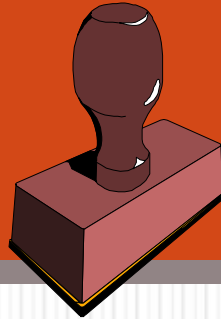
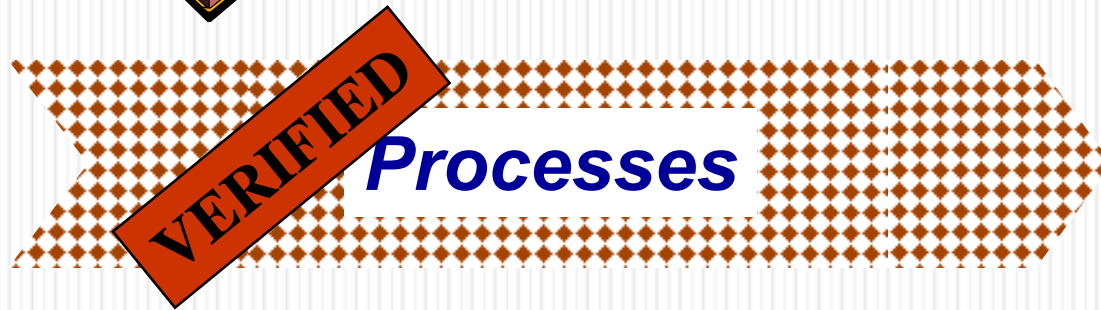


Verification Auditing



Inputs



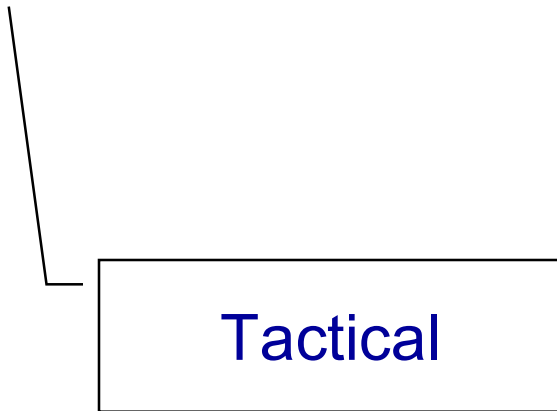
Outputs

By: J.P. Russell
E-learning at www.QualityWBT.org

Verification Audits

“little q”

- Process audit
- Product audit
- Service audit



“Big Q”

- System audit
- Integrated audit



System Audit



Process Audit

**Product
Audit**

Verification Audit



Verification Methods

- Audit?

Other methods?

Verification Audit

- The act or process of verifying product and service characteristics by means of observation and examination
- Means to confirm and authenticate actions
- Isolated activities or part of project execution
- Yes-No outcomes

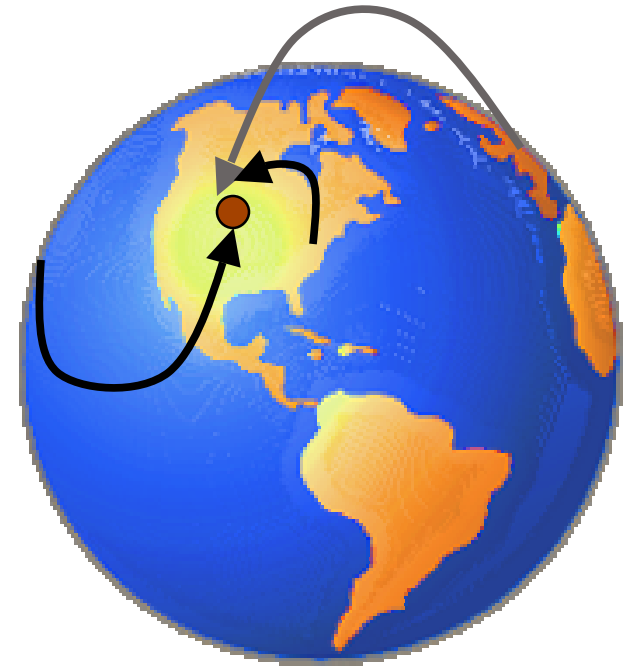
Why Verify?

- Standards require it
- Lower risk of failure
 - product/ service
 - process
- Prudent due to qualitative nature
 - amount transacted, not reversible, nature of product or service (i.e. medical, nuclear).
- Business/ relationship environment

Or increase?

Outsourcing

- Reliance on critical products and **services**
- Organizations with different goals, skills, values, cultures, management styles
- Tomorrow



More options but advantages must be verified

Field Failure

- Broken spring to 9 month old saltwater- ready trolling motor. Spring engages locking mechanism during operation and storage. Used less than 12 times.



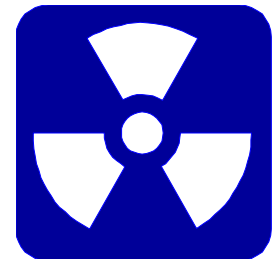
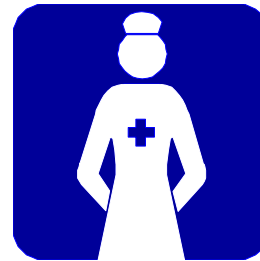
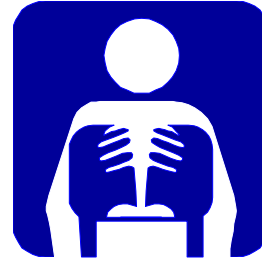
Project Design/ Construction

- Outsource elements of design
- Verify materials and services used in implementation/ construction of project design/ plan



In-house verification/ validation

- Verify process inputs, outputs and performance
 - complexity
 - not able to verify by inspection or test
 - critical due to negative consequences



FMEA

Verification Audit Preparation

- Criteria
 - procedures, methods, standards
 - product/service specifications
 - product/service performance
- Approved Equipment? How approved?
- Qualifications of personnel/operators
 - method?
- Ongoing process verification

Internal Audit Objectives

- Verify process
 - special test or procedure
- Verify product characteristics/ performance
- Verify project implementation
 - new product
 - construction
- Verify defects/ nonconformities addressed
- Verify training, equipment capabilities, process setting(s)

2nd Party Audit Objectives

- Verify supplier processes
 - calibration process
 - heat treatment
 - maintenance
- Verify supplier product/service characteristics or performance measures
- Verify conformance to contract requirements
- Verify nonconformities have been addressed
- Verify material sources and traceability

Others?

