

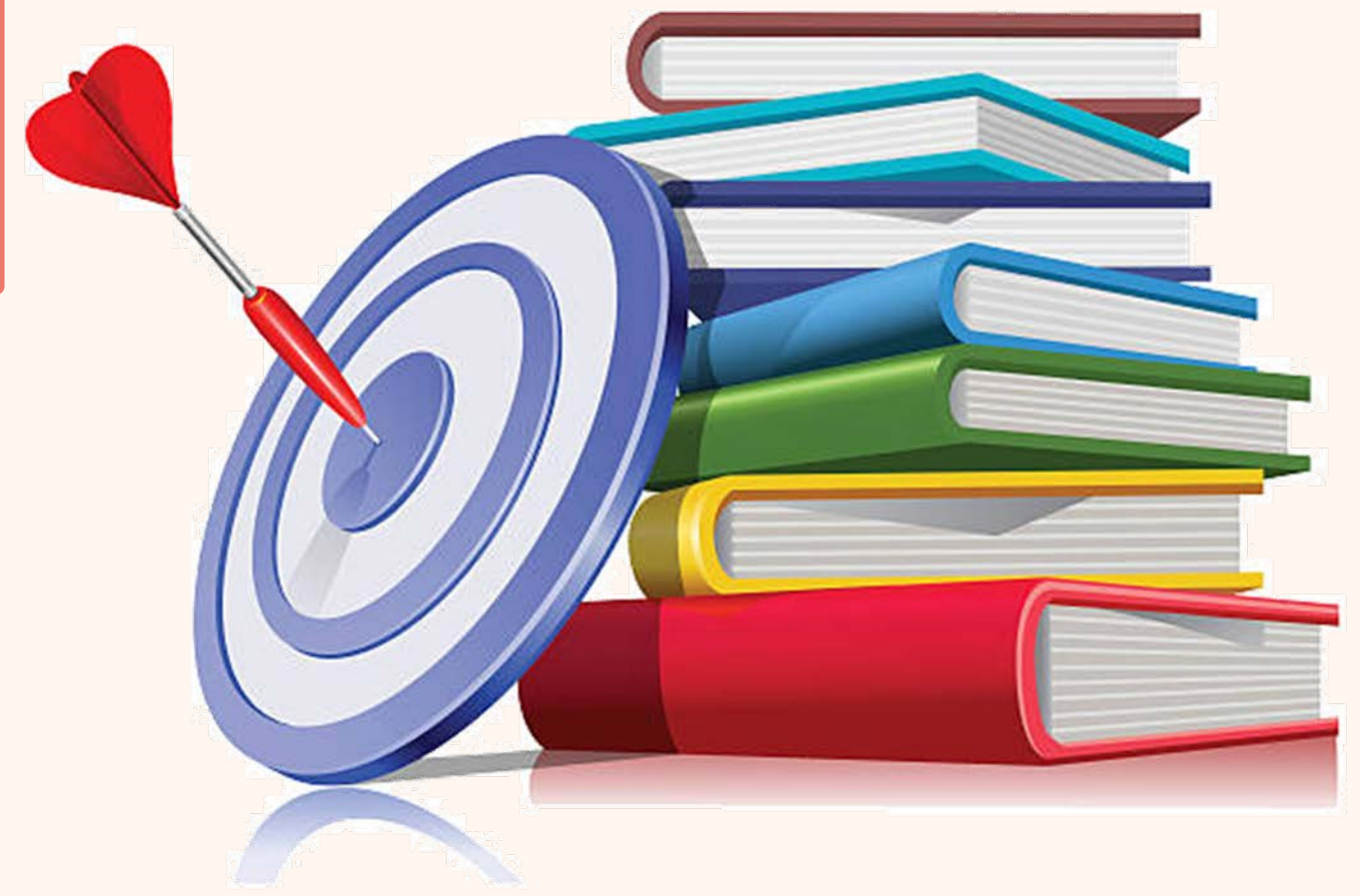


# **OVERVIEW OF QUALITY MANAGEMENT SYSTEMS (QMS), UNDERSTANDING QMS, Q&A SESSION**

24.09.2024

# OBJECTIVES

Understanding the need for (quality) management system and the principles of the ISO 9001 standard.



# WHY QUALITY MANAGEMENT SYSTEM?



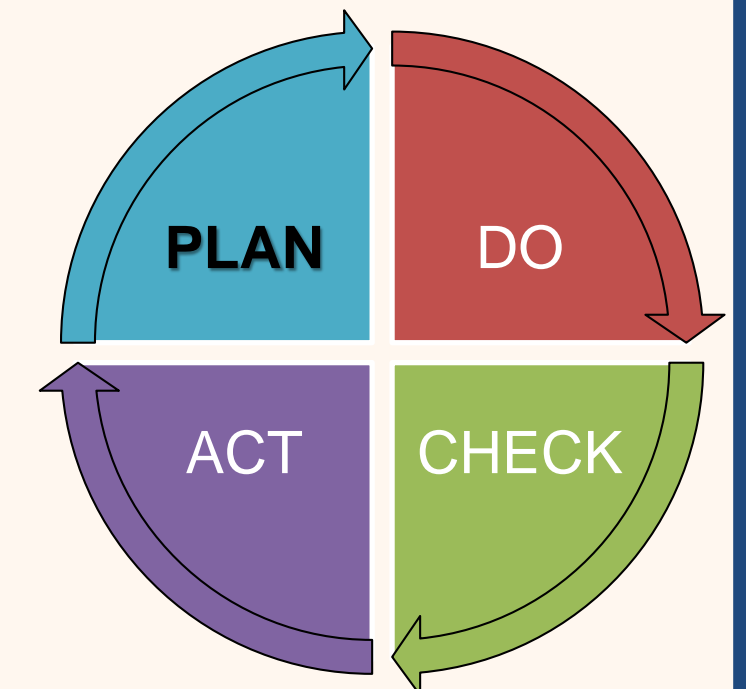
A Quality system does the following:

