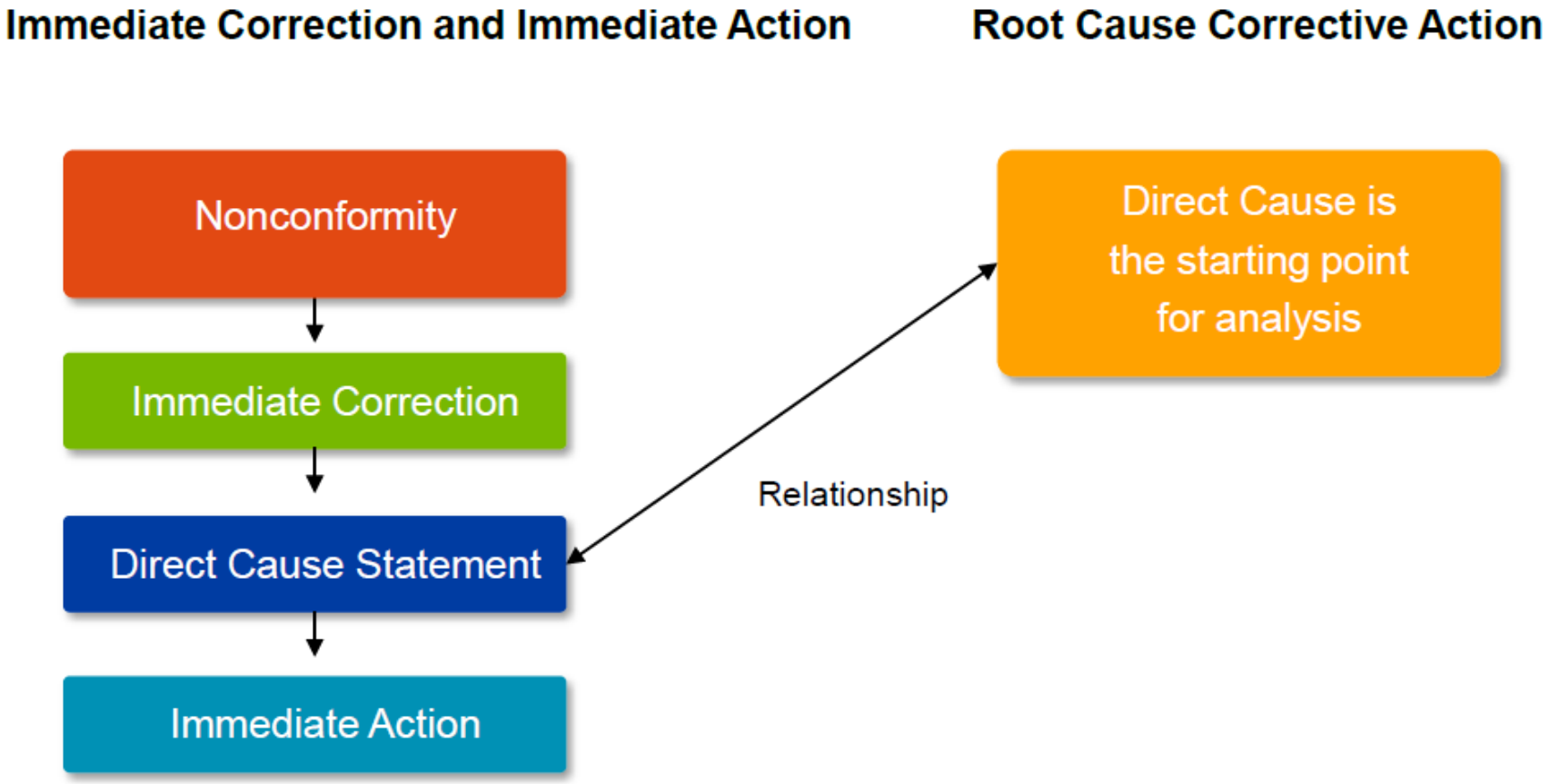
Root Cause

Root Cause Defined

The root cause statement shall be a statement of fact (or facts if there are multiple root causes) and must address basic systemic issue(s) without any obvious embedded “why” questions.

