Internal audits

Fundamentals – conformance & effectiveness

Introductions

- Dylan Parsons
- Introduction
- Background

Agenda & session aims

- The fundamentals of internal audit
- Reporting conformance and performance
- An overview of what makes an effective audit
- Planning an audit – the process approach
- Conducting an audit
- Managing non-conformities

Auditing Experience

1. Heard about audits
2. Observed an audit
3. Have been audited
4. Trained as an auditor
5. Performed an audit
6. Led an audit team
7. Taught auditing to others
8. Audited a supplier
9. Audited for a certification body

Recap from session 1

6 steps of an audit lifecycle

Audit scheduling & planning

Audit objectives

Audit scope

Audit execution

Audit reporting

Audit follow up & closure

Audit scheduling and planning - **priority, importance, risk**
Audit objectives - **clarity of purpose**
Audit scope - **clear boundaries**
Audit execution - **methods, approach, technique etc**
Audit reporting - **summary, detail, findings and conclusions**
Audit follow up & closure - **RCCA, adequacy and effectiveness**

Audit

“A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled.”

Quality System Audits

- An integral part of ISO 9001 and AS91XX

"organization shall conduct internal audits at planned intervals to determine whether the quality system conforms to … and is effectively implemented and maintained."

Benefits of Auditing

- Verifies conformity to requirements
- Increases awareness and understanding
- Provides a quality measurement to management
- Reduces risk of product failure
- Identifies improvement opportunities
- Precipitates the corrective action cycle
- Precipitates the preventive action cycle

Dimensions of Auditing

Intent	Does Top Management intend to implement a QMS and how is this intent communicated?
Implementation	Does the implementation of the QMS reflect the intent of Top Management?
Effectiveness	Is the implementation effective (*i.e.*, does it meet the parameters established by the intent)

Audit Principles

Auditing relies on the following principles:

- Integrity: the foundation of professionalism
- Fair presentation: the obligation to report truthfully and accurately
- Due professional care: the application of diligence and judgement in auditing
- Confidentiality: security of information
- Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions
- Evidence-based approach:

Adhering to principles is a pre-requisite for:

- Providing audit conclusions that are relevant and sufficient
- Enabling auditors working independently to reach the similar conclusions in similar circumstances

Positive auditor behaviour

- Ethical
- Open minded
- Diplomatic
- Observant
- Perceptive
- Versatile
- Tenacious
- Decisive
- Self-reliant