- Assesses the activity
- Reflects the activity in documented procedures
- Audits to ensure activities are completed in accordance with the procedures (and that the intent is being met)
- Improves the activity and procedures where required



# ISO 9001 – REQUIREMENTS

Clause 4: <b>CONTEXT OF THE ORGANIZATION</b>	Clause 5: <b>LEADERSHIP</b>	Clause 6: <b>PLANNING</b>	Clause 7: <b>SUPPORT</b>
<p>4.1 Understand the organization and its context</p> <p>4.2 Understanding the needs and expectations of interested parties</p> <p>4.3 Determining the scope of the OMS</p> <p>4.4 OMS and its processes</p>	<p>5.1 Leadership and commitment</p> <ul style="list-style-type: none"> <li>• Customer focus</li> </ul> <p>5.2 Policy</p> <p>5.3 Organizational roles, responsibilities and authorities</p>	<p>6.1 Actions to address risk and opportunities</p> <p>6.2 Quality objectives and planning to achieve them</p> <p>6.3 Planning of changes</p>	<p>7.1 Resources</p> <ul style="list-style-type: none"> <li>• People</li> <li>• Infrastructure</li> <li>• Environment for the operation of processes</li> <li>• Monitoring and measuring resources</li> <li>• Organizational knowledge</li> </ul> <p>7.2 Competence</p> <p>7.3 Awareness</p> <p>7.4 Communication</p> <p>7.5 Documented information</p> <ul style="list-style-type: none"> <li>• Creating and updating</li> <li>• Control of documented information</li> </ul>



# ISO 9001 – REQUIREMENTS

## Clause 8: **OPERATION**

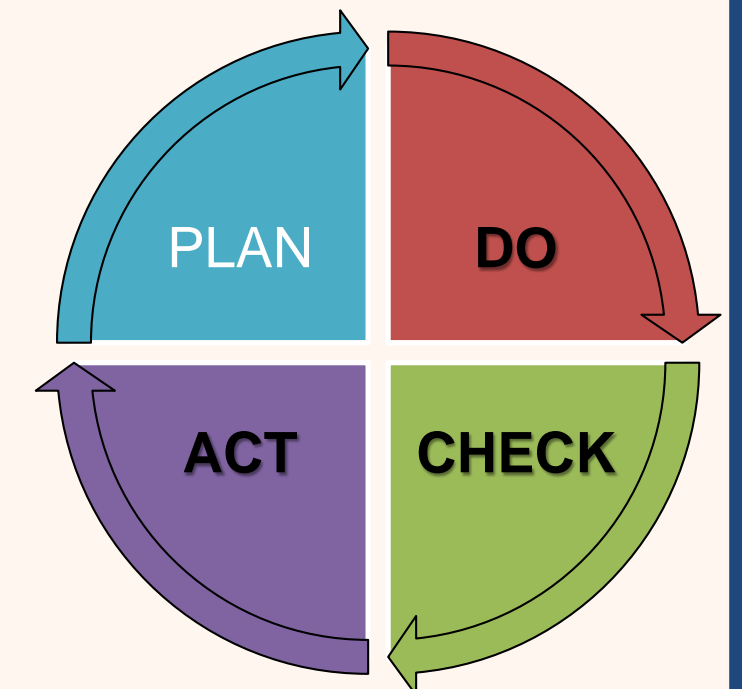
- 8.1 Operational planning and control
- 8.2 Requirements for products and services
  - Customer communication
  - Determining the requirements for products and services
  - Review of the requirements for products and services
  - Changes to requirements for products and services
- 8.3 Design and development of products and services
- 8.4 Control of externally provided processes, products and services
- 8.5 Production and service provision
- 8.6 Release of products and services
- 8.7 Control of nonconforming outputs

## Clause 9: **PERFORMANCE EVALUATION**

- 9.1 Monitoring, measurement, analysis and evaluation
  - Customer satisfaction
  - Analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review