Root Cause

Now that you have completed your Immediate Actions, you can use your Direct Cause as your starting point for your Root Cause Analysis



Root Cause Analysis

Root Cause Analysis (RCA) Defined

Utilization of one or more RCA tools is a necessary part of the process and identification required in the RCCA response.

Available tools include but are not limited to:

- Brainstorming
- Cause and Effect Analysis (Fishbone)
- Fault Tree Analysis
- Time Line
- 5-Why
- Process Analysis

Note: It is strongly recommended that you take additional training to gain a better understanding of these and other Corrective Action tools and their applications.

Root Cause Statement Unacceptable

Root Cause Corrective Action (RCCA)	
RCCA Team Members	
Name	Function / Title *(add more lines if necessary)*
	Ship/Rec Manager
	Operations Manager
	General Manager
	Quality Manager
RCCA Methodology *(Select all applicable)*	
☐ Brainstorming ☐ Pareto ☐ Flowchart ☐ Fishbone ☑ 5 Why's ☐ Correlation Chart ☐ Other	
Root Cause Statement	
Shipping and Receiving personnel did not include the shipper in the deliverable to the customer.	

Unacceptable Example

1

1. The Root Cause Statement does not address the Root Cause of the problem(s) based on the Statement of Nonconformity and is a restatement of the Direct Cause Statement.

STELIA NORTH AMERICA

Root Cause Statement Acceptable

Root Cause Corrective Action (RCCA)	
RCCA Team Members	
Name	Function / Title *(add more lines if necessary)*
John, Doe	General Manager
Johnny, Begood	Quality Manager
Suzy, Q	Ship/Rec. Man.
RCCA Methodology *(Select all applicable)*	
☐ Brainstorming ☐ Pareto ☐ Flowchart ☐ Fishbone ☑ 5 Why's ☐ Correlation Chart ☐ Other	
Root Cause Statement	
1 The current procedure does not provide enough clarity to ensure compliance of the process.	

Acceptable Example

1. The Root Cause Statement is short and concise. It is also free of narrative or distractive statements.

STELIA NORTH AMERICA

RCCA Plan Development

A RCCA Plan incorporates the identified solution(s) into a Corrective Action Plan that eliminates or mitigates the Root Cause(s).

Note: It is strongly recommended that you take additional training to gain a better understanding of other Corrective Action tools and their applications.

RCCA Plan Guidance

- The RCCA Plan must address the Root Cause(s) of a detected nonconformity, including actions for implementation.
- The plan must reference any changes to policies, procedures, or work instructions, as well as affected supporting documents.
- Each task must identify objective evidence that supports task completion and should identify the following: *Who, What, When, and How.*
- The RCCA Plan should include criteria that will be used to verify that Corrective Action tasks have been implemented and objective evidence that supports implementation.

STELIA NORTH AMERICA

RCCA Plan Guidance

- The RCCA Plan will include tasks that address identified Root Cause and does not repeat items identified in the IA plan.
- Root Cause Correction MUST be focused on long-term corrective action – NOT a “quick fix”.
- The plan must reference any changes to policies, procedures, or work instructions, as well as affected supporting documents, that address the identified cause.
- Each task identifies objective evidence to support task completion.

RCCA Plan Unacceptable

1

	Task Description *(add more lines if necessary)*	Type of Evidence	Resp	Due Date
1	Training will be conducted for all employees	N/A		ck to enter date.
2				ck to enter date.
3				Click to enter date.
4				Click to enter date.
RCCA Implementation Date	15-Jul-15	Verificatio	itation Date	15-Sep-15

Unacceptable Example

1. The RCCA Plan is not complete nor concise and it should address the *Who, What, When and How* elements to ensure that the necessary and appropriate actions are taken in a timely manner.