3rd-Party Audit Objectives

- Approve/Disapprove **process** for license or certification
- Approve/Disapprove **product** or service for license or certification

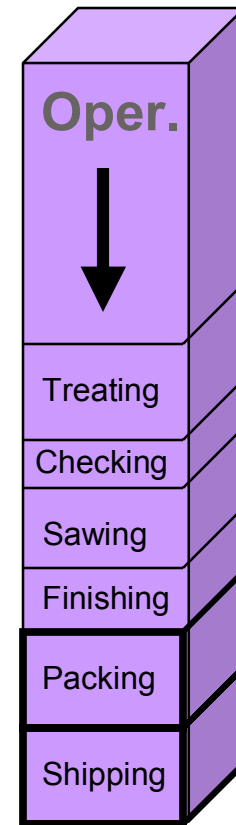
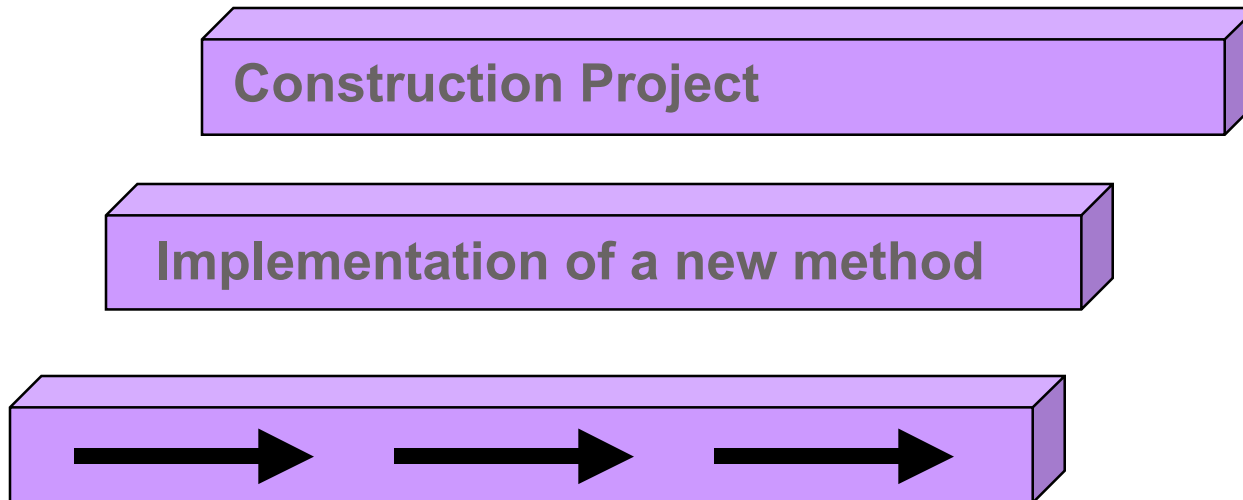
Scope

- Product, service, process
- Internal or supplier
- One time, many times, depends

