Deviation SOP

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A Larsen & Toubro Group Company

Document Authorization

Role	Name	Signature	Date
Author			
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Compliance Manager	Anjana Gopalakrishnan	Refer to e mail authorization	
Approver			
Compliance COE -Head	G S Vijayakumar	Refer to e mail approval	

Note: Refer to e-mail approval attached at the end of the procedure

Document History

Version	Change Description	Author	Date
1.00	*Initial version*	*Swati Kochukulam*	*26 May 2020*

Version	Change Description	Author	Date
1.01	*1. Section 1.4 updated to elaborate compliance team member responsibility* *2. Document title changed from* *OLS_05_00P_ Deviation SOP_Procedure* *OLS_05_01T_Deviation Form_Unplanned Deviation_Template* *OLS_05_02T_Deviation Log_Template* *OLS_05_03T_Ishikawa Root Cause Analysis_Template* *OLS_05_04T_5 Why-2 H Root Cause Analysis_Template* *OLS_05_05T_FMEA Root Cause Analysis_Template* *OLS_05_06T_Deviation Form_Planned Deviation_Template* *To below* *OLS-05-00P- Deviation SOP_Procedure* *OLS-05-01T-Deviation Form-Unplanned Deviation-Template* *OLS-05-02T-Deviation Form-Planned Deviation-Template* *OLS-05-03T-Deviation Log-Template* *OLS-05-04T-Ishikawa Root Cause Analysis-Template* *OLS-05-05T-5 Why Root Cause Analysis-Template* *OLS-05-06T-FMEA Root Cause Analysis-Template*	*Swati Kochukulam*	*26 Aug 2020*

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1 Introduction

Departure from established processes occur in an organization due to various reasons sometimes unavoidable and these departures are termed as Deviations. These are typically divergence from approved standards, specifications, tolerances etc., While the instances of such occurrence have to be kept minimal, nevertheless a process has to exist to handle those that occur.

1.1 Executive Summary

As per GAMP5 guidelines there should be a documented process for deviation. This procedure will ensure that any deviation observed is documented, evaluated and appropriate corrective action and preventive action items have been suggested and are tracked and closed in time.

1.2 Objective

The objective of this SOP is to ensure deviations are identified, reported, assessed, investigated and appropriate corrective and preventive actions are taken as applicable to safeguard the quality attribute of the affected computer system and control systemic practices and ensure that such departure from established practices are kept minimal.

1.3 Scope

This SOP shall be applicable to handling of internal GxP relevant systems of LTI or GxP projects executed for Life Sciences customers. Deviations with respect non-adherence to appropriate prescribed Life science specific processes and SOPs have to be addressed using this procedure.

1.4 Roles and Responsibilities

- **Process Owner is responsible for the following:**
  - Assign a designee/ team member to initiate deviation
  - Track the status of deviation.
  - Review deviation details
  - Approve pre-implementation of proposed CA and PA.
  - Approve post-implementation of proposed CA and PA.
  - Approve the target date and description for the Deviation
  - Monitor the progress for implementation of CA and PA action plan
  - Ensure timely implementation of CA and PA and closure of the Deviation
  - Review justification for extension to Deviation and closure

- **Deviation Owner is responsible for the following**
  - Initiate the deviation
  - Identify type of deviation
  - Perform investigation and impact assessment of deviation
  - Timely implementation of CA and PA
  - Perform root cause analysis of deviation

- Initiate closure of deviation

- **Compliance Team member is responsible for the following:**
  - Issuance and allocation of Number to deviation form
  - Review deviation form
  - Update and maintain deviation log
  - Follow up on outstanding Deviation Form
  - Periodic review of repetitive deviation
  - Review Deviation log periodically
  - Pre implementation and Post implementation Review and Approval of deviation form
  - Define action plan for the repetitive deviations
  - Ensure adherence to this SOP
  - Approve/Reject extension request to Deviation and closure

- **Delivery Manager and Delivery Head responsible for the following:**
  - Pre implementation Approval of deviation form for Planned Deviations
  - Review extension request for the Deviation and closure
  - Define action plan for the repetitive deviations and ensure effective implementation of the plan

2 Terms, Abbreviations and Definitions

Term/Abbreviation	Description/ Definition
CA	Corrective Action
PA	Preventive Action
RCA	Root Cause Analysis
SOP	Standard Operating Procedure
QMS	Quality Management System
cGxP	Current Good x (M=Manufacturing, L= Laboratory, C= Clinical, D= Documentation) Practice
LTI	Larsen and Toubro Infotech
MSA	Master Service Agreement
GAMP	Good automated manufacturing practice
COE	Center of Excellence
Corrective Action	Action to eliminate detected non-conformity or another undesirable situation
Deviation	Departure from an approved procedure/SOP/ practice under LifeScience set of processes having GxP impact
Planned Deviation	A temporary, proposed and deliberate change to any approved procedure, document or specification prior to execution
Unplanned Deviation	Deviation identified during and/or after the activity has been carried out
Preventive Action	Action to eliminate the cause of the potential nonconformity or other potential undesirable situation
Root Cause	The source of origin of deviation