## Clause 10: **IMPROVEMENT**

- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement



# PURPOSE OF QUALITY MANAGEMENT SYSTEM



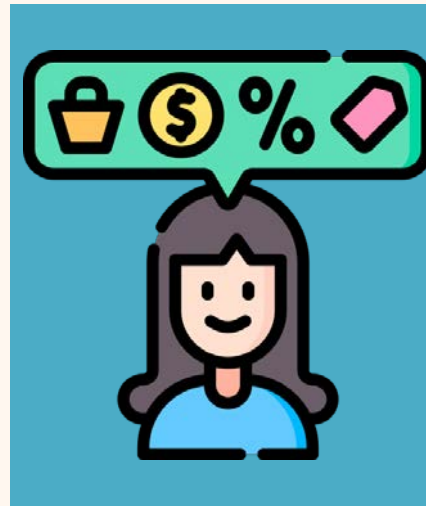
Predictable results



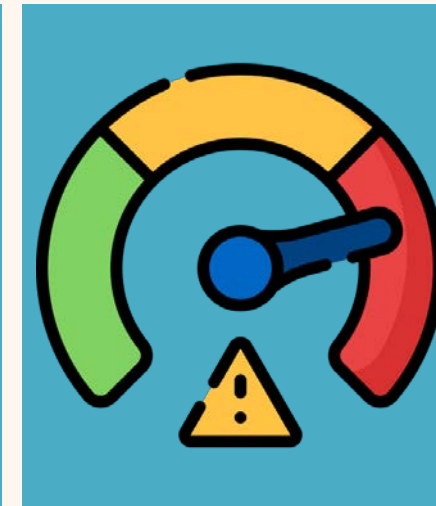
Systematic approach for performance improvement



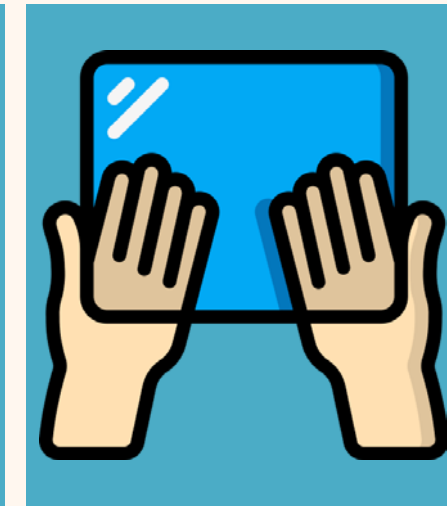
Evidence of the organization's capability