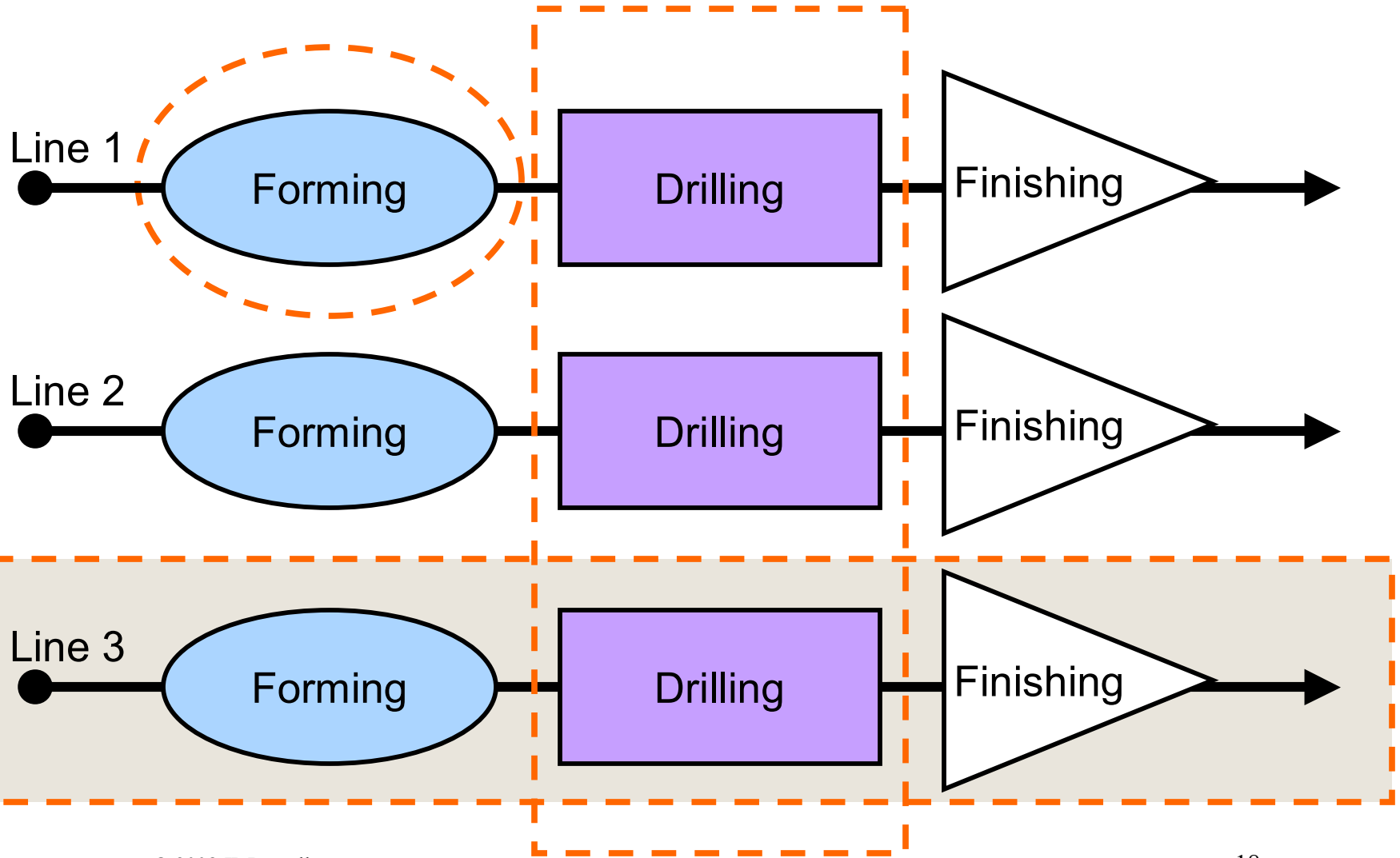
Auditing Strategies

Project and Department Activities

Projects



Process Auditing Scope



Verification Audit Preparation

- Auditor
 - product (equipment) knowledge
 - process/service knowledge (good practices)
- How many auditors?
 - how many processes?

Verification Audit Preparation

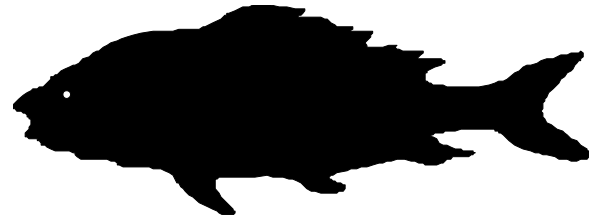
- Contact the auditee
 - request documents related to product/service or process
- Verify
 - coordinate time of visit
- Surprise?

Understand the process

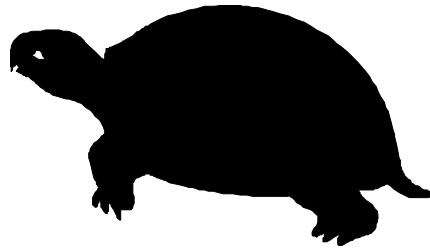
- Prior experience
- Use tools to evaluate

Tools

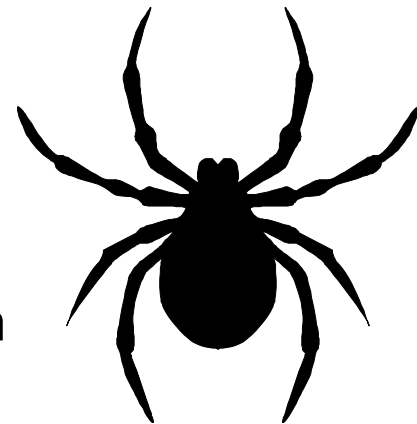
Fishbone Diagram/Cause and Effect Diagram



Turtle Diagram



Spider Diagram



Turtle Diagram for Realization

People (who):

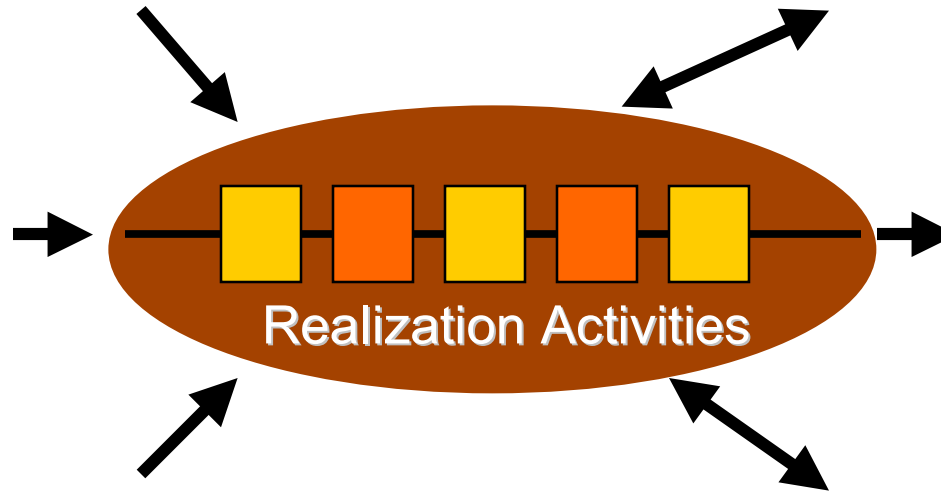
- competence (skills, knowledge and training)

Materials/Equipment/Service (what):

- defined and approved
- maintained (in-sourced and outsourced)

Inputs:

- product
- material
- information (drawings, specifications)



Outputs:

- completed service
- finished product

Methods (how):