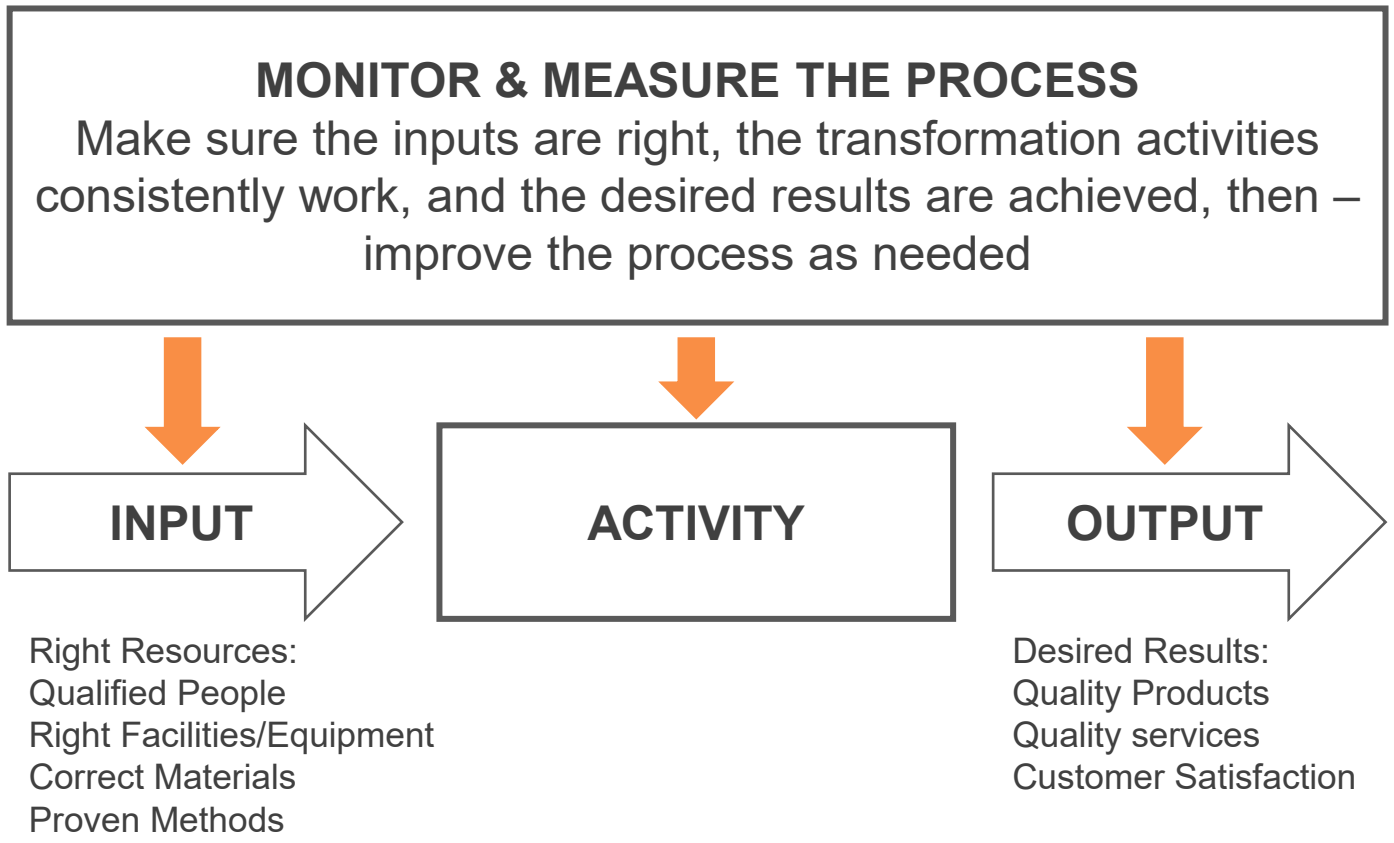
Planning the audit - Process auditing

Process Auditing

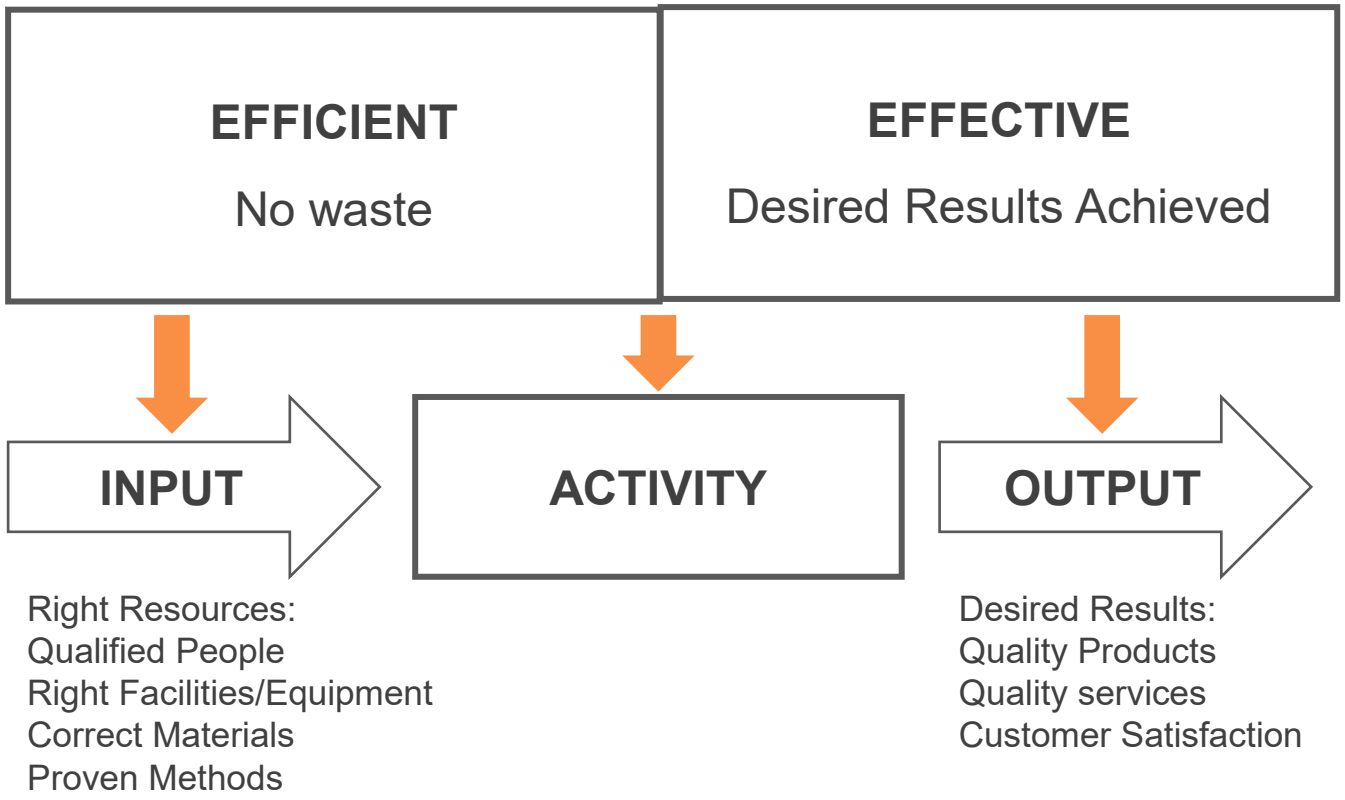
Process Auditing

- Individual process:
  - Input/output/value added activity
  - Plan → Do → Check → Act
  - Resources
- Relationship with other processes:
  - Flow/sequence/linkage combination
  - Interaction/communication
  - Audit trails
  - Customer contract

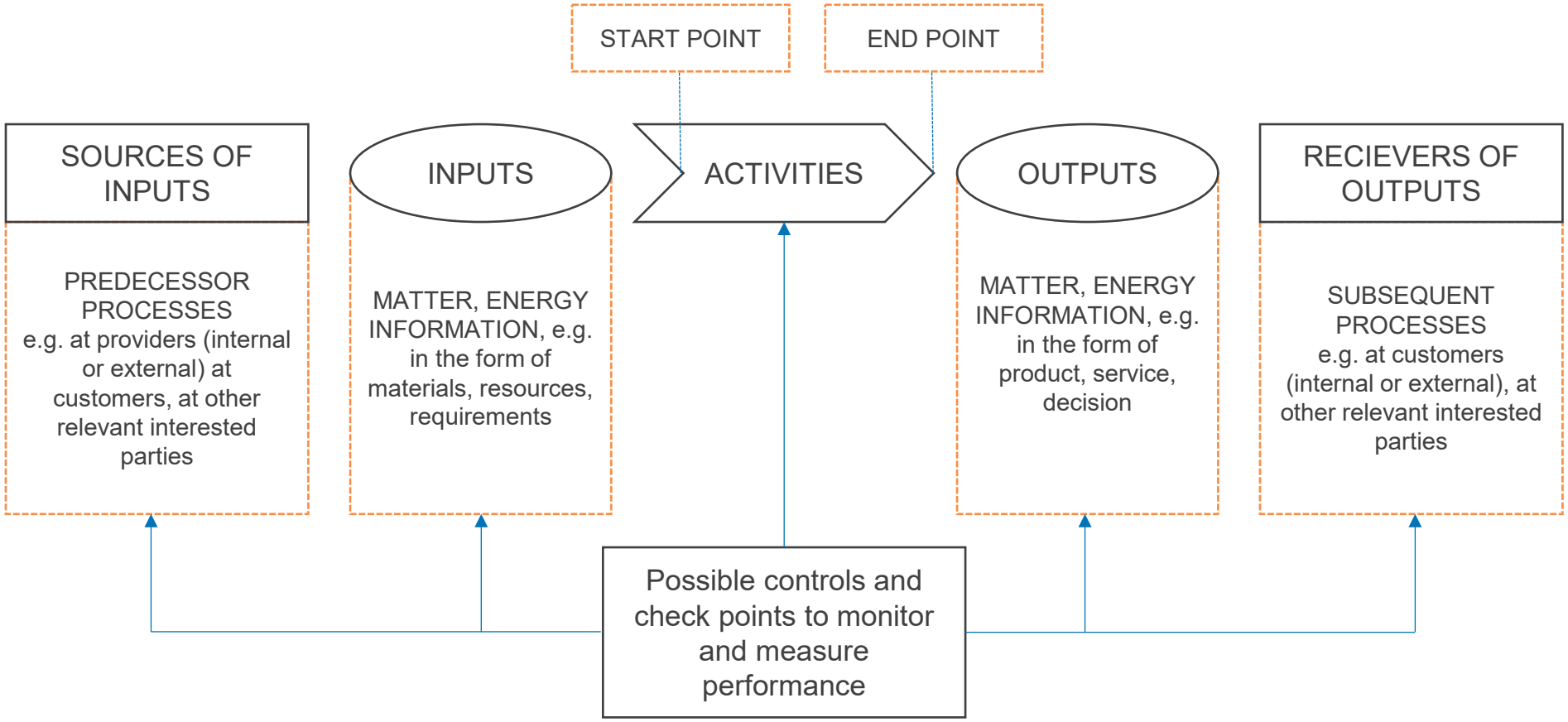
How is a process managed?



