


# Software Quality Assurance

## Part 4 -- Process Audit

Software Engineering

Liu Jia -2017

# Introduction to Auditing

The background of the slide features a dark, almost black, field with several vibrant, horizontal light streaks. These streaks, in shades of purple, pink, orange, and yellow-green, appear to be motion-blurred light sources, creating a sense of dynamic energy and modern technology. The streaks are more concentrated on the left side and fan out towards the right.

## What is an Audit?

*( ISO 19011:2002 Clause 3.1)*

- Systematic, Independent and documented process for obtaining audit evidence (3.3) and evaluating it objectively to determine the extent to which the audit criteria (3.2) are fulfilled.

## Why Audit?

- Requirement of ISO 9001/TL9000
- Monitor and measure the QMS
- Promote continuous improvement of the Management system

# Principles of auditing



## Principles relating to auditors

- Ethical Conduct: Trust, integrity, confidentiality and discretion are essential
- Fair Presentation: Report truthfully and accurately
- Professional care: Diligent and prudent attitude during the audit

*Note: referenced to ISO 19011: Clause number 4.0*

## Principles relating to audit

- Independence: Avoid conflict of interest to ensure that audit findings are based only on the audit evidence.
- Evidence-based Approach: Rational method to get reliable and reproducible audit findings.

# Benefits of auditing

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## Benefits of an audit

- Verify conformity to ISO 9001 and QMS requirements
- Provide a measurement of effectiveness of the QMS to Top Management
- Reduce risks of management system failure
- Continuous improvement the organization and its QMS
- Increase business awareness and understanding
- Identify and implement the improvement opportunities

# Types of Audits



## Types of audits

- Internal audits: so called "first-party audits" are conducted by or on behalf of the organization itself for internal purposes
  - Example: Gap assessment, process auditing
- External audits include what is generally called "audit of a second or third party. "
  - The second party audits are conducted by parties such as customers, with an interest in the company, or by others on their behalf.
    - Example: supplier contract,
  - The third-party audits are conducted by independent external bodies. Such organizations generally accredited (see NF ISO / IEC 17021),
    - Example: the registration or certification of compliance to requirements such as ISO 9001 or 14001....

# Process Approach



## What is a process:

- Sequence of interdependent and linked procedures which, at every stage, consume one or more resources (employee time, energy, machines, money) to convert inputs (data, material, parts, etc.) into outputs. These outputs then serve as inputs for the next stage until a known goal or end result is reached.(ISO 9000:2005)
- Looking at processes in term of proactive thinking in risk management

## The process approach emphasize the importance of:

- Understanding and meeting the requirements of QMS
- Looking at processes in term of proactive thinking in risk management
- Looking at processes in terms of business added value
- Obtaining results of process performance
- Continual improvement of process

# Management System standards and the process approach



## ISO 9001-2008:

- Based upon the PDCA cycle which can be applied to processes
- Applies the PDCA cycle to implementing, operating, monitoring, exercising, maintaining and improving the effectiveness of QMS

## ISO 19011-2002:

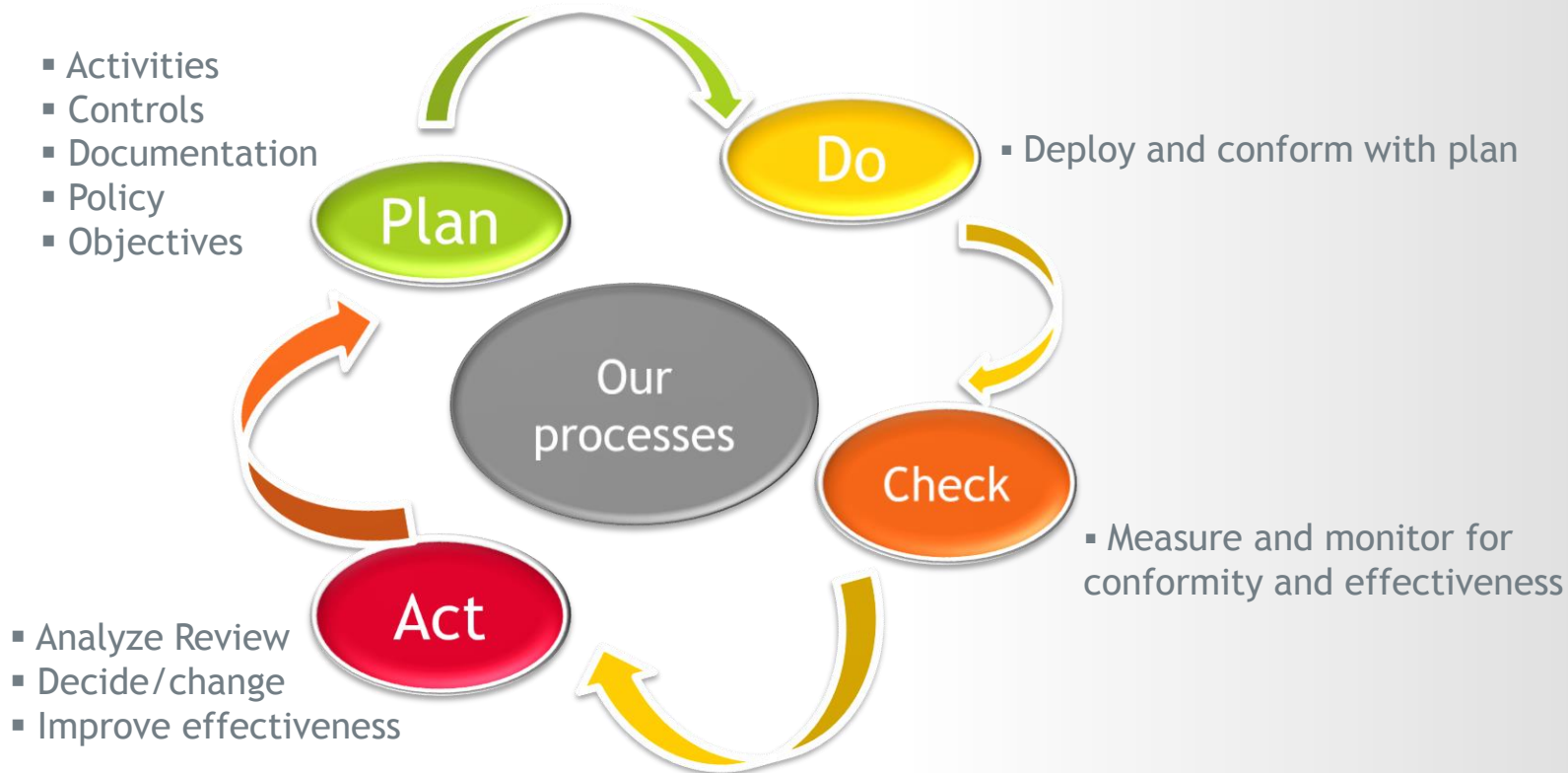
- Does not explicitly mention process audits, but is written for application to all management system audits.

