

AS9100C Pitfalls

“Common Problem Areas”

Discussion Approach

- **Issues will be discussed by Clauses of the standard (e.g. 1, 2, 3, 4, 5, 6, 7, 8)**
 - Reflect on the requirement
 - Identify common nonconformity
 - Discuss expectations

It would be helpful to have the AS9100 standard available to follow along

Please hold questions to the end. Adequate time will be allotted for your questions.



Clause 1 - Scope

➤ Issue with exclusions:

- **Post Delivery Support 7.5.1.4b if warranty work is accomplished**
- **Applicable standard (AS9100, AS9110, AS9120)**
- **Scope (SIC, EA, NACE)**
- **Site Designation (Single, Multiple, Campus, Several, Complex)**

Note: No exclusions can be made outside of Clause 7

1.2 Application
...Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.....
Organizations whose primary business is providing maintenance, repair and overhaul services for aviation commercial and military products; and original equipment manufacturers with maintenance, repair and overhaul operations that operate autonomously, or that are substantially different from their manufacturing/production operations; should use the IAQG-developed 9110 standard (see Bibliography).
Organizations that procure parts, materials and assemblies and resell these products to a customer in the aviation, space and defense industries, including organizations that procure products and split them into smaller quantities for resale, should use the IAQG-developed 9120 standard...

Clause 2 – Normative References

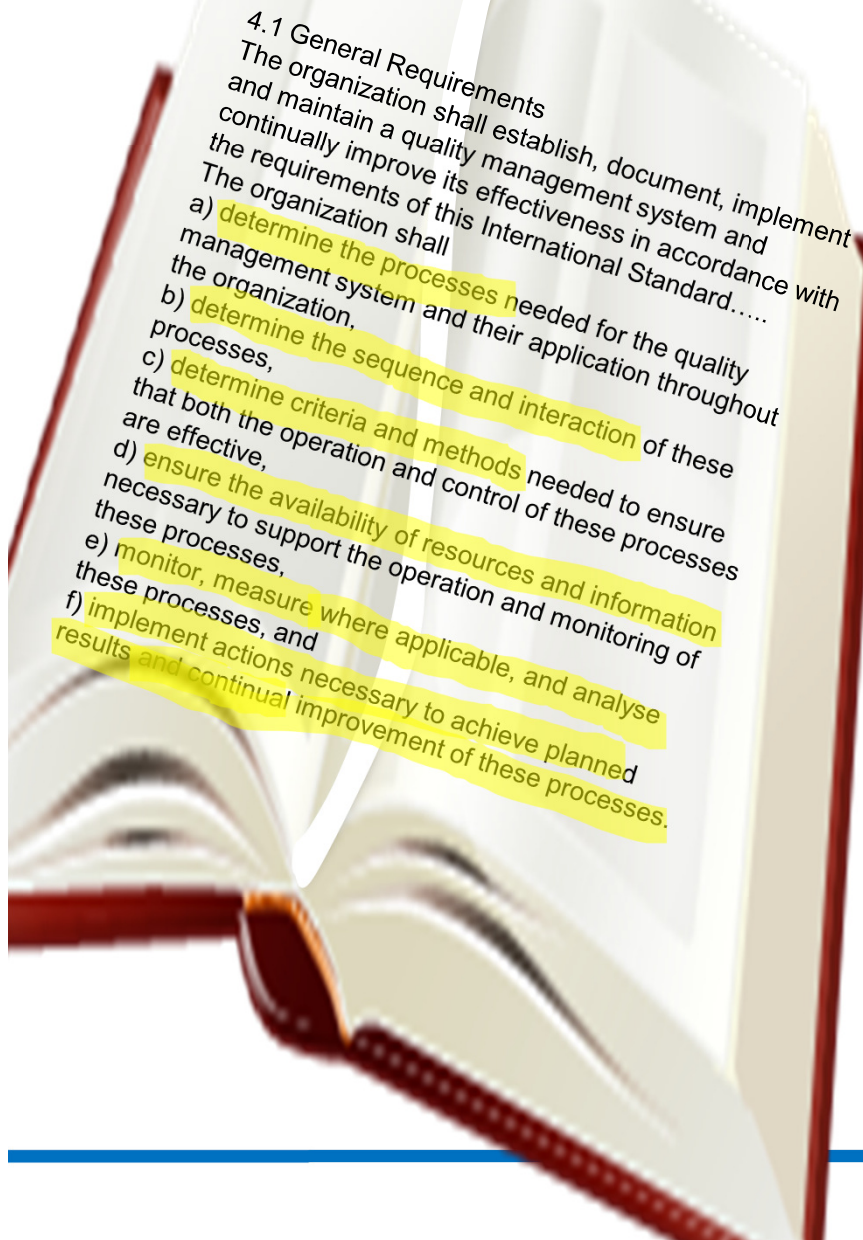
Clause 3 – Terms & Definitions

- **No common issues in these Clauses**



Clause 4 – Quality Management System

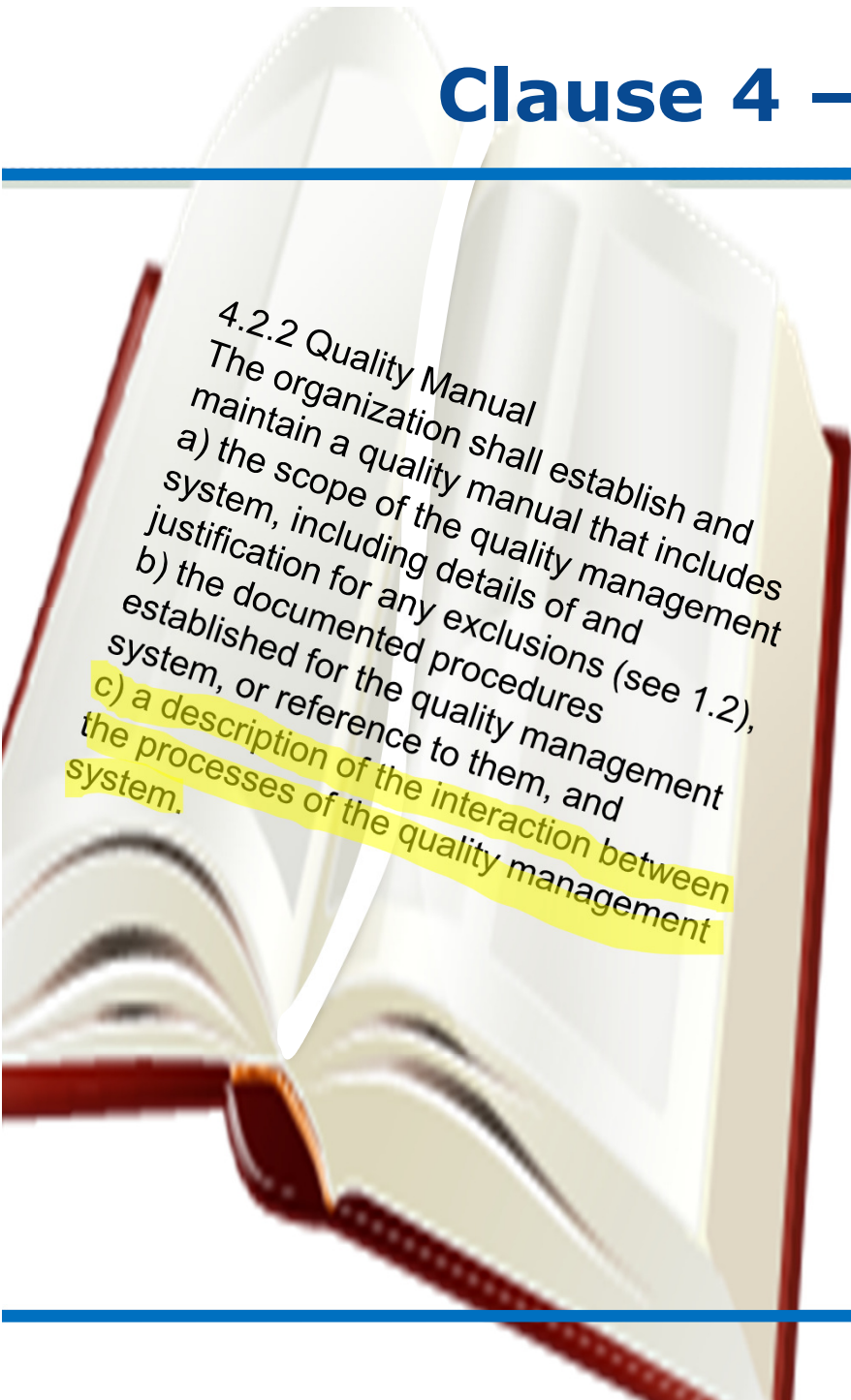
- **Inadequate definition of QMS processes**
 - **Linked to Quality Manual (4.2.2c) and Process Monitoring & Measurement of Processes 8.2.3**
 - **Linked to Analysis of Data (8.4) and Continual Improvement (8.5.1)**
- **The lack of a complete set of QMS processes lead to many issues during an audit.**
- **Although not required to be documented, auditors will ask for the information in 4.1a-f.**



Clause 4 – QMS (Cont'd)

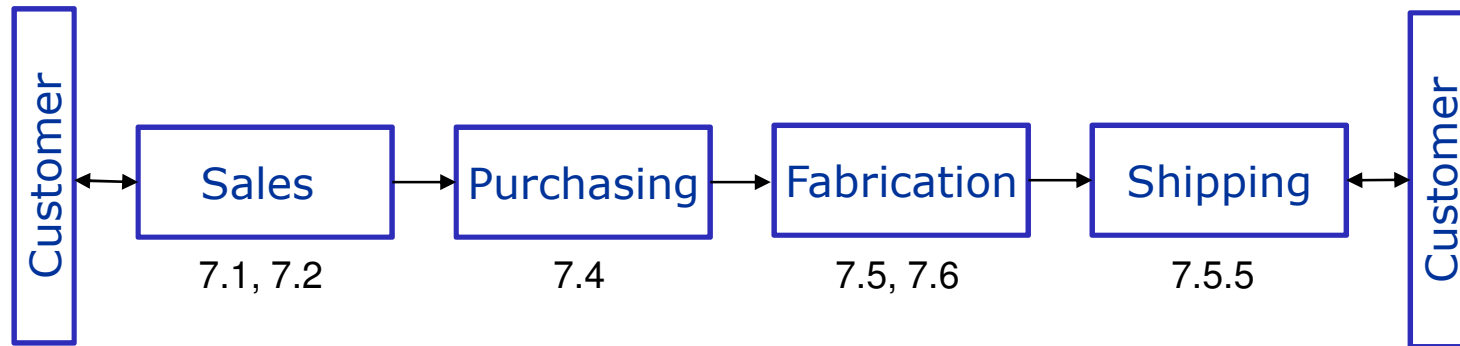
➤ Inadequate description of interactions between processes

- **Most Quality Manuals include an IOP that shows the process sequences and shows that there is some interaction, but does not provide a "description of the interactions..."**
- *Note: Interaction of Processes commonly called an IOP.*



4.2.2 Quality Manual
The organization shall establish and maintain a quality manual that includes
a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

Acceptable IOP?



- **Is this an acceptable IOP?**
- **Does it clearly describe the interaction between processes?**
- **Does it include all the QMS clauses?**
(Where are Clauses 4, 5, 6, 8?)

Requirement (4.1a)

...The organization shall

- a) determine the processes needed for the QMS.