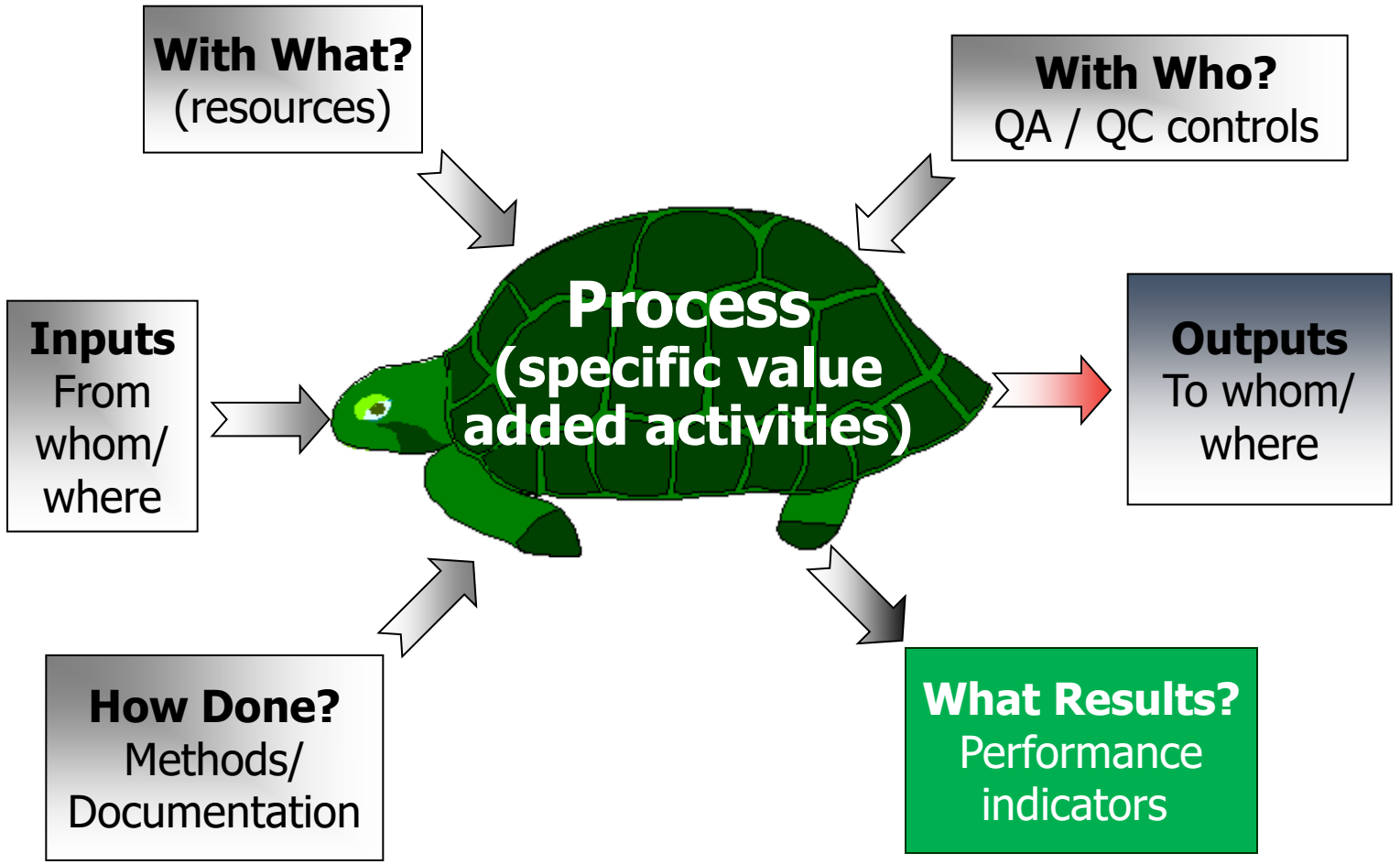
How is the process measured?