*Note: Same approach is used for TL 9000 which is ISO 9001 plus TL adder requirements*



# PDCA (Plan-Do-Check-Act)

The PDCA methodology has to be applied to all the processes



# Applying the process approach to auditing



Auditors can apply the process approach to auditing by ensuring the auditee:

- Can define the objectives, inputs, outputs, activities and resources for its processes
- Analyze, monitors, measures and improves its processes
- Understands the sequence and interaction of its processes

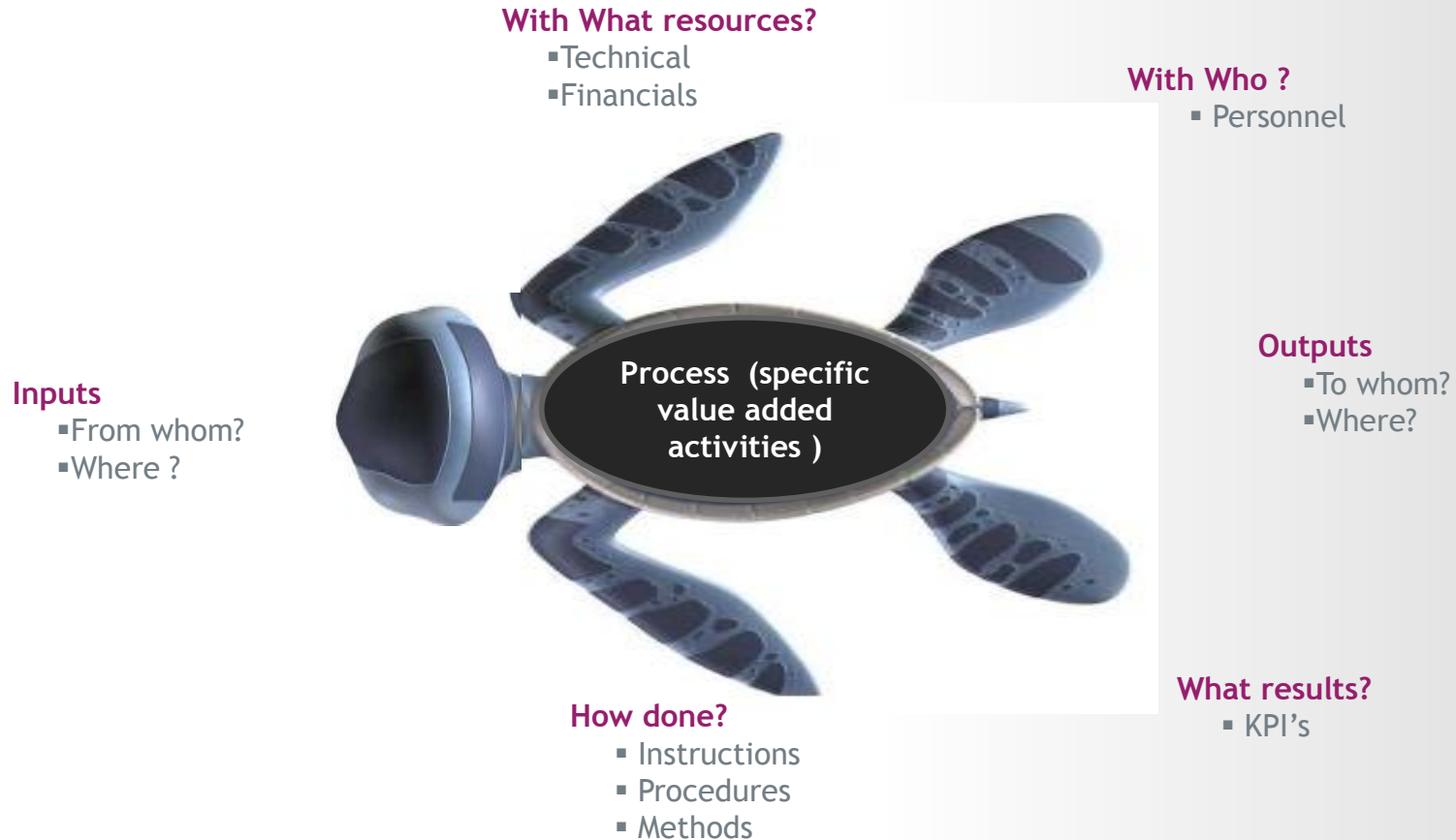
## Individual Process

- Input/output/ Value added activities
- Plan- Do-Check-Act
- Resources

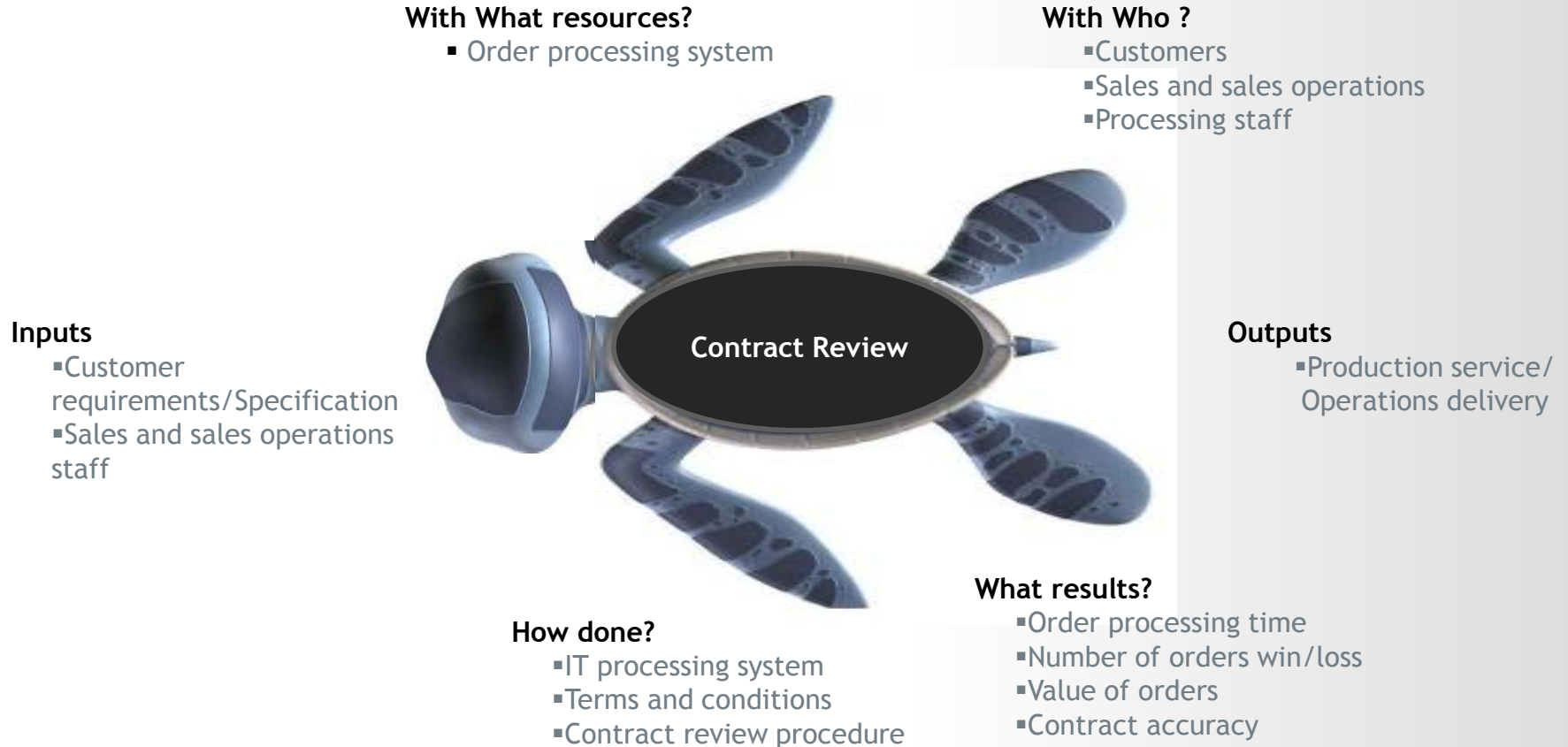
## Relationship with other processes

- Flow/sequence/ linkage/combination
- Interaction/ communication
- Evidence
- Customer requirements and supplier inputs

# Process auditing - turtle diagram



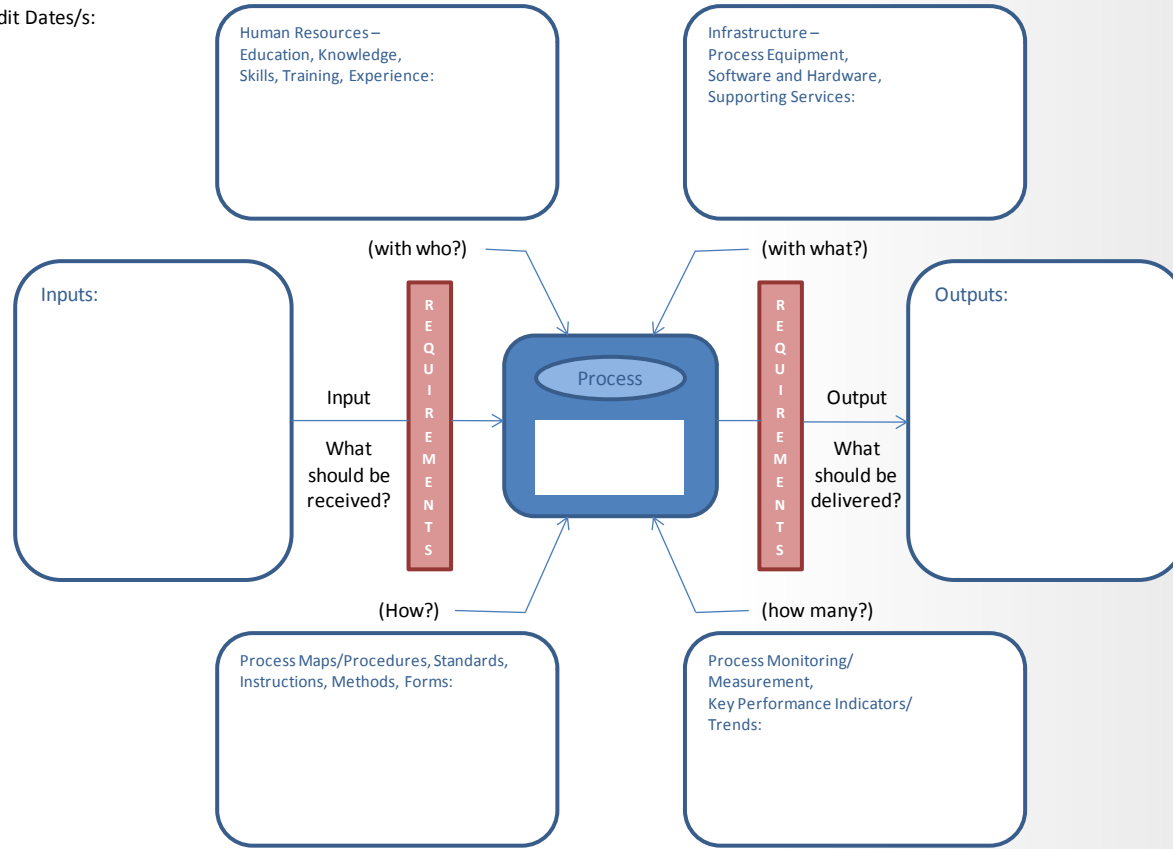
# Process auditing - turtle diagram example