Customer expectations and needs to achieve organization's objectives



Risks are controlled



Create transparency

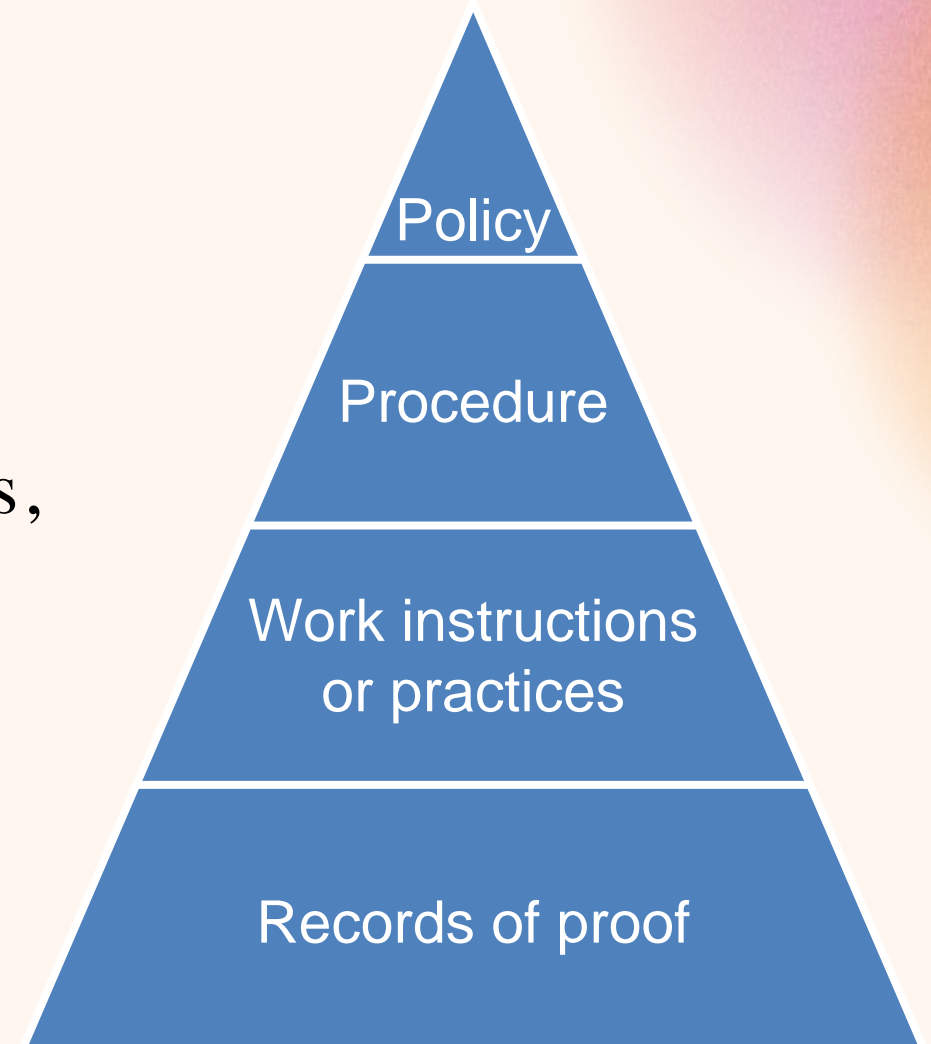
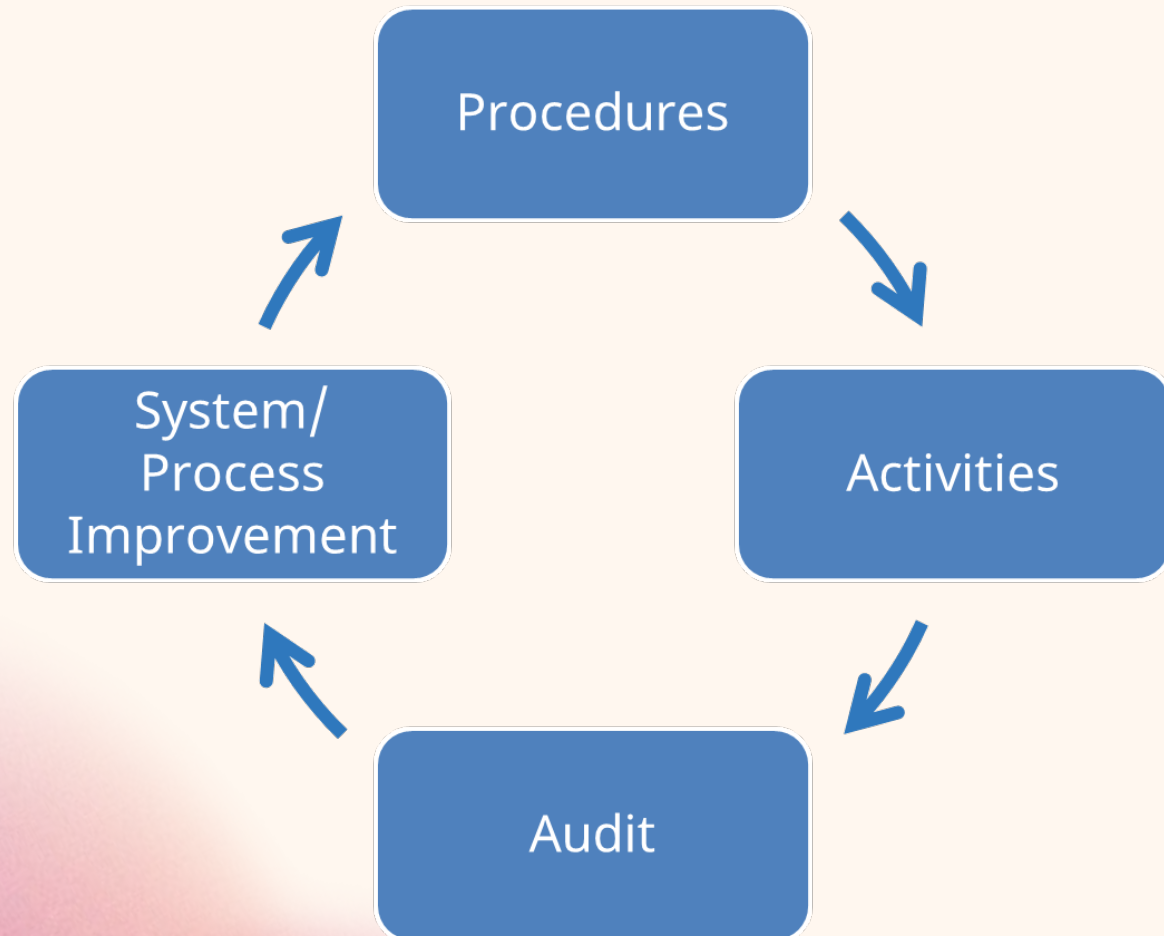
# PRINCIPLES OF QUALITY MANAGEMENT SYSTEM