Requirement (4.2.2c)

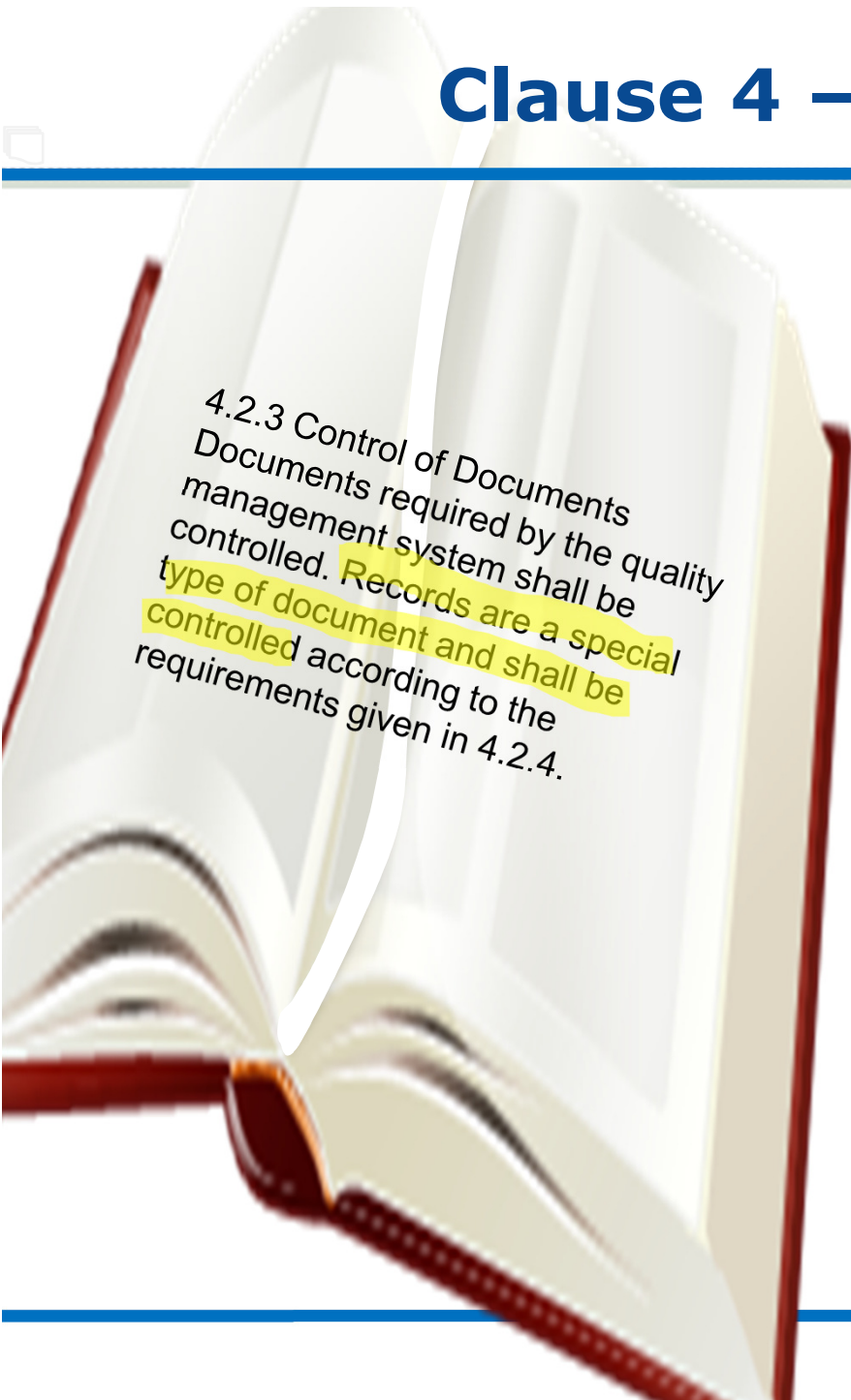
...a quality manual that includes

- c) a description of the interaction between the processes of the QMS.

Clause 4 – QMS (Cont'd)

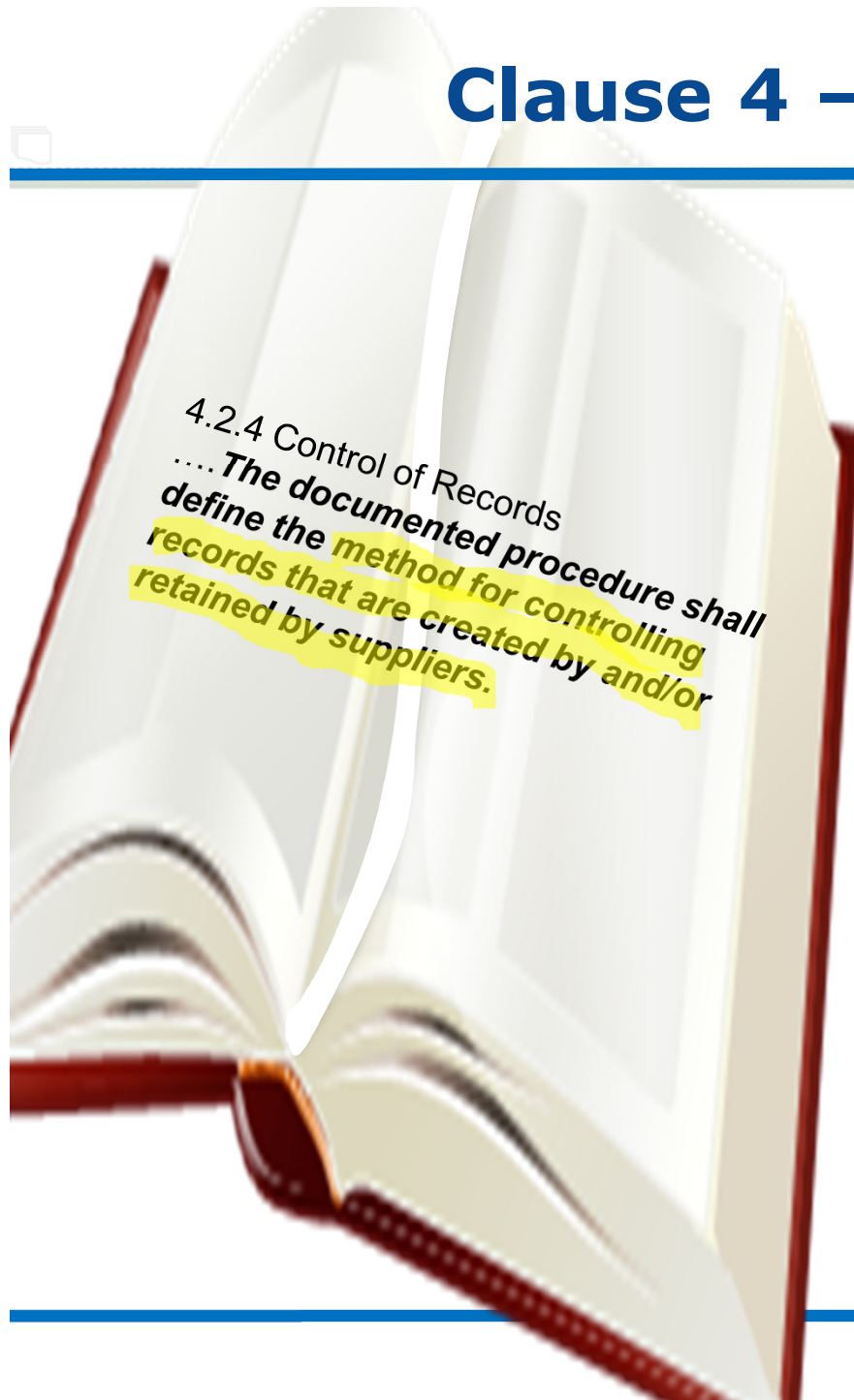
➤ Inadequate control of forms (documents)

- **Forms used to record evidence of Quality Management System (4.2.4 reference) or product compliance or customer required must reflect document controls (release date, revision letter, etc.)**



4.2.3 Control of Documents
Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

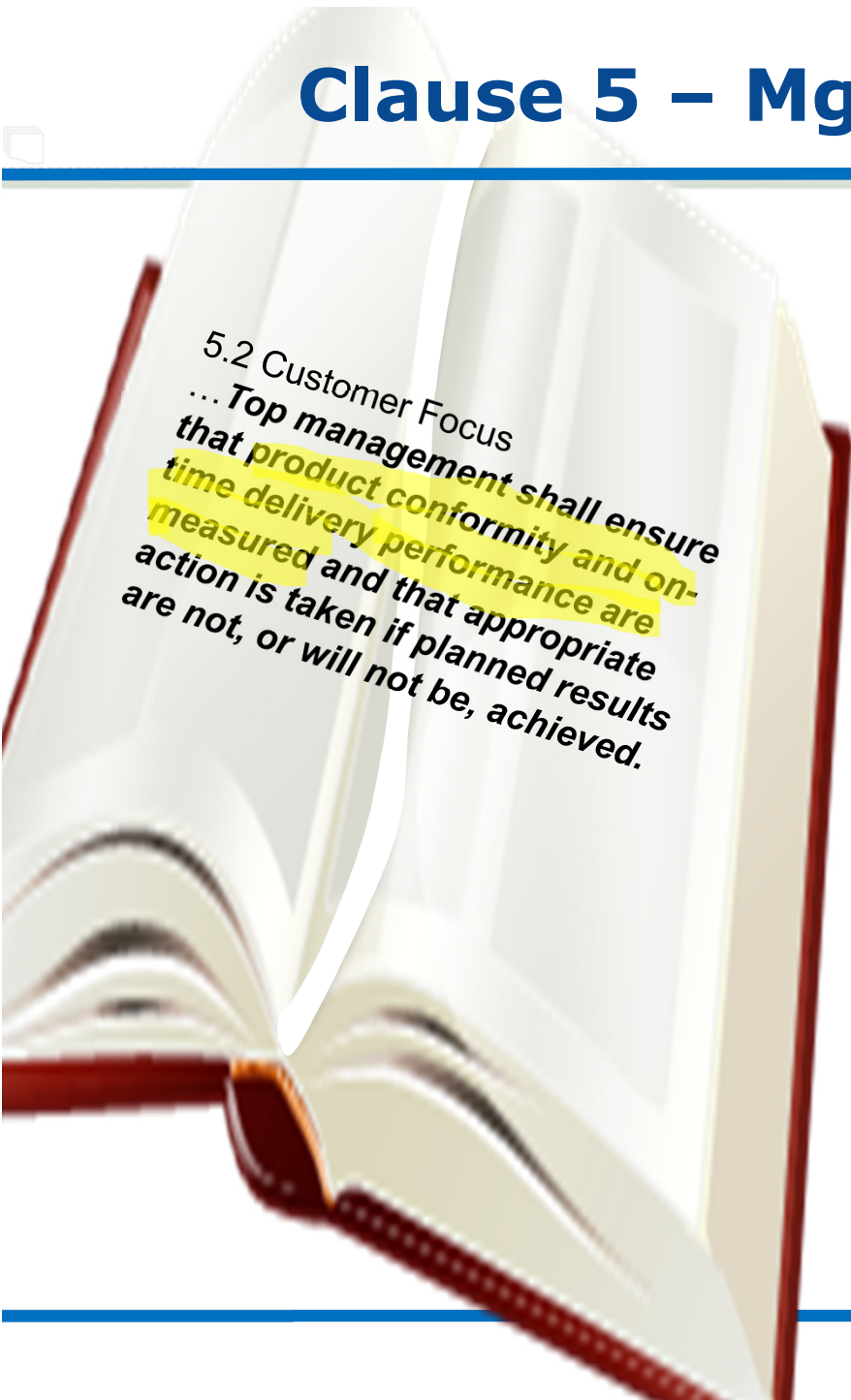
Clause 4 – QMS (Cont'd)



➤ Control of Records procedure must define the method for controlling records created by and/or retained by suppliers

- Often times the procedure says the company does it, but does not define the method.
- Expected controls should consider the type of records, the retention times, the retrieval expectations and any specific customer flow down requirements.

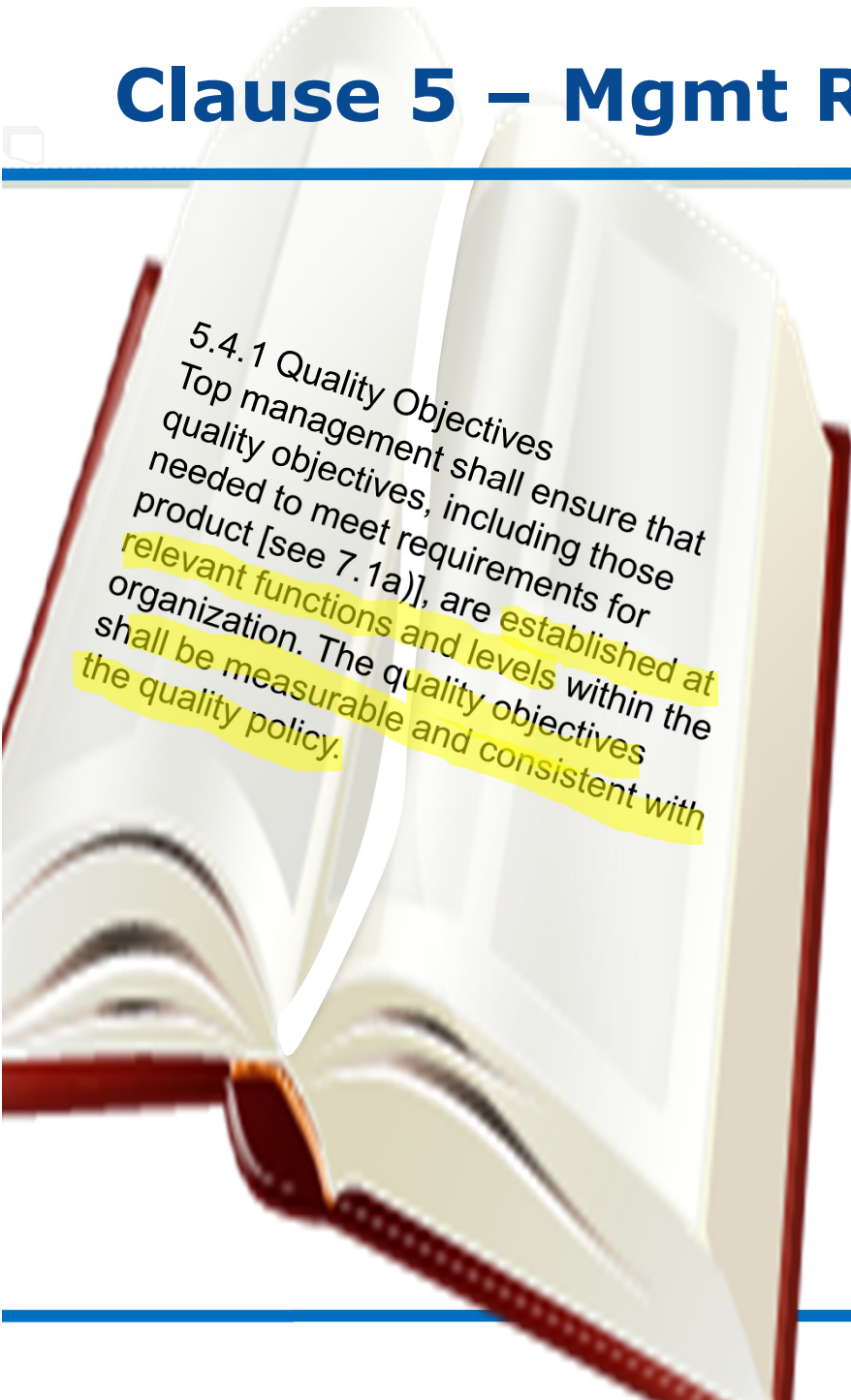
Clause 5 – Mgmt Responsibility



5.2 Customer Focus
... **Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.**

- **As a minimum Product Conformity and On-Time Delivery must be measured and appropriate actions taken if planned results are not achieved.**
 - **Expectation that the Quality and OTD measures are:**
 - **consistent with customer requirements**
 - **aim for enhancing customer satisfaction**