- step-by-step
- procedures
- standards

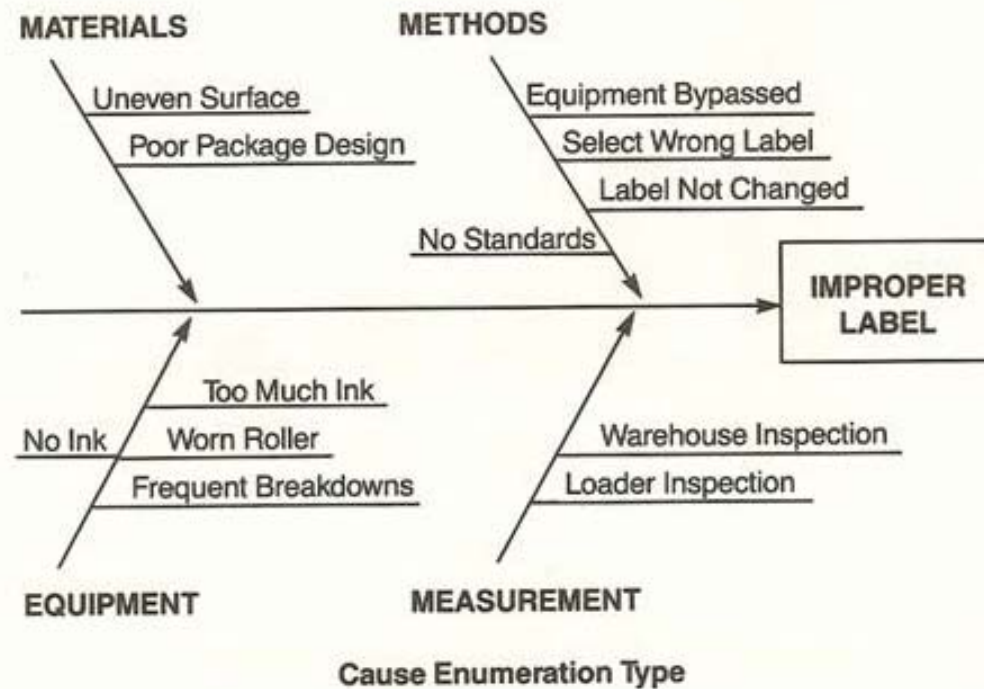
Measures (results):

- rate or units completed
- rate or units defined
- rate or units monitored

CE Diagram

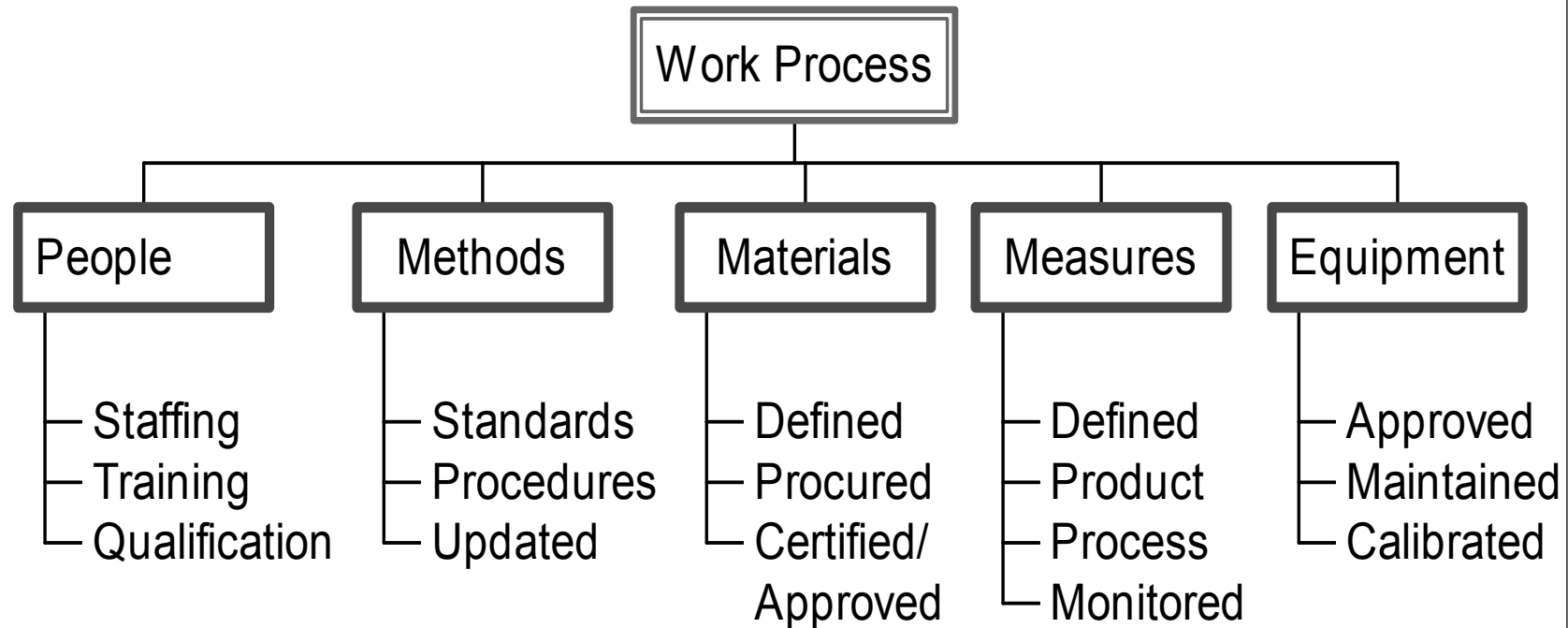
Exhibit C: Cause-and-Effect Diagram

IMPROPER PACKAGE LABEL (Code & Series)