3 Process

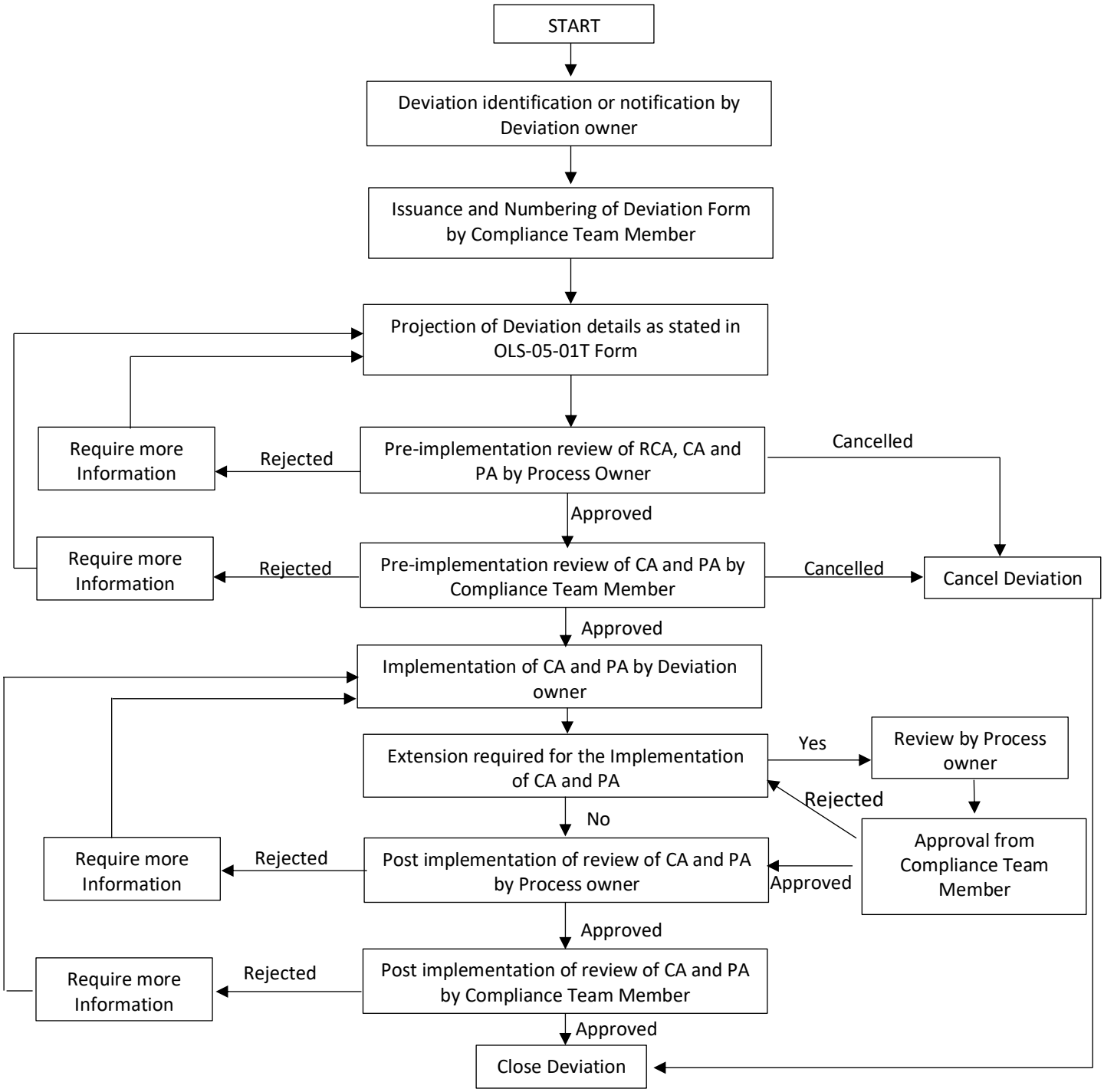
3.1 Deviation Management Process

There are two types of Deviation - “Planned Deviation” and “Unplanned Deviation”.

3.1.1 Unplanned Deviation:

Unplanned deviation shall be initiated for the situation where departure from the laid down procedure has occurred unintentionally and identified by the process owner during the course of normal operation and brought to the notice of the Compliance team for appropriate handling and management. CA and PA are normally applicable for unplanned critical and major category of deviations Justification for unplanned deviation shall be recorded in deviation form (OLS-05-01T-Deviation Form-Unplanned Deviation-Template).

Figure 1: Flow diagram for Unplanned Deviation



3.1.1.1 Deviation Initiation

- Deviations shall be initiated by the concerned Process owner/ Delivery team. In special cases, the deviations shall be initiated by the Compliance team for special business reasons affecting the whole unit.
- Compliance team member shall issue a deviation form (OLS-05-01T-Deviation Form-Unplanned Deviation-Template) by making relevant entries in Deviation log.
- Deviation shall be numbered as "DVT/YY/XXX", where YY is the Current Year and XXX is the serial number starting from 001.
- Compliance team member shall assign the deviation form to Deviation Owner.
- Alternatively, all the Deviation management process shall happen through a Deviation system when such solutions are available and validated.

3.1.1.2 Define RCA and CAPA

- For major and critical unplanned deviations, RCA and CAPA shall be mandatory
- Deviation owner shall perform following steps:
  - Perform investigation of deviation through RCA.
  - Document justification for deviation.
  - Perform impact assessment.
  - Identify and initiate CA and PA for deviation
- Process owner team member may use one of the below methodologies for performing RCA of deviation:

Methodology	Description
Ishikawa (OLS-05-04T-Ishikawa Root Cause Analysis-Template)	Also known as Fishbone diagram/Cause Effect Diagram. Ishikawa diagram illustrate a graphical representation of relationship between a given problem and all the factors that influence the problem. ➢ Step I: Identify and clearly define the problem ➢ Step II: Identify the major cause of problem ➢ Step III: For each major cause identify sub-causes ➢ Step IV: Analyze the diagram for most probable cause Root cause identified shall reveal logical/scientific relationship to the identified problem stated at head of fish bone diagram.
5 Why-2 H Approach (OLS-05-05T-5 Why Root Cause Analysis-Template)	The 5-Why-2H method helps to determine the cause-effect relationship in a problem or a failure event. After identifying the problem, investigator/investigating team shall ask at minimum 5 times "why", "How" and "How Much" question as part of interview/interaction. The last response received for answering the questions is considered as the root cause of the issue. If the last answer is something which cannot be controlled, consider the previous answer.

- Deviation owner shall submit duly filled deviation form to Process owner for review.
- Deviation owner shall mention the Proposed CA and PA in the deviation form and submit it for pre-implementation review to Process owner.

3.1.1.3 Pre-implementation approval by process owner

Process owner shall review the details filled in deviation form and will take one of the following actions:

- Send back the deviation form in case more information is required
- Cancel the deviation in case deviation is not required.
- Approve or Reject the deviation form

3.1.1.4 Pre-implementation approval by Compliance Team Member

Compliance Team Member shall review the deviation form and take one of the following actions:

- Send back the deviation form in case more information is required
- Cancel the deviation in case deviation is not required.
- Approve or Reject the deviation form

3.1.1.5 Implementation of CA and PA

- After approval of deviation form and pre-implementation review, Deviation owner shall implement the proposed corrective and preventive actions.
- After implementation of CA and PA, Deviation owner shall submit the deviation form to Process owner and Compliance Team Member for post implementation review and approval.