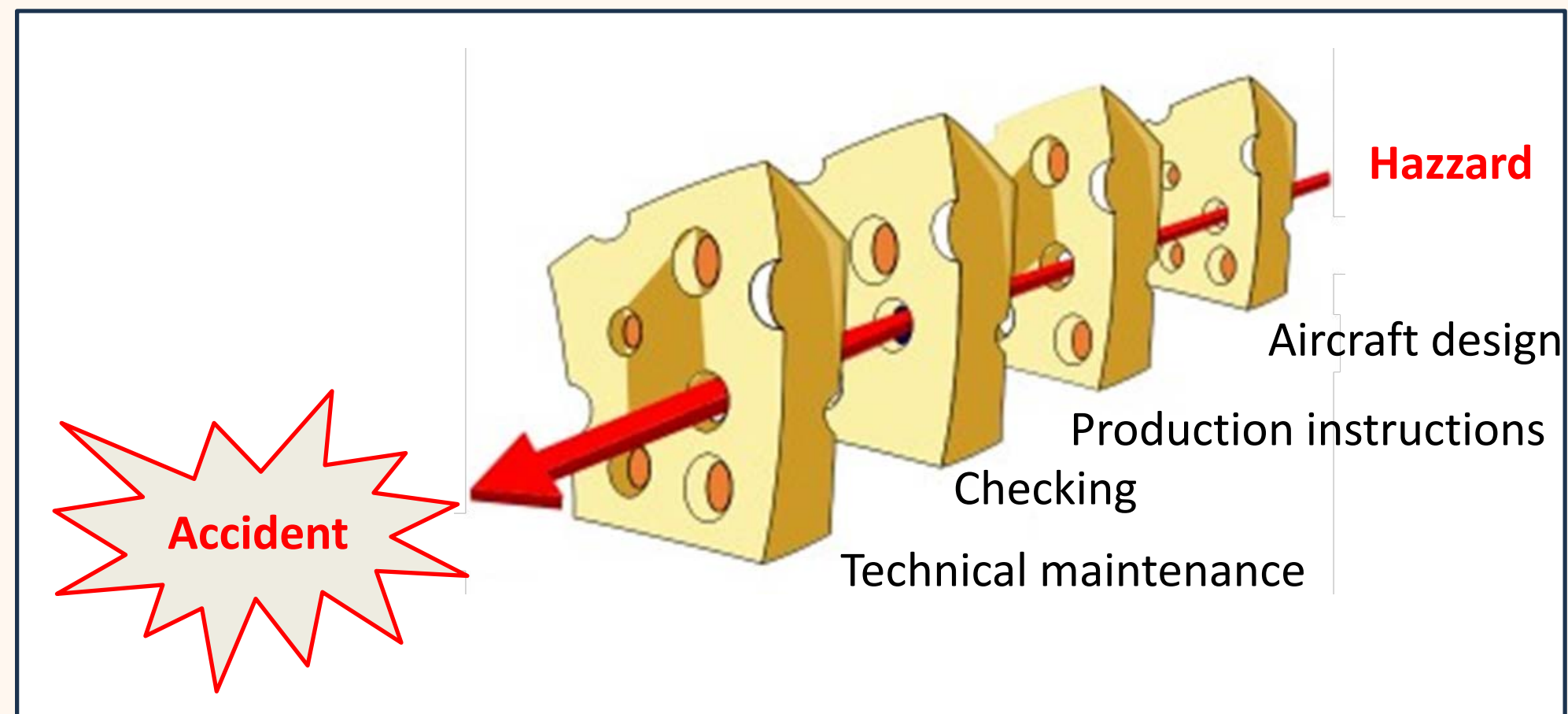
# SCOPE OF ISO 9001

- Identify the process
- Determine the process sequences
- Set methods for effective operation and control of process
- Ensure availability of resources and information for the process
- Monitor, measure and analyze the process
- Continually improve the process
