PERRY JOHNSON REGISTRARS™

# AS9100C Pitfalls

*"Common Problem Areas"*

**Larry Beck**

November 2014

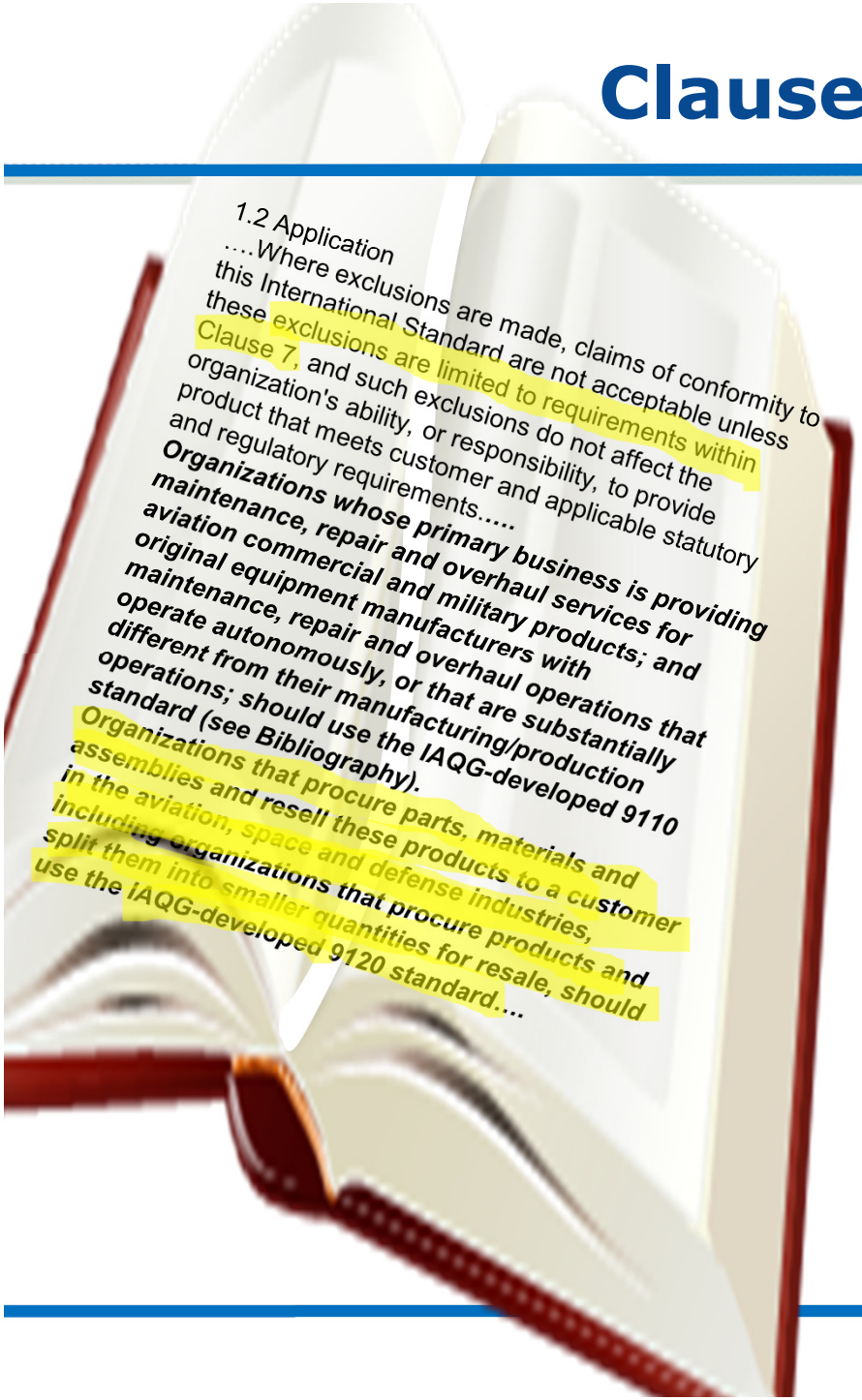
# Discussion Approach

- **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



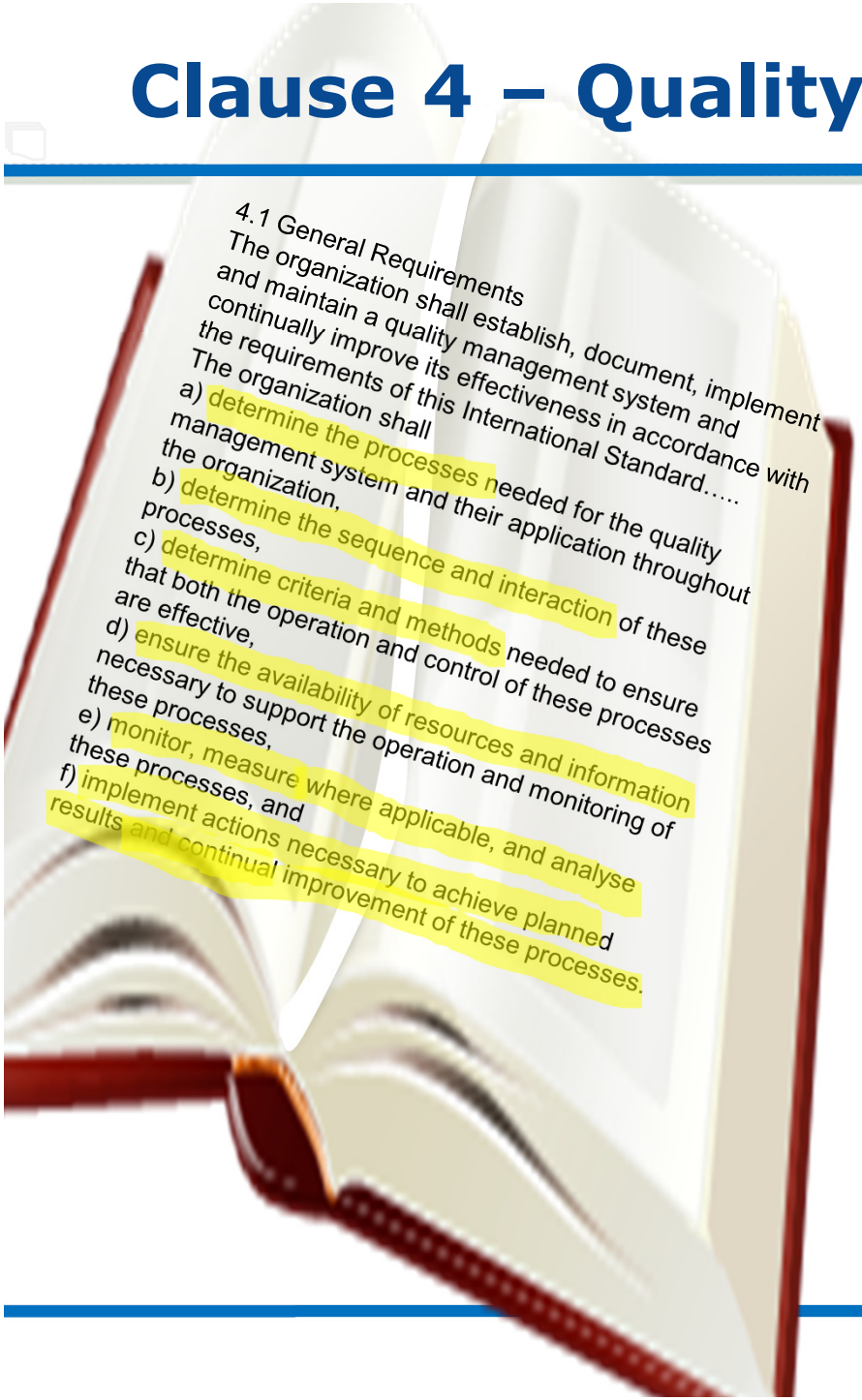

- **Issue with exclusions:**
  - **Post Delivery Support 7.5.1.4b if warranty work is accomplished**
  - **Applicable standard** (AS9100, AS9110, AS9120)
- **Scope** (SIC, EA, NACE)
- **Site Designation** (Single, Multiple, Campus, Several. Complex)

*Note: No exclusions can be made outside of Clause 7*

# Clause 2 – Normative References
# Clause 3 – Terms & Definitions

- **No common issues in these Clauses**

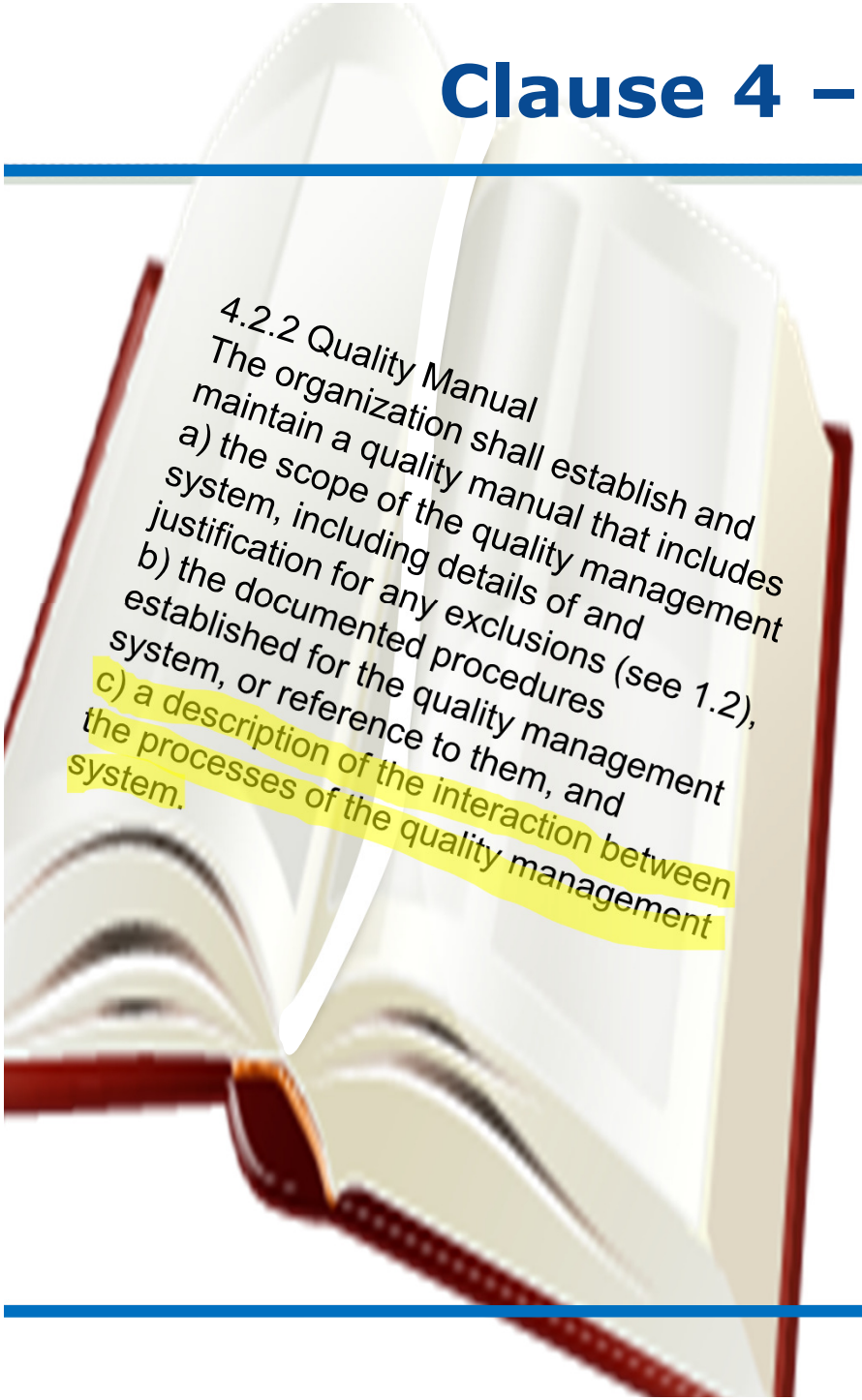
# Clause 4 – Quality Management System




- **Inadequate definition of QMS processes**
  - **Linked to Quality Manual (4.2.2c) and Process Monitoring & Measurement of Processes8.2.3**
  - **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.**