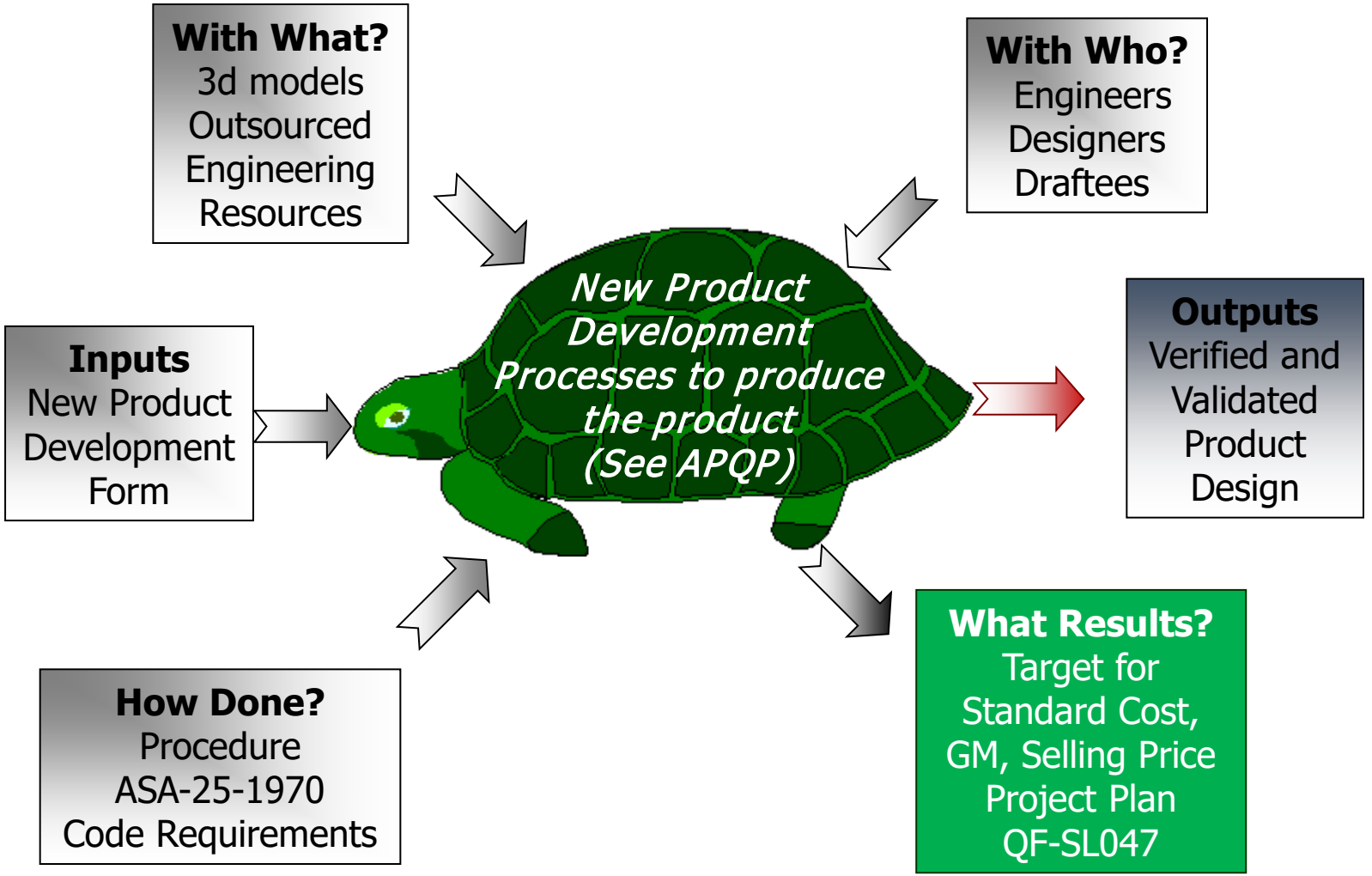
Interaction of process elements



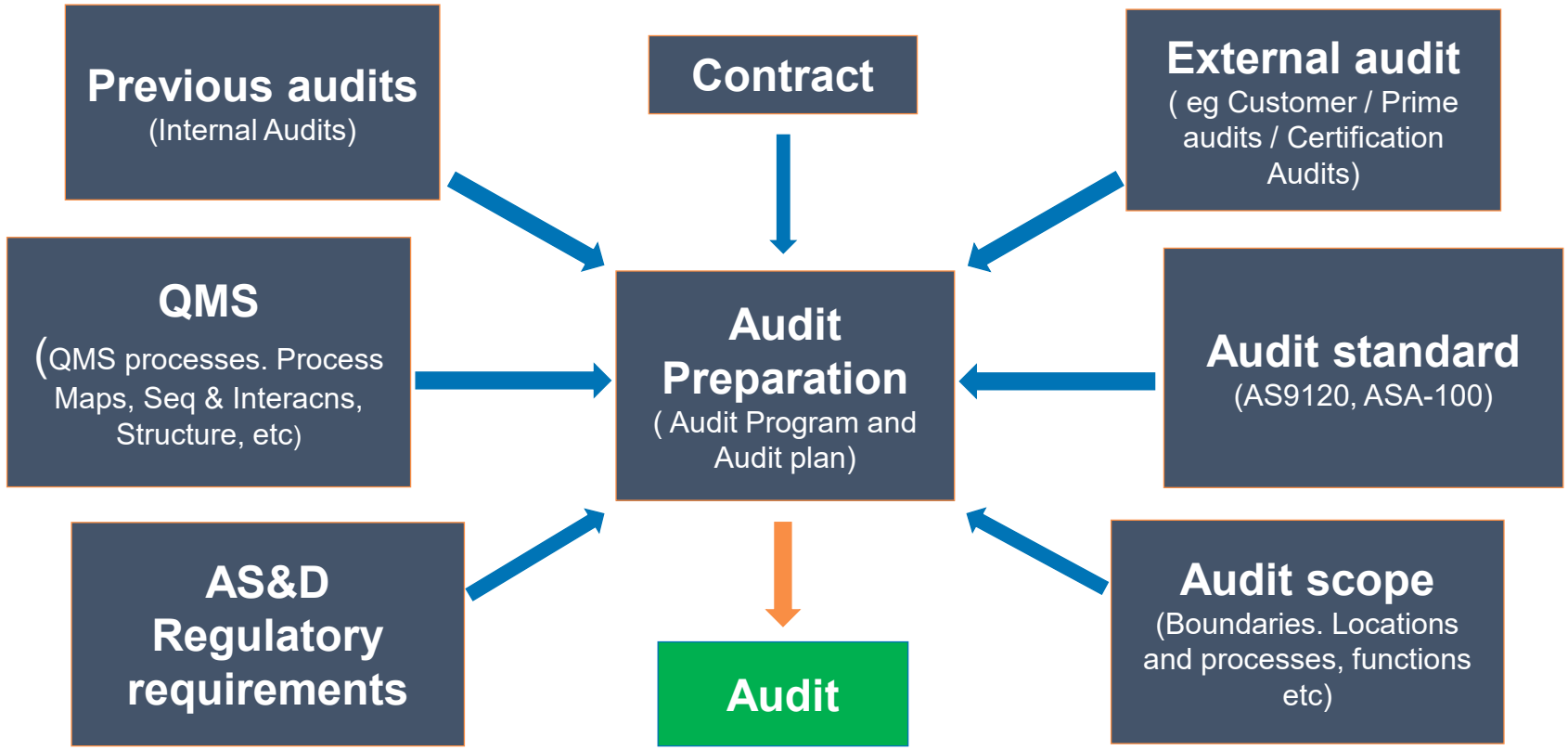
Process Auditing

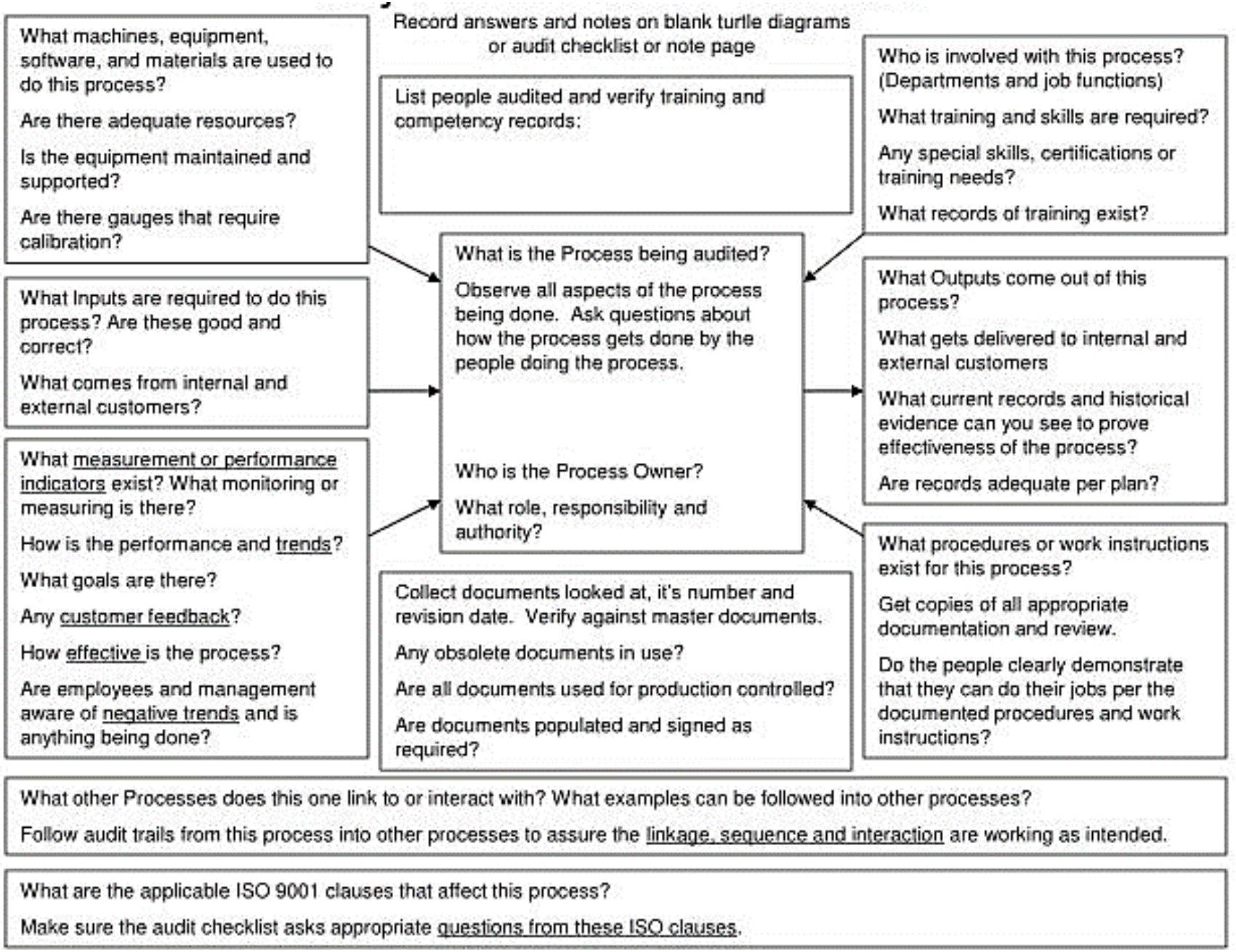


Process Auditing Example



Audit preparation – inputs




Record answers and notes on blank turtle diagrams or audit checklist or note page
What machines, equipment, software, and materials are used to do this process?
Are there adequate resources?
Is the equipment maintained and supported?
Are there gauges that require calibration?
List people audited and verify training and competency records:
Who is involved with this process? (Departments and job functions)
What training and skills are required?
Any special skills, certifications or training needs?
What records of training exist?
What is the Process being audited?
Observe all aspects of the process being done. Ask questions about how the process gets done by the people doing the process.
Who is the Process Owner?
What role, responsibility and authority?
What Inputs are required to do this process? Are these good and correct?
What comes from internal and external customers?
What Outputs come out of this process?
What gets delivered to internal and external customers
What current records and historical evidence can you see to prove effectiveness of the process?
Are records adequate per plan?
What measurement or performance indicators exist? What monitoring or measuring is there?
How is the performance and trends?
What goals are there?
Any customer feedback?
How effective is the process?
Are employees and management aware of negative trends and is anything being done?
Collect documents looked at, it's number and revision date. Verify against master documents.
Any obsolete documents in use?
Are all documents used for production controlled?
Are documents populated and signed as required?
What procedures or work instructions exist for this process?
Get copies of all appropriate documentation and review.
Do the people clearly demonstrate that they can do their jobs per the documented procedures and work instructions?
What other Processes does this one link to or interact with? What examples can be followed into other processes?
Follow audit trails from this process into other processes to assure the linkage, sequence and interaction are working as intended.
What are the applicable ISO 9001 clauses that affect this process?
Make sure the audit checklist asks appropriate questions from these ISO clauses.