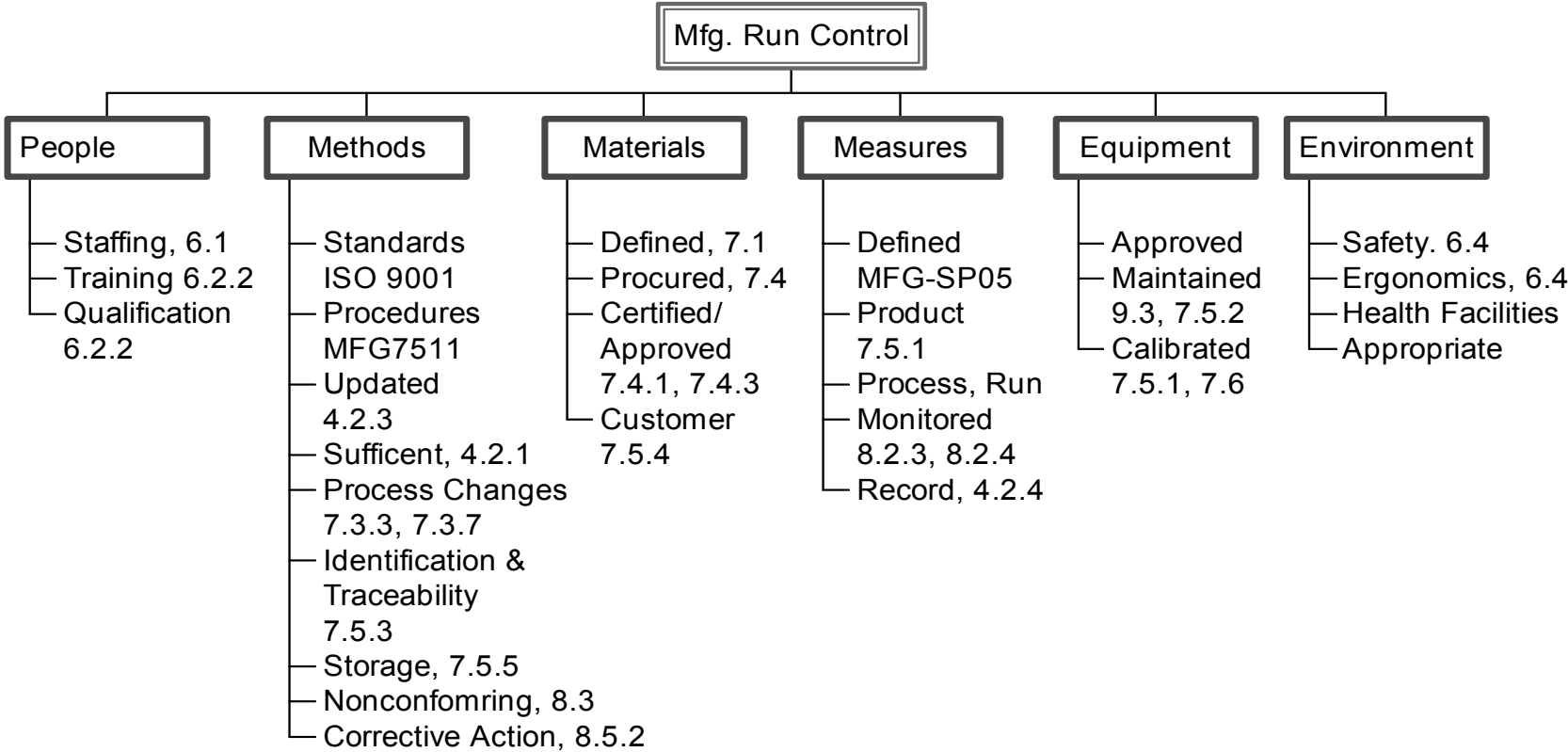


Tree Diagrams - for Processes

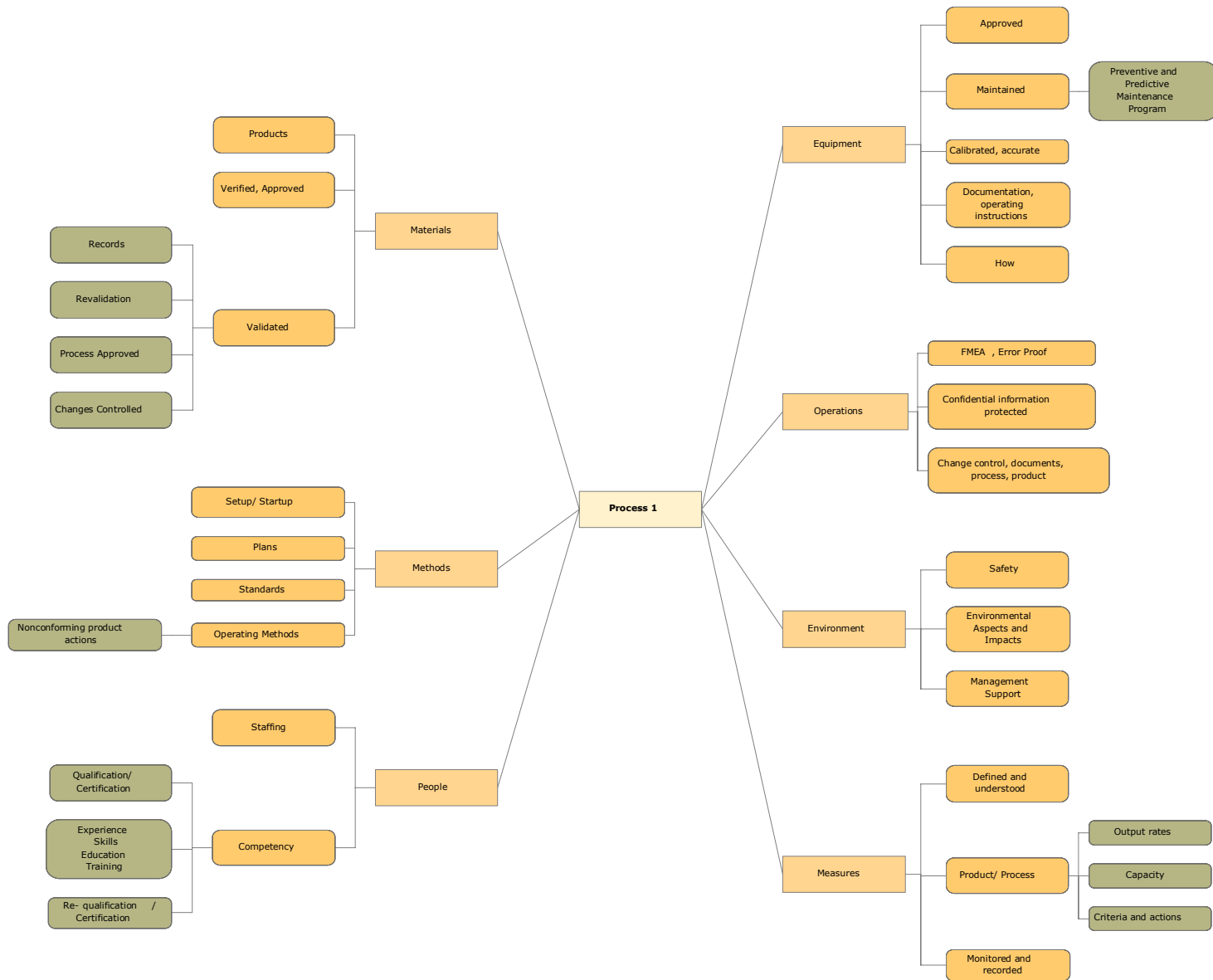
Grouping



Check-Diagram for Production



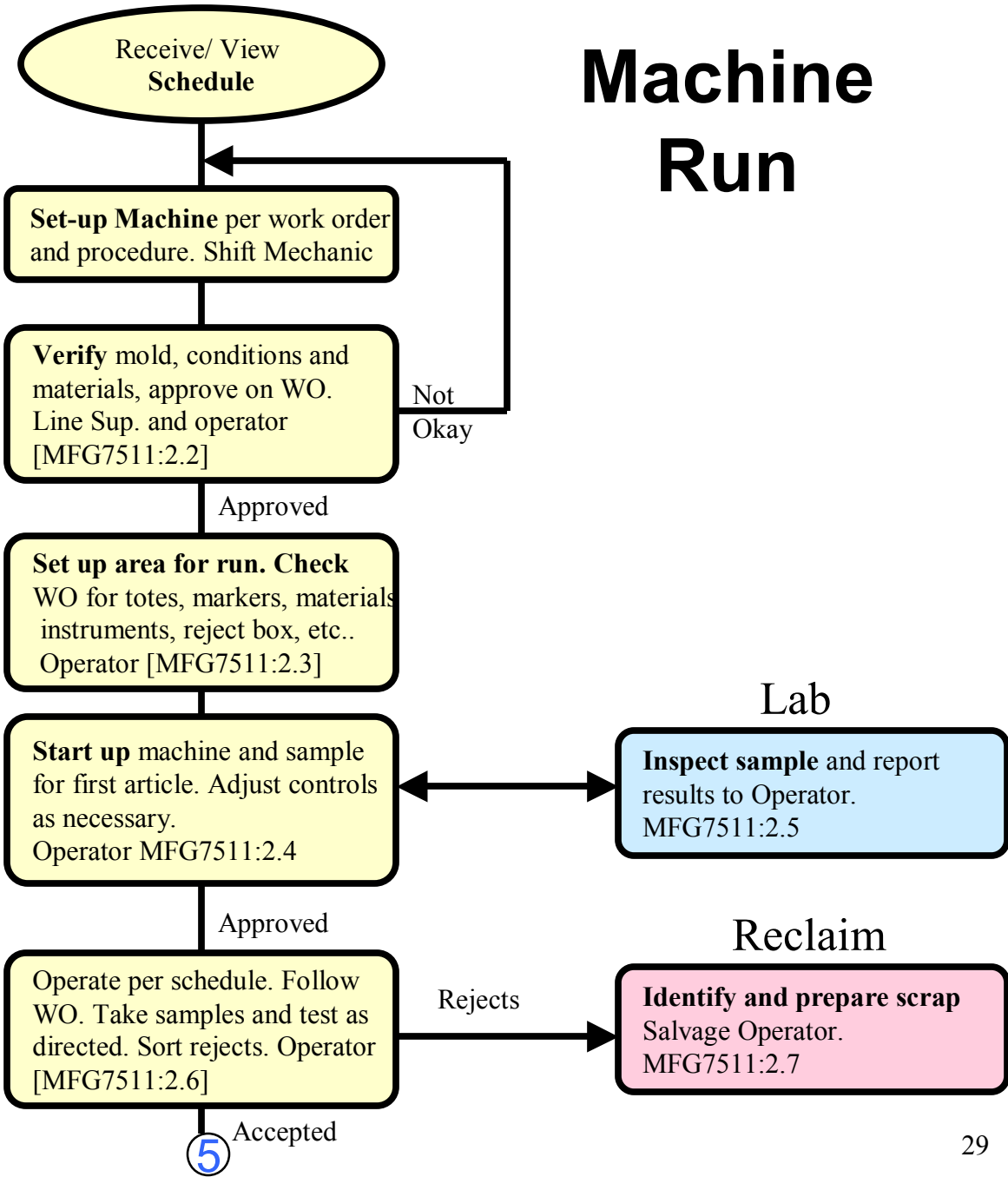
Spider Diagram



Checklist

- Checklist
- Diagrams
- Flowchart

Machine Run



Documentation

- Plans
- Methods
- Output criteria
 - specification, list
 - drawing, picture, diagram
 - desired result or avoidance of undesired result
- Non conforming product/service controls

Other criteria?