Clause 5 – Mgmt Responsibility (Cont'd)



5.4.1 Quality Objectives
Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

- **Quality Objectives must be established for relevant functions and levels of the organization (linked to 4.1a)**
- **Quality Objectives must be measurable**
- **Quality Objectives must be consistent (support) the Quality Policy (linked to 5.3) for continual improvement.**
- *Note: Quality Objectives are often high level (10% Increase Profitability) and supported by QMS Process measures (Mfg Process – Reduce scrap by 18%)*

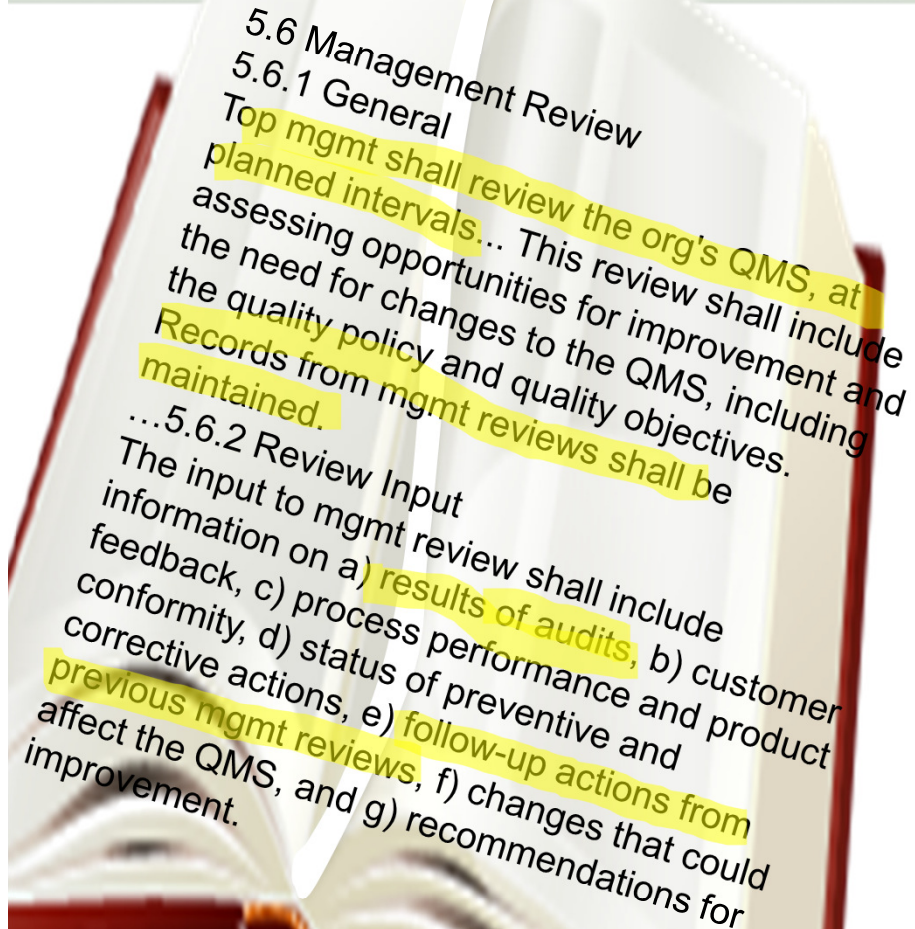
Clause 5 – Mgmt Responsibility

- **Management Rep must be appointed from the company's management team.**
- **Mgmt Rep is sometimes inappropriately identified as an outside consultant**

5.5 Responsibility, Authority and Communication
5.5.1 Responsibility and Authority
Top management shall ensure that responsibilities and authorities are defined and communicated within the org.
5.5.2 Management Representative
Top mgmt shall appoint a member of the org's mgmt ..., shall have responsibility... that includes a) ensuring that processes needed for the QMS are established, implemented and maintained, b) reporting to top mgmt..., c) ensuring the promotion of awareness of customer req'mts throughout the org, **and d) the organizational freedom and unrestricted access to top mgmt...**
5.5.3 Internal Communication
Top mgmt shall ensure that appropriate communication ...are established within the org and...communication takes place regarding the effectiveness of the QMS.

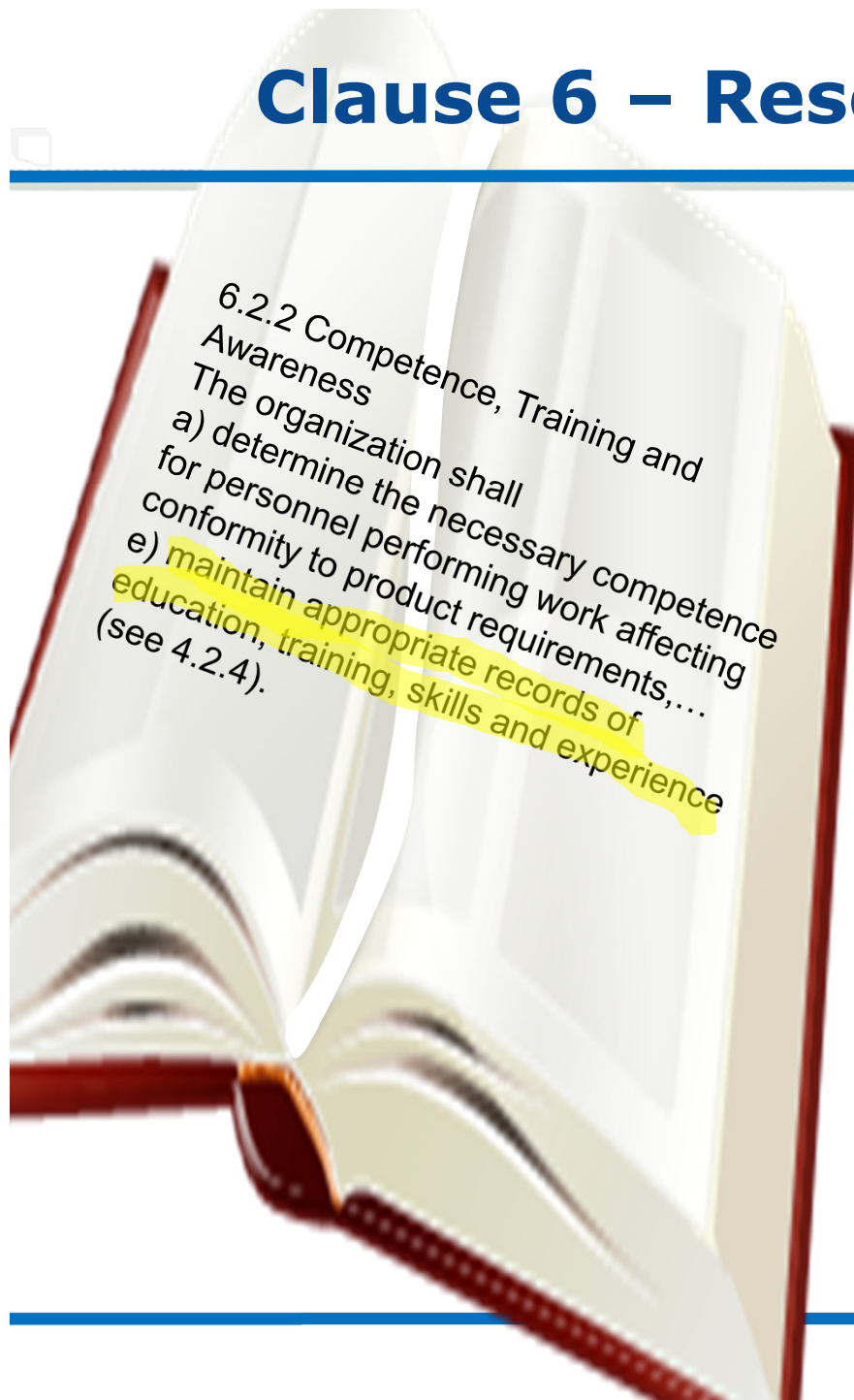
Clause 5 – Mgmt Responsibility (Cont'd)

- **Inadequate Management Review Records**
 - **Management Review records only reflect a review of internal audits**
 - **Lack of Objective Evidence that Action Items from previous meetings are closed**
- **Issues with of Management Review Effectiveness include:**
 - **Lack of Action Items**
 - **Effective Frequency**
 - **Lack of Attendance**



5.6 Management Review
5.6.1 General
Top mgmt shall review the org's QMS, at planned intervals... This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. Records from mgmt reviews shall be maintained.
...5.6.2 Review Input
The input to mgmt review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous mgmt reviews, f) changes that could affect the QMS, and g) recommendations for improvement.

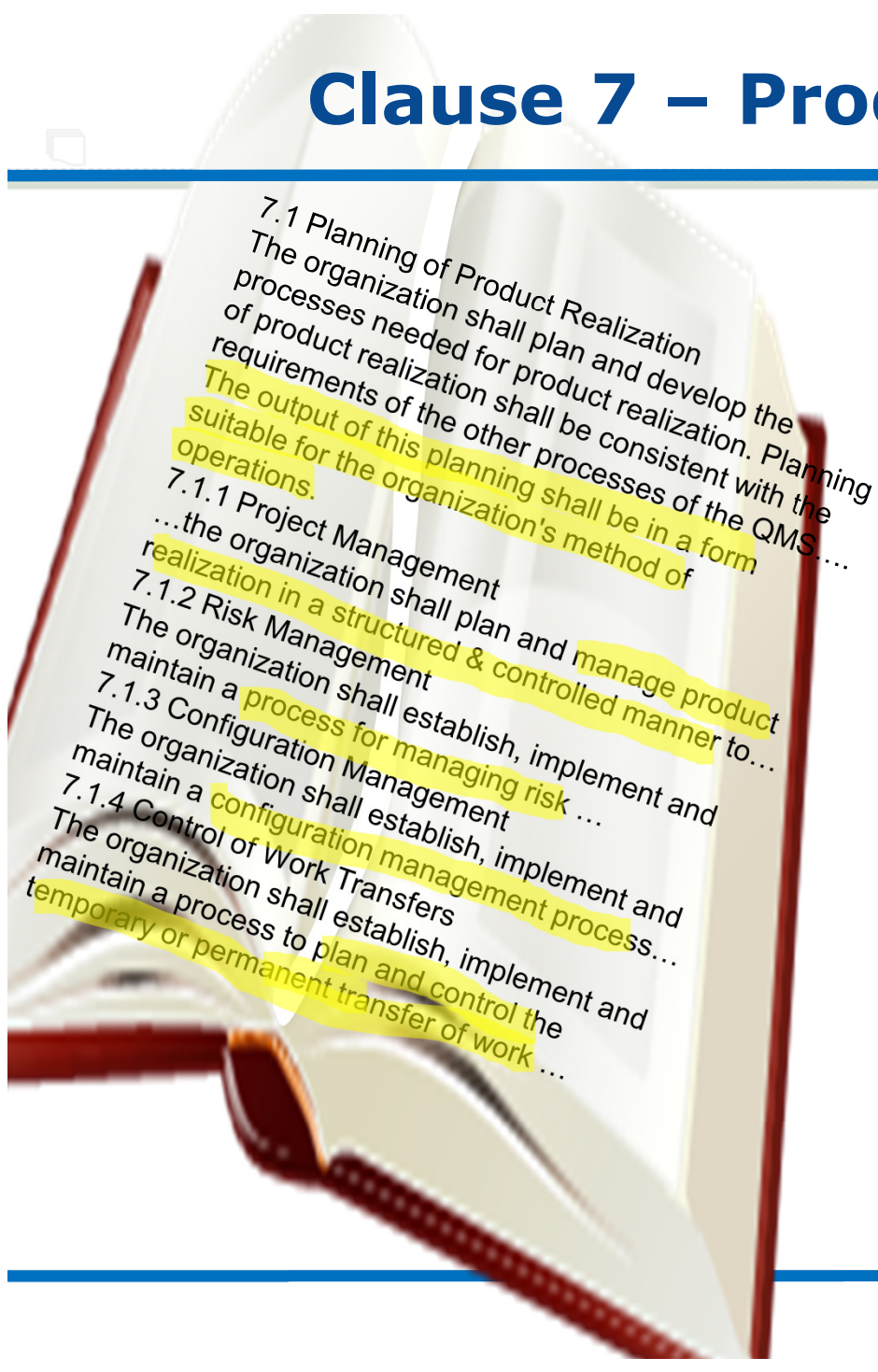
Clause 6 – Resource Management



- **Although not specifically required, Job Descriptions are often used by companies to determine competency. Many times these Job Descriptions do not reflect document controls.**
- **Often Training records do not exist for all personnel (Mgmt, Admin, etc)**

Clause 7 – Product Realization

- **Common issues include:**
- **No evidence that Project Management has been addressed.**
- **No evidence that the company has a process to consider Risk (links to 7.4.1.f 3.1, 7.1.1, 7.2.2 & 8.5.3), Configuration Management and/or Work Transfers. (Linked to 7.2)**



7.1 Planning of Product Realization
The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the QMS....
The output of this planning shall be in a form suitable for the organization's method of operations.