STELIA NORTH AMERICA

RCCA Plan Acceptable

1

	Task Description *(add more lines if necessary)*	Type of Evidence	Responsible	Due Date
1	Shipping/Receiving Manager to develop a department aid (SRXXX-XX-AID) to communicate internal requirements for customer-specific documentation to be included as a required element of shipping activity.	Completed and Approved SRXXX-XX-AID		Click to enter da
2	Shipping/Receiving Manager to update supplier procedure (SRXXX-XX) to include department aid SRXXX-XX-AID as a supplemental document to be maintained and utilized by all S/R personnel.	Revised and released SRXXX-XX		
3	Shipping/Receiving Manager to provide shift training for all personnel to the department aid SRXXX-XX-AID as well as changes to Procedure SRXXX-XX and ensure that Training Plan has been updated	2 ea. Training Form TFXXX-XX (Day and Night Shift)		te.
4	Quality Manager will no later than September 21, 2015 verify that Tasks 1 through 3 have been completed per the RCCA Plan as previously submitted and agreed to with the Customer. A brief audit report will be composed and uploaded into our internal non-conformance database.	Special Audit Results		Click to enter date.
	RCCA Implementation Date 21-Aug-15		Verification of Implementation Date	30-Sep-15

2

3

Acceptable Example

1. RCCA Plan Task(s) are complete and concise and should identify the *Who, What, When and How* for all the actions taken.
2. RCCA Plan Implementation Date reflects the effective date that all of the RCCA Plan Tasks will be completed.
3. Verification of Implementation Date is the short-term verification for plan effectiveness (this is usually 1 to 6 months from the date of RCCA Plan Implementation completion).

STELIA NORTH AMERICA

Verification of RCCA Implementation

Documents such as planning, drawing changes, training records and purchase order changes are often used as verification of implementation.

Physical changes such as tool revisions, facility upgrades (lighting, floor mats, etc.), shadow boards or machine repairs are also common verifications.

Verification of RCCA Implementation
(CA Response Example – RCCA Plan)

	Task Description *(add more lines if necessary)*	Type of Evidence	Responsible	Due Date
1	Remove rev levels from process reference sheet	Revs removed		Click to enter date.
2	Revision levels were removed from process summary sheet	Verified revisions were removed		
3				
4				Click to enter date.
RCCA Implementation Date	23-Aug-13	Verification of Implementation Date		30-Aug-13

Unacceptable Example

It is imperative that adequate detail be provided in the RCCA Plan Task Descriptions. Each task must define the corrective or preventative action that is to be performed.

It is a best practice to include verification criteria for each action in the Task Description. This will ensure that sufficient objective evidence is provided.

STELIA NORTH AMERICA

Verification of RCCA Implementation

(CA Response Example – RCCA Plan)

Root Cause Statement				
Ineffective contract review process implemented. Contract review procedures do not adequately describe effective PO review process. Vendor unable to properly execute de-bur criteria and receiving inspection magnification level unable to detect small burs.				
	Task Description *(add more lines if necessary)*		Type of Evidence	Responsible	Due Date
1	Quality, with Sales, initiated rewriting Procedure for Purchase Contract OP-800.11 5/23/15		OP-800.11 updated. ECS September 24 2015 Quality to verify procedure.		
2	Quality and Sales establish Voice of the Customer Review. This comprehensive view of top customers will be reviewed semiannually at the Quality Management Review (QMR). Roll out August 2015.		Customer satisfaction scorecard reviewed semiannually during Quality Management Review (example attached)		
3	Shipping department now staging paperwork to prevent any issues with any one page being separated from the package. 6/5/15		Quality will review shipping files		ate.
4	Vendor is single source manufacture of the case and lids. We will 100% inspect, and rework as necessary, all parts received until second supplier is qualified, for the program, to manufacture the cases and lids. ECD 2/15/16		Receiving inspection plan updated with 10X magnification – June 6, 2015		r date.
RCCA Implementation Date		24-Sep-15	Verification of Implementation Date		09-Oct-15