Case study workshop

- Let’s take one of the following process areas and create an audit plan

- Sales
- Distribution
- Warehouse
- Material processing

- Take 20 mins to draft a plan based on the previous slide

Feedback…

Performing the audit

Opening Meeting

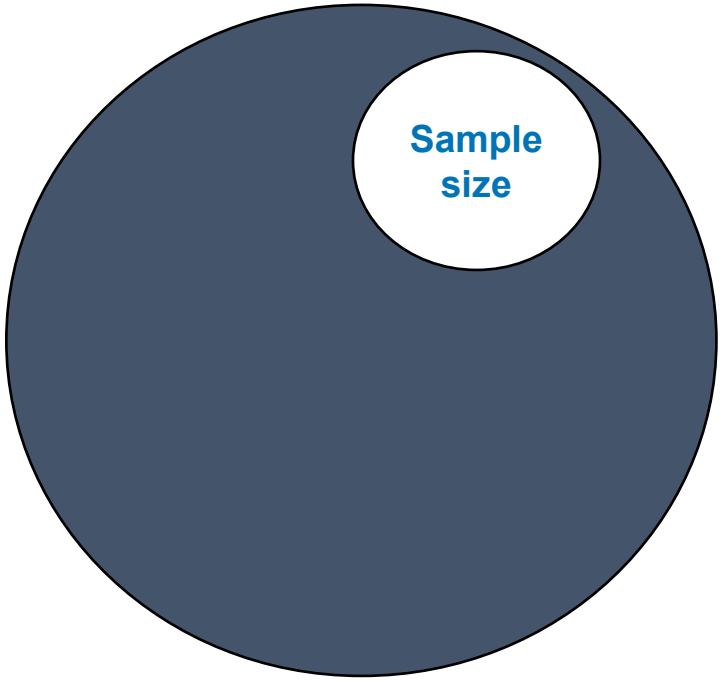
- Typically short and informal
- Introduction of participants
- Confirmation of the audit plan
- Short summary of audit activities
- Confirm communication channels
- Provide an opportunity for questions

Performing the Audit

- Auditing is also a process
- General sequence:
  - Establish the facts
  - Record the facts
  - Evaluate the facts
  - Classify the findings

How to sample – discussion

- What to sample?
- Risk factors to consider?
- How many samples to take?
- How far back in time?
- Who should take the sample?



Performing the Audit

Keep control of the audit:

- Do the audit planning
- Collect your thoughts
- Be polite and courteous
- Ask permission to seek, to speak with
- Use the checklist
- Remember the audit objectives

Performing the Audit

- Audit trails:
  - Links evidence to requirements/objectives
  - Observations within the scope
  - Related and relevant
- Possible options:
  - Follow-up accordingly
  - Advise team leader for follow-up
  - Note for follow-up at later audit

Performing the Audit

Objective Evidence – what is it?

- Traceable facts
- Based on observation or documentation
- Related to scope of the audit
- Uninfluenced by emotion or opinion
- Can be verified and is traceable

Performing the Audit

Interview personnel that manage, perform, and verify activities:

Observe:

Identity, status, condition, activities, processes, equipment, environment, people

Review:

Documents that describe activities, plans, specs, criteria, controls, inspections, and tests

Verify:

Quality records for evidence of conformity to documents

Communicating Effectively

Interviewing techniques

Types of questions:

- Open ended questions
- Closed ended questions
- Leading questions

Listening skills

Communicating Effectively

Open-ended questions:

- Cannot be answered “yes” or “no”
- Generate a discussion – How? Show me.
- Include various techniques of usage
- Begin with the 5-W’s:
  - Who
  - What
  - When
  - Where
  - Why

Communicating Effectively

Closed-end questions:

- Can be answered very briefly
- Avoid overuse
- Benefits:
  - Warming up the auditee
  - Getting to a specific point
  - Controlling “ramblers”

Communicating Effectively

Leading questions contain the answer:

- Do you check this two times?
- You are trained for this, aren't you?

AVOID leading questions

Communicating Effectively

Recognise human differences:

- Communication skill
- Personality
- Working relationships
- Background
- Ability
- Experience

Communicating Effectively

DON'T be:

- Arrogant
- Rude
- Impatient
- Condescending
- Argumentative
- Threatening

Communicating Effectively

Good practices:

- Ask the right person
- Ensure questions are understood
- Follow a logical order
- Give time to answer
- Listen to response
- Stay impartial
- Give praise when deserved
- Maintain mutual respect and trust

Communicating Effectively

Unhelpful practices:

- Asking too many questions at once
- Arguing/challenging
- Saying you understand, when you don’t
- Criticizing an approach
- Blaming the person
- Judging success of the audit by the nonconformity count

Positive auditor behaviour

Ethical	Open minded	Diplomatic	Observant
Perceptive	Versatile	Tenacious	Decisive
Self-reliant			

Communicating Effectively

- What if the auditor is wrong??
- If objective evidence should prove the auditor has made an error:
  - Admit it
  - Apologize
  - Learn from the mistake
  - Move on

Communicating Effectively

Attending behavior types:

- Body language
- Eye contact
- Vocal
- Verbal tracking
- Encouragement to talk
- Dealing with resistance

Collecting Information

- Collect information relevant to:
  - Audit objectives, scope, and criteria
  - Interfaces between functions, activities and processes
- Collect audit evidence by appropriate sampling and verify and record it
- Be aware of sampling limitations, if acting on the audit conclusion
- Use only information that is verifiable as audit evidence

Collecting Information

- Keep notes of observations (3Cs):
  - Clear
  - Complete
  - Concise
- Serve as record of sample taken
- Valuable in writing the audit report

Collecting Information

Some examples of good notes:

- The documented requirement
  - Procedure number or document title
- Admissible statements:
  - Person responsible for the work
- Details of the observation:
  - Part number, product lot, sample size, number of nonconforming product
- A written record/report

Verifying Information

- Auditor must make a judgment
- Evidence establishes the facts
- Conformance is established through objective evidence
- Compare the facts vs. the requirements that are stated

Audit Findings

- Audit findings may indicate conformity or nonconformity
- Verify each audit finding:
  - Is there sufficient evidence?
  - Is the requirement clear?
  - Is there a clear lack of required evidence?
  - Is the evidence objective in nature?
- If it cannot be verified, the finding must remain as an observation only

Audit Findings

- Communicate findings:
  - Inform the auditee at the time a concern is raised
  - Get auditee corroboration or
  - Listen to auditee challenge
- Never leave the audit area without alerting the auditee of any concerns to that point

Questions?