7.1.1 Project Management
...the organization shall plan and manage product realization in a structured & controlled manner to...

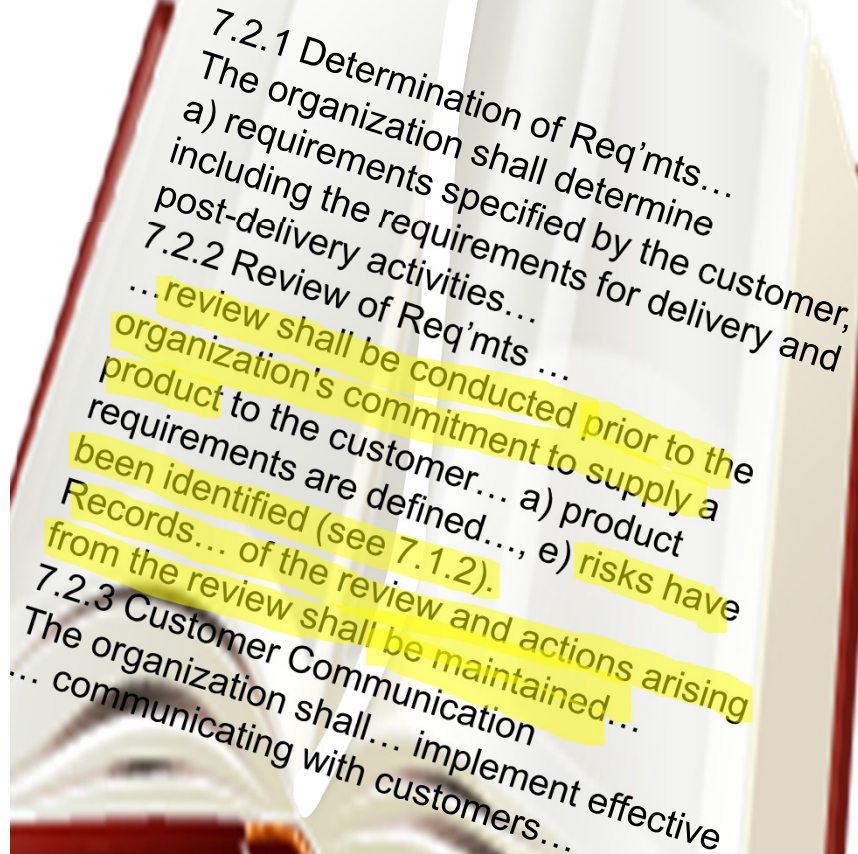
7.1.2 Risk Management
The organization shall establish, implement and maintain a process for managing risk ...

7.1.3 Configuration Management
The organization shall establish, implement and maintain a configuration management process...

7.1.4 Control of Work Transfers
The organization shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work ...

Clause 7 – Product Realization (Cont'd)

- **Records of Contract Reviews not available for all contracts**
- **No evidence that Risks have been identified with mitigation plans shown**
- **Customer specific requirements not addressed**



7.2.1 Determination of Req'mts...
The organization shall determine
a) requirements specified by the customer,
including the requirements for delivery and
post-delivery activities...
7.2.2 Review of Req'mts ...
...review shall be conducted prior to the
organization's commitment to supply a
product to the customer... a) product
requirements are defined..., e) risks have
been identified (see 7.1.2).
Records... of the review and actions arising
from the review shall be maintained...
7.2.3 Customer Communication
The organization shall... implement effective
... communicating with customers...

Clause 7 – Product Realization (Cont'd)

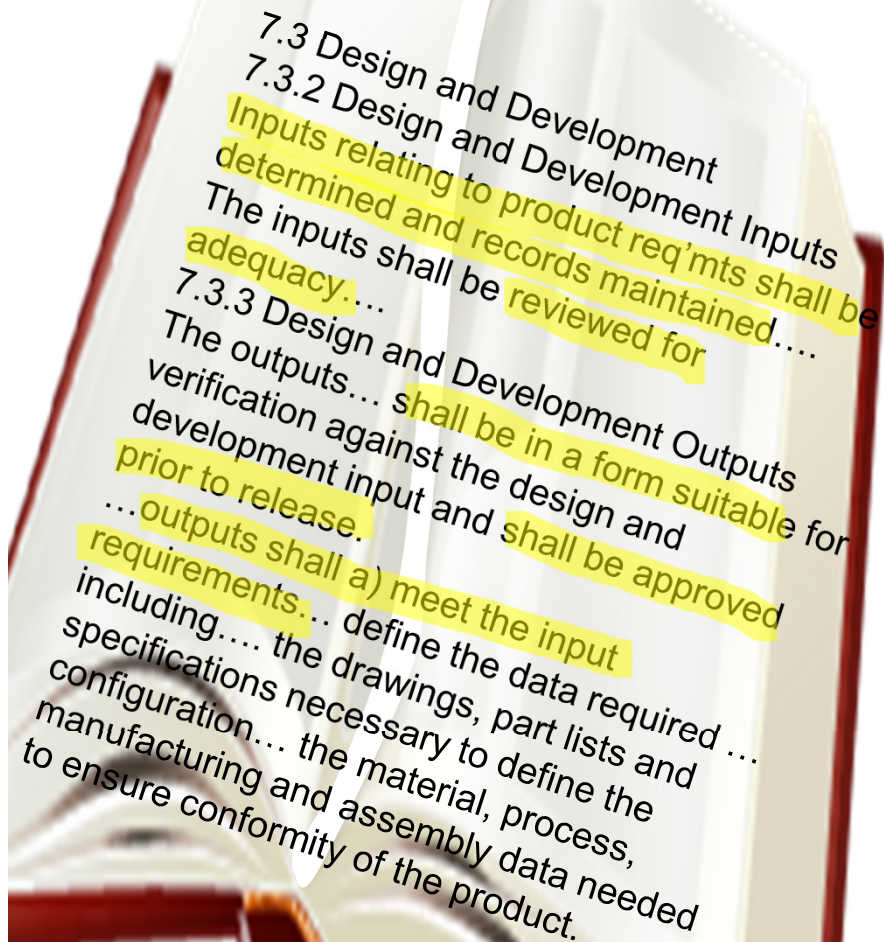
- No evidence of design plans
- Design Plans do not reflect design activities (stages) with responsibilities (and time frames) identified
- No evidence that affected groups are included with the design & development activities



7.3 Design and Development
7.3.1 Design and Development Planning
The organization shall plan and control the design and development of product.
During the design and development planning, the organization shall determine
a) the design and development stages,
...c) the responsibilities and authorities for design and development.
... Design and development planning shall consider the ability to produce, inspect, test and maintain the product.
The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility....

Clause 7 – Product Realization (Cont'd)

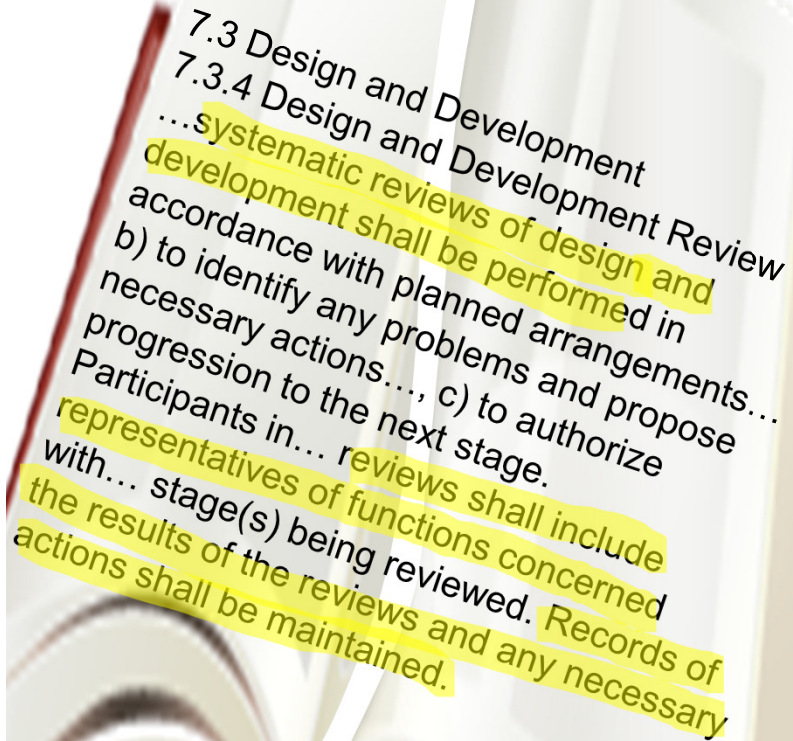
- No evidence that design outputs are reviewed prior to release
- Some of the design inputs are not addressed in the design outputs



7.3 Design and Development
7.3.2 Design and Development Inputs
Inputs relating to product req'mts shall be determined and records maintained....
The inputs shall be reviewed for adequacy....
7.3.3 Design and Development Outputs
The outputs... shall be in a form suitable for verification against the design and development input and shall be approved prior to release.
...outputs shall a) meet the input requirements... define the data required ... including... the drawings, part lists and specifications necessary to define the configuration... the material, process, manufacturing and assembly data needed to ensure conformity of the product.

Clause 7 – Product Realization (Cont'd)