History

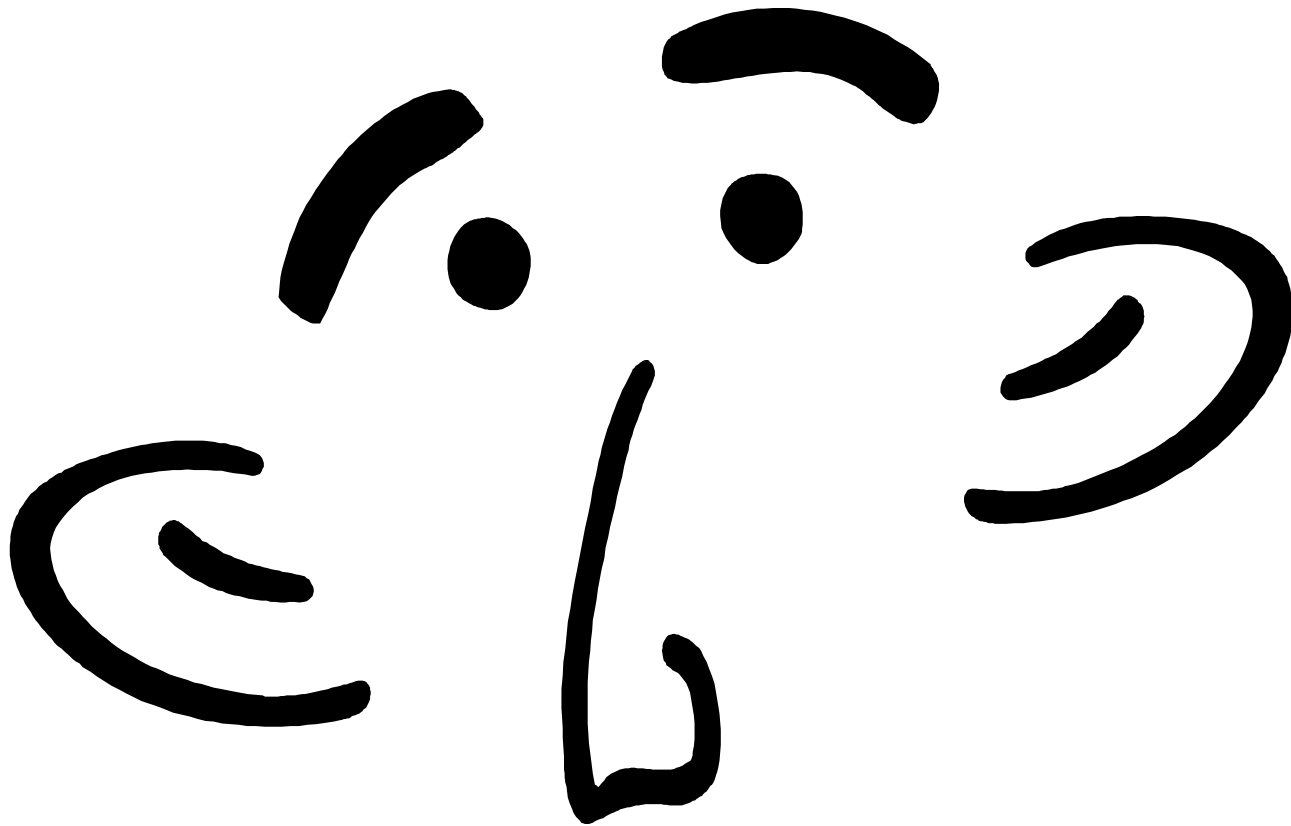
- History
 - defects and corrections made
 - internal and field failures
 - process and product changes
 - operator/technician changes
 - corrective actions
 - safety
 - environmental aspects
 - customer complaints

Performing

- Meet with area supervisor/ manager
- Observe process
- Sample product, records and people
- Interview (if process)
- Collect evidence
- Verify characteristics
- Verify outputs

Validate?