3.1.1.6 Deviation Extension

- Deviation need to be closed within 30 Calendar days.
- Deviation owner shall initiate deviation extension request providing justification for the extension in deviation form (OLS-05-01T-Deviation Form-Unplanned Deviation-Template) if the CA and PA will be taking more time and crossing the time limit defined for the deviation closure.
- Process owner and compliance team member shall review the extension request.
- Compliance Team member shall Reject or approve the extension request by specifying the details in the form.

3.1.1.7 Post-implementation approval by Process owner

Process owner shall perform one of the following actions after implementation of CA and PA:

- Review the implemented CA and PA and approve deviation form
- Request to Deviation owner for additional information (if any)
- If Deviation found OK, then Process owner shall fill the details and route the deviation for approval.

3.1.1.8 Post-implementation approval by Compliance Team Member

Compliance Team Member approver shall perform one of the following actions after implementation of CA and PA:

- Review the implemented CA and PA and approve deviation form.

- Request to Deviation owner for additional information (if any)
- If Deviation found OK, then Compliance team member shall fill the details and approve the Deviation.
- The deviation status is considered closed and deviation log is updated.

3.1.1.9 Once the Deviation is approved, Deviation owner shall scan and upload the Deviation copy at LTI Share point and submit the hardcopy to compliance team member.

3.1.1.10 Compliance team member ensure the availability of scan copy and update the log entry and then destroy the Deviation form.

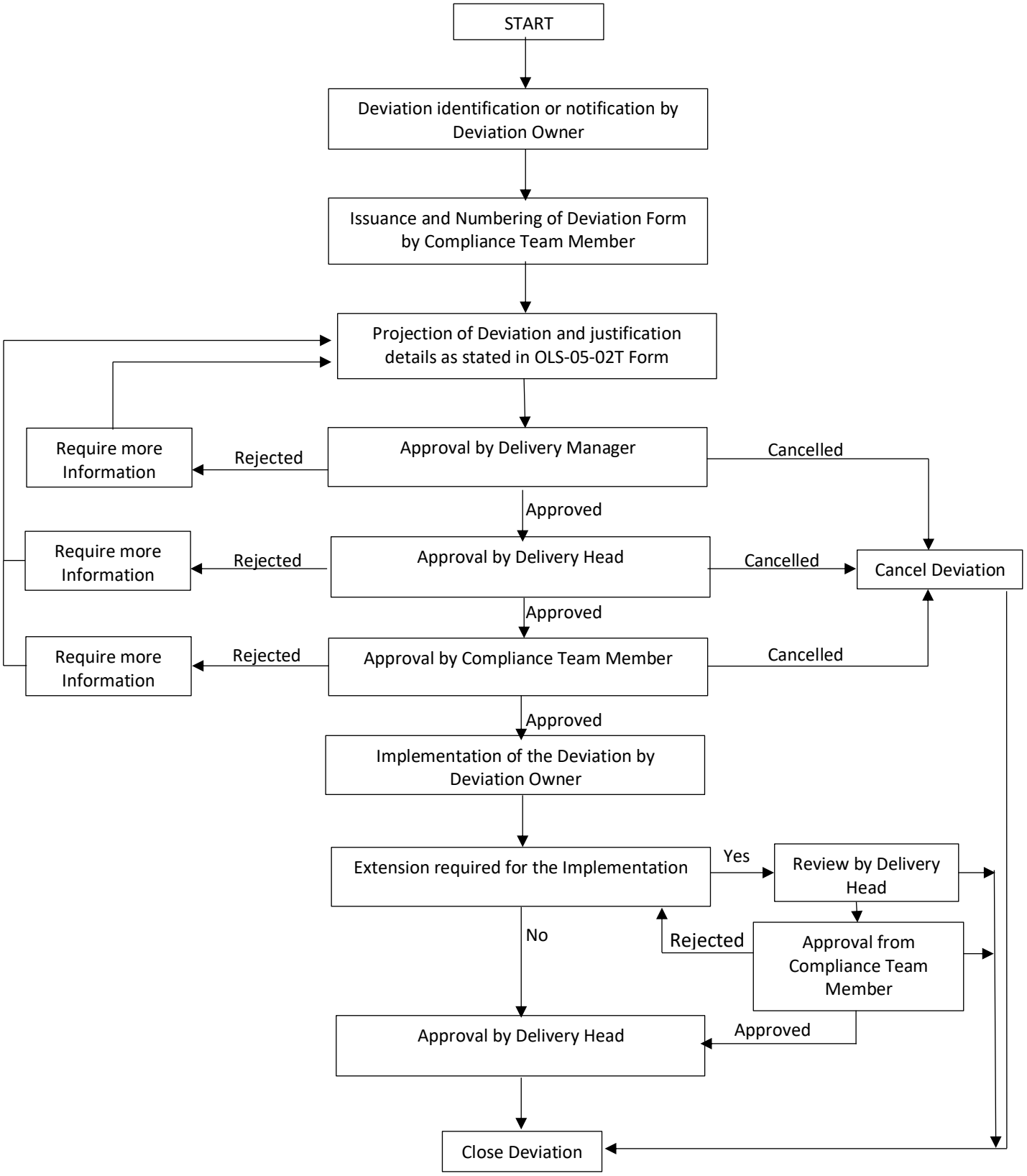
3.1.1.11 All deviations shall be reviewed and analyzed on an annual basis to identify trends and organization preventive actions towards opportunities for process improvement, revisit / reinforcement of trainings etc.,

3.1.2 Planned Deviation:

Planned deviation shall be taken under the situation where departure from the approved procedure is done intentionally due to unavoidable or special circumstance. Justification for planned deviation shall be recorded in deviation form. If the planned deviation is known to be effective for a fixed periodicity or a fixed number of events, then time period should be assigned for planned deviation in “Valid till” section of deviation form. Typically, CA and PA are not applicable for planned deviations and only justifications are given for appropriate approval.

Planned deviations are initiated by the process owners and shall be sent for approval by the Delivery manager and Delivery Head prior to approval by the Compliance Head. Deviation shall be rejected if such justifications are found to be inappropriate and detrimental to patient safety, product quality or data integrity.

Figure 2: Flow diagram for Planned Deviation



3.1.2.1 Deviation Initiation

- Deviations shall be initiated by the concerned Process owner/ Delivery team. In special cases, the deviations shall be initiated by the Compliance team for special business reasons affecting the whole unit.
- Compliance team member shall issue a deviation form (OLS-05-02T-Deviation Form-Planned Deviation-Template) by making relevant entries in Deviation log.
- Deviation shall be numbered as "DVT/YY/XXX", where YY is the Current Year and XXX is the serial number starting from 001.
- Compliance team member shall assign the deviation form to Deviation Owner.
- Alternatively, all the Deviation management process shall happen through a Deviation system when such solutions are available and validated.

3.1.2.2 Planned Deviation – Justification

Justification for planned deviation shall be documented in deviation form (OLS-05-02T-Deviation Form-Planned Deviation-Template).

Note: RCA shall not be applicable in case of planned deviation.

3.1.2.3 Delivery Manager Approval

Delivery Manager shall review the details filled in deviation form and will take one of the following actions:

- Send back the deviation form in case more information is required
- Cancel the deviation in case deviation is not required.
- Approve or Reject the deviation form

3.1.2.4 Delivery Head Approval

Delivery Head shall review the details filled in deviation form and will take one of the following actions:

- Send back the deviation form in case more information is required
- Cancel the deviation in case deviation is not required.
- Approve or Reject the deviation form

3.1.2.5 Compliance Team Member Approval

Compliance Team Member shall review the deviation form and take one of the following actions:

- Send back the deviation form in case more information is required
- Cancel the deviation in case deviation is not required.
- Approve or Reject the deviation form

3.1.2.6 Deviation Extension

- Deviation need to be closed within 30 Calendar days.
- Deviation owner shall initiate deviation extension request providing justification for the extension in deviation form (OLS-05-02T-Deviation Form-Planned Deviation-Template)
- Process owner and Compliance team member shall review the extension request.
- Compliance Team Member shall Reject or approve the extension request by specifying the details in the form.

3.1.2.7 Post Implementation Approval by Compliance Team Member

Compliance Team Member approver shall perform one of the following actions after implementation:

- Review the action taken
- Request to Deviation owner for additional information (if any)
- If Deviation found OK, then Compliance Team Member shall fill the details and approve the Deviation.
- The deviation status is considered closed and deviation log is updated.

3.1.2.8 Once the Deviation is approved, Deviation owner shall scan and upload the Deviation copy at LTI Share point and submit the hardcopy to Compliance Team Member.

3.1.2.9 Compliance Team Member will ensure the availability of scan copy and update the log entry and then destroy the Deviation form.

3.1.2.10 All deviations shall be reviewed and analyzed on an annual basis to identify trends and organization preventive actions towards opportunities for process improvement, revisit / reinforcement of trainings etc.,

3.1.3 Deviation Categorization

Deviation can be categorized into

- Critical
- Major
- Minor

Defect Category	Details
Critical	Critical GxP failure occurs when a deviation could give rise to a product which would be harmful to the patient or animal, or which has produced a harmful product, impacts potency, purity, patient treatment, or adversely affects the rights, safety or well-being of patients/ subjects, poses a potential risk to public health, jeopardizes the quality and integrity of data, or contribute to withholding information that may constitute a fraud or falsification of products or data; A deficiency in complying with Company and Client Standards, applicable Regulatory requirements etc., in GXP space. A combination of major deviation, which indicates a serious system failure, may also be classified as a critical observation. Deviation that would result in a failure of the quality system that would have an effect on the finished product quality or may result in not achieving management system certification
Major	Any deviation may be classified as major for the following reasons: • Non-critical deviation which has produced or may produce a product, which does not comply with GxP/ GCP guidelines that which can potentially turn critical if not addressed in a timely manner • A combination of several “other” deficiencies, none of which on their own may be major, but which may occur in a particular area together represent a major observation

Defect Category	Details
	• Repeated minor deviations in the same area that could lead to system failure
Minor	• Any deviation that is less serious and isolated in nature which cannot be classified as either critical or major, but which indicates a departure from good manufacturing practice. • Inconsistency or missing link in a process not expected to adversely affect the rights, safety or well-being or jeopardizes the quality, integrity of data • Deviation that would result in a failure of one or more quality system processes that may have an effect on the finished product quality or may result in problems achieving management system certification.

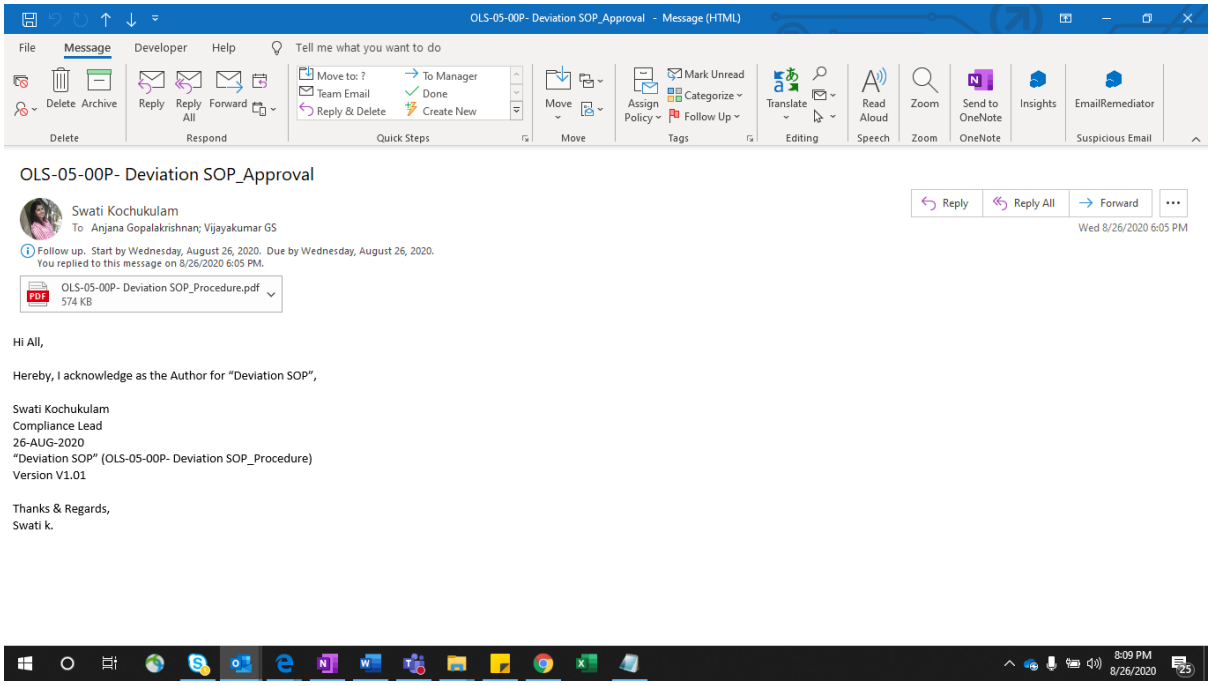
4 Annexure

4.1 Templates, Tools and Checklists

Sr. No.	QMS Template Number	Document Name
1.	OLS-05-01T-Deviation Form-Unplanned Deviation-Template	Deviation Form Template for Unplanned deviation
2.	OLS-05-02T-Deviation Form-Planned Deviation-Template	Deviation Form Template for planned deviation
3.	OLS-05-03T-Deviation Log-Template	Deviation Log Template
4.	OLS-05-04T-Ishikawa Root Cause Analysis-Template	Ishikawa Root Cause Analysis
5.	OLS-05-05T-5 Why Root Cause Analysis-Template	5 Why-2 H Root Cause Analysis
6.	OLS-05-06T-FMEA Root Cause Analysis-Template	FMEA Root Cause Analysis

4.2 References

- GAMP 5 A Risk Based Approach to Compliant GxP Computerized System
- SOP on SOPs: OLS-02-00P - SOP on SOP-Procedure



OLS-05-00P- Deviation SOP_Approval - Message (HTML)

File Message Developer Help Tell me what you want to do

Delete Archive Reply Reply All Forward Move to: ? To Manager Team Email Done Reply & Delete Create New Move Assign Policy Mark Unread Categorize Follow Up Translate Read Aloud Zoom Send to OneNote Insights EmailRemediator

Delete Respond Quick Steps Move Tags Editing Speech Zoom OneNote Suspicious Email

OLS-05-00P- Deviation SOP_Approval

Swati Kochukulam
To Anjana Gopalakrishnan; Vijayakumar GS

Reply Reply All Forward

Wed 8/26/2020 6:05 PM

Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
You replied to this message on 8/26/2020 6:05 PM.

OLS-05-00P- Deviation SOP_Procedure.pdf
574 KB

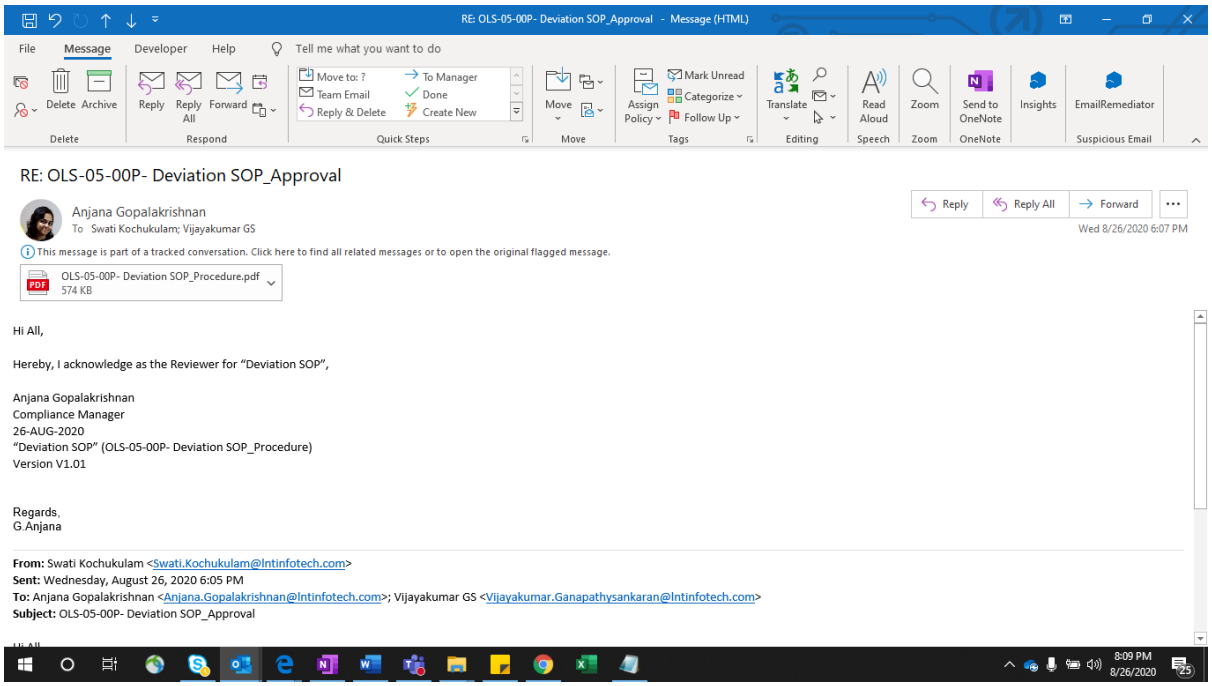
Hi All,

Hereby, I acknowledge as the Author for "Deviation SOP",

Swati Kochukulam
Compliance Lead
26-AUG-2020
"Deviation SOP" (OLS-05-00P- Deviation SOP_Procedure)
Version V1.01

Thanks & Regards,
Swati k.

8:09 PM
8/26/2020



RE: OLS-05-00P- Deviation SOP_Approval - Message (HTML)

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Delete Respond Quick Steps Move Tags Editing Speech Zoom OneNote Suspicious Email

RE: OLS-05-00P- Deviation SOP_Approval

Anjana Gopalakrishnan
To Swati Kochukulam; Vijayakumar GS

Reply Reply All Forward

Wed 8/26/2020 6:07 PM

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OLS-05-00P- Deviation SOP_Procedure.pdf
574 KB

Hi All,

Hereby, I acknowledge as the Reviewer for "Deviation SOP",

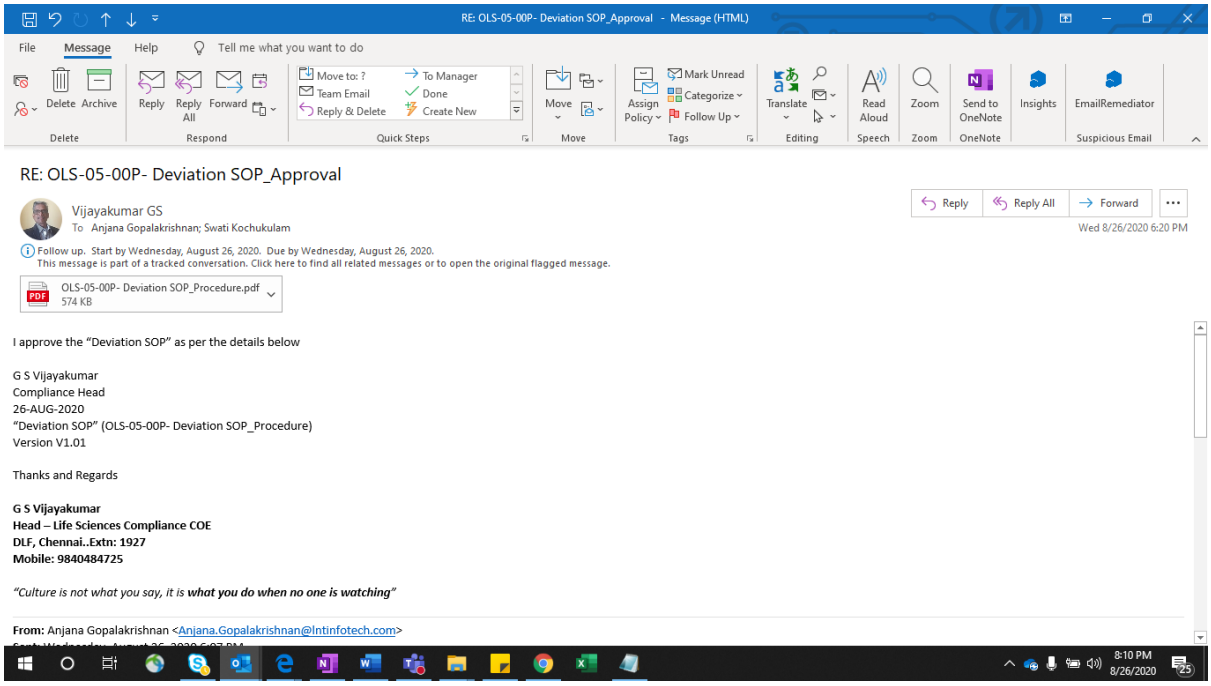
Anjana Gopalakrishnan
Compliance Manager
26-AUG-2020
"Deviation SOP" (OLS-05-00P- Deviation SOP_Procedure)
Version V1.01

Regards,
G.Anjana

From: Swati Kochukulam <Swati.Kochukulam@lntinfotech.com>
Sent: Wednesday, August 26, 2020 6:05 PM
To: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@lntinfotech.com>; Vijayakumar GS <Vijayakumar.Ganapathysankaran@lntinfotech.com>
Subject: OLS-05-00P- Deviation SOP_Approval

Hi All,

8:09 PM
8/26/2020


RE: OLS-05-00P- Deviation SOP_Approval - Message (HTML)
File
Message
Help
Tell me what you want to do
Delete
Archive
Reply
Reply All
Forward
Move to: ?
To Manager
Team Email
Done
Reply & Delete
Create New
Move
Assign Policy
Mark Unread
Categorize
Follow Up
Translate
Read Aloud
Zoom
Send to OneNote
Insights
EmailRemediator
Delete
Respond
Quick Steps
Move
Tags
Editing
Speech
Zoom
OneNote
Suspicious Email
RE: OLS-05-00P- Deviation SOP_Approval
Vijayakumar GS
To Anjana Gopalakrishnan; Swati Kochukulam
Reply
Reply All
Forward
Wed 8/26/2020 6:20 PM
Follow up. Start by Wednesday, August 26, 2020. Due by Wednesday, August 26, 2020.
This message is part of a tracked conversation. Click here to find all related messages or to open the original flagged message.
OLS-05-00P- Deviation SOP_Procedure.pdf
574 KB
I approve the "Deviation SOP" as per the details below
G S Vijayakumar
Compliance Head
26-AUG-2020
"Deviation SOP" (OLS-05-00P- Deviation SOP_Procedure)
Version V1.01
Thanks and Regards
G S Vijayakumar
Head – Life Sciences Compliance COE
DLF, Chennai..Extn: 1927
Mobile: 9840484725
"Culture is not what you say, it is what you do when no one is watching"
From: Anjana Gopalakrishnan <Anjana.Gopalakrishnan@Intinfotech.com>
8:10 PM
8/26/2020

Annexure 1
Deviation Form Template_Unplanned Deviation

Deviation Form	
Deviation Number	*<Specify Deviation number>*
Date Opened	*<Specify date on which deviation is initiated>*
Date Closed	*<Specify date on which deviation is closed>*
Source Document No	*<Source document where the deviation is related to>*
Project Name and ID No.	*<Project Name in which Deviation is occurred>*
Deviation Initiation	
Initiated by	*<Deviation owner's name >*
Title/Short Description	*<Provide brief description of deviation>*
Deviation Type	*<Specify deviation type>*
Assigned To	*<Specify name of personnel to whom deviation is assigned>*
Valid Till	*<Specify due date of deviation>*
Description of Deviation	*<Provide description of deviation>* _____ _____ _____ _____ _____
Root Cause Analysis (RCA)	Select RCA methodology used: ☐ Ishikawa ☐ 5 Why 2 H Approach ☐ FMEA RCA description: *<Provide brief description of RCA and attach RCA template as enclosure to deviation>*
Categorization	**CRITICAL** ☐ **MAJOR** ☐ **MINOR** ☐
Impacted system details	*<List system impacted by deviation>*
Document impacted details	*<List documents impacted by deviation>*
Corrective Action	_____ _____ _____