- Document (quality policies, manuals, procedures)
- Set controls for documents and maintain records of conformance



# EFFECTIVE CONTROL

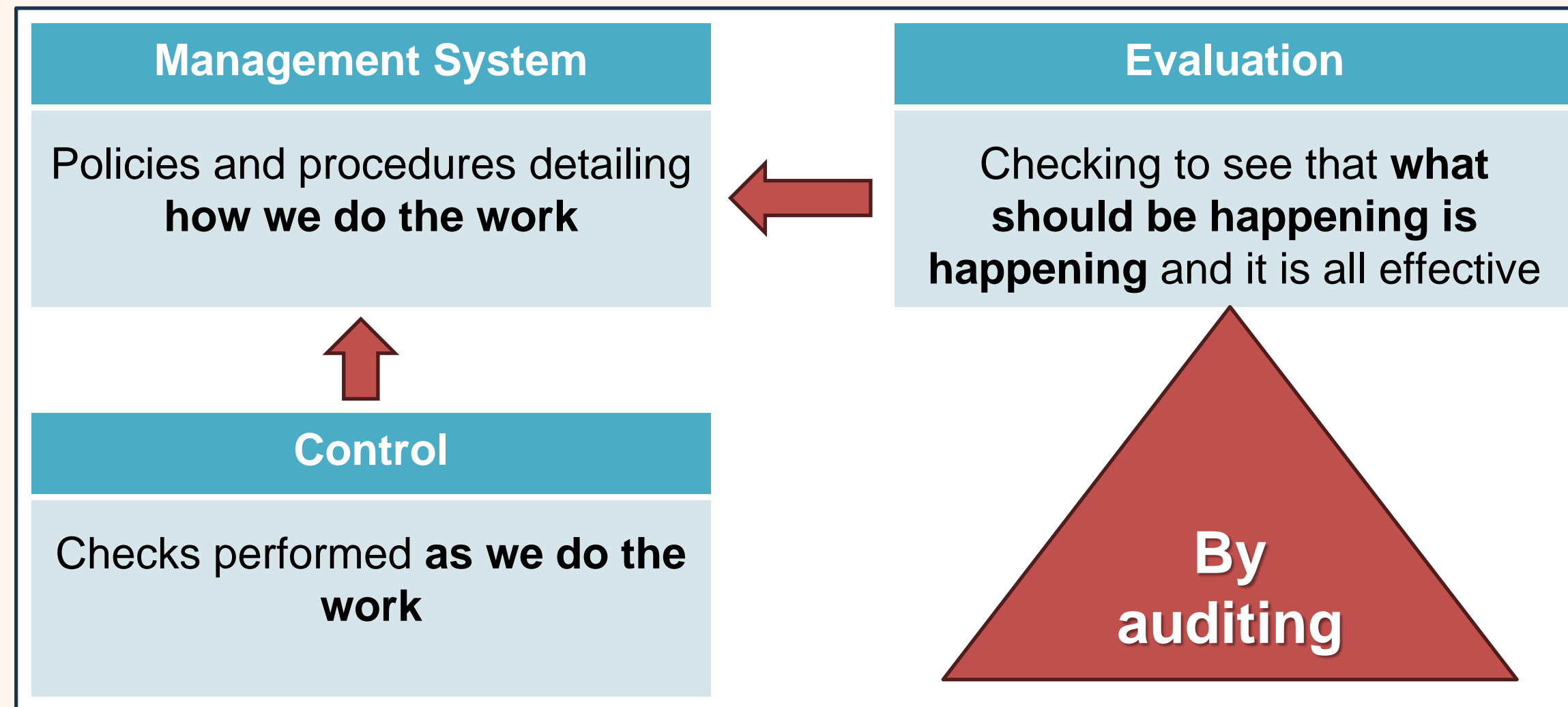
The aviation system is made up of complex combined protection (barriers), the attention paid to each of them reduces the probability of accidents.