# Process auditing - turtle diagram

Date:  
Audit Location/s:  
Audit #:  
Audit Dates/s:

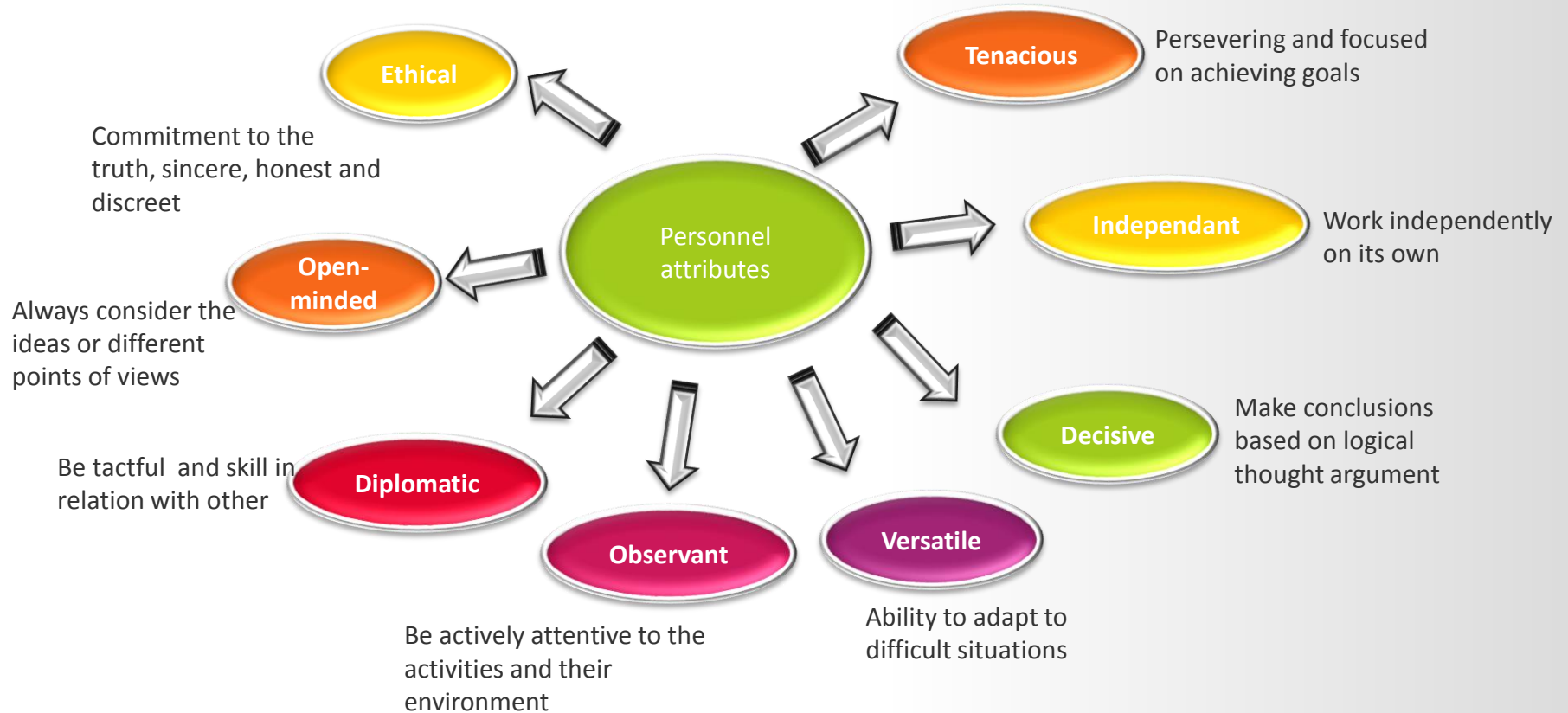
## Process Based Audit Approach




# Audit Responsibilities

Roles	Responsibilities
Lead Auditor	<ul style="list-style-type: none"><li>• Developing and gaining audit authority approval of the audit schedule</li><li>• Planning the detail of the forthcoming audit</li><li>• Planning and preparing the audit team safety needs</li><li>• Conducting the audit</li><li>• Acting as the audit team leader</li><li>• Resolving conflicts</li><li>• Formally report the audit result</li><li>• Following up on actions taken</li></ul>
Auditor	<ul style="list-style-type: none"><li>• Comply with applicable audit requirements</li><li>• Communicating and clarifying audit requirements</li><li>• Planning and carrying out audit</li><li>• Documenting audit observations and report audit result</li><li>• Verify effectiveness of corrective actions</li></ul>
Auditee	<ul style="list-style-type: none"><li>• Cooperating with the auditors</li><li>• Providing access to facilities and materials</li><li>• Providing resourcing needed by audit team</li><li>• Determining and initialing corrective actions</li></ul>