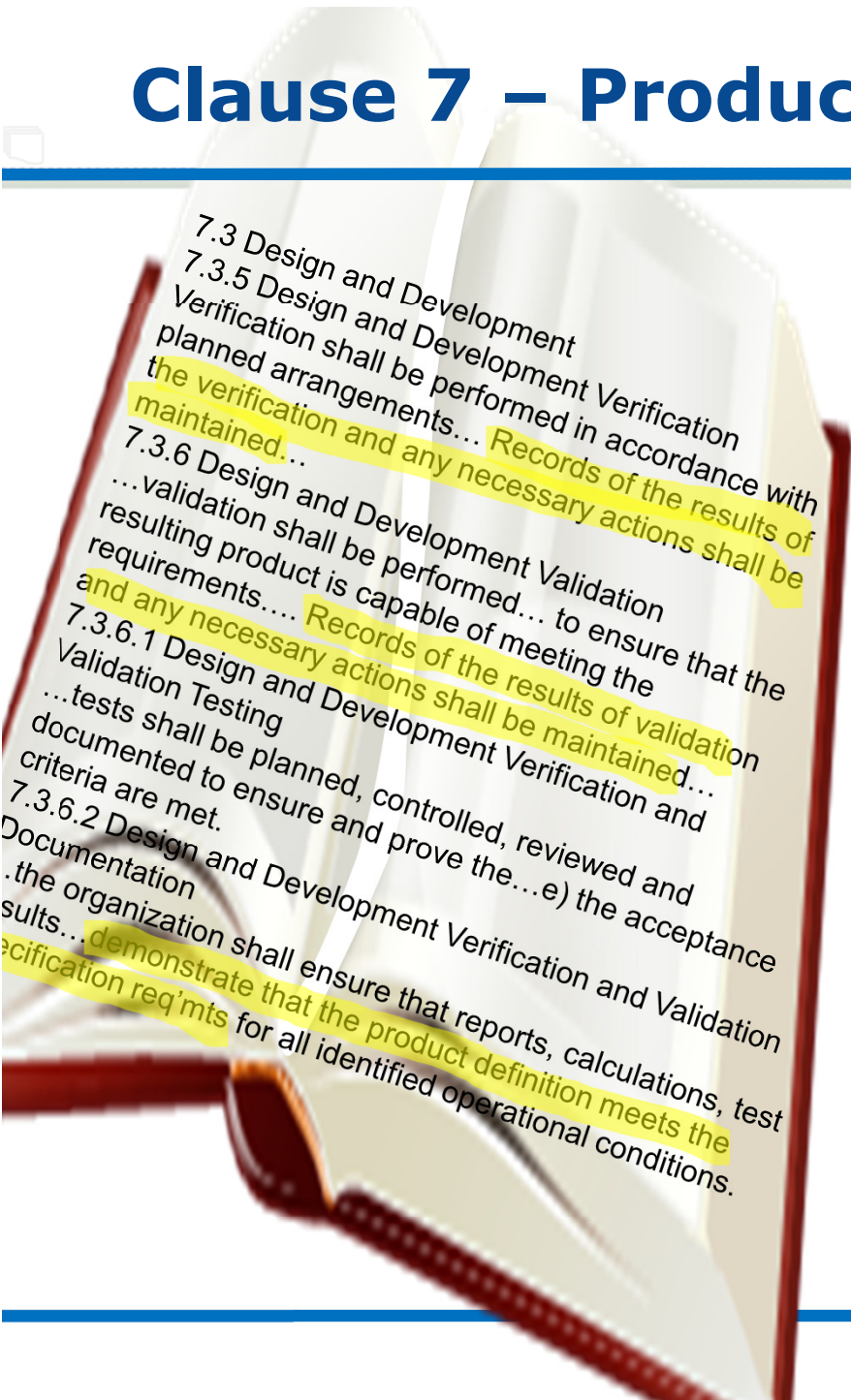
- **No records of design reviews being conducted in accordance with the design plan**
- **No evidence that affected functions are included with the design reviews**



7.3 Design and Development Review
7.3.4 Design and Development Review
...systematic reviews of design and development shall be performed in accordance with planned arrangements... b) to identify any problems and propose necessary actions..., c) to authorize progression to the next stage.
Participants in... reviews shall include representatives of functions concerned with... stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.

Clause 7 – Product Realization (Cont'd)

- **No records of verification and/or validation testing (with necessary actions).**
- **No evidence that all operational conditions have been met.**



7.3 Design and Development Verification
7.3.5 Design and Development Verification shall be performed in accordance with planned arrangements... Records of the results of the verification and any necessary actions shall be maintained...

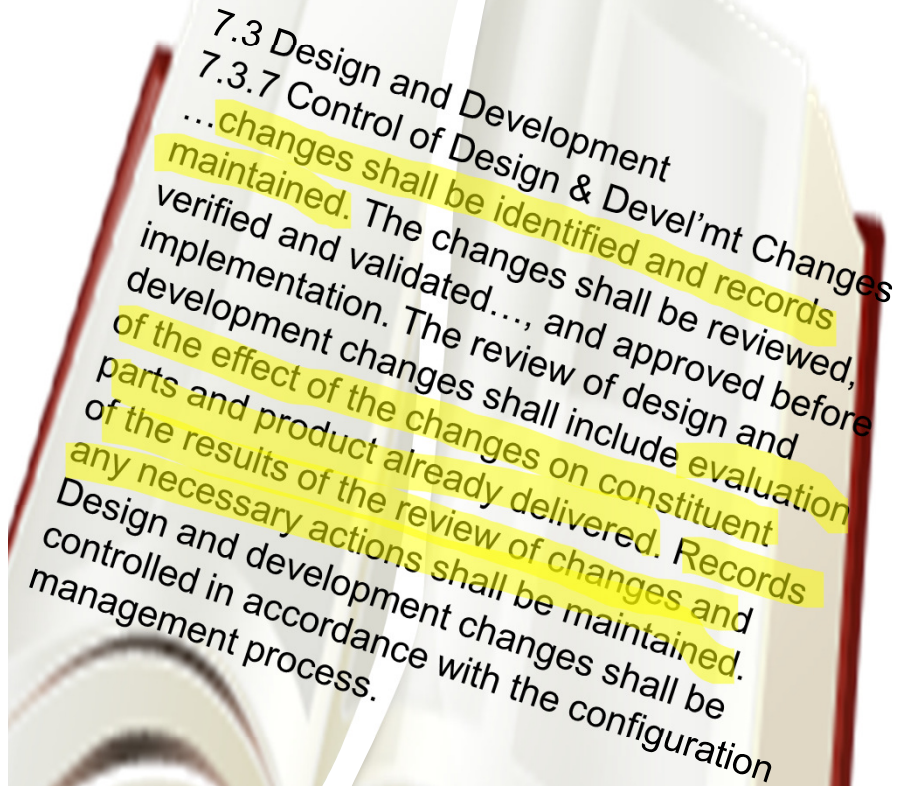
7.3.6 Design and Development Validation
...validation shall be performed... to ensure that the resulting product is capable of meeting the requirements.... Records of the results of validation and any necessary actions shall be maintained...

7.3.6.1 Design and Development Verification and Validation Testing
...tests shall be planned, controlled, reviewed and documented to ensure and prove the...e) the acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation Documentation
...the organization shall ensure that reports, calculations, test results... demonstrate that the product definition meets the specification req'ts for all identified operational conditions.

Clause 7 – Product Realization (Cont'd)

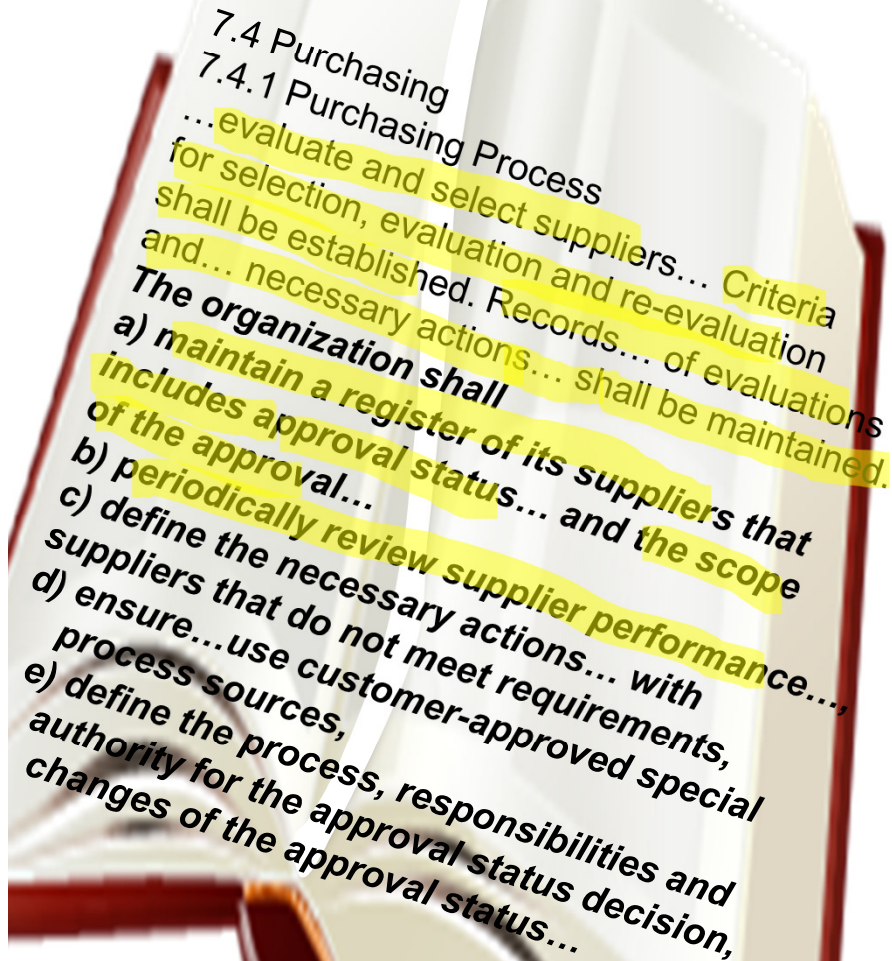
- **No records available to demonstrate that design changes considered the effect on constituent parts and product already delivered.**



7.3 Design and Development
7.3.7 Control of Design & Development Changes
...changes shall be identified and records maintained. The changes shall be reviewed, verified and validated..., and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained. Design and development changes shall be controlled in accordance with the configuration management process.

Clause 7 – Product Realization (Cont'd)

- Register of approved suppliers does not include Approval Status and/or Scope of Approval
- Register of approved suppliers does not list all suppliers that effect product quality (e.g. service providers)
- Periodic review of supplier performance not evident.



7.4 Purchasing
7.4.1 Purchasing Process
...evaluate and select suppliers... Criteria for selection, evaluation and re-evaluation shall be established. Records... of evaluations and... necessary actions... shall be maintained.
The organization shall
a) maintain a register of its suppliers that includes approval status... and the scope of the approval...
b) periodically review supplier performance...
c) define the necessary actions... with suppliers that do not meet requirements,
d) ensure...use customer-approved special process sources,
e) define the process, responsibilities and authority for the approval status decision, changes of the approval status...

Clause 7 – Product Realization (Cont'd)


➤ **No evidence that appropriate QMS requirements (and customer quality req'mts) are being flowed down to suppliers.**

- **Records retention**
- **Process or product change notification**
- **Right of Entry**
- **Customer Requirements**
 - **Defense Priority Ratings, Approved Processors, Certifications, DARS, FARS, etc.**

7.4 Purchasing Information
7.4.2 Purchasing information shall describe the . . .
Purchasing information... g) requirements
c) QMS requirements... supplier to - notify the org of
regarding... nonconforming product, - obtain org
approval for nonconforming product
disposition, - notify the org of changes in
product and/or process, changes of
suppliers, changes of mfg facility location
and... obtain org approval, and - flow
down to the supply chain the applicable
requirements including customer req'mts,
h) records retention req'mts, and i) right of
access by the org, their customer and
regulatory authorities....

Clause 7 – Product Realization (Cont'd)

- **Delegation activities not addressed and/or a register of delegations is not available or has not been maintained current.**



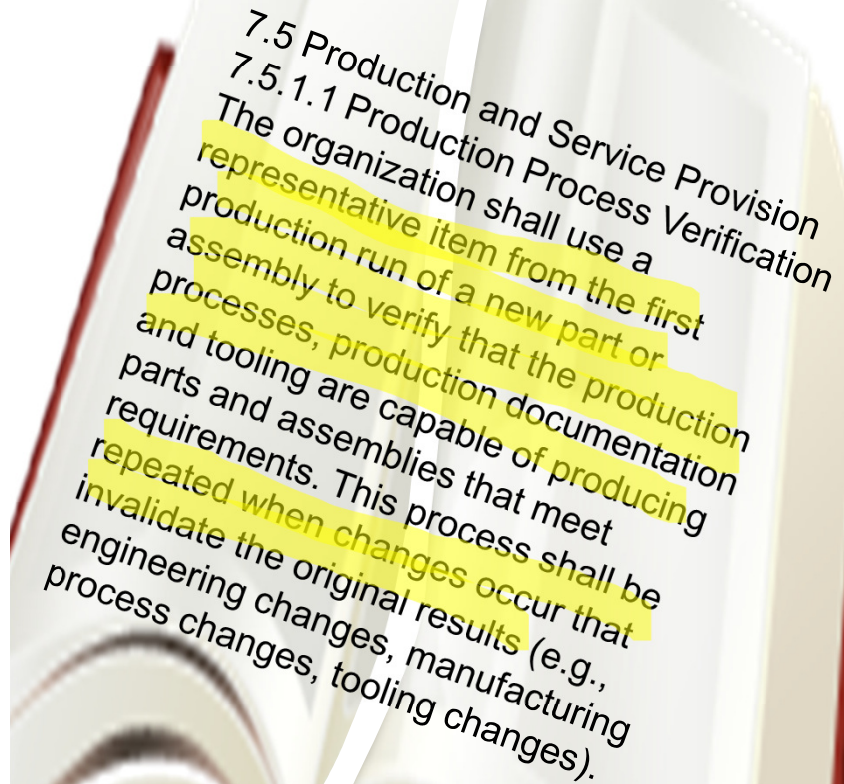
7.4 Purchasing
7.4.3 Verification of Purchased Product
The org shall... **implement the inspection or... activities necessary for ensuring... purchased product meets specified purchase req'mts...**
Where the org delegates verification activities to the supplier, the **requirements for delegation shall be defined and a register of delegations maintained.**
Where the org or its customer intends to perform verification at the supplier's premises, the org shall state the intended verification arrangements and method of product release in the purchasing information.