Effective implementation of control mechanisms (including monitoring activities) helps to reduce the risk of adverse events.

# QUALITY ASSURANCE

Quality Assurance is a systematic method used to ensure that a product or service meets specified requirements and standards.

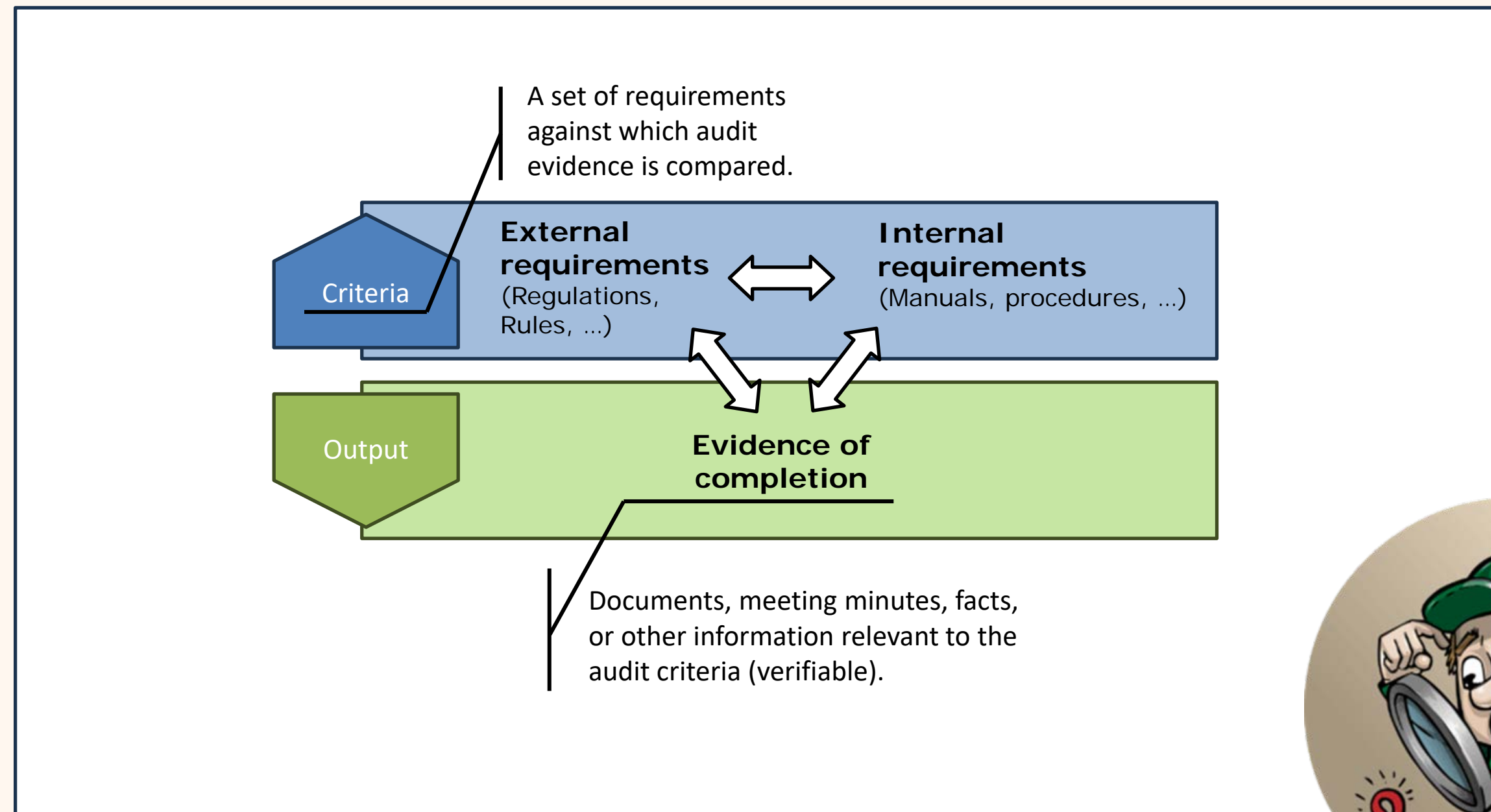


**Management System** - Policies and procedures detailing how we do the work

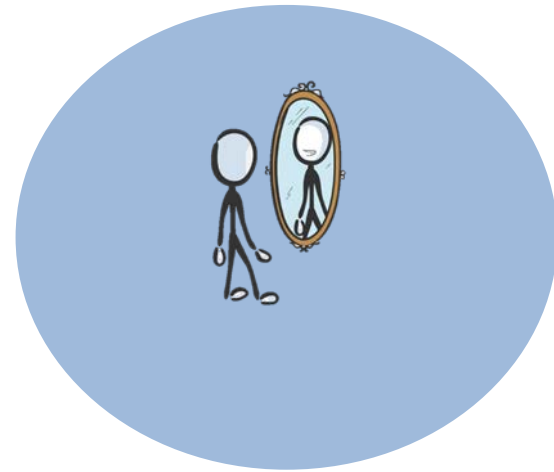
**Control** - Checks performed as we do the work

**Evaluation** - Checking to see that what should be happening is happening and it is all effective

# AUDIT

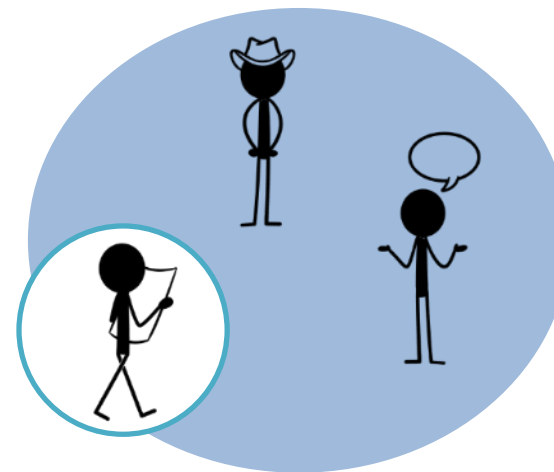


# TYPES OF AUDIT



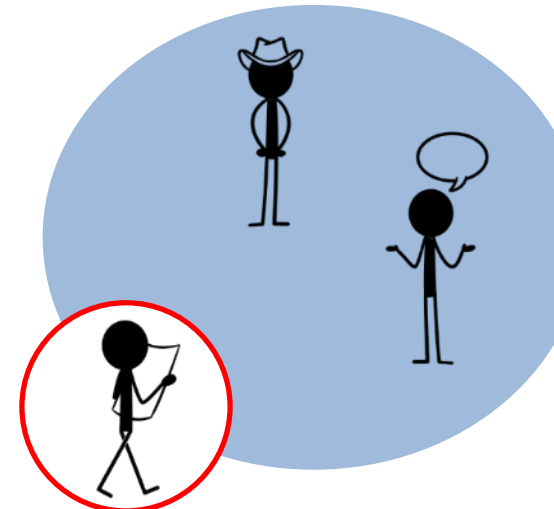
**1st party (internal) audit**

It is carried out **by the organization itself** for internal needs (review, improvement)



**2nd party (external) audit**

Performed by **parties who have an interest** in the organization, such as a client or others in its engagement.



**3rd party (external) audit**

Conducted by **external, independent** audit organization (certification organization or state authority)

# COMPETENCE OF AUDITORS

Understanding of the organization being audited and its context

Knowledge of requirements set out in standards, regulations, rules, etc.