# Auditor Competencies

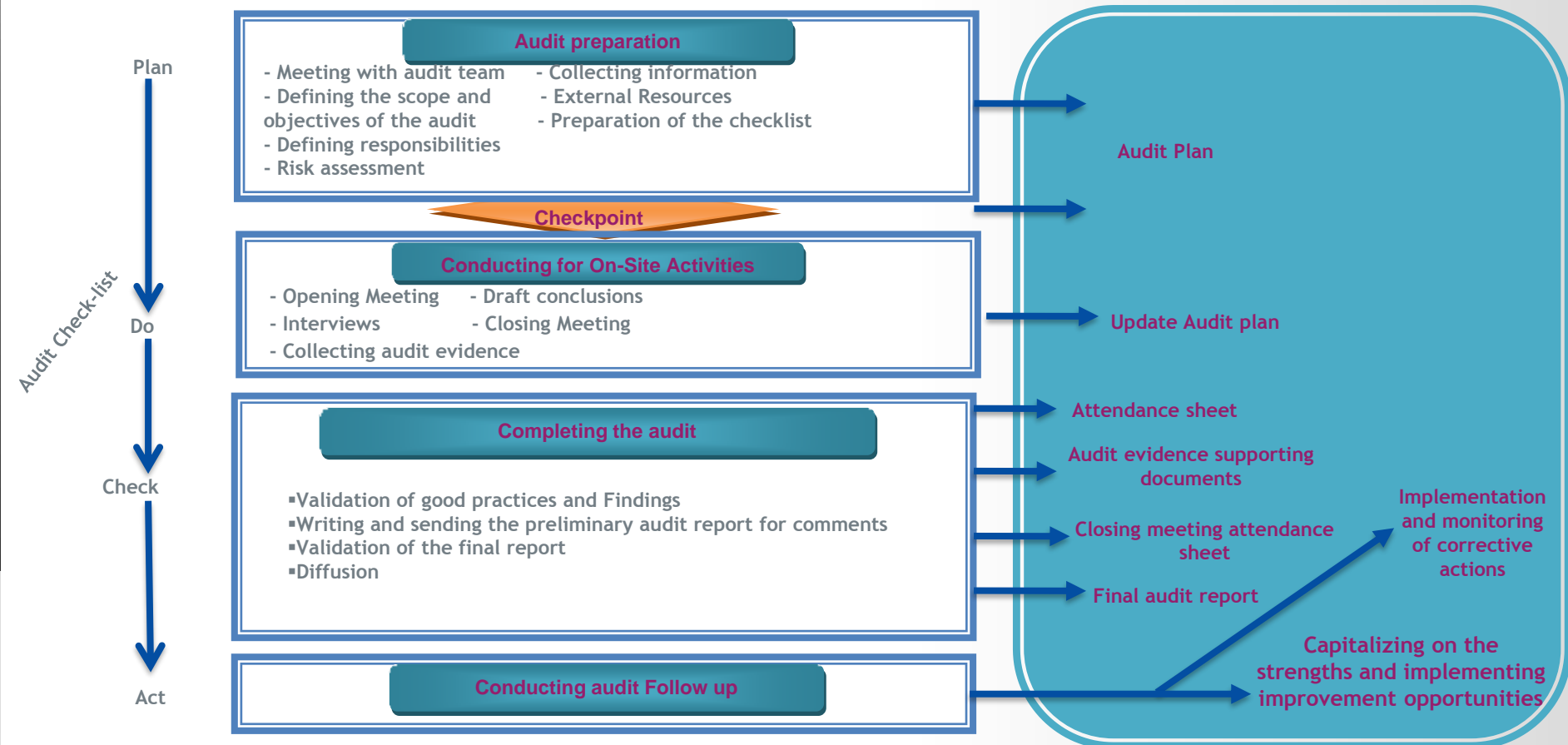


# Managing an Audit Program

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# Audit Process and PDCA



# Initiating the audit



## Initiating the audit includes

- Appointing the audit team leader
  - Reviewing list of auditors
  - Get to know the background of each auditor
  - Check their availability

6.2.1

## Initiating the audit includes

- Selecting the audit team: For team size and competence, consider
  - Audit objectives, scope, criteria and duration
  - Whether audit is combined or joint
  - Competence of team to meet objectives
  - Statutory, regulatory, contractual and accreditation
  - Independence

6.2.4

# Initiating the audit



## Initiating the audit includes

- Defining audit objectives, scope, criteria may include:
  - Determining of the extent of conformity of auditee's QMS with audit criteria
  - Evaluation of capacity of QMS to ensure compliance with statutory, regulatory and contractual requirements
  - Evaluation of effectiveness of the QMS to meet its objectives
  - Identification of areas of improvement



Examples	Reason for audit	Audit objectives
1	Customers have complained about response time too long	Investigate the causes why response time are too long
2	We want to verify if the supplier will provide satisfactory service	Verify that the system of quality management of the supplier meets the requirements of ISO 9001
3	Verify that the system of quality management of the supplier meets the requirements of ISO 9001	Ensure that legal, regulatory and contractual requirements are met

- Determining the feasibility of the audit
  - Check the availability of resources: human, technical, financial and logistical
  - Determine the duration: Based on the experience and feedback

# Initiating the audit - Internal audit schedule

AM2016\_schedule [Compatibility Mode] - Excel

FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW TEAM

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SECURITY WARNING Macros have been disabled. Enable Content

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Audit Ref #	SITE			SCOPE				highlight process(s) to be audited	Detail of audit scope	Lead Auditor	Other Auditor(s)	JAN	FEB	MAR	APR	MAY
	INDY	LAW	MONT	SW	HW	M&R	other									
AMSW16-01	X	X		X				Customer Care	Management Process	capturing of customer requirements, testing and verification, validation and acceptance by customer, bug tracking and resolution.	Craig Downey	Ron Denney				X
								Customer Program Management	Measurement & Improvement Process							
								Environmental	Operations							
								ETM	Quality							
								Generic & Platform Management	Sales							
								Human Resources	Sourcing							
Information Technology	Supplier Selection & Evaluation Process															

AM2015 schedule Codes Audits by Clause

ENTER 60%

# Preparation for the audit

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## Audit Planning What needs to be done

- Determine the objective of the audit
- Identify specified requirements
- Determine audit duration
- Contact the auditee – agree on the dates
- Define the audit plan
- Review with audit team
- Prepare work document



## Conducting Document review



- Should be conducted prior to on-site audit activities unless deferring the review is not detrimental to the effectiveness of the audit
- May include relevant QMS documents, records and previous audits reports for the scope audited

## Purpose of document review

- Allow the auditor to become familiar with the processes and system requirements management
- Avoid difficulties during the audit

# Preparation for the audit

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## Prepare work documents

- Use as a reference and for recording audit proceedings
- Include checklists based on applicable standard, sampling, plans and forms
- Keep checklist flexible to allow changes resulting from information collected during document review
- Safeguard any confidential and proprietary information
- Retain work documents as reference until corrective actions are closed.