Non-conformity management

A poor nonconformity statement

"I feel the assembly supervisor is correct in stating that the QC inspectors have not been adequately trained, particularly because the final QC inspector on 2nd shift, who has only been on the job 6 weeks, has been reported asking production employees if they think that certain defects are rejectable, or not, and probably isn't following the procedure."

A better nonconformity statement

"The QC Department procedure for final testing of finished PC boards requires that all final test inspectors be trained in operation of the software validator. A 2nd shift tester had no training records for this operation."

A “good” nonconformity statement

“Training records could not be located for 2nd shift QC tester #58, who was performing software validation test #5 on series 910 PC boards. Procedure P-1465 part 2.2 requires documented training.”

Major NCR definition

A non-fulfillment of a requirement which is likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/services; it can be one or more of the following situations:

- A nonconformity where the effect is judged to be detrimental to the integrity of the product or service;
- The absence of or total breakdown of a system to meet a 9100-series standard requirement, an organization procedure, or customer quality management system requirement;
- Any nonconformity that would result in the probable shipment of nonconforming product; and/or
- A condition that could result in the failure or reduce the usability of the product or service and its intended purpose

Minor NCR definition

A non-fulfillment of a requirement which is not likely to result in the failure of the quality management system or reduce its ability to assure controlled processes or compliant products/ services; it can be either one of the following situations:

- A single system failure or lapse in conformance with a 9100-series standard or customer quality management system requirement; or
- A single system failure or lapse in conformance with a procedure associated to the organization's quality management system.

Non-conformity definition

‘Non-fulfilment of a requirement’

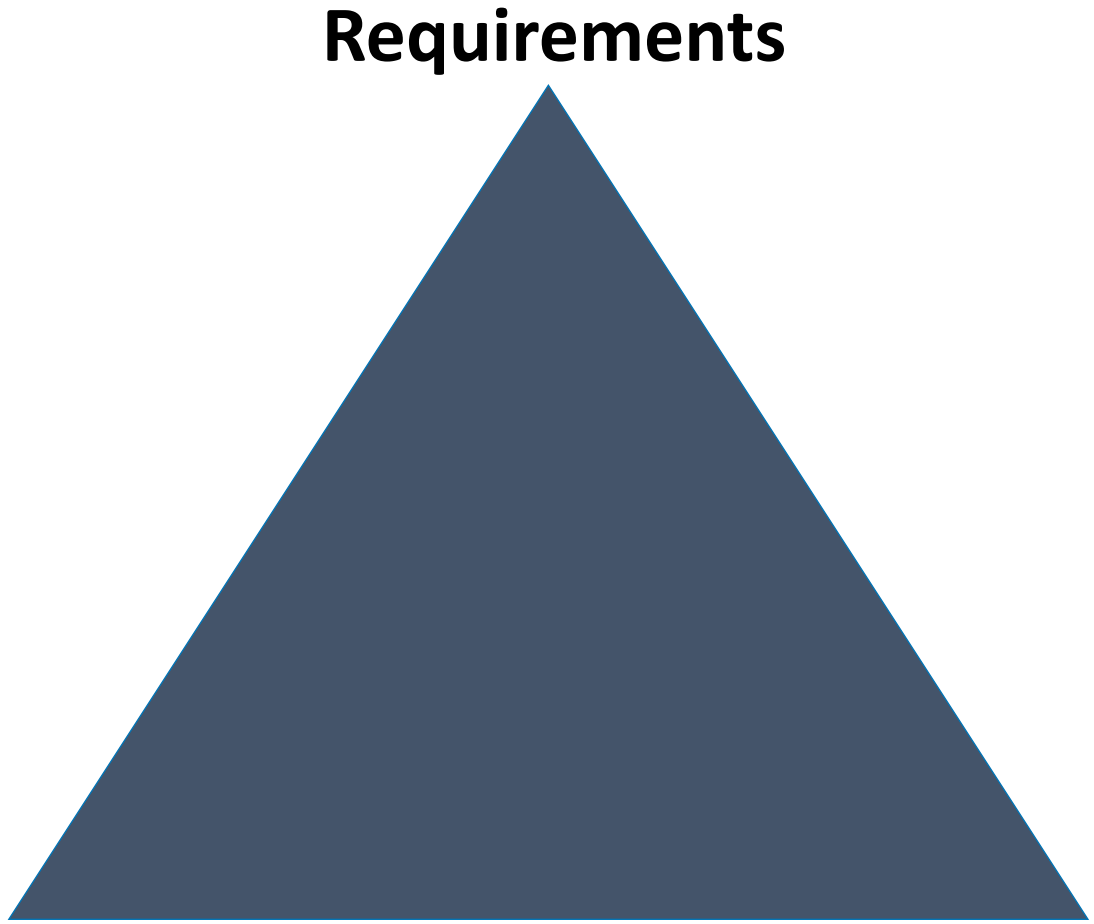
Non-conformity examples

- Procedures = operational issues
- Quality Manual = organizational issues
- Standard = policy issues
- Contract = customer issues
- Legislation = Regulatory issues

Reasons to raise a non-conformity

- Practice does not comply with the documented system
- The system does not reflect actual practice
- Practice/system does not comply with AS91XX, ASA-100 etc
- Practise /system/product or service does not meet contract or customer requirement
- Incomplete or incorrect flow-down of customer or contract requirements into internal documents, procedures and work instructions
- Breach of a legal or regulatory or other requirement of AS&D industry
- Breach in commitment to continual improvement

The non-conformance triangle



Non-conformities should be…

Non-conformities should be:

- Factual
- Objective
- Concise
- Traceable
- Clear
- Helpful

NCR discussion

Review each of the following audit findings. Then, decide if there is a non-conformity, or nothing to report.