Knowledge of auditing principles, processes and methods

Professional behavior



# INTERNAL AUDIT SCHEDULE

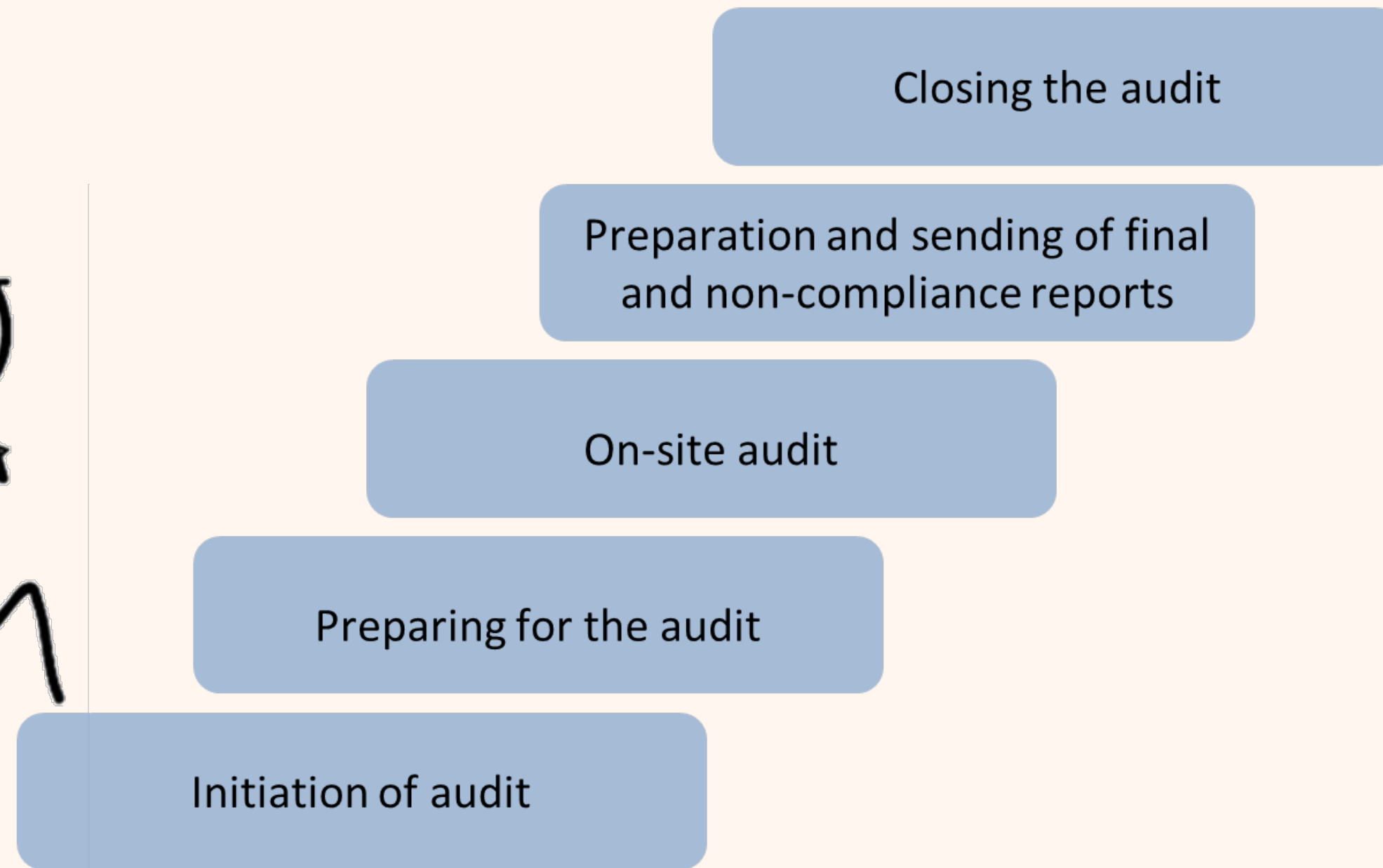
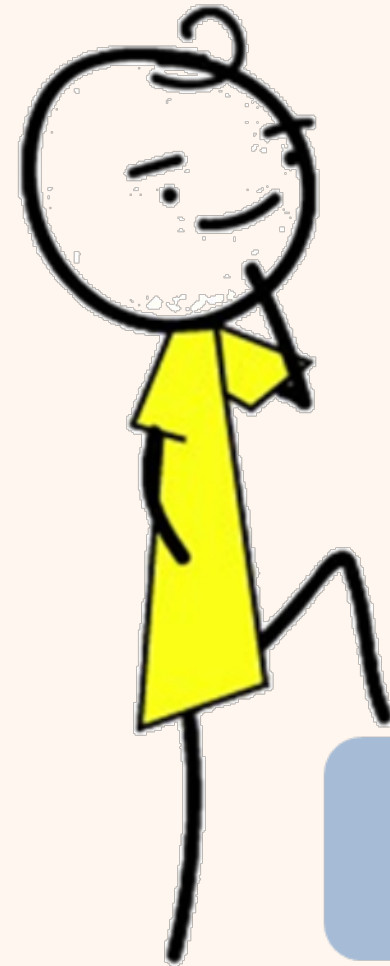
## Oversight schedule-

a set of one or more audits that are planned within a certain time frame and carried out to achieve a certain goal.

- ✓ The organization must establish and maintain a oversight schedule.
- ✓ It must be developed taking into account the specifics of the organization, the complexity of its activities and the results of previous certification and/or monitoring activities, and is based on an assessment of the associated risks.

Internal Audit Schedule Form	January	February	March	April	May	June	July	August	September	October	November	December
Process Name												
Bid Process & Review of Customer Requirements	X											
Design and Development	X						X					
Purchasing		X										
Receiving, PMI, Inventory (FIFO)		X										
Kitting			X									
Assembly			X						X			
Inspection and Testing				X								
Shipping				X								
Calibration					X							
Customer Satisfaction											X	
Control of Nonconforming Product				X						X		
Corrective Action								X				
Management Review										X		
Internal Audits								X				

# AUDIT PROCESS



# VERIFICATION OF PROCEDURES



One of the objectives of the audit is to check whether the procedures achieve the objectives:

- Attention is needed, a comprehensive approach;
- The focus should be on the purpose of the claim.

Therefore, when reviewing the procedures, the auditor should ask several questions:

- Will the goal be achieved?
- Is it clear, unambiguous and feasible?
- Is the format of the procedure and the language used appropriate/understandable?
- Is it a procedure (not just a general set of theses)?

Can you find answers to the questions in the procedure:

Who?

What?

When?

Where?

How?





# MANAGEMENT SYSTEM DOCUMENTATION (EXAMPLE)