Clause 7 – Product Realization (Cont'd)

- **Planning (Job Tickets, Routers, etc.) not document controlled.**
- **Missed operation and/or inspection steps**
- **Accountability of all parts not evident.**
- **Referenced work instructions and/or workmanship documents not controlled**
- **No evidence of FOD provisions**

7.5 Production and Service Provision
7.5.1 Control of Production & Service Provision
The organization shall plan and carry out production and service provision under controlled conditions.... Include... b) the availability of (necessary) work instructions, c) the use of suitable equip, d) the availability and use of monitoring and measuring equip, g) accountability for all product during production verification ops have been completed... h) evidence that all production and insp / removal of foreign objects... k) criteria for workmanship... Planning shall consider... - establishing, implementing and maintaining processes to manage critical items, - designing, mfg and using tooling to measure variable data, - identifying in-process insp/verification points....

Clause 7 – Product Realization (Cont'd)



7.5 Production and Service Provision
7.5.1.1 Production Process Verification
The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

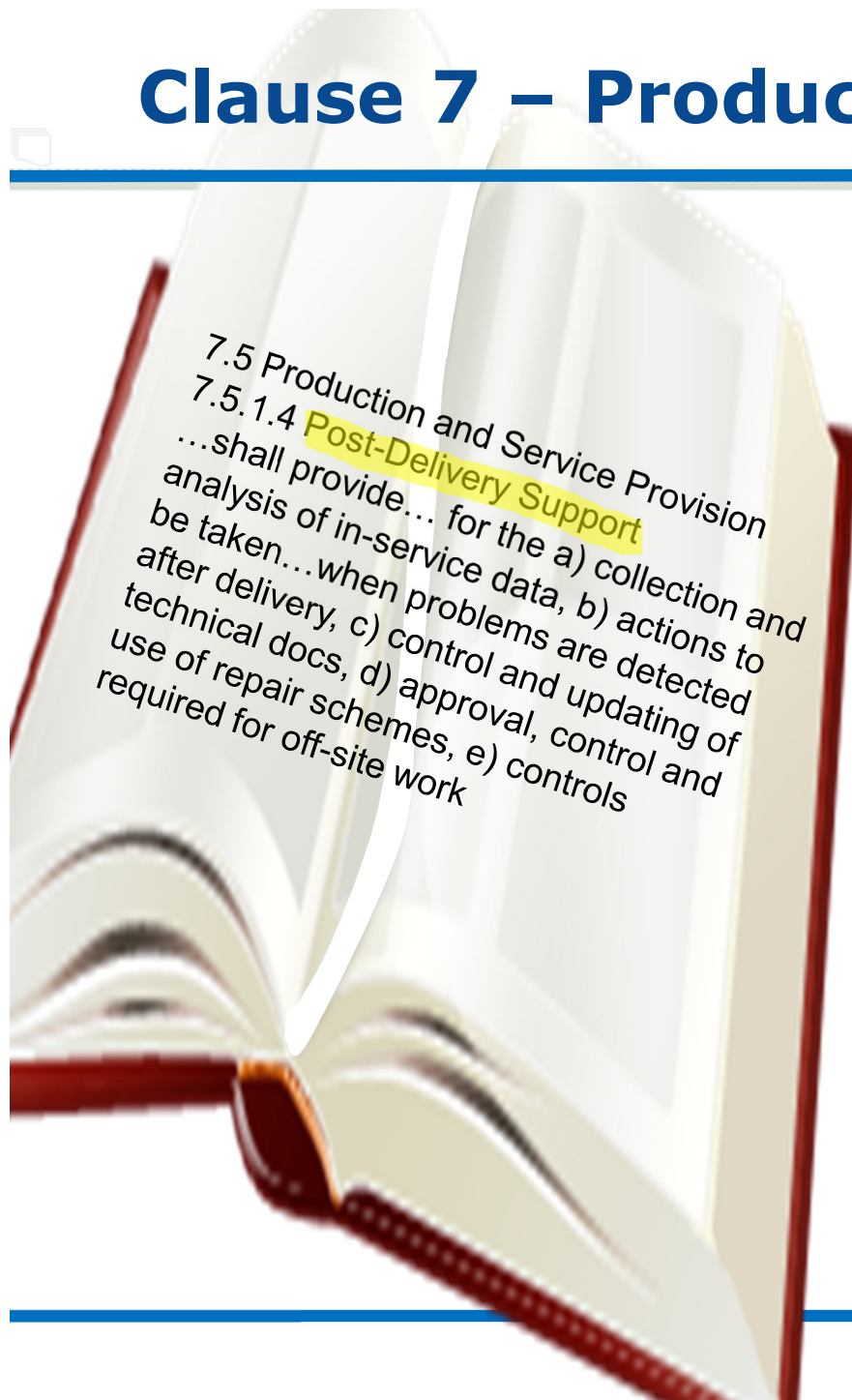
- **No evidence that a Production Process Verification (First Article Inspection) has been performed.**
- **No FAI performed since a process/tooling change.**
- **Errors on the FAI reports**

Clause 7 – Product Realization (Cont'd)

- Personnel authorized to make planning changes not identified.
- Authorized changes to planning.
- No evidence that stored production equipment or tooling is being periodic checked.

7.5 Production and Service Provision
7.5.1.2 Control of Prod Process Changes
Personnel authorized to approve changes shall be identified.
The org shall control and document changes to production processes, production equipment, tools or software programs.
The results of changes to production processes shall be assessed...
7.5.1.3 Control of Prod Equip, Tools and Software Programs
Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.
Storage requirements, including periodic preservation / condition checks, shall be defined for production equipment or tooling in storage.

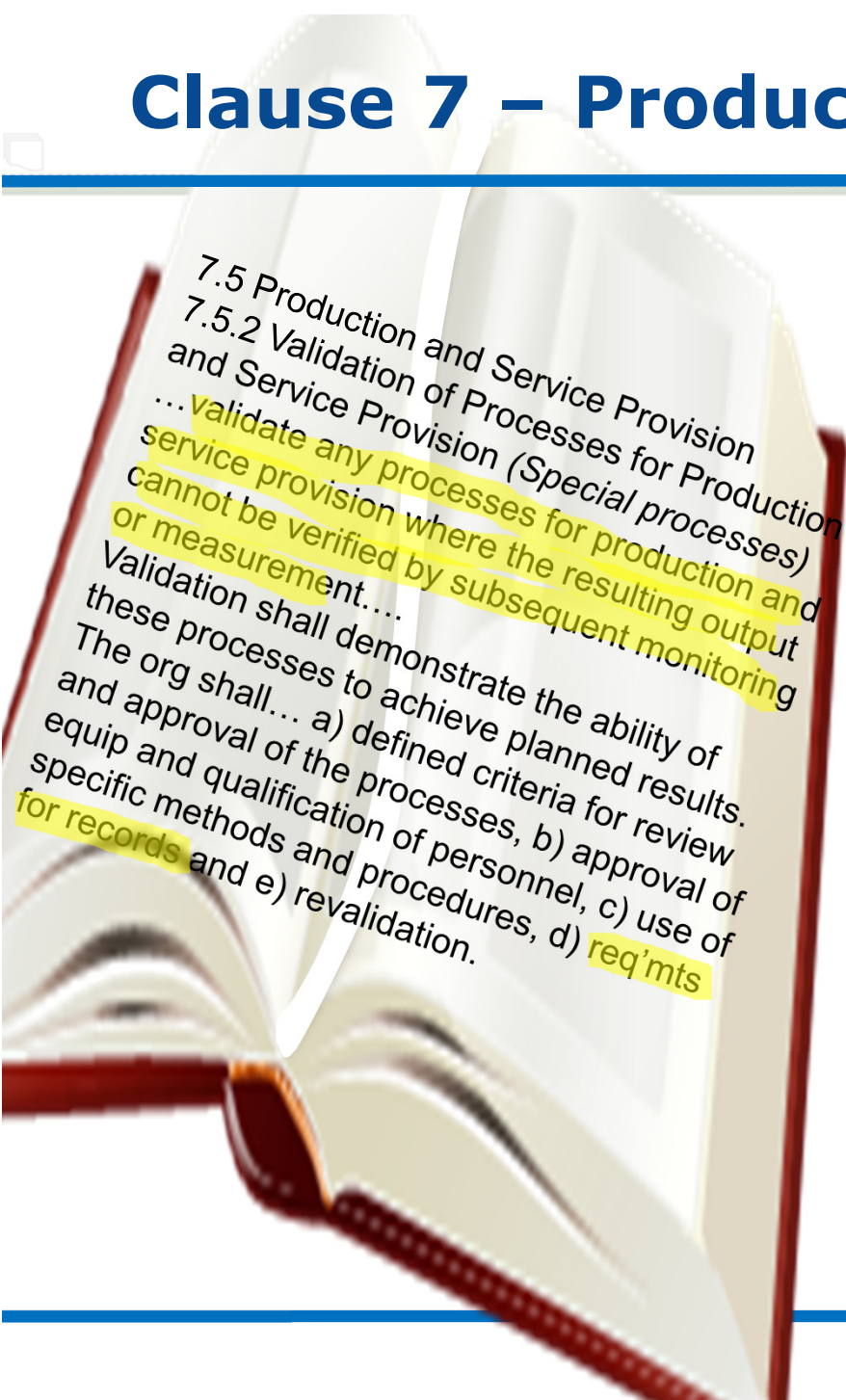
Clause 7 – Product Realization (Cont'd)



- **Post Delivery Support is often times excluded**
- **Applicable to companies that perform post-delivery support (e.g. service contracts for repair, in service training, field service support, warranty provisions, etc)**

Clause 7 – Product Realization (Cont'd)

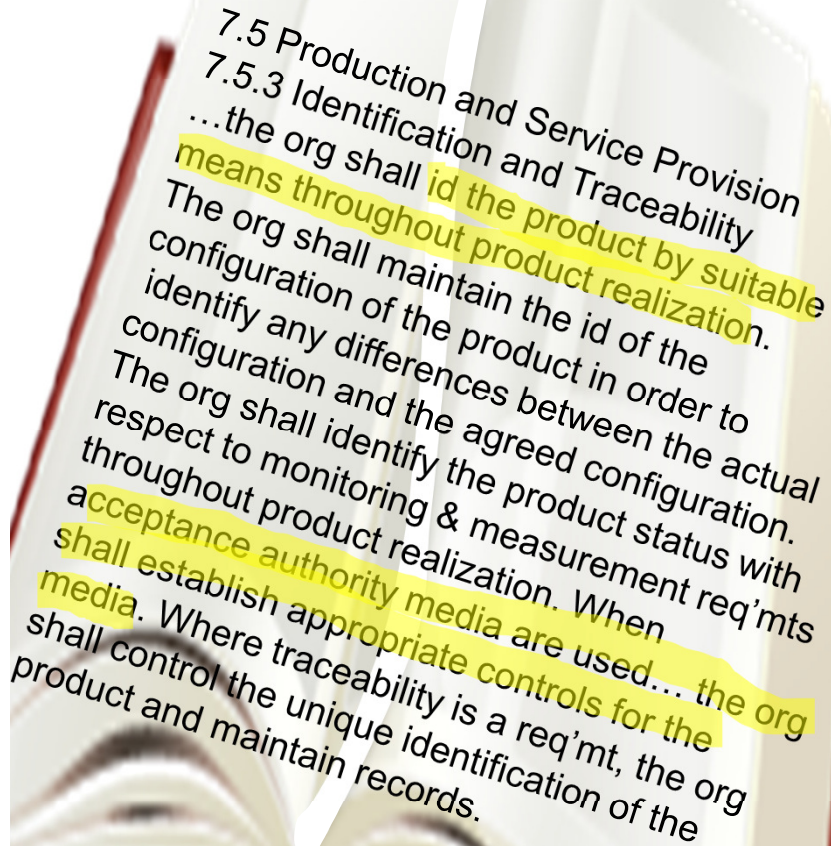
- **Special Processes not defined as such by the company.**
- **No records of special process validations and/or re-evaluations.**



7.5 Production and Service Provision
7.5.2 Validation of Processes for Production and Service Provision (Special processes)
... validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement....
Validation shall demonstrate the ability of these processes to achieve planned results. The org shall... a) defined criteria for review and approval of the processes, b) approval of equip and qualification of personnel, c) use of specific methods and procedures, d) req'mts for records and e) revalidation.