# Preparation for the audit



## Checklists preparation: One approach is to :

- Identify audit scope and process(es) within the scope
- Identify applicable factors ( Inputs, outputs, KPI's, resources and Activities...)
- Use these points and other requirements ( ISO 9001: 2008, TL 9000 R5, system documentation etc...) to
  - Plan what to look at
  - Plan what to look for ( audit evidence)

- Examples of checklist structure

Process/Activities Audited			
Requirement	Sources	Evidence	Notes
ISO 9001 Clauses # or other requirement	« What to look at »	« What to look for »	Relevant information gathered during the interview



# Audit checklist

TL9000 5.5 Audit Check List - Excel

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Clause	TL ADDER Rating	ISO Rating	Audit point (Notes in <i>italic</i> are for guidance)	Projects Sampled:	Notes
4			<b>Quality Management System</b>		
4.1		#N/A	<b>General Requirements</b>		
			The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with requirements of this International Standard.		
		Satisfied Mostly Satisfied Partially Satisfied Not Satisfied	a) determine the processes needed for the quality management system and their application throughout the organization b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes, e) monitor, measure where applicable, and analyse these processes, and f) implement actions necessary to achieve planned results and continual improvement of these processes.		
			These processes shall be managed by the organization in accordance with the requirements of this International Standard.		
			Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.		
			NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.		
			NOTE 2 An "outsourced process" is a process that the organization needs for its quality management system and which the organization chooses to have		

Summary 5.5 Req Questions TL 5.5 Rating\_Key Rating\_Analysis color coded clauses Sheet2

READY 100%

# Conducting On-site Audit

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# Conducting On-site Audit

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## What needs to be done:

- Conducting opening meeting (lead)
- Communicate during the audit
- Explain roles and responsibilities of participants
- Conducting the Interviews
- Collect and verify information
- Generate audit findings
- Prepare audit conclusions (lead)
- Conduct closing meeting (lead)

# Conducting On-site Audit



## Opening meeting : People attending this meeting

- The Lead Auditor or his delegate
- The auditors responsible for the audit
- Management of entity (ies) audited (s)
- may include the entire staff or entity (ies) audited (s) or process owners

## Opening meeting Content

- Brief introduction of the Audit team and the auditees
- Objectives of the audit
- Context = why of the mission (performance of audit program, specific reasons...)
- Scope of the audit: entity(s) or process(es) concerned
- How the audit will be conducted
- Presentation and explanation of the methodology.
- Audit Report issue date
- Action plan and audit follow up as applicable

# Conducting On-site Audit

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## Goods Practices for Opening Meeting

- Prepare properly
- Ensure meeting is held in a suitable place
- Have a agenda
- Use time carefully ( 30mins)
- Explain exactly what is to happen
- Create a positive impression

# Conducting On-site Audit

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## Interview process

- Identify individual to be audited
- Introduce yourself
- Explain why you are there
- Ask Open questions
- Ask detailed questions
- Do 'show me please'
- Check facts and make notes
- Thank auditee

# Conducting On-site Audit

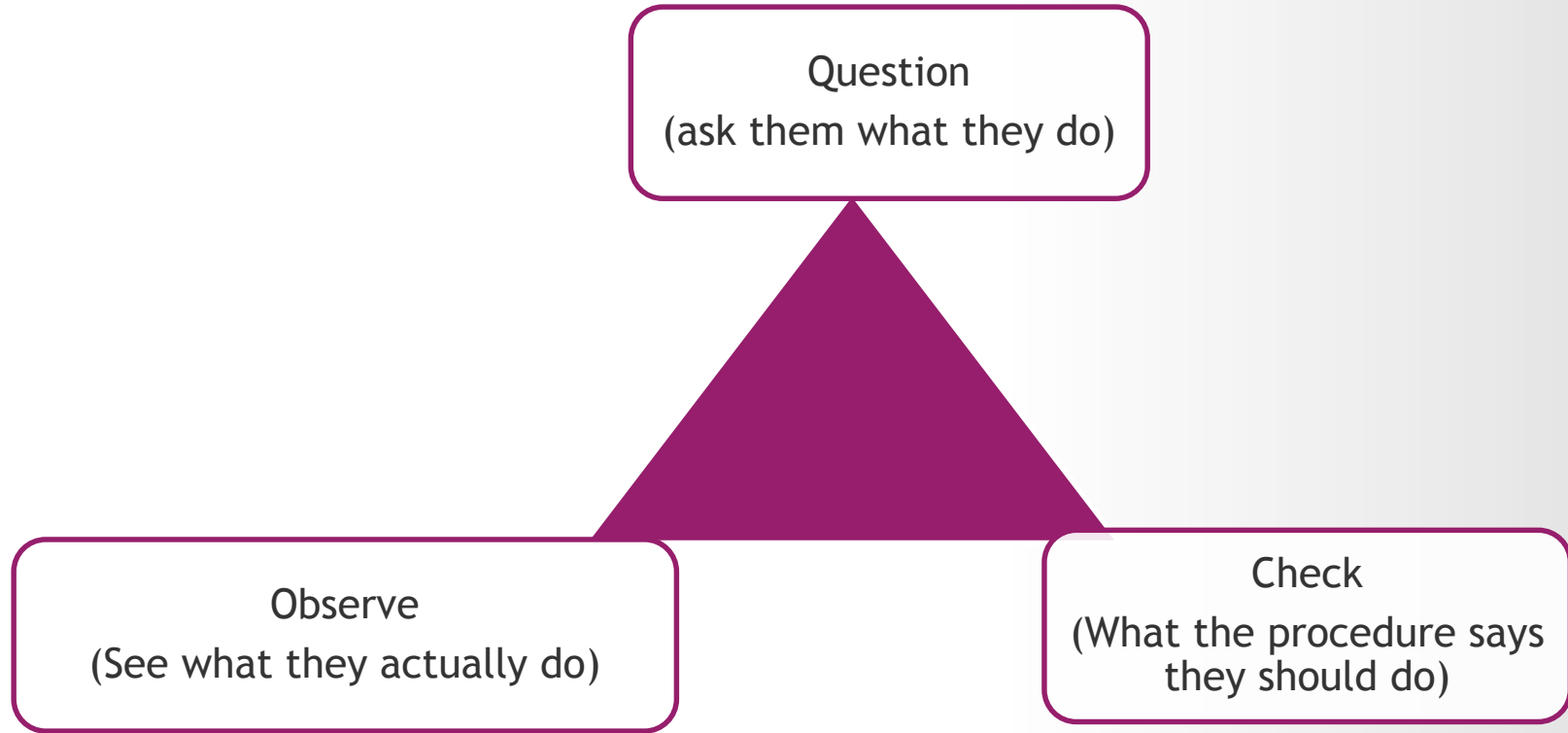
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## Suggest Checkpoint in Audit