Acceptable Example

Supplier's CA response RCCA Plan section contains:

- Verification actions have been identified along with objective evidence artifact information (best practice would be to have the verification actions identified in the Task Description field)

Verification of Effectiveness Plan

Supplier Verification of Effectiveness Plan must include:

- Identified Measures of Effectiveness (MoE) to confirm whether implemented actions produced the intended results.
- The date when the Corrective Action plan will be verified by the supplier as complete and effective.
- **The definition of Measure of Effectiveness is:** "The criteria and method(s) used to conduct verification of effectiveness."

Note: The supplier-stated MoE must verify that the RCCA Plan continues to be effective in the long term. The response may include as many MoE's as necessary to document that actions produced intended results.

STELIA NORTH AMERICA

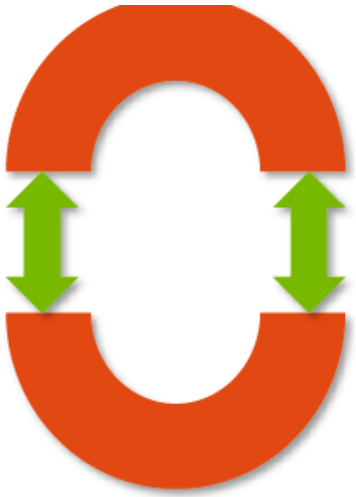
Measure of Effectiveness

The purpose of the MoE described in the RCCA Plan, is to verify the Root Cause Corrective Action was effective in precluding recurrence of the nonconformity.

This is accomplished by obtaining objective evidence such as quality records, audit results, data analysis, nonconformity history, and process yield.

Note: More than one MoE may be necessary.

MoE Closes the loop on the RCCA Process and is NOT optional.



MoE Unacceptable

	Measure of Effectiveness *(add more lines if necessary)*	Type of Evidenc	
1	Audit will be performed		r date.
2			Click to enter date.
Verification of Effectiveness Date			30-Sep-15

1

2

Unacceptable Example

1. Measure of Effectiveness Plan Tasks are not complete or concise. It should identify the *Who, What, When and How* for all the actions required to validate and verify the plan's completion and effectiveness with respect to the Statement of Nonconformity.
2. Measure of Effectiveness Date does not allow for sufficient time to elapse (usually 6 to 12 months) to establish a stable and repeatable process.

STELIA NORTH AMERICA

MoE Acceptable

1

	Measure of Effectiveness *(add more lines if necessary)*	Type of Evidence	Responsible	Due Da
1	Quality Manager or designee will perform 2 spot audits of the process between September 30, 2015 and December 31, 2015 with the goal of 0 non-conformances and document the results on Internal Audit Form IAFXXX-XX. Results will be documented within the internal RCCA database.			
2				Click to enter date.
Verification of Effectiveness Date				31-Dec-15

Acceptable Example

2

1. Measure of Effectiveness Plan Task(s) are complete and concise and identifies the *Who, What, When and How* for all required actions to validate and verify plan completion and effectiveness.
2. Measure of Effectiveness Date represents sufficient time that should elapse (usually 6 to 12 months) to establish a stable and repeatable process if positive results are achieved.

Verification of Effectiveness

Verification of Effectiveness closes the loop in the RCCA process to ensure the problem was removed or mitigated.