Clause 7 – Product Realization (Cont'd)

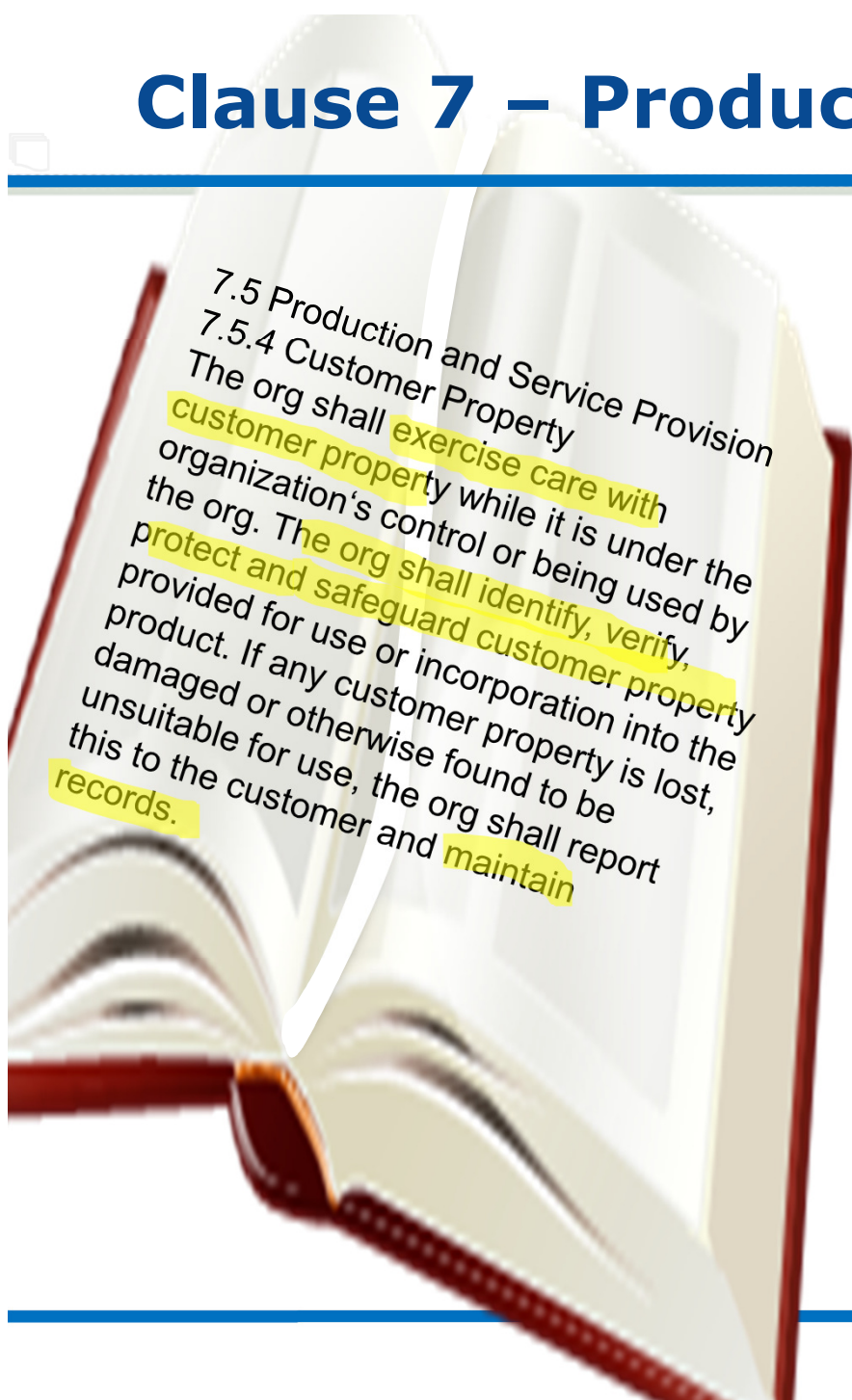
- **Inadequate stamp controls**
- **Parts in-work without product identification and/or planning paperwork.**



7.5 Production and Service Provision
7.5.3 Identification and Traceability
...the org shall **id the product by suitable means throughout product realization.**
The org shall maintain the id of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
The org shall identify the product status with respect to monitoring & measurement req'mts throughout product realization. When **acceptance authority media are used... the org shall establish appropriate controls for the media.** Where traceability is a req'mt, the org shall control the unique identification of the product and maintain records.

Clause 7 – Product Realization (Cont'd)

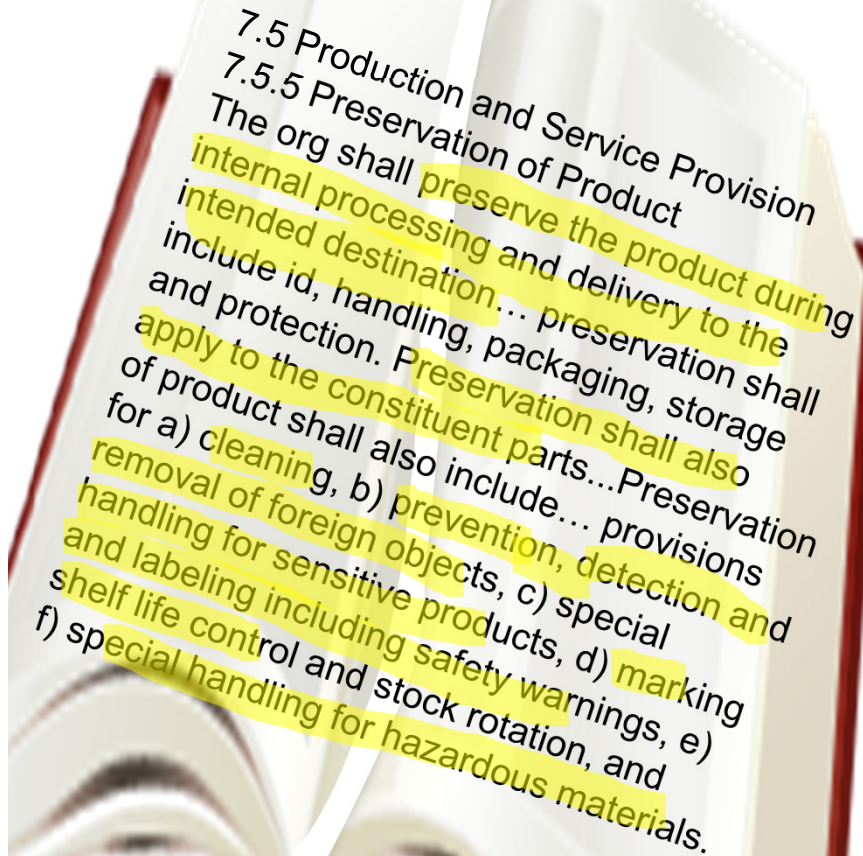
- **Inadequate control of customer property (e.g. comingling, protection against damage, etc.)**



7.5 Production and Service Provision
7.5.4 Customer Property
The org shall exercise care with customer property while it is under the organization's control or being used by the org. The org shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the org shall report this to the customer and maintain records.

Clause 7 – Product Realization (Cont'd)

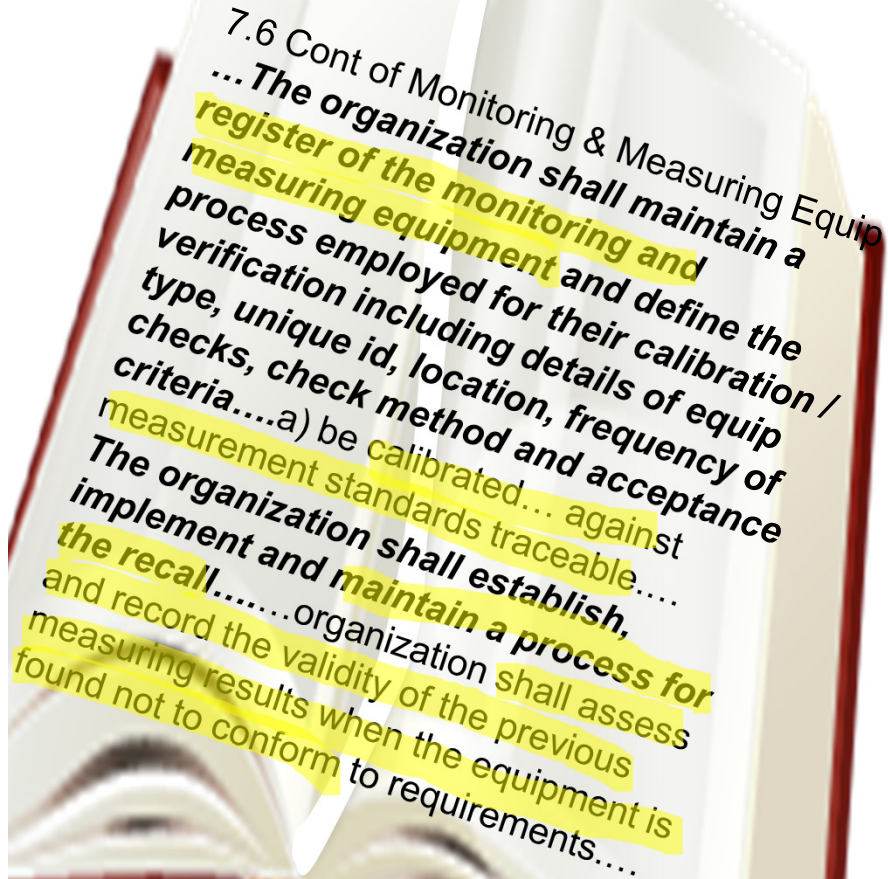
- **No provision for FOD controls in-place.**
- **Expired shelf life materials.**
- **Inadequate handling of hazardous materials.**
- **Inadequate environmental controls for stored or warehoused materials and/or parts.**



7.5 Production and Service Provision
7.5.5 Preservation of Product
The org shall preserve the product during internal processing and delivery to the intended destination... preservation shall include id, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts... Preservation of product shall also include... provisions for a) cleaning, b) prevention, detection and removal of foreign objects, c) special handling for sensitive products, d) marking and labeling including safety warnings, e) shelf life control and stock rotation, and f) special handling for hazardous materials.

Clause 7 – Product Realization (Cont'd)

- **One of the most common areas of findings are in the calibration process:**
 - **Out of Calibration equipment found in use**
 - **Delinquent equipment**
 - **Equipment not in the Calibration recall system**
 - **No records of validity assessments (when equipment is found not to conform during the calibration)**



7.6 Cont of Monitoring & Measuring Equip
...**The organization shall maintain a register of the monitoring and measuring equipment** and define the process employed for their calibration / verification including details of equip type, unique id, location, frequency of checks, check method and acceptance criteria....a) be calibrated... against measurement standards traceable....**The organization shall establish, implement and maintain a process for the recall.....organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements....**

Clause 8 – Measurement, Analysis And Improvement

8.2.2 Internal Audit
The organization shall conduct internal audits at planned intervals to determine whether the quality management system The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
.... The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

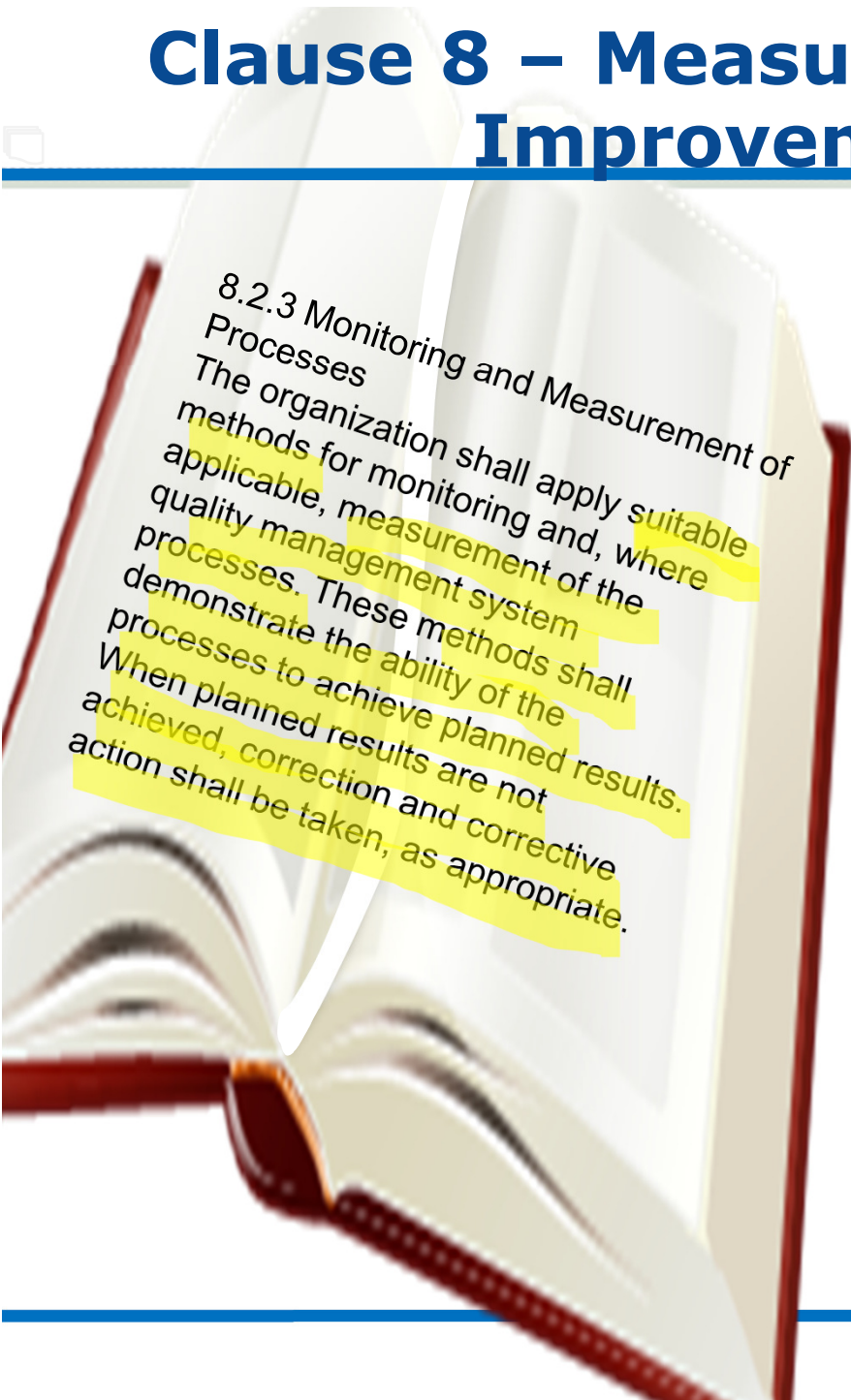
- **Issues include:**
- **Not conducting audits at the frequency defined by the company's procedure**
- **Not auditing all processes**
- **Untrained Auditors**
- **Impartiality of auditors**
- **Not documenting findings**
- **Inadequate Corrective Action**
- **Lack of Follow-up**

Clause 8 – Measurement, Analysis And Improvement (Cont'd)

➤ Issues include:

- **Inadequate or no monitors and measures for QMS processes (linked to 4.1a)**
- **No evidence that action plans are in-place for underachieving measures**

Note: Monitors can be various methods, but must relate to the activities of the processes and demonstrate the ability of the processes to achieve planned results. (e.g. metrics, measurement devices w/controls, etc.)