- The purpose, input, output, controls and resources applicable to each process are clear
- Links are established between process and high level and local objective
- The output of the process are compared with desired outcomes, the purpose of the process
- The steps in the process and associated responsibilities are determined,
- Inter-relating processes are identified
- Process measurement are identified
- Evidence of continual improvement is sought
- Needs of internal and external customer are clear

# Conducting On-site Audit





# Conducting On-site Audit

## Questioning techniques

### Closed questions

- Get yes or no answer
- Avoid using too often
- Get confirmation

### Open questions

Using Why, what, where, when, or how get more than a yes or no answer

### Opinion questions

Ask opinion about the current point

### Repetitive questions

Repeat back response in form of a question

### Hypothetical questions

Use what if, suppose that etc

### Non Verbal Questions

- Silence: to get more information
- Non-verbal: uses body language, for example raise eye-brow to elicit further information

# Conducting On-site Audit

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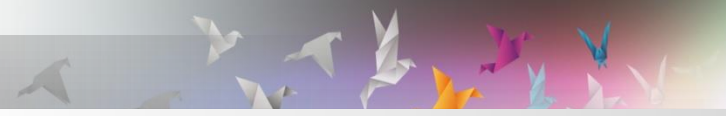


## Generate audits findings:

- Evaluate audit evidence against Audit criteria to generate audit findings
- Indicate if findings are conformities, non-conformities , areas of concerns or opportunities for improvement
- Meet with (audit team) to review the findings
- Specify (with supporting evidences) or summarize conformity by location, function or processes, as required by audit plan
- Record non-conformity findings and supporting evidence
- Obtain auditee acknowledgement of non-conformities for the accuracy and understandability
- Try and resolve differences of opinion
- keep a record of unresolved issues

# Conducting On-site Audit

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## Non conformity:

- Non fulfillment of a specified requirement:
  - Not doing it
  - Partially doing it
  - Doing it in the wrong way
- Specified requirement
  - Conditions of the customer contract
  - Quality standard ( ISO 9001: 2008)
  - Quality Management system
  - Statutory or regulatory requirements

# Conducting On-site Audit



## Non conformity: Critical Definition: Customer Risk is Immediate or Process not defined/applied

- Critical level means a problem which may lead to :
  - a customer safety issue
  - a production stop that affect deliveries
  - a high return rate (in general this means when the failure rate  $\geq$  to 5 % for one issue noticed )

## Non conformity: Major Definition: Customer risks identified

- Absence or a total breakdown of the system to meet the requirement,
- A full number of minors related to the same clause or requirement,
- non-conformity that experience and judgment indicate will likely result in QMS failure or significantly reduce its ability to assure controlled processes and products

## Non conformity: Minor

- Failure to comply with a requirement which based on (judgment and experience) is not likely the result in QMS failure
- Single observed lapse or isolated incident
- Minimal risk of non-conforming product or service

# Conducting On-site Audit

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## Preparing audit conclusions

- Audit team meets prior the closing meeting
  - Plan for the closing meeting
  - Review audit findings and other information
  - Agree on audit conclusions
  - Prepare the audit report and recommendations
  - If included in the audit plan, discuss audit follow-up