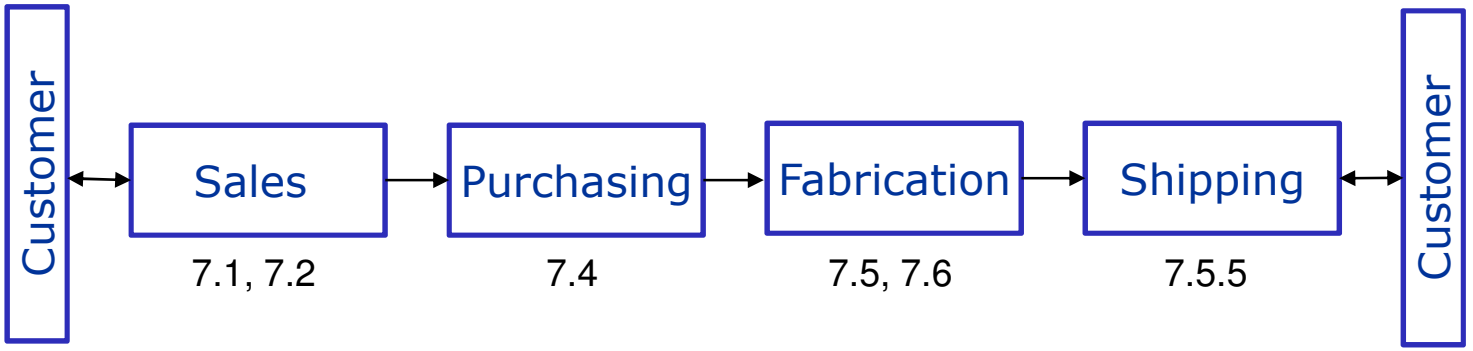
PERRY JOHNSON REGISTRARS™

# 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.*

# Acceptable IOP?

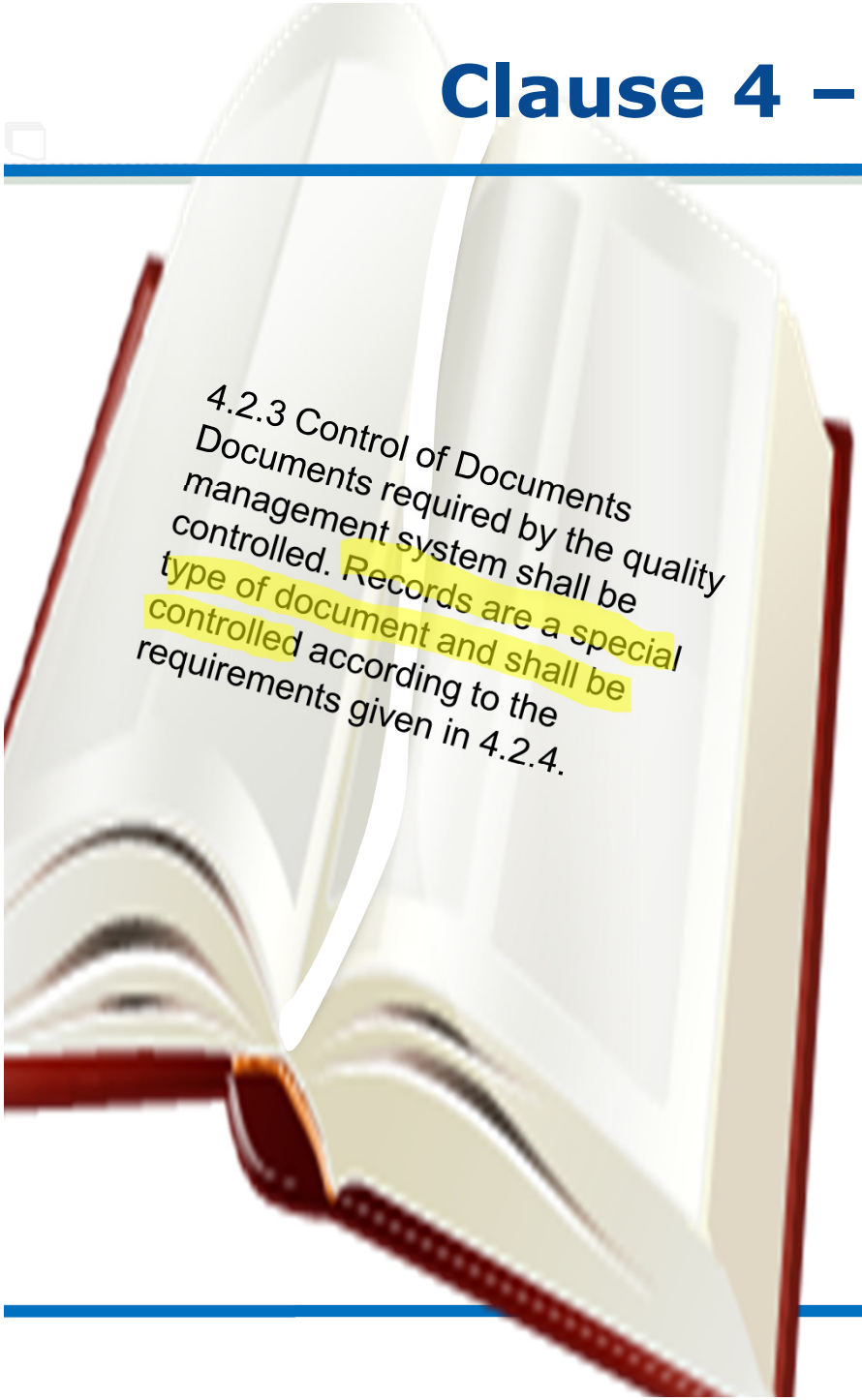



- **Is this an acceptable IOP?**
- **Does it clearly descript the interaction between processes?**
- **Does it include all the QMS clauses?**

*(Where are Clauses 4, 5, 6, 8?*

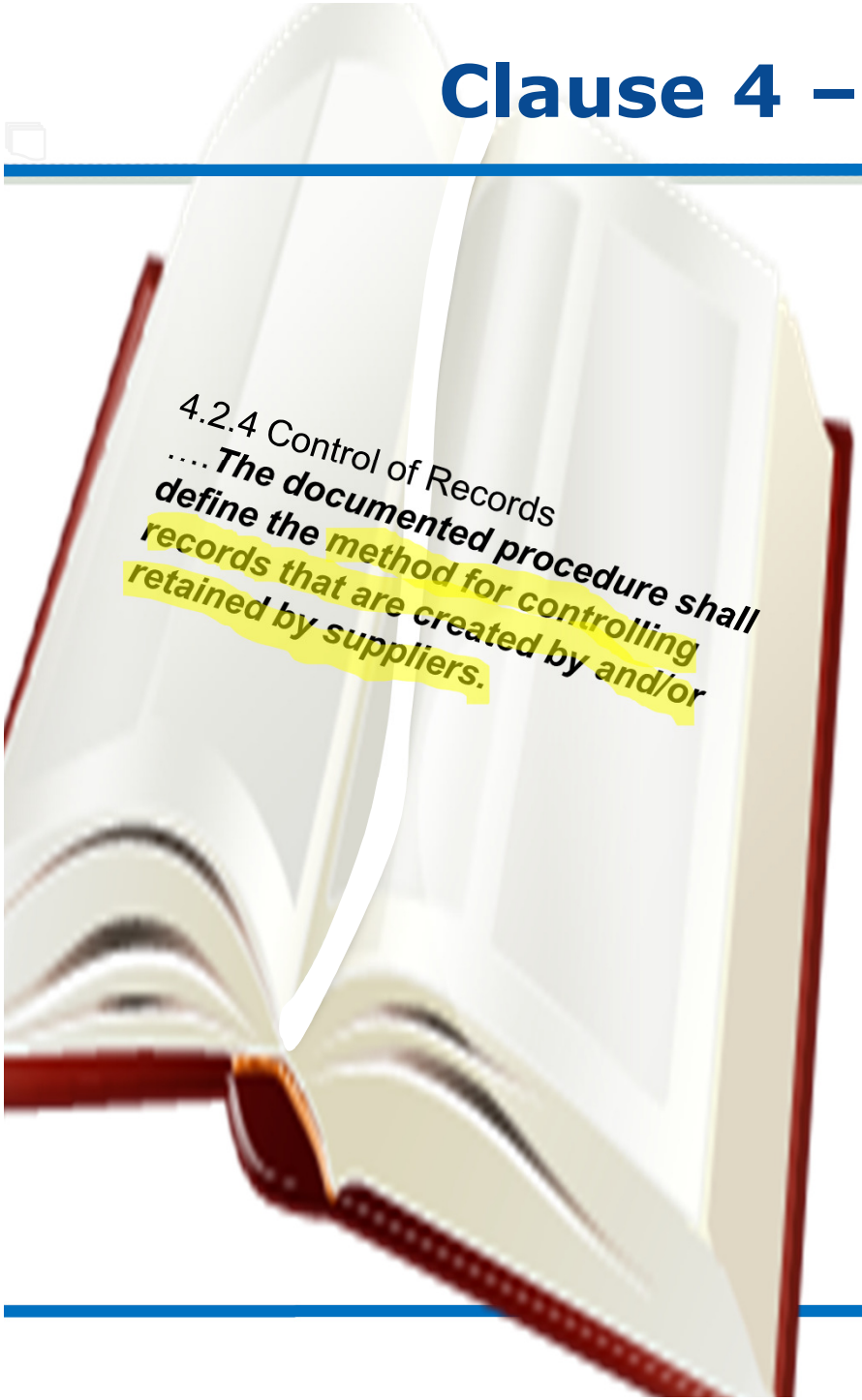
Requirement (4.1a)
…The organization shall
a) determine the processes needed for the QMS.
Requirement (4.2.2c)
…a quality manual that includes
c) a description of the interaction between the processes of the QMS.

# Clause 4 – QMS (Cont'd)



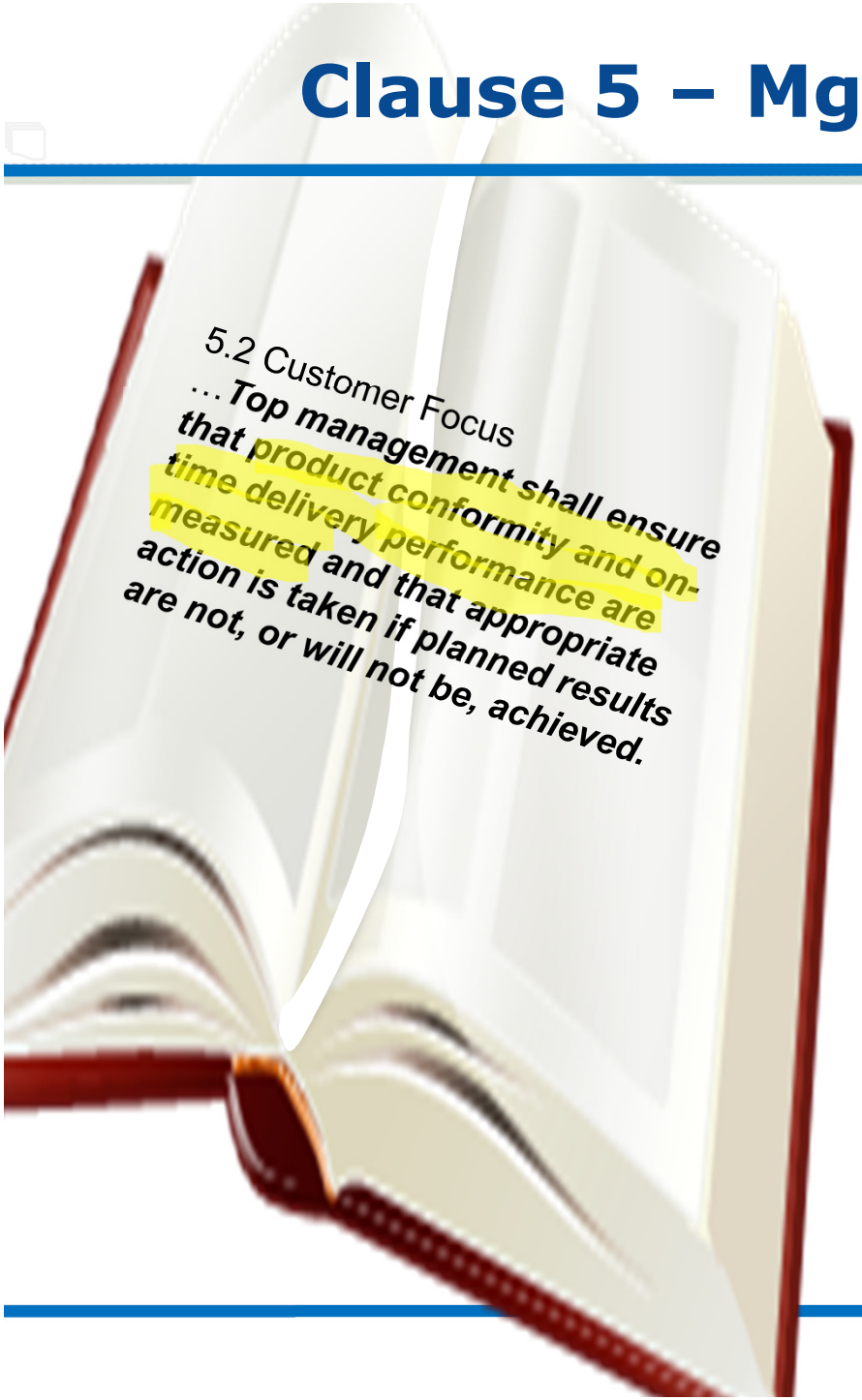

- **Inadequate control of forms (documents)**
  - **Forms used to record evidence of Quality Management System (4.2.4 reference) or product compliance or customer required must reflect document controls (release date, revision letter, etc.)**

# Clause 4 – QMS (Cont'd)



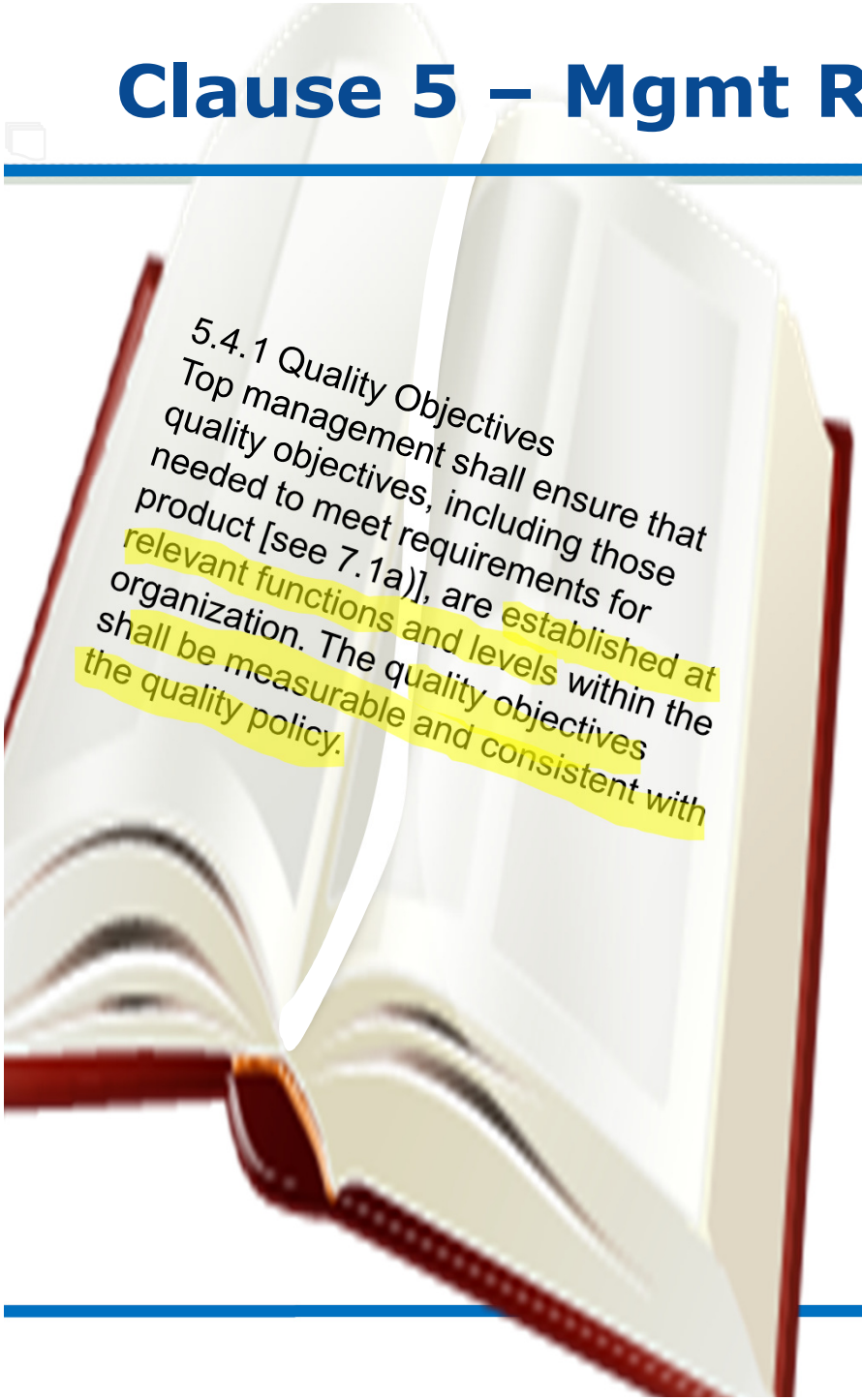

- **Control of Records procedure must define the <u>method</u> for controlling records created by and/or retained by suppliers**
  - **Often times the procedure says the company does it, but does not define the method.**
  - **Expected controls should consider the type of records, the retention times, the retrieval expectations and any specific customer flow down requirements.**

# Clause 5 – Mgmt Responsibility



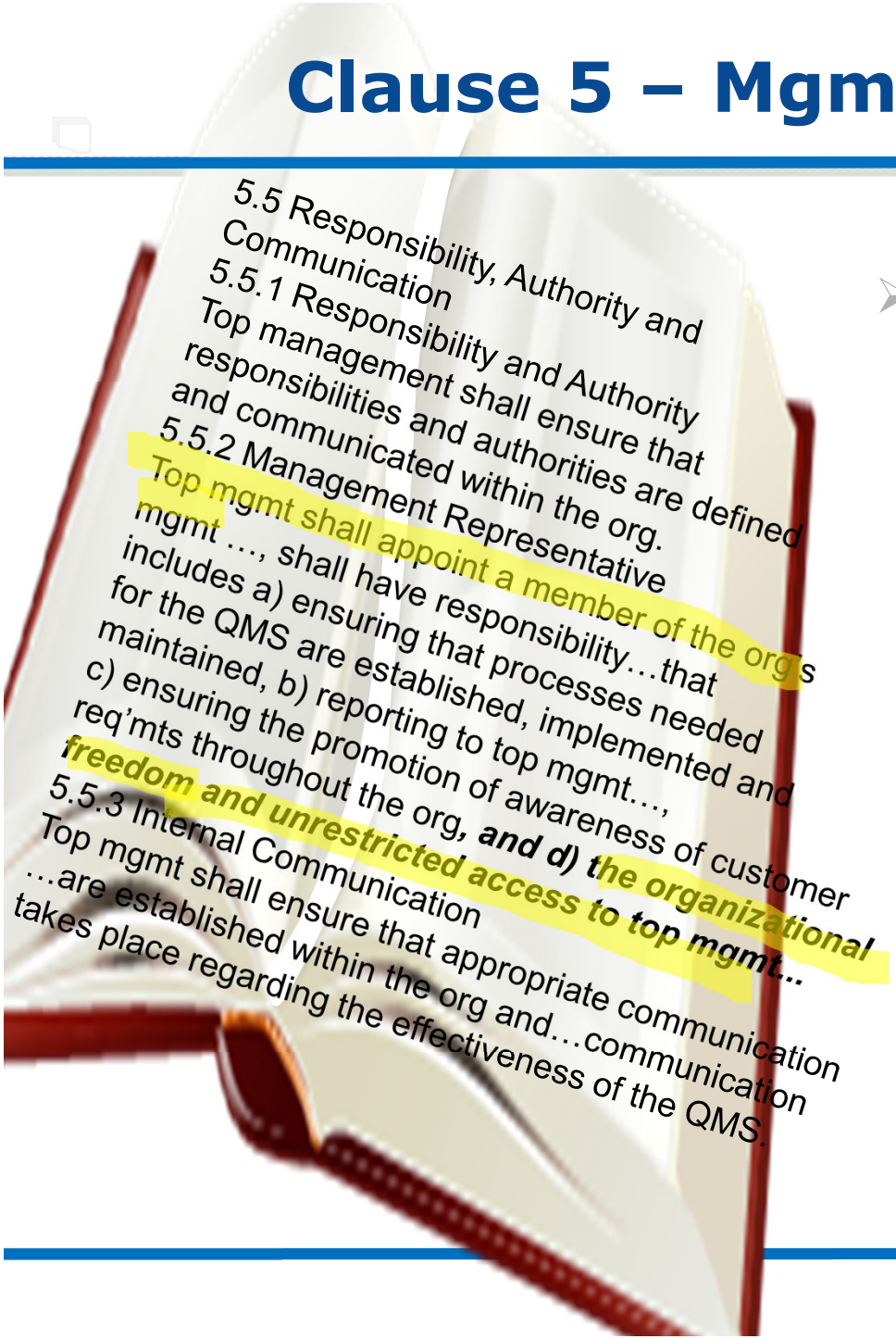

- **As a minimum Product Conformity and On-Time Delivery must be measured and appropriate actions taken if planned results are not achieved.**
  - **Expectation that the Quality and OTD measures are:**
    - **consistent with customer requirements**
    - **aim for enhancing customer satisfaction**

# Clause 5 – Mgmt Responsibility (Cont'd)



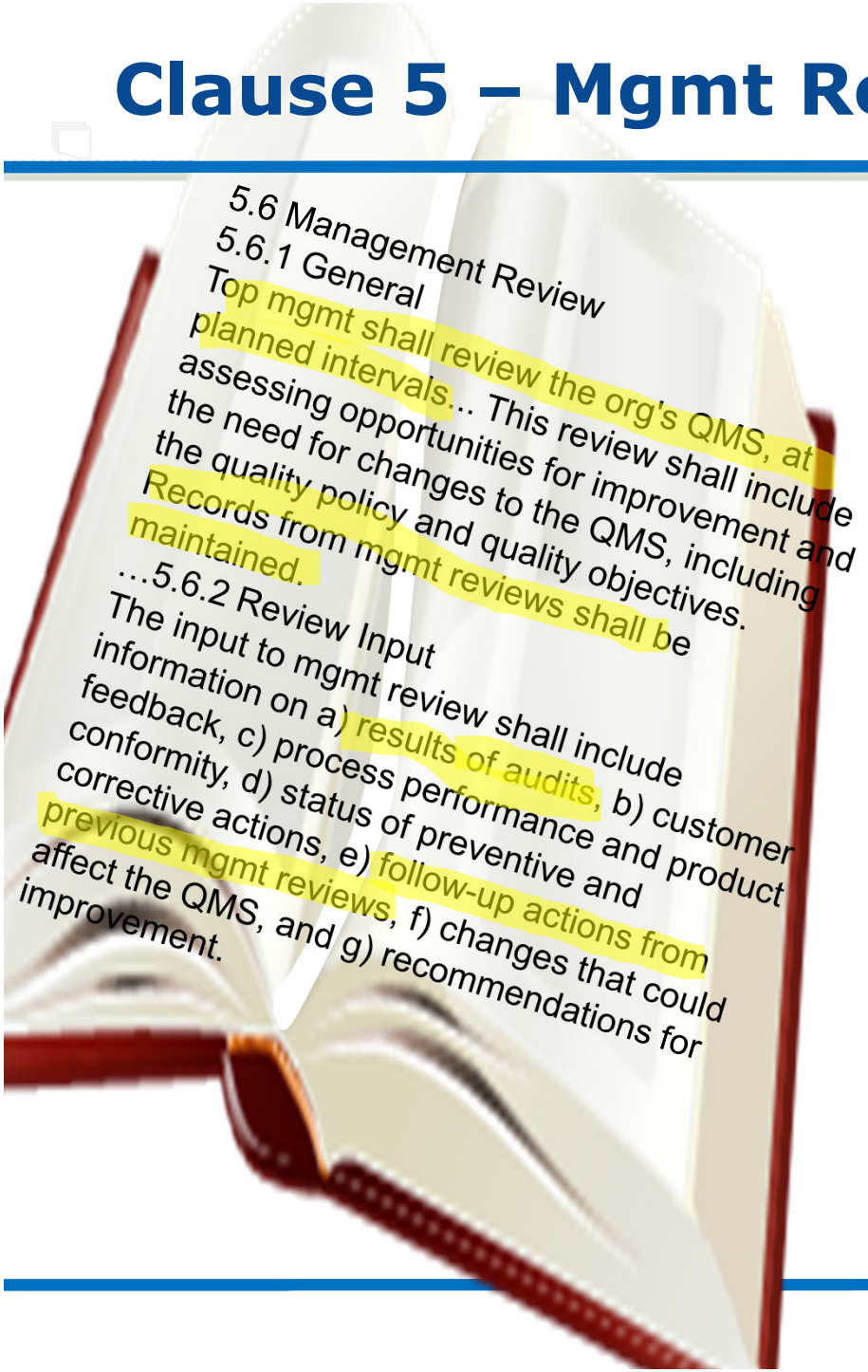

- **Quality Objectives must be established for relevant functions and levels of the organization (linked to 4.1a)**
- **Quality Objectives must be measureable**
- **Quality Objectives must be consistent (support) the Quality Policy (linked to 5.3) for continual improvement.**
- *Note: Quality Objectives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

# Clause 5 – Mgmt Responsibility



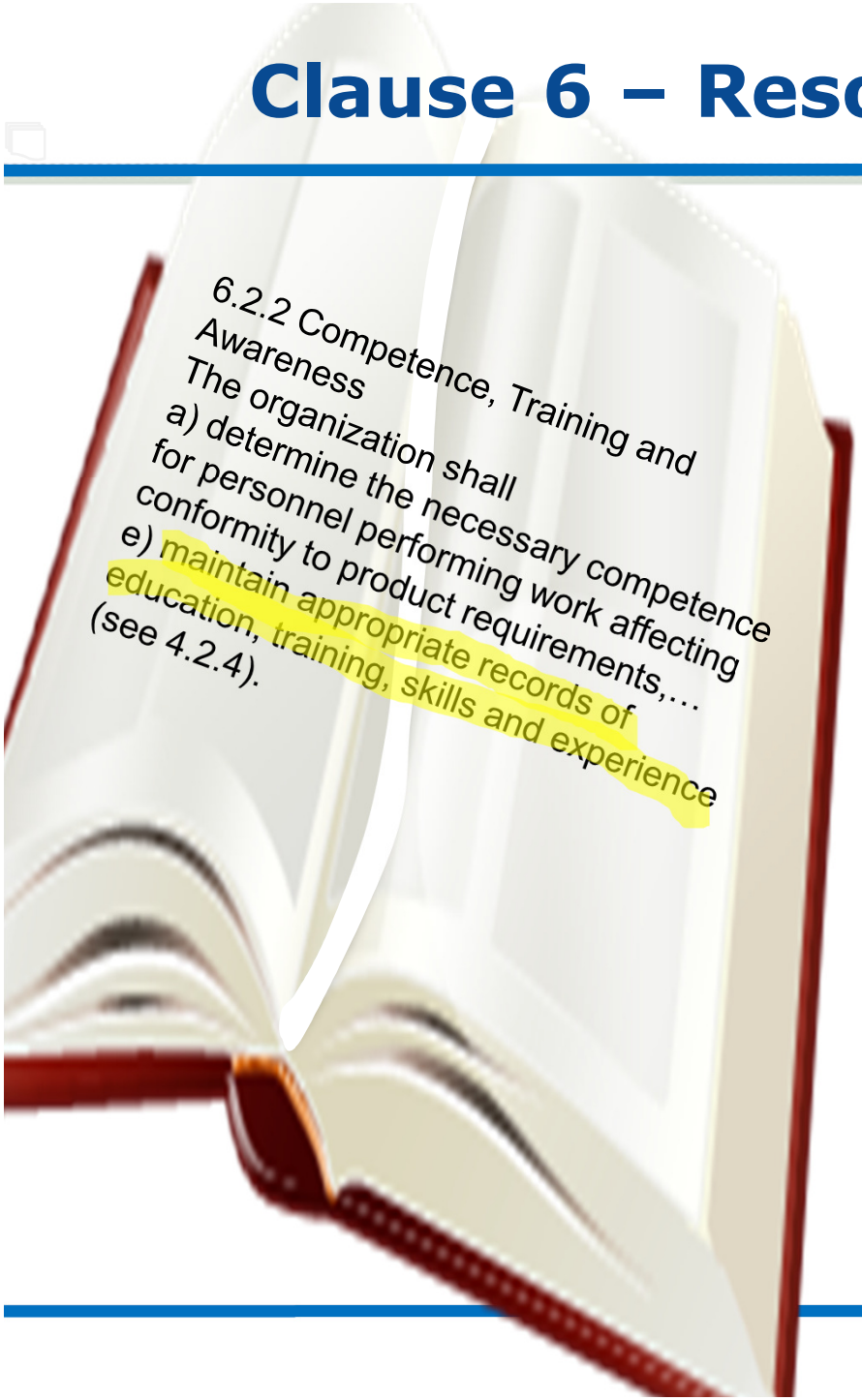

- **Management Rep must be appointed from the company's management team.**
  - **Mgmt Rep is sometimes inappropriately identified as an outside consultant**

# Clause 5 – Mgmt Responsibility (Cont'd)



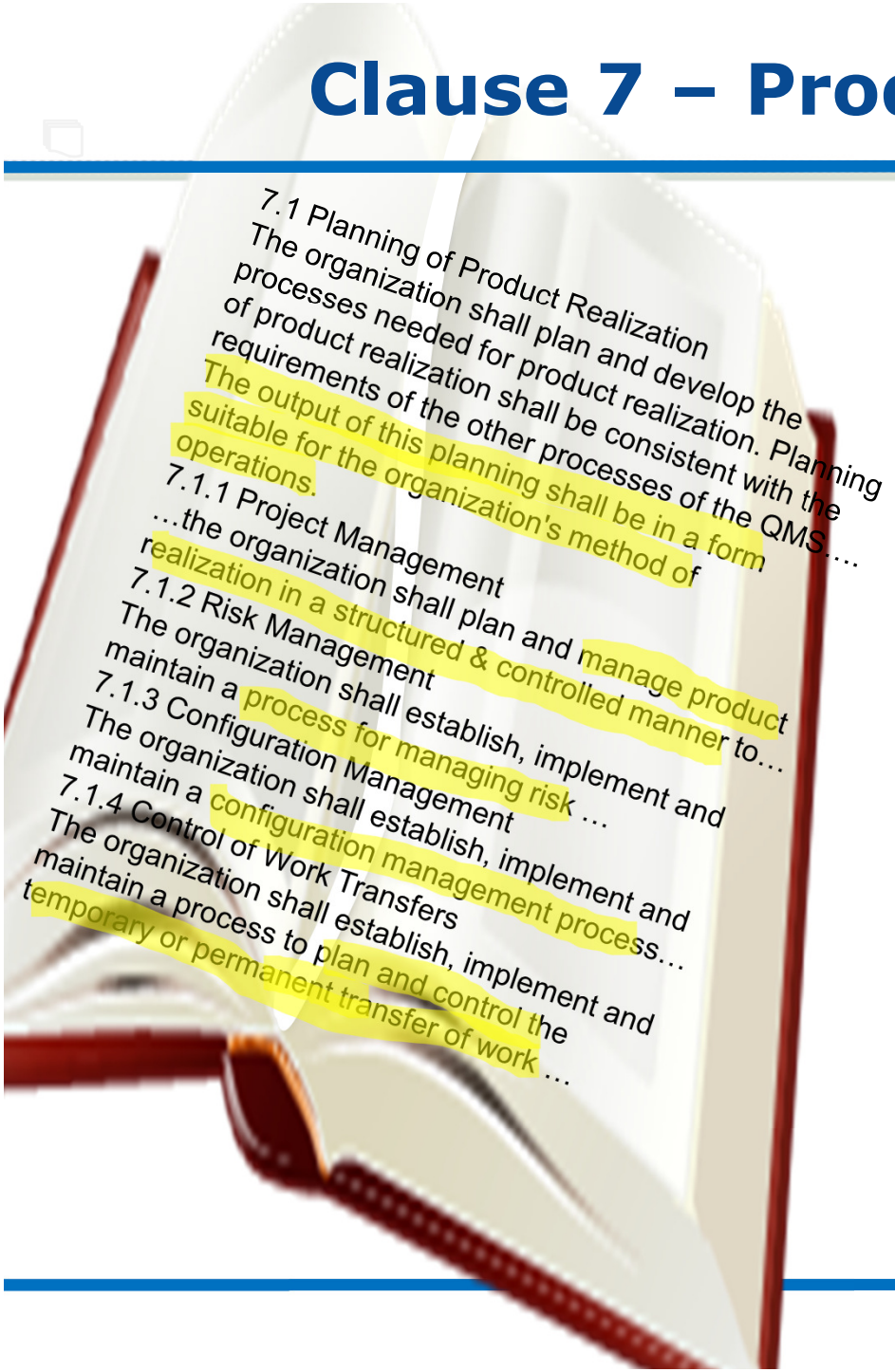

- **Inadequate Management Review Records**
  - **Management Review records only reflect a review of internal audits**
  - **Lack of Objective Evidence that Action Items from previous meetings are closed**
- **Issues with of Management Review Effectiveness include:**
  - **Lack of Action Items**
  - **Effective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

# Clause 6 – Resource Management




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

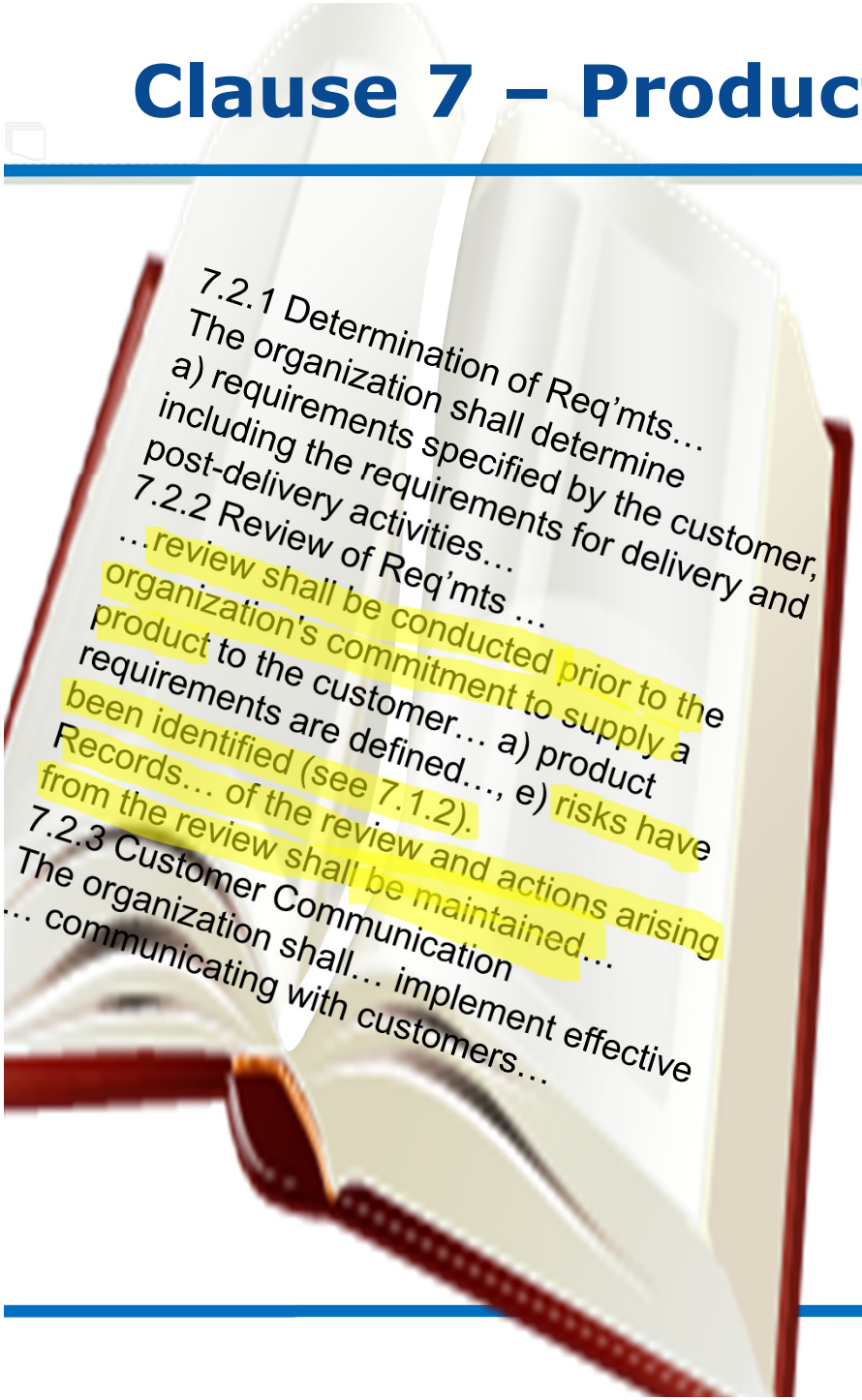
# Clause 7 – Product Realization




- **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)**

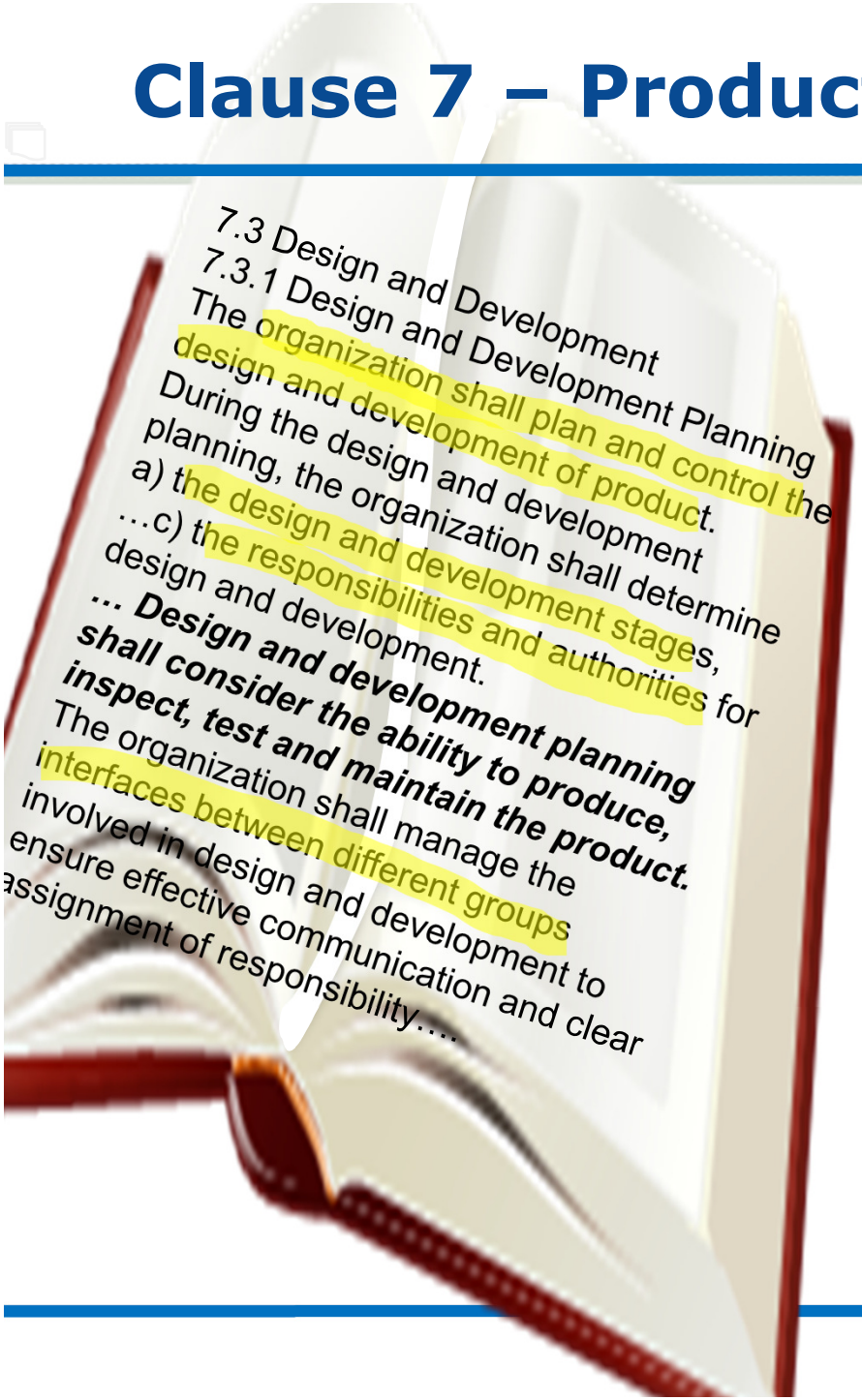
PERRY JOHNSON REGISTRARS™

# Clause 7 – Product Realization (Cont'd)



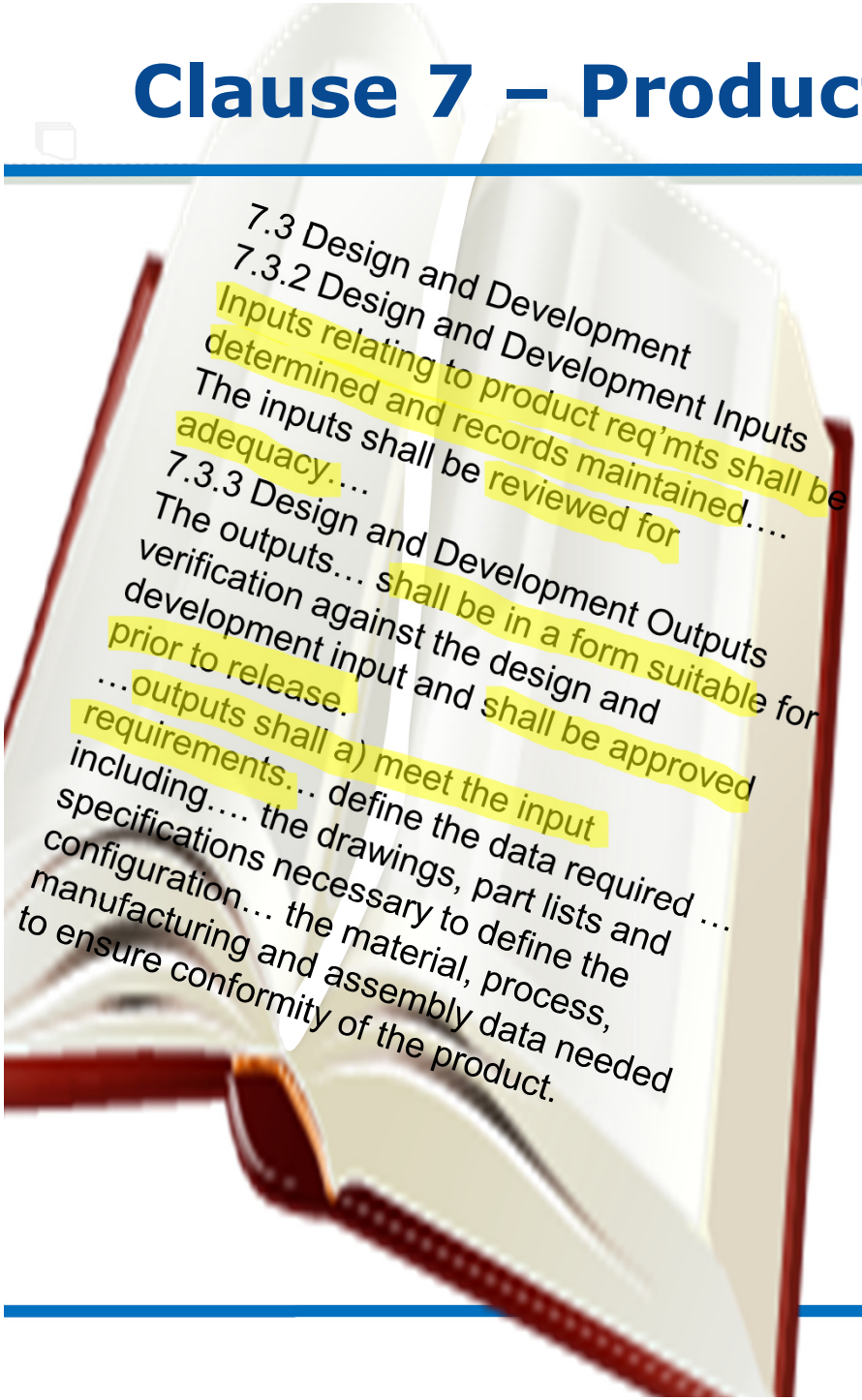

- **Records of Contract Reviews not available for all contracts**
- **No evidence that Risks have been identified with mitigation plans shown**
- **Customer specific requirements not addressed**

# Clause 7 – Product Realization (Cont'd)



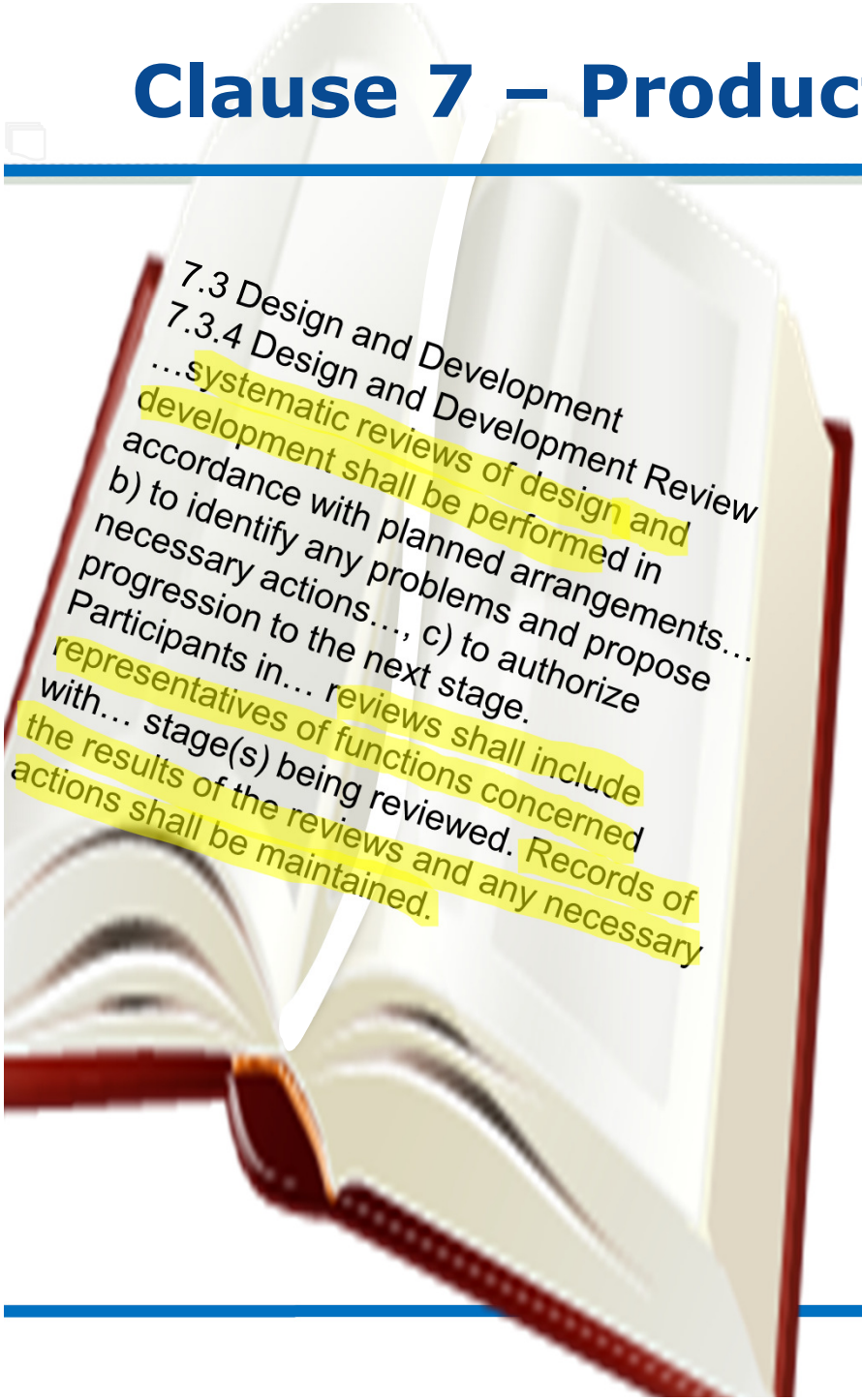

- **No evidence of design plans**
- **Design Plans do not reflect design activities (stages) with responsibilities (and time frames) identified**
- **No evidence that affected groups are included with the design & development activities**

# Clause 7 – Product Realization (Cont'd)



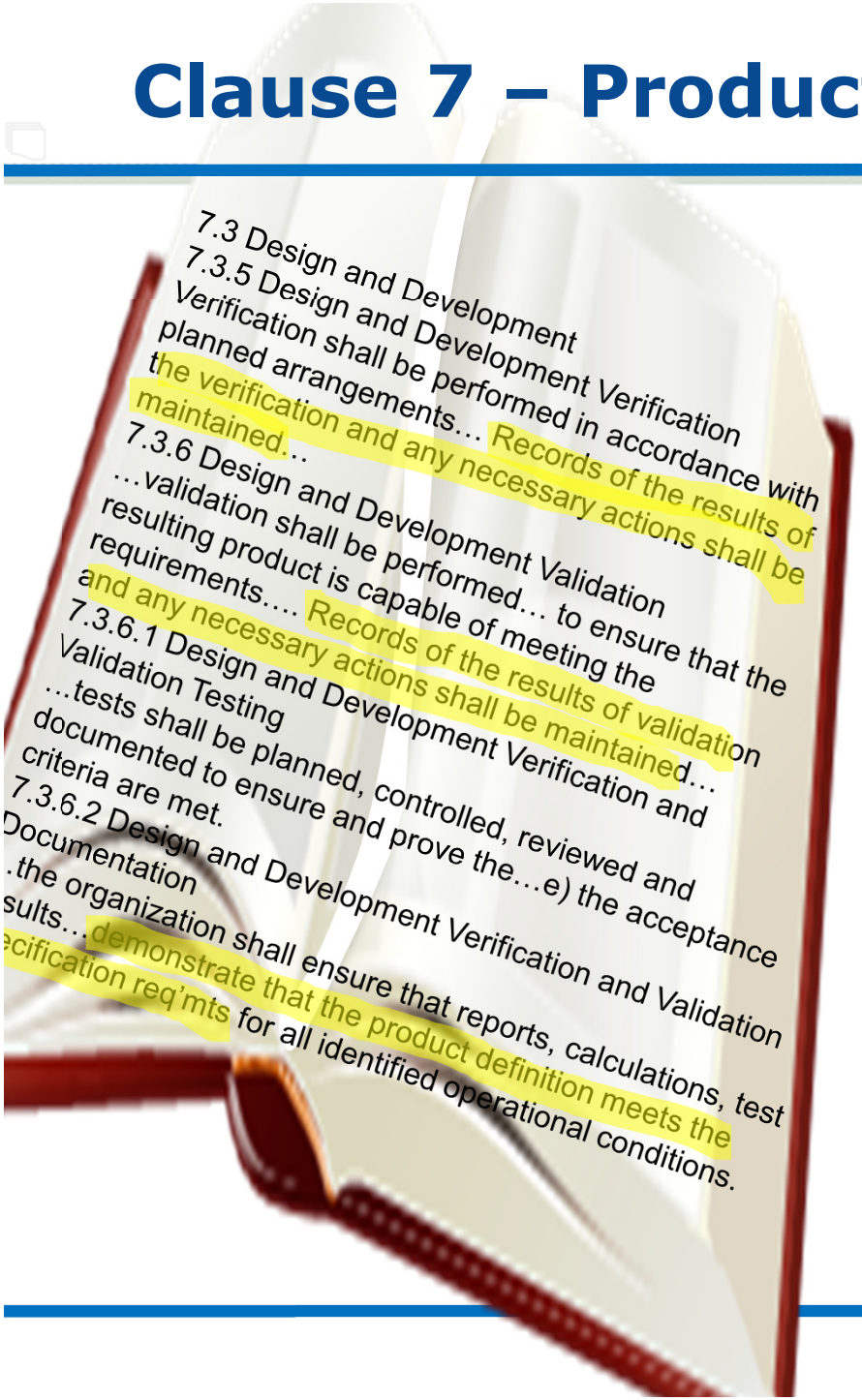

- **No evidence that design outputs are reviewed prior to release**
- **Some of the design inputs are not addressed in the design outputs**

# Clause 7 – Product Realization (Cont'd)



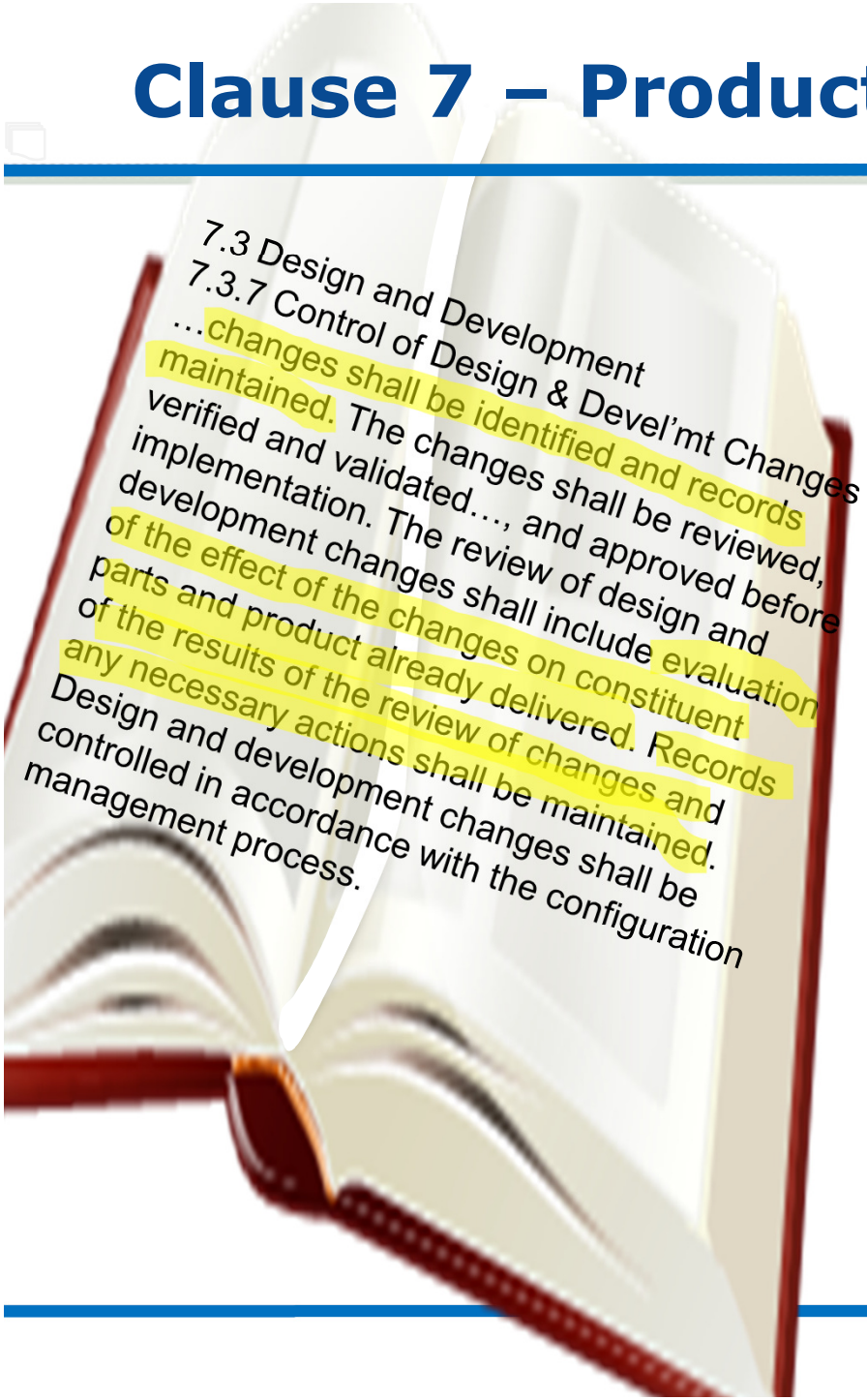

- **No records of design reviews being conducted in accordance with the design plan**
- **No evidence that affected functions are included with the design reviews**

# Clause 7 – Product Realization (Cont'd)



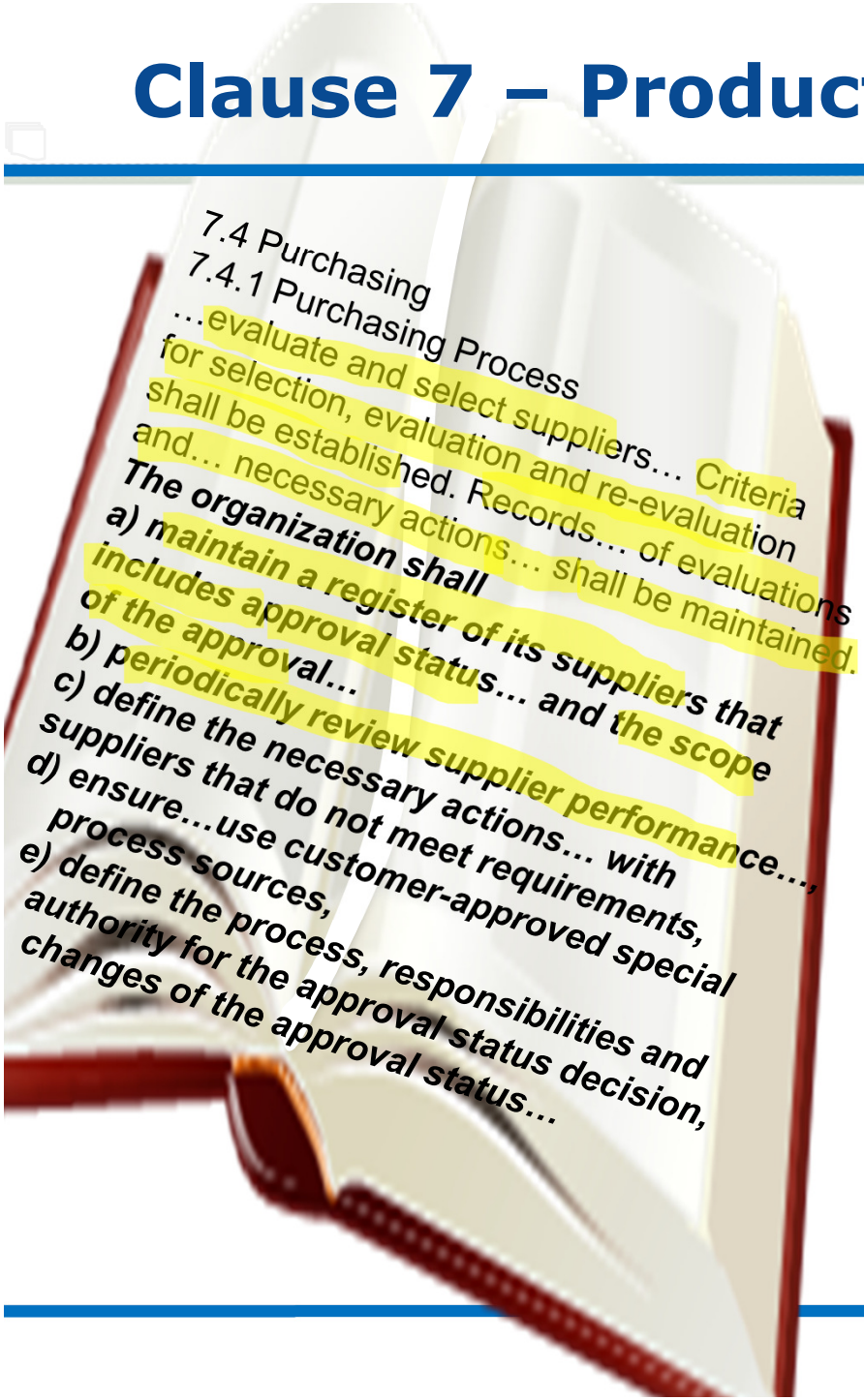

- **No records of verification and/or validation testing (with necessary actions).**
- **No evidence that all operational conditions have been met.**

# Clause 7 – Product Realization (Cont'd)



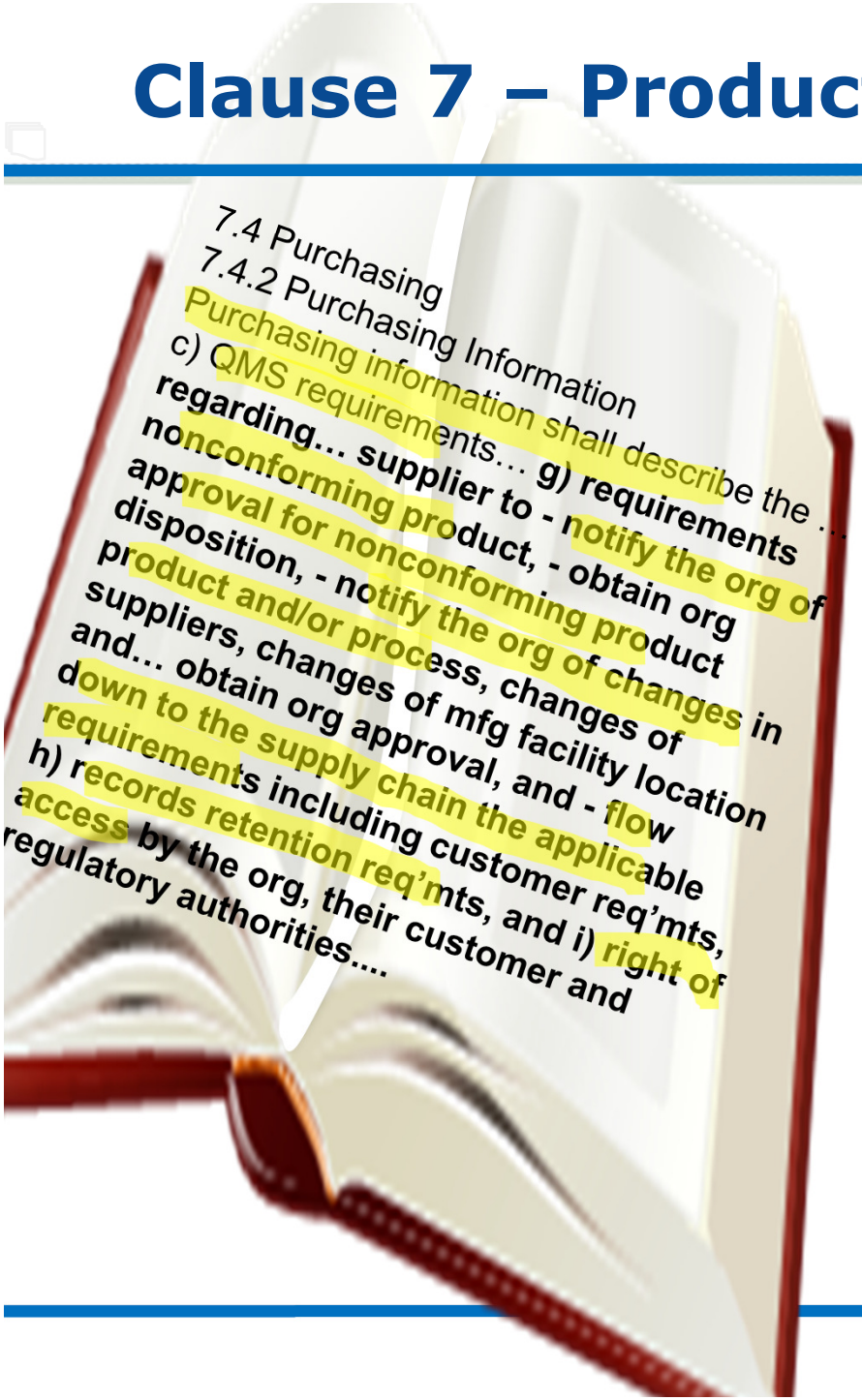

- **No records available to demonstrate that design changes considered the effect on constituent parts and product already delivered.**

# Clause 7 – Product Realization (Cont'd)



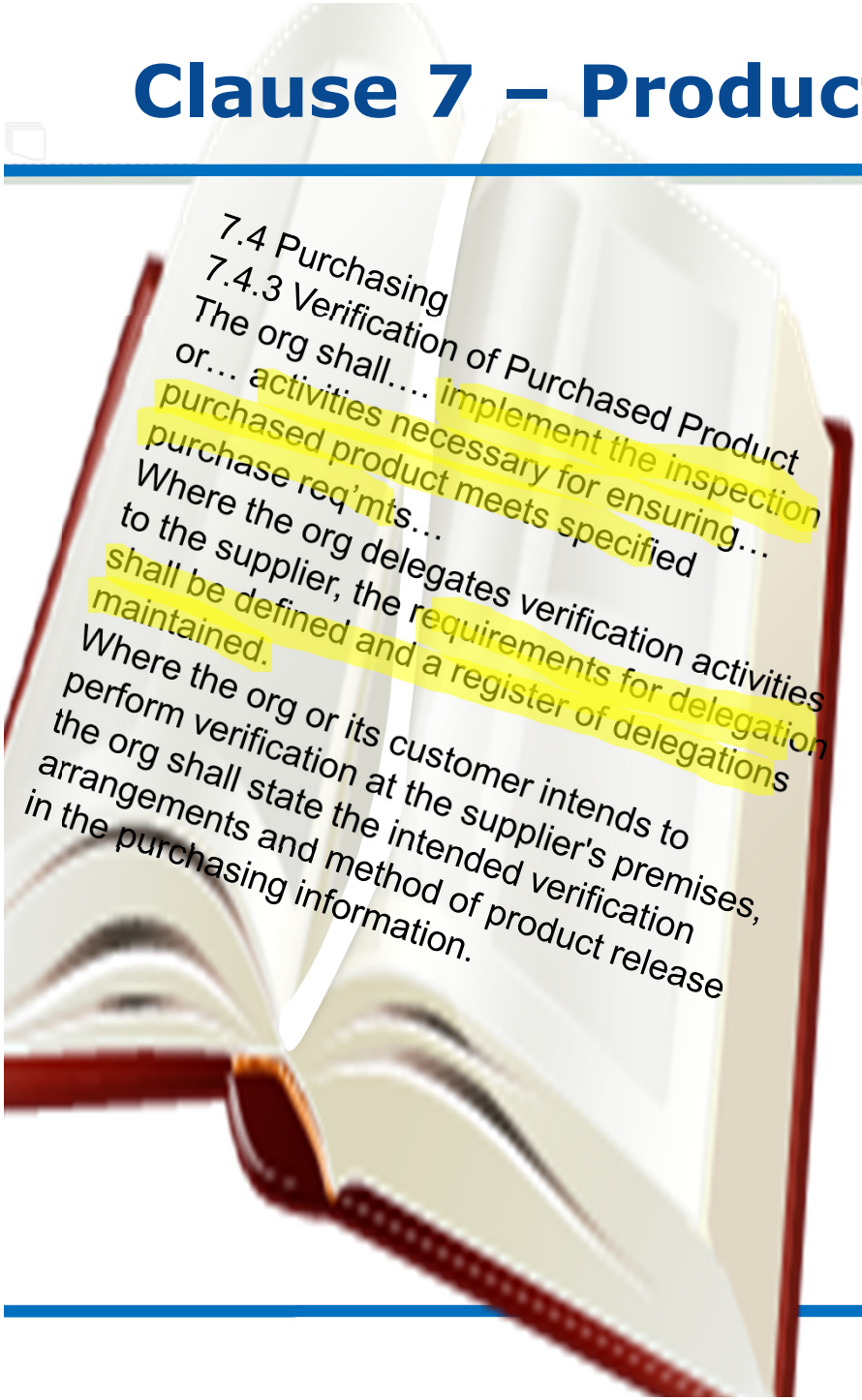

- **Register of approved suppliers does not include Approval Status and/or Scope of Approval**
- **Register of approved suppliers does not list all suppliers that effect product quality (e.g. service providers)**
- **Periodic review of supplier performance not evident.**

# Clause 7 – Product Realization (Cont'd)



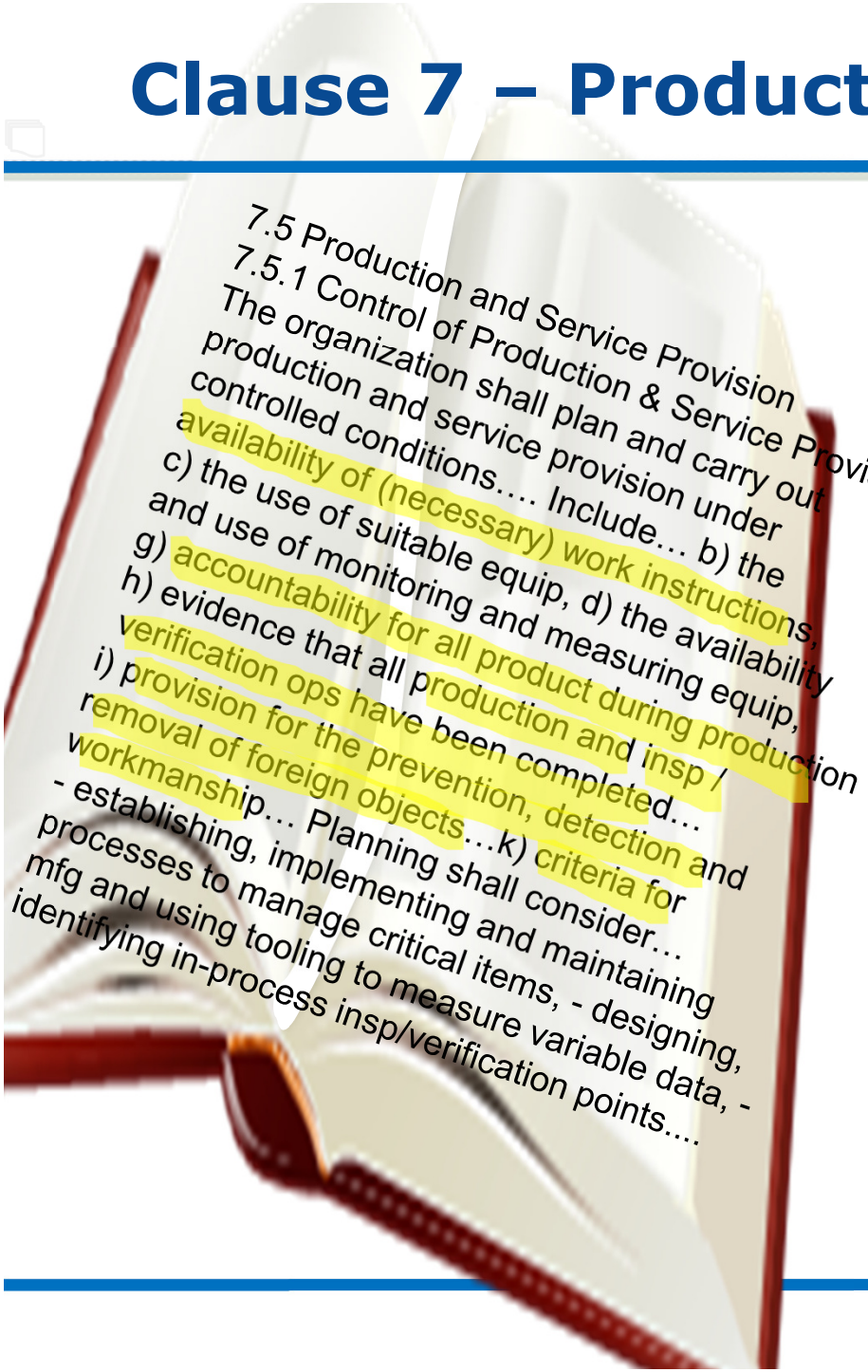

- **No evidence that appropriate QMS requirements (and customer quality req'mts)are being flowed down to suppliers.**
  - **Records retention**
  - **Process or product change notification**
  - **Right of Entry**
  - **Customer Requirements**
    - **Defense Priority Ratings, Approved Processors, Certifications, DARS, FARS, etc.**

# Clause 7 – Product Realization (Cont'd)



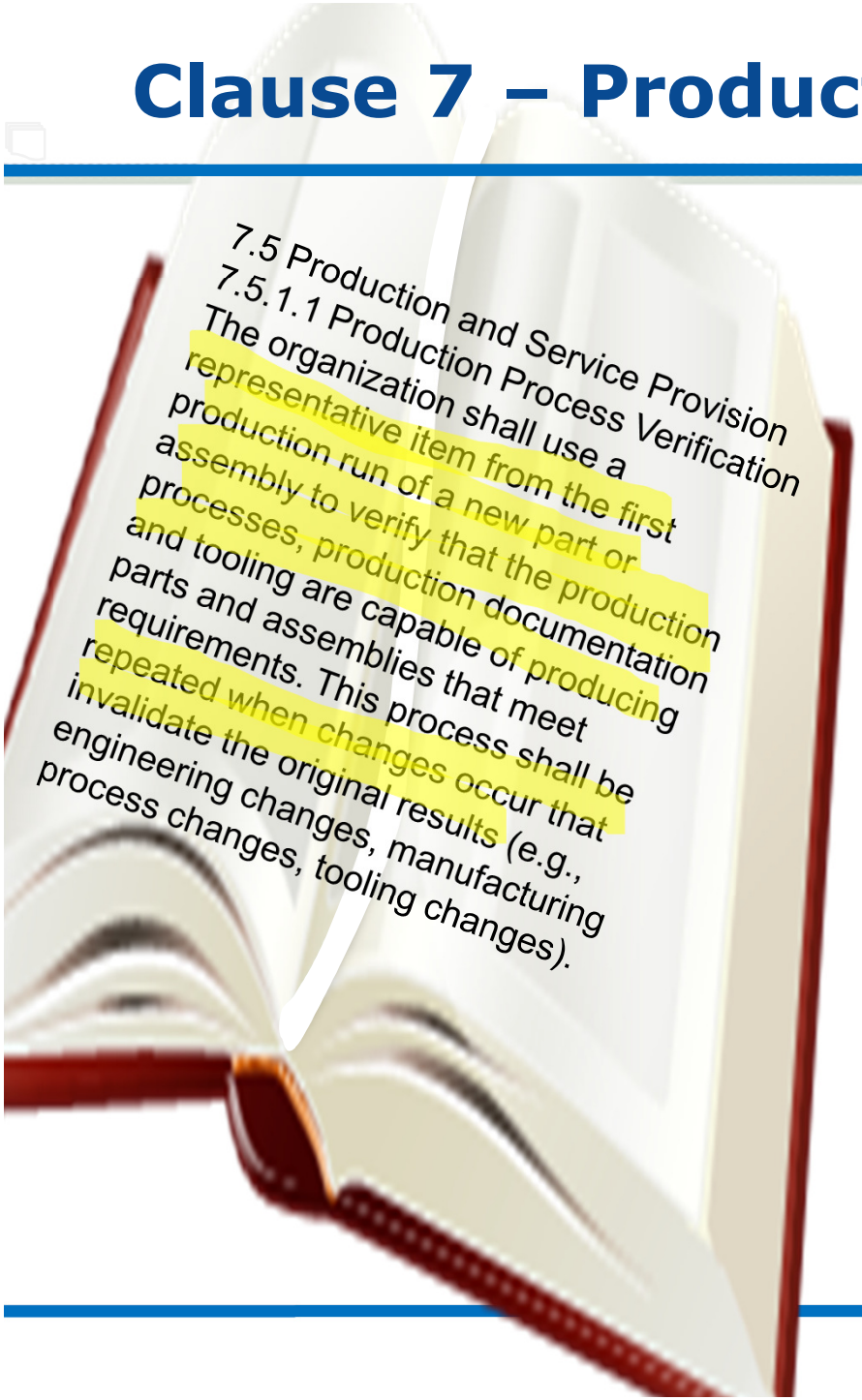

- **Delegation activities not addressed and/or a register of delegations is not available or has not been maintained current.**

# Clause 7 – Product Realization (Cont'd)



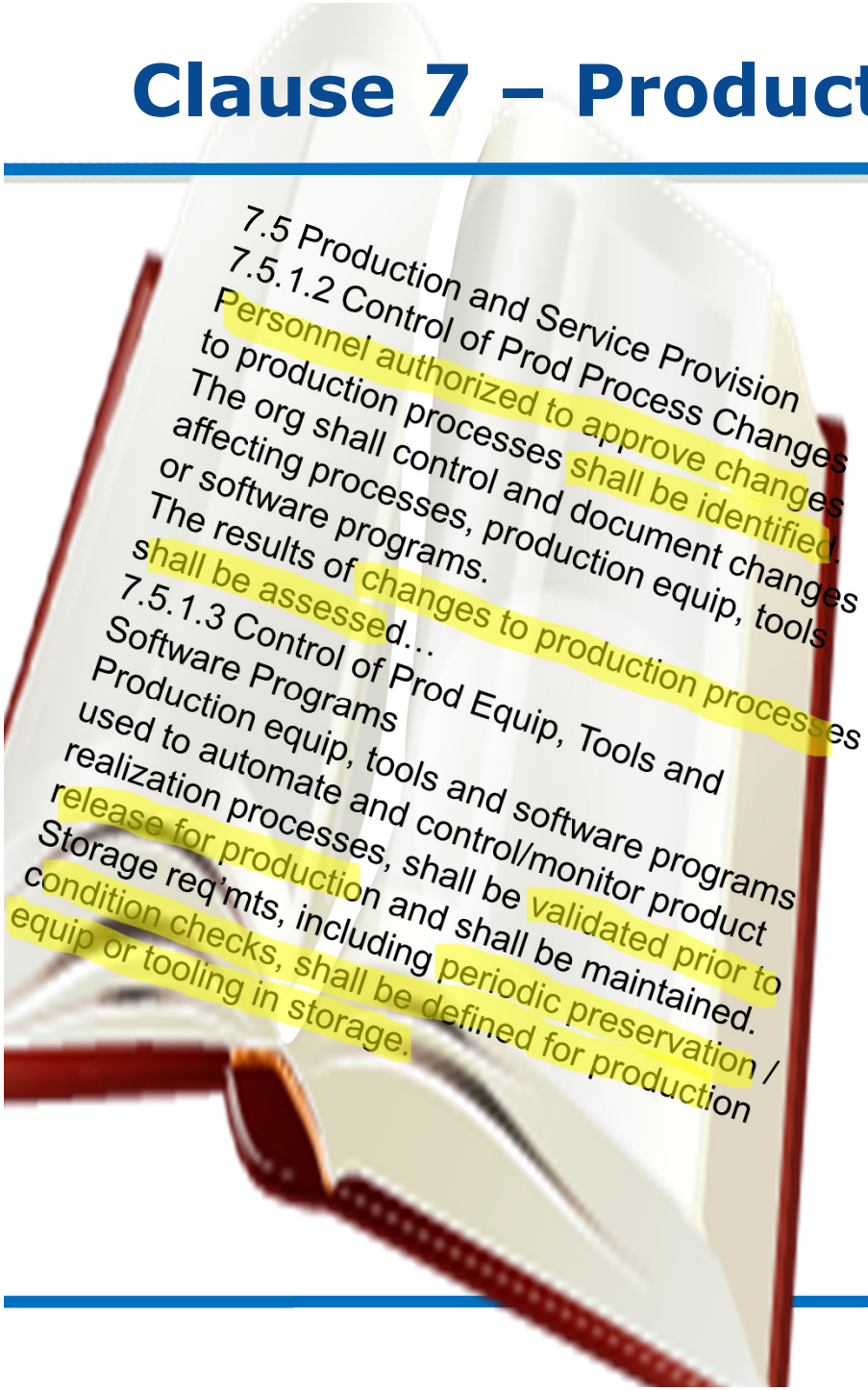

- **Planning (Job Tickets, Routers, etc.) not document controlled.**
- **Missed operation and/or inspection steps**
- **Accountability of all parts not evident.**
- **Referenced work instructions and/or workmanship documents not controlled**
- **No evidence of FOD provisions**

# Clause 7 – Product Realization (Cont'd)