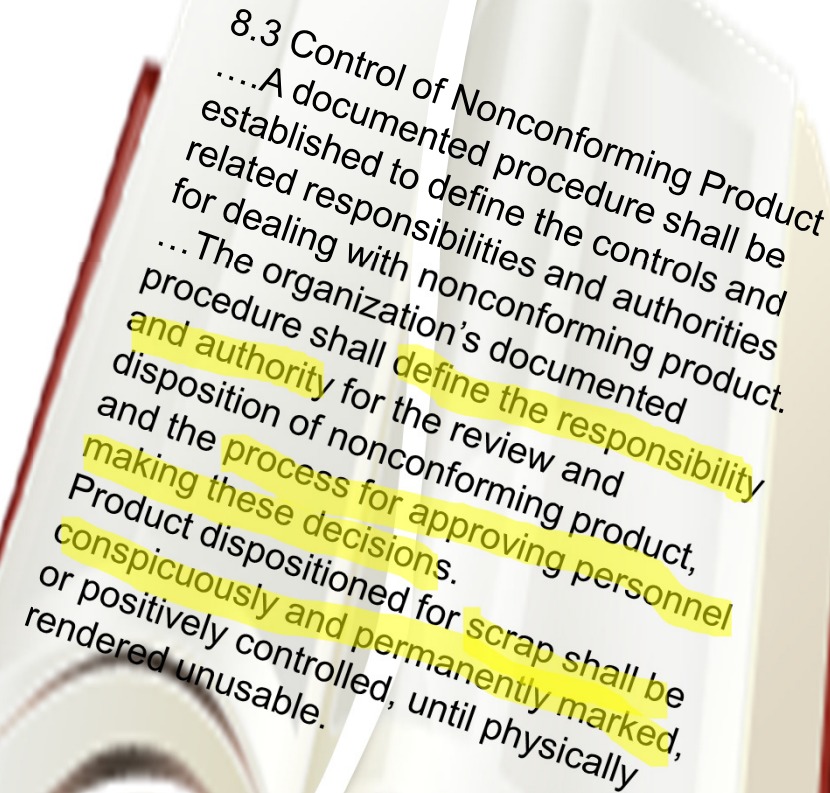
8.2.3 Monitoring and Measurement of Processes
The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

Clause 8 – Measurement, Analysis And Improvement (Cont'd)

8.2.4 Monitoring & Measurement of Product
... Evidence of conformity with the acceptance criteria shall be maintained. Measurement requirements for product acceptance shall be documented and shall include...
b) where in the sequence measurement and testing operations are to be performed,
c) required records of the measurement results ...
...the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use...

- **Common issues include:**
 - **Missing acceptance for operations (inspection and/or manufacturing)**
 - **Unauthorized planning changes**
 - **Questionable sampling plans**

Clause 8 – Measurement, Analysis And Improvement (Cont'd)

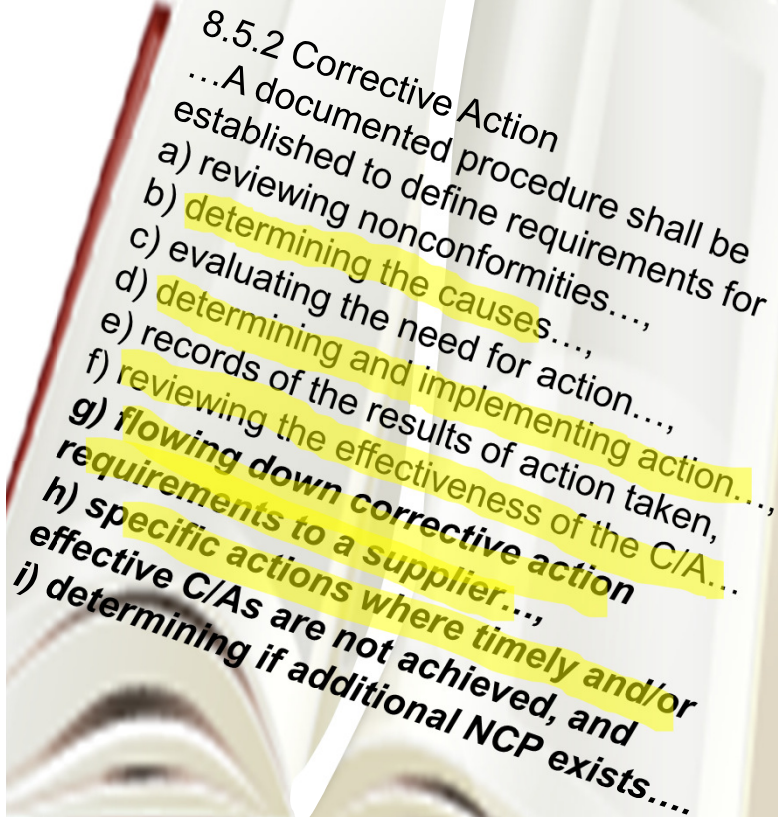


8.3 Control of Nonconforming Product
....A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.
...The organization's documented procedure shall **define the responsibility and authority** for the review and disposition of nonconforming product, and the **process for approving personnel making these decisions.**
Product disposed for **scrap shall be conspicuously and permanently marked,** or positively controlled, until physically rendered unusable.

- **Control of Nonconforming Product procedure must:**
 - **Define the responsibility and authority for the review and disposition of NCP**
 - **NCP procedure must define the process for approving personnel making disposition decisions.**
- **Scrap must conspicuously and permanently marked or positively controlled, until physically rendered unusable.**

Clause 8 – Measurement, Analysis And Improvement (Cont'd)

- **Common problem areas include:**
 - **Lack of good Root Cause analysis**
 - **Lack of acceptable Corrective Actions**
 - **Lack of timely implementation of corrective actions**
 - **Lack of documented follow-up activities**
 - **Lack of supplier CARs**
 - **Lack of Customer Complaint documentation and/or corrective actions**

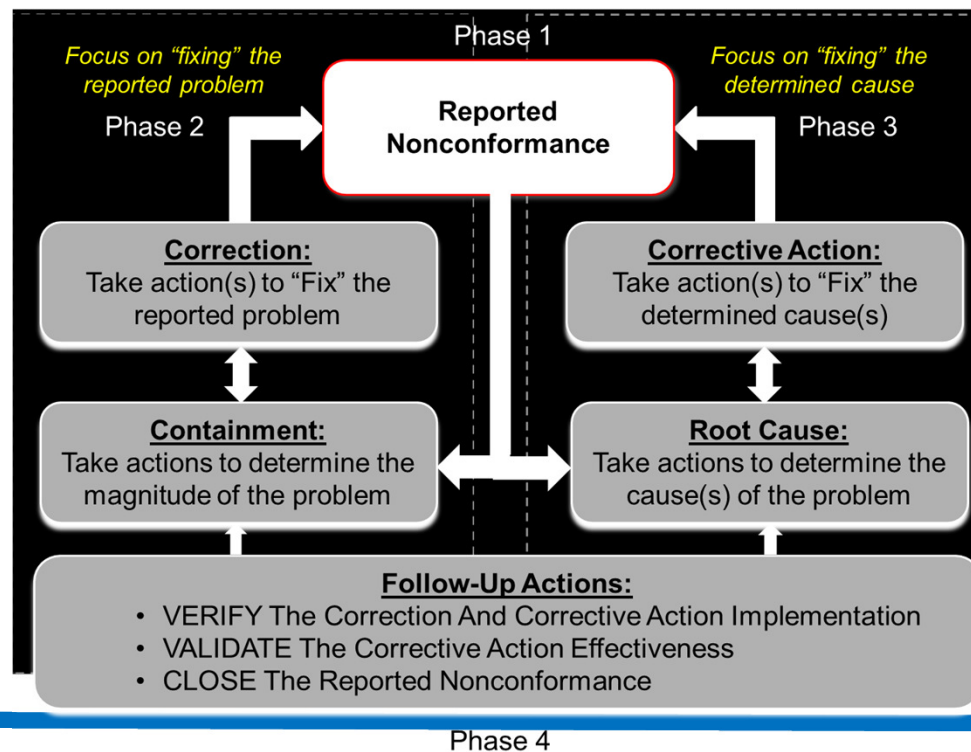


8.5.2 Corrective Action
...A documented procedure shall be established to define requirements for

- a) reviewing nonconformities....,
- b) **determining the causes....,**
- c) evaluating the need for action....,
- d) **determining and implementing action....,**
- e) records of the results of action taken,
- f) **reviewing the effectiveness of the C/A....,**
- g) **flowing down corrective action requirements to a supplier....,**
- h) **specific actions where timely and/or effective C/As are not achieved, and**
- i) **determining if additional NCP exists....**

Corrective Action

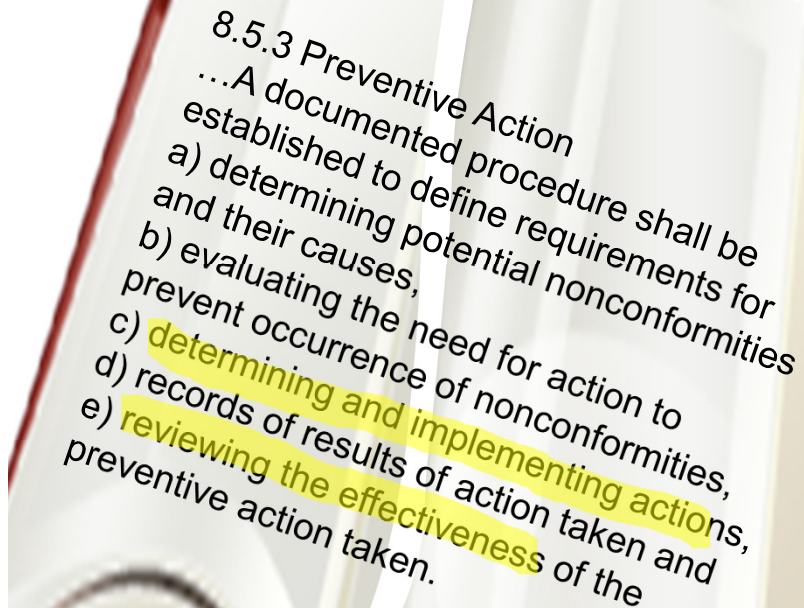
- **The number one reasons audit packages get rejected is for poor corrective action**
- **The number one reason companies get suspended is for poor corrective action**
 - Lack of restoring conformity within 60 days
 - Same (or similar) findings on consecutive audits



Clause 8 – Measurement, Analysis And Improvement (Cont'd)

➤ Issues include:

- **Lack of documented Preventive Actions**
- **Lack of timely actions being taken**
- **Lack of documented Follow-up activities**



8.5.3 Preventive Action
...A documented procedure shall be established to define requirements for
a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) **determining and implementing actions,**
d) records of results of action taken and
e) **reviewing the effectiveness** of the preventive action taken.

Final Thoughts

- **Keys to a Successful audit include:**
 - Good Process Identifications
 - Good Process Measures/Actions
 - Good Management Reviews
 - Good Internal Audits
 - Good Corrective Actions
 - Good Customer Focus

QUESTIONS



IAQG FAQ Link
<http://www.sae.org/iaqg/projects/9100faq.pdf>