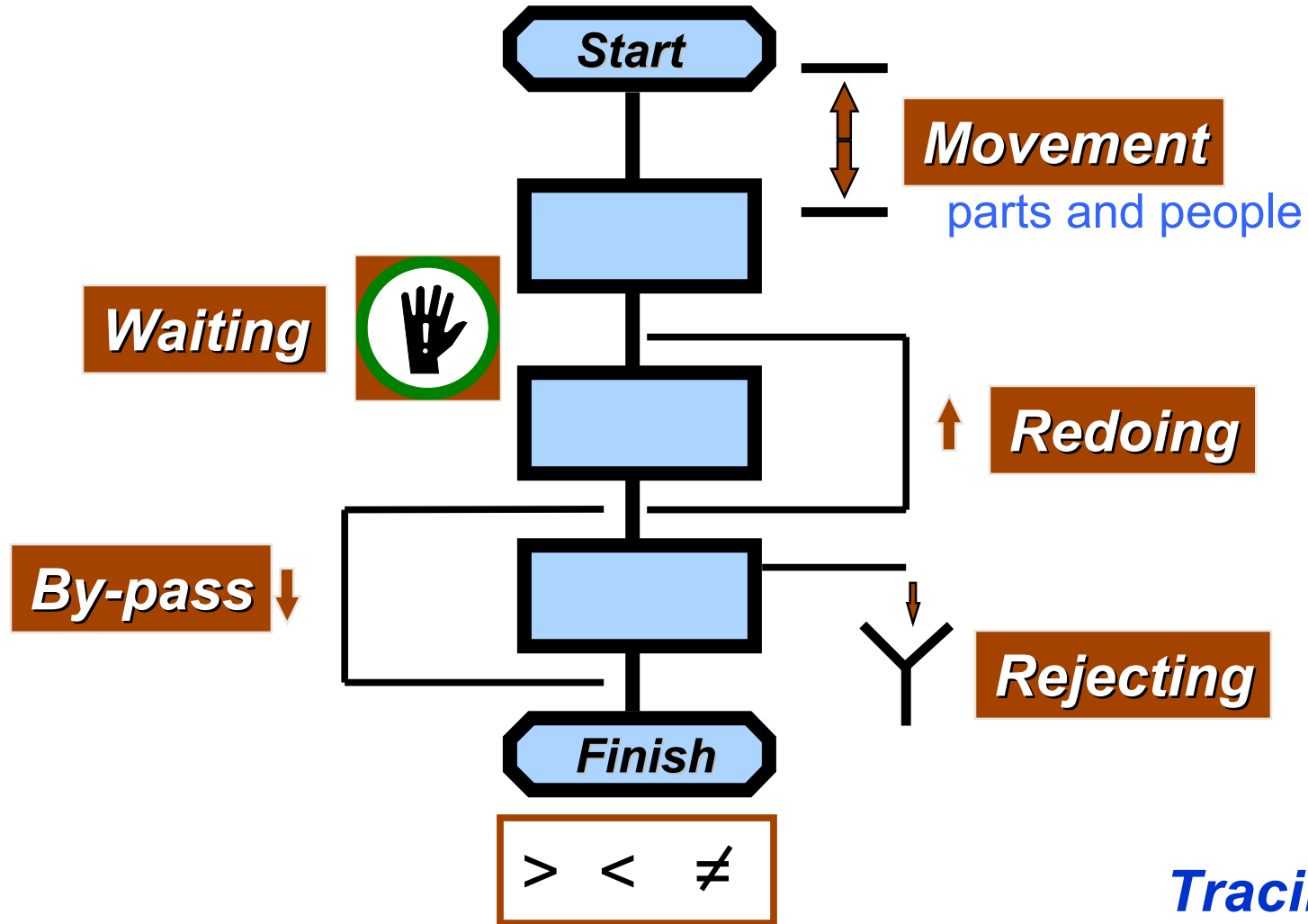
Make Observations



Performing plus

- Mistake proofing
- Lean/ performance indicators
- Opportunities for improvement
- Good practices

Process Performance Indicators



Tracing?

Report

- Keep it short and to the point
- Address objectives/purpose

Process Audit Report and Corrective Action Record

To:			Audit Date(s):		Report Date:		
From:					Audit No.:		
Copy:					Auditor(s):		
Process Audited:							
Purpose:							
Standard – Procedure – Instruction:							
Overall Findings/ Conclusion:							
	Report Details				Status		
No.	Finding/ Nonconformance	Ref # Para	Follow-up Action Remedial and/or Corrective Action	Planned Comple- tion Date	Plan Approve d	Actual Comple- tion Date	Verified

What should you audit?

- Based on Risk
 - direct dollars (cost)
 - indirect dollars (customer goodwill)
- Areas of weakness
- Legal, regulatory requirements
- Consistent with organization's risk policy
- Consider alternate less expensive verification methods

Risk

Event—likelihood—consequences (in **dollars**)

Prevention—acceptable--consequences

Use **collaborative approach** involving a wide cross-section of interested parties and participants

Rebar not installed correctly, mix-up of organ donor records, spring not heat-treated, contamination, metal fatigue, discoloration..



Results come from checking,
not expecting.

J.P. Russell

Contact information:

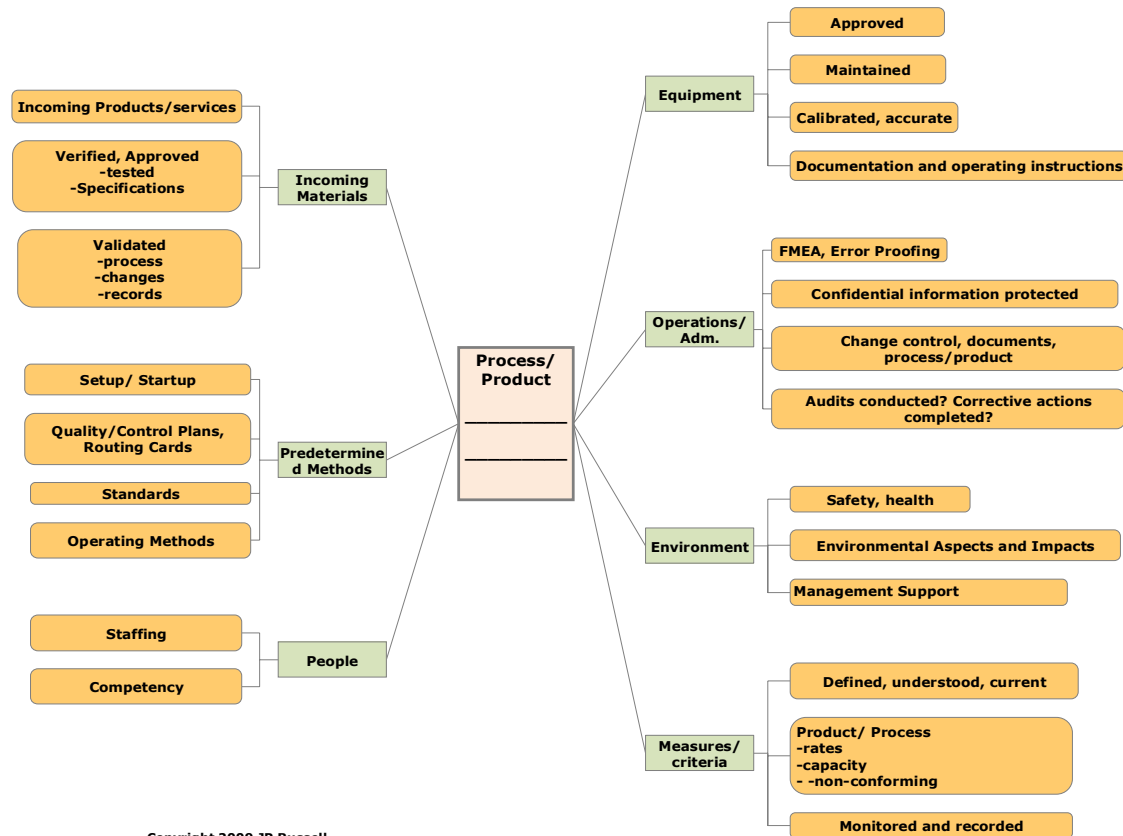
Web-based training at: www.QualityWBT.com

JP Russell at: www.JP-Russell.com

E-mail: JPR@JP-Russell.com

Telephone: 888.737.4488

Verification Audit Elements (simplified)
Product and process verification



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