- If you think there is a non-conformity, identify it and suggest suitable wording.
- If you do not think there is a non-conformity present say how and why you would report it.
- If you do not think there is no non-conformity explain why not.

Examples part one

- The purchasing procedure stated that all purchase orders would be authorised prior to release. Out of 5 purchase orders checked, only 2 had been authorised.
- The service level agreement established with the customer had not been made available to the service engineers performing the work. On checking the information on customer satisfaction, it showed that there were no problems with the work being performed.
- The minutes from management review meetings had not been circulated to all attendees, only those who had actions to perform.
- The sales department were not sending out customer satisfaction questionnaires to their customers.
- The work instructions defined for Plating activities at the Production Department was not available at the points of use, i.e., at the plating work centre. Example WI/03.

Examples part two

- A raw material for a critical item/part was accepted by the goods inward receiving inspection based on a delivery note from the raw material distributor.
- The review of purchase order for an aircraft part has been conducted by the Marketing executive without coordinating the review with other relevant functions of the organization and the order acceptance given to the customer.
- Evaluation and re-evaluation of approved suppliers and their periodic supplier performance review and rating not evidenced as per Procedure 593-610
- The effectiveness of analysis for some of the trainings not evaluated. Example training conducted on 13 Oct ‘24.
- The Quality objective of Plan Vs Actuals of the PPC department is showing a negative trend in the last 6 months yet no action is being taken.
- There are 6 customer complaints in the last 2 months. However, the analysis & evaluation on the customer complaint number 431, 432 and 434 dated 8 Aug ’21, 22nd Nov 21 and 3rd Jan 22 were not evidenced.

Examples part one

- The purchasing procedure stated that all purchase orders would be authorised prior to release. Out of 5 purchase orders checked, only 2 had been authorised. **(NCR)**
- The service level agreement established with the customer had not been made available to the service engineers performing the work. On checking the information on customer satisfaction, it showed that there were no problems with the work being performed. **(PNCR)**
- The minutes from management review meetings had not been circulated to all attendees, only those who had actions to perform. **(OBS or NCR)**
- The sales department were not sending out customer satisfaction questionnaires to their customers. **(OBS?)**
- The work instructions defined for Plating activities at the Production Department was not available at the points of use, i.e., at the plating work centre. Example WI/03. **(NCR)**

Examples part two

- A raw material for a critical item/part was accepted by the goods inward receiving inspection based on a delivery note from the raw material distributor. **(Major NCR)**
- The review of purchase order for an aircraft part has been conducted by the Marketing executive without coordinating the review with other relevant functions of the organization and the order acceptance given to the customer **(PNCR)**
- Evaluation and re-evaluation of approved suppliers and their periodic supplier performance review and rating not evidenced as per Procedure 593-610 **(NCR)**
- The effectiveness of analysis for some of the trainings not evaluated. Example training conducted on 13 Oct ‘24. **(OBS or NCR?)**
- The Quality objective of Plan Vs Actuals of the PPC department is showing a negative trend in the last 6 months yet no action is being taken. **(PNCR)**
- There are 6 customer complaints in the last 2 months. However, the analysis & evaluation on the customer complaint number 431, 432 and 434 dated 8 Aug ’21, 22nd Nov 21 and 3rd Jan 22 were not evidenced. **(NCR)**

NCR examples

How to do it?

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes.

Controls for controlling material changes were not found to be effective

WO 290570 was reviewed as it was held in quarantine pending a material issue. Material issue concerned the manufacture of parts using material grade A, which it not listed on drawing as approved material. Material on drawing is material grade B. Items were placed on hold as concession was initiated (24-303) and submitted to customer. Customer had rejected this until a concession is submitted in line with their requirements. Records state Engineering do not have resource.

However, whilst 2 batches were held correctly in MRB, the material used had been purchased circa 2019 and 5 orders have been completed and shipped to customer with grade A material. There was no record at time of audit available of any approval of material use, no concessions or customer notification for change. Items are potentially in flight.

How to do it?

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization

At the time of the audit, whilst the organisation charts are partly reflected in TEAMs, it was not clear how previous versions are controlled and not all reporting lines were reflected, i.e. dotted line for Supply Chain Manager. The organisation charts are also reflected in SharePoint, but again, not all reporting lines were reflected, ie dotted line for Supply Chain Manager and it was not clear how previous versions are maintained as records of the Business. Linked with the above, the 'Responsibilities' of the Supply Chain Management were not documented and available on general access (ie communicated).

How to do it?

- *Within the Project X a few documentation issues were noted highlighting that the control of changes is not fully effective :-*
  Risk & Opportunity Management – It was established at the time of the audit that there are currently 5 individual Risk Registers. However, the following 2 documents have not been kept up to date :-
- *Project Plan, Ref : M-2024, Issue : H, Dated : 14-Jan-25 – Defines within Section 12 – Risks & Opportunities that there are 3 Risk Registers and this is supported with only 3 being listed in Section 15 – References [34], [35], [36]*
- *Risk and Opportunity Management Plan, Ref : M-0002, Issue : C, Dated : 27-Feb-23 – Defines only 4 Risk & Opportunity Registers within the 'References' Section.*
- *Project Plan, Ref : M-2025, Issue : H, Dated : 14-Jan-25 – Section 15 of the Project Plan covers the reference of key documents, ie Ref [19] = Software Development Plan, Ref : M-91210. However, this has not been kept up to date as the Software Development Plan has now been updated to M-91211.*
- *Software Development Plan , Ref : M-1004, Issue : E, Dated : 14-May-24 – Section 2 covers the references of key documents, i.e Project Plan at Issue : E. However, this has not been kept up to date as the Project Plan is now at Issue : H.*

NCR management – audit follow-up

- Nonconformities initiate the corrective action process:
  - Begins with response to nonconformity
  - Auditee determines corrective action
  - Auditee assigns responsibility for action
  - Auditee ensures completion of action
- Not considered to be part of the audit
- Verification may be part of later audits
- Using the expertise of auditors adds value

Any questions?

Thank-you for your attendance.