If the Verification of Effectiveness results indicate that Corrective Action has been successful, there are still a few loose ends to tie up:

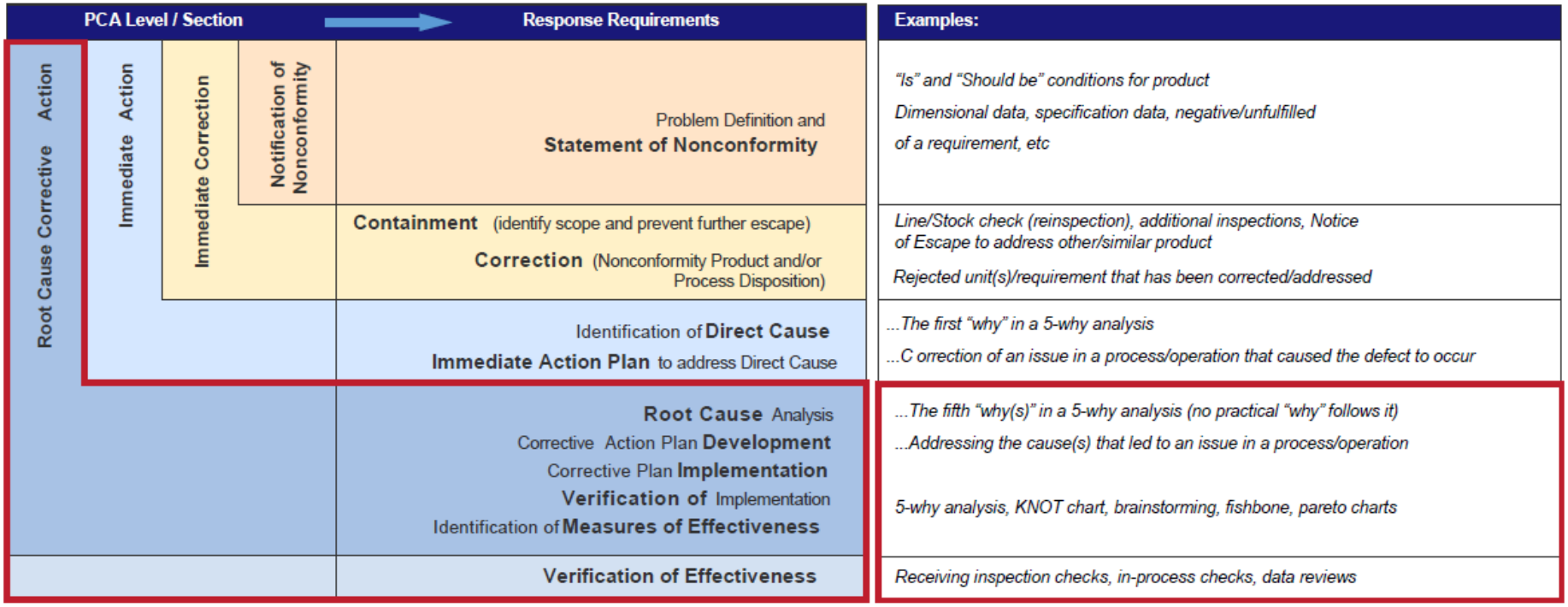
- Survey the customer
- Complete the documentation
- Close the record
- Communicate and share the results
- And celebrate your success!

STELIA NORTH AMERICA

Lesson 3 Summary

In this lesson you learned to:

- Identify and define the Root Cause.
- Develop the Root Cause Corrective Action plan.
- Verify implementation of the plan.
- Verify effectiveness utilizing the defined MoE.



Supplier Corrective Action Response Review

Training Summary

In this training, you learned

- How to formulate an Immediate Correction plan to contain and correct the nonconformity, as well as communicate awareness
- How to identify the Direct Cause and develop an Immediate Action plan to prevent it from recurring
- How to identify Root Cause Analysis (RCA) tools and formulate the Root Cause Statement
- How to develop a Root Cause Corrective Action (RCCA) Plan and implement it to mitigate the identified Root Cause
- How to verify the plan was implemented and effective

Glossary

- Apparent Cause
  - The event or action that immediately results in or precedes the nonconformity. May also be called obvious cause, direct cause, or immediate cause.
- Communication
  - Addressing how all affected parties have been notified of suspect conditions and products across the organization to ensure “like” items and “like” conditions do not impact other Programs or Operational areas.
- Containment
  - Action taken to determine the magnitude of a detected nonconformity or other undesirable situation, and minimize the impact, and prevent growth. Examples of containment include, but are not limited to, line or stock checks and requests for re-inspection. Complete containment addresses Correction, Containment and Communication.
- Contributing Causes
  - Causes that taken alone would not cause the problem but can increase the risk of the issue to occur. Analysis of these causes generally requires taking small steps (or a finer look) to identify and fix the problem.

Glossary

- Correction
  - Actions taken to correct detected nonconformities. This may involve reworking or scrapping and replacing the product or correcting paperwork.
- Corrective Action (CA)
  - Action to eliminate or mitigate the cause(s) of a detected nonconformity or other undesirable situation to prevent recurrence.
- Corrective Action Plan
  - A plan that documents the root cause(s) of a detected nonconformity or other undesirable situation, a solution to eliminate or mitigate the cause(s), a schedule of actions for implementation, and measures of effectiveness (MoE).
- Direct Cause(s)
  - Event(s), action(s) or condition(s) that directly result in a detected nonconformity or other undesirable situation that, if eliminated or mitigated, would prevent occurrence.
- Immediate Action
  - A type of corrective action taken to address direct cause(s).
    Note: The immediate action plan includes a verification plan.

Glossary

- Immediate Correction
  - Actions taken to fix the nonconformity, including containment of all nonconformities associated with the cause(s), and communication actions to all affected parties.
- Measure of Effectiveness (MoE)
  - The criteria and method(s) used to verify the root cause corrective action was effective in precluding recurrence of the nonconformity. This is accomplished by obtaining objective evidence during verification of effectiveness.
- Notification of Nonconformity (NN)
  - A notification of nonconforming product when formal corrective action response to SNA is not required. Internal corrective action by supplier is recommended.
- Notification of Escapement (NoE)
  - External supplier disclosure/notification to SNA of non-conforming or suspected non-conforming product to purchase contract requirements that has already been delivered to SNA, our suppliers and/or SNA's customers.
- Nonconformity
  - Non-fulfillment of a requirement. Note: It may be a non-conforming product but also incorrect paperwork, or incorrect process (production or QMS (Quality Management System) related).

Glossary

- Objective Evidence
  - Data supporting the existence or verity (actuality) of something. Note: You can obtain objective evidence through observation, measurement, testing, or other means.
- Recurrence
  - To occur again after an interval.
- Root Cause Analysis (RCA)
  - The process of identifying the root cause(s) of a detected or potential nonconformity or other undesirable situation using one or more RCA methods or tools (for example, cause and effect diagram, 5 whys analysis, fault tree).
- Root Cause Corrective Action (RCCA)
  - A type of corrective action (CA) that requires root cause analysis to be performed and action taken to address root cause(s). Note: RCCA includes a verification plan.
- Root Cause(s)
  - The initiating event(s), action(s) or condition(s) in a chain of causes that lead to a detected or potential nonconformity or other undesirable situation. Root causes have no practical preceding related events, actions, or conditions.

Glossary

- Verification of Implementation
  - An element of supplier corrective action that provides evidence the corrective action(s) were implemented as planned.
- Verification of Effectiveness
  - Use of the Measures of Effectiveness (MoE) defined in a Corrective Action Plan (CAP) to confirm that implemented actions have prevented a detected nonconformity or other undesirable situation from recurring. Can be performed by Supplier and by SNA.
- Statement of Nonconformity
  - The documented non-conformance description which clearly identifies and locates the conditions departing from a specific requirement. Also known as a Problem Statement, the statement of nonconformity should address the “IS” and “SHOULD BE” condition(s).