Annexure 1
Deviation Form Template_Unplanned Deviation

Deviation Form	
	_____ _____ _____ _____ _____
Preventive Action	_____ _____ _____ _____ _____ _____ _____
Pre-Implementation Approval	
Process Owner	
Process Owner Comments: _____ _____ _____ **Approved / Rejected/Cancel** - Name: _____ Signature: _____ Date (DD/MM/YYYY):_____	
Compliance Team Member	
Compliance Team Member Comments: _____ _____ _____ **Approved / Rejected/Cancel** - Name:_____ Signature:_____ Date (DD/MM/YYYY):_____	

Annexure 1
Deviation Form Template_Unplanned Deviation

Deviation Form	
Deviation Extension Request	
Reason for extension: _____ _____ _____ _____	
Requested by/ Date (DD/MM/YYYY)	*<Specify name of personnel who requested extension and date on which extension was requested>*
Revised Target Date	*<Specify proposed new target date>*
Reviewed by: *(to be signed and dated (DD/MM/YYYY) by process owner)*	
Approved by: *(to be signed and dated (DD/MM/YYYY) by Compliance Team Member)*	**Approved/Rejected -**
Post Implementation Approval	
Process Owner	
Process Owner Comments: _____ _____ _____ _____ _____	
Approved / Rejected - Name:_____ Signature:_____ Date (DD/MM/YYYY):_____	
Compliance Team Member	
Compliance Team Member Comments:	

Annexure 1
Deviation Form Template_Unplanned Deviation

Deviation Form
Approved / Rejected -
Name:_____
Signature:_____ Date: (DD/MM/YYYY):_____

Note: Remove blue text before final usage of template.

Annexure 2
Deviation Log Template

Sr. No	Initiation Date	Deviation No.	Deviation Categorization	Deviation Type	Assigned To	Description of Deviation	Source document No.	Project Name and ID No.	Issued by/Date (DD/MM/YYYY)	Target Date of Closure	Revised Target Date	Status	Closed Date	Remark

Annexure 3
Ishikawa Root Cause Analysis

Directions:

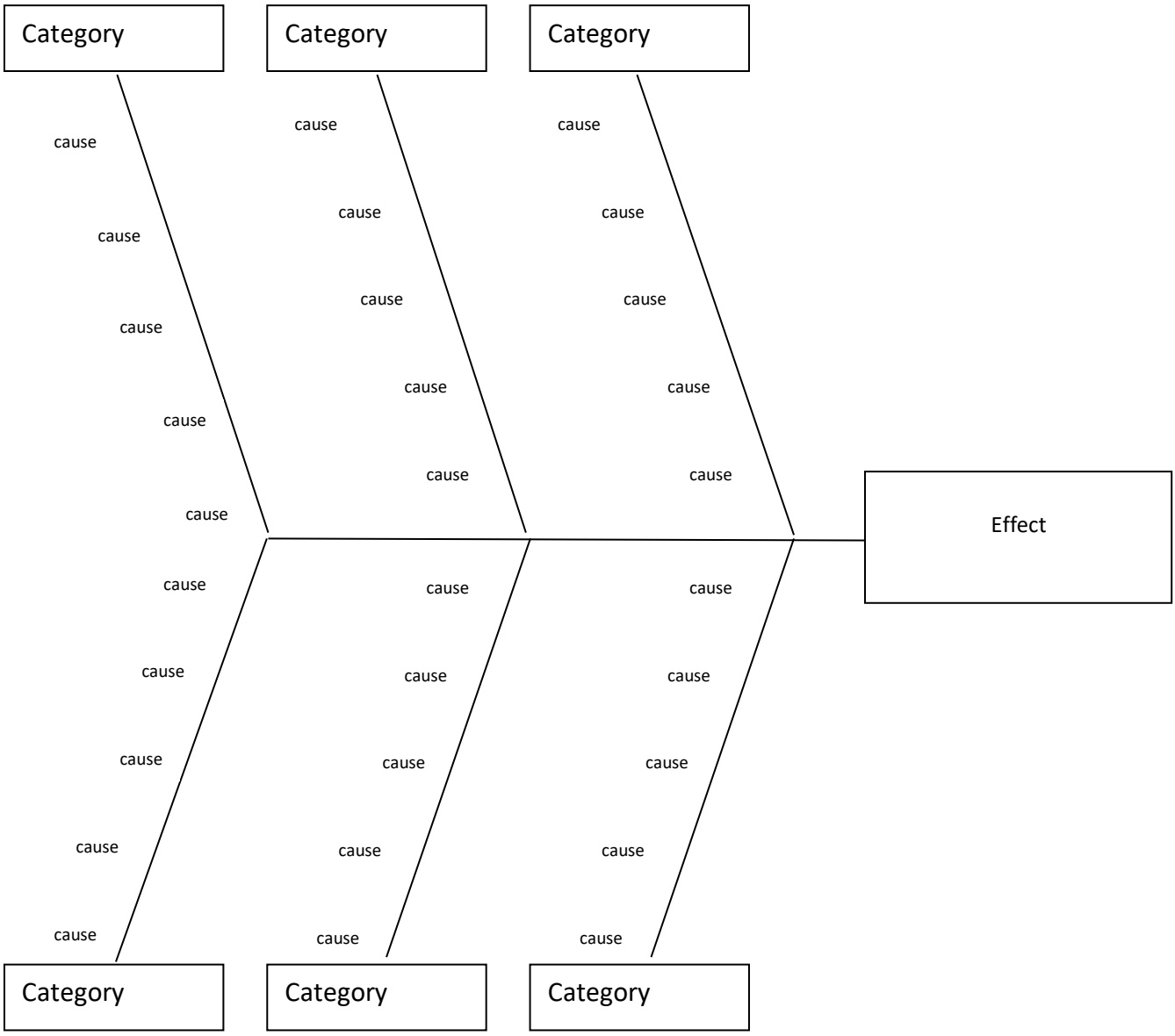
The team using the fishbone diagram tool should carry out the steps listed below.

- Agree on the problem statement (also referred to as the effect). This is written at the mouth of the "fish." Be as clear and specific as you can about the problem. Beware of defining the problem in terms of a solution (e.g., we need more of something).
- Agree on the major categories of causes of the problem (written as branches from the main arrow). Major categories often include equipment or supply factors, environmental factors, rules/policy/procedure factors, and people/staff factors.
- Brainstorm all the possible causes of the problem. Ask "Why does this happen?" As each idea is given, the facilitator writes the causal factor as a branch from the appropriate category (places it on the fishbone diagram). Causes can be written in several places if they relate to several categories.
- Again asks "Why does this happen?" about each cause. Write sub-causes branching off the cause branches.
- Continues to ask "Why?" and generate deeper levels of causes and continue organizing them under related causes or categories. This will help you to identify and then address root causes to prevent future problems.

Tips:

- Use the fishbone diagram tool to keep the team focused on the causes of the problem, rather than the symptoms.
- Consider drawing your fish on a flip chart or large dry erase board.
- Make sure to leave enough space between the major categories on the diagram so that you can add minor detailed causes later.
- When you are brainstorming causes, consider having team members write each cause on sticky notes, going around the group asking each person for one cause. Continue going through the rounds, getting more causes, until all ideas are exhausted. How to Use the Fishbone Tool for Root Cause Analysis Disclaimer: Use of this tool is not mandated by CMS, nor does its completion ensure regulatory compliance.
- Encourage each person to participate in the brainstorming activity and to voice their own opinions.
- Note that the "five-whys" technique is often used in conjunction with the fishbone diagram – keep asking why until you get to the root cause.
- To help identify the root causes from all the ideas generated, consider a multi-voting technique such as having each team member identify the top three root causes. Ask each team member to place three tally marks or colored sticky dots on the fishbone next to what they believe are the root causes that could potentially be addressed.

Annexure 3
Ishikawa Root Cause Analysis



Annexure 4
5Why-2H Root Cause Analysis

5 WHYs – 2H

Define the Problem:

Why is it happening? *(Identify each as a concern, influence or control.)*

1.	→ Why is that? ↓
2.	→ Why is that? ↓
3.	→ Why is that? ↓
4.	→ Why is that? ↓
5.	→ Why is that? ↓
6.	→ How? ↓
7.	→ How Much?

Note: If your last answer is something you cannot control go back up to previous answer.

Annexure 5
FMEA Root Cause Analysis

Below steps shall be followed to perform FMEA Root Cause Analysis:

- List all the process steps and potential failures.
- Each index ranges from 1 (lowest risk) to 3 (highest risk).
- The overall risk of each failure is called Risk Priority Number (RPN) and the product of Severity (S), Occurrence (O), and Detection (D) rankings: RPN = S × O × D.
- The RPN (ranging from 1 to 27) is used to prioritize all potential failures to decide upon actions leading to reduce the risk, usually by reducing likelihood of occurrence and improving controls for detecting the failure.

  RPN = Severity X Occurrence X Detection

- The goal is to reduce RPNs through a reduction in severity, occurrence, and detection rankings.

Annexure 5
FMEA Root Cause Analysis

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY (1 - 3)	Potential Causes	OCCURRENCE (1 - 3)	Current Controls	DETECTION (1 - 3)	RPN	Action Recommended	Resp.	Actions Taken	SEVERITY (1 - 3	OCCURRENCE (1 - 3)	DETECTION (1 - 3)	RPN
What is the process step, change or feature under investigation ?	In what ways could the step, change or feature go wrong?	What is the impact on the customer if this failure is not prevented or corrected ?		What causes the step, change or feature to go wrong? (how could it occur?)		What controls exist that either prevent or detect the failure?			What are the recommended actions for reducing the occurrence of the cause or improving detection?	Who is responsible for making sure the actions are completed ?	What actions were completed (and when) with respect to the RPN?				

Annexure 6
Deviation Form Template_Planned Deviation

Deviation Form			
Deviation Number	*<Specify Deviation number>*		
Date Opened	*<Specify date on which deviation is initiated>*		
Date Closed	*<Specify date on which deviation is closed>*		
Source Document No	*<Source document where the deviation is related to>*		
Project Name and ID No.	*<Project Name in which Deviation is occurred>*		
Deviation Initiation			
Initiated by	*<Deviation Owner's name >*		
Title/Short Description	*<Provide brief description of deviation>*		
Deviation Type	*<Specify deviation type>*		
Assigned To	*<Specify name of personnel to whom deviation is assigned>*		
Valid Till	*<Specify due date of deviation>*		
Description of Deviation and action planned	*<Provide description of deviation and action planned>*		
Justification	*<Specify justification for deviation>*		
Categorization	**CRITICAL** ☐	**MAJOR** ☐	**MINOR** ☐
Impacted system details	*<List system impacted by deviation>*		
Document impacted details	*<List documents impacted by deviation>*		

Annexure 6
Deviation Form Template_Planned Deviation

Delivery Manager Approval
Delivery Manager Comments: _____ _____ _____ **Approved / Rejected/Cancel** - Name: _____ Signature: _____ Date (DD/MM/YYYY): _____
Delivery Head Approval
Delivery Head Comments: _____ _____ _____ **Approved / Rejected/Cancel** - Name: _____ Signature: _____ Date (DD/MM/YYYY): _____
Compliance Team Member Approval
Compliance Team Member Comments: _____ _____ _____ **Approved / Rejected/Cancel** - Name: _____ Signature: _____ Date (DD/MM/YYYY): _____
Deviation Extension Request
Reason for extension: _____ _____ _____

Annexure 6
Deviation Form Template_Planned Deviation

Requested by/ Date (DD/MM/YYYY)	*<Specify name of personnel who requested extension and date on which extension was requested>*
Revised Target Date	*<Specify proposed new target date>*
Reviewed by: *(to be signed and dated (DD/MM/YYYY) by Delivery Head)*	
Approved by: *(to be signed and dated (DD/MM/YYYY) by Compliance Team Member)*	**Approved/Rejected -**
Post Implementation Approval	
Compliance Team Member	
Compliance Team Member Comments: _____ _____ _____ **Approved / Rejected** - Name:_____ Signature:_____ Date: (DD/MM/YYYY):_____	

Note: Remove blue text before final usage of template.