# Conducting On-site Audit

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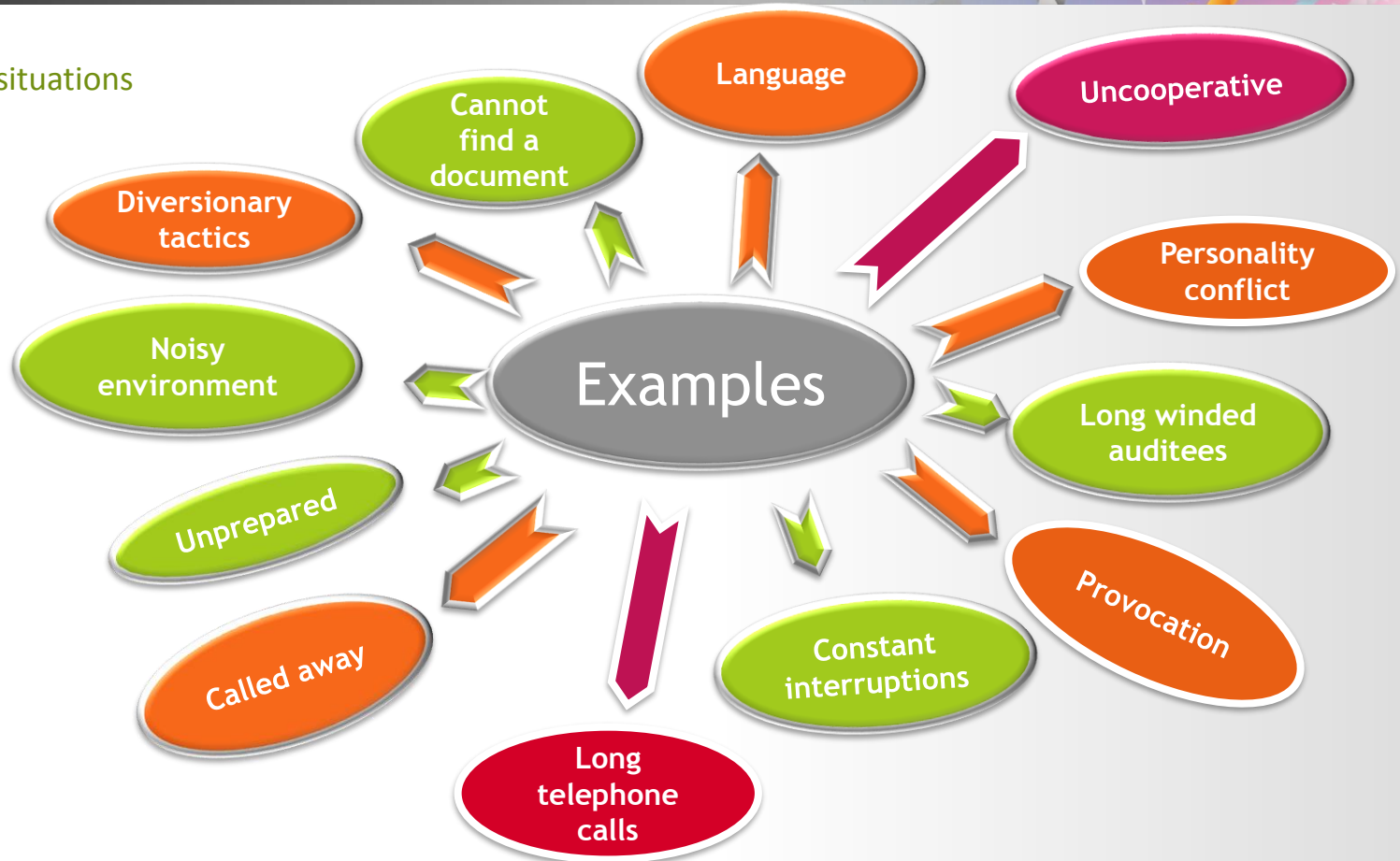
## Closing meeting

- Present audit findings and conclusions
- Cover situations encountered during the audit that may decrease reliance of the audit conclusions
- Discuss and resolve conflicting audit findings and conclusions
- Keep a record if not conflicts are not resolved
- Provided recommendations for improvement where specified by audit objectives
- Keep attendance records


Note: for internal audits, closing should be informal

# Conducting On-site Audit

## Handling difficult situations



# Completing the Audit

The background of the slide features a dark, almost black, field. Across the middle, there are several horizontal streaks of light. On the left, a bright purple and pink streak curves upwards towards the right. To its right, a yellow and green streak also curves upwards. Further right, a blue streak is visible. The overall effect is one of dynamic energy and modern technology.



# Completing the audit

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## Completing the audit

- Audit is complete when all activities in audit plan have been carried out and audit report is distributed
- Maintain or dispose the audit documents based on Contractual, regulatory and audit program procedures
- If required, maintain confidentiality of audits documents, information and report

# Completing the audit

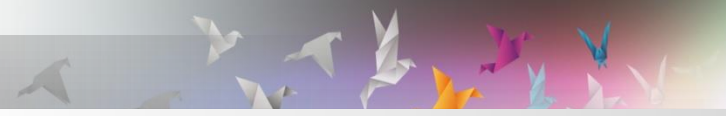


## Prepare, Approve & Distribute Audit Report

- Audit Report must include
  - Audit reference
  - Client and Auditee details
  - Audit team details
  - List of auditee representatives
  - Objectives, scope and criteria
  - Audit Plan- dates, places, areas audited and timing
  - Summary of audit process
  - audit summary of results including findings
  - Uncertainly due to sampling

# Completing the audit

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## Audit report distribution

- Audit Report has to be:
  - Issued within agreed time period
  - If delayed, provide reasons and agree on new issue date
  - Report must be dated, reviewed, and approved with team
  - Distributed to designated recipients
  - Report is a property of QMS
  - Recipients and audit team must respect the confidentiality of the report

# Completing the audit



## Conducting the follow up

- Audit conclusion may require corrective, preventive, or improvements actions
- Auditee decides and carries out these actions within agreed timeframe
- **These actions are not the part of the audit**
- Auditors/QMS should verify completion and effectiveness of actions taken
- Verification may be part of subsequent audit
- Maintain independence in subsequent audit activities

# After the audit: corrective actions

## Corrective actions follow up

### Step 1

- Auditee receives the corrective action request
- Auditee performs root cause analysis
- Auditee prepares and approves a corrective action plan

### Step 2

- Auditee submits the plan to QMS
- Auditors or QMS evaluate and approve the plan

### Step 3

- Auditee implements the corrective action plan
- Auditor or QMS verifies the implementation and effectiveness.

System  
Planning & Scheduling

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Internal Audit # 4420415-05technicalcolor

### Audit Interview Sheet

# Practice

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## Process audit

- Opening Meeting
- Perform the audit
- Closing Meeting
- Corrective action follow up


# Final report

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## 以小组形式练习- Process audit

- Auditor小组提供给Auditee小组Check list
  - Auditor小组提前review Auditee 小组相关材料
  - 最后一次课现场评审process audit
- 
- 课后各小组完成process audit report 以及corrective actions report





Thank you  
Questions are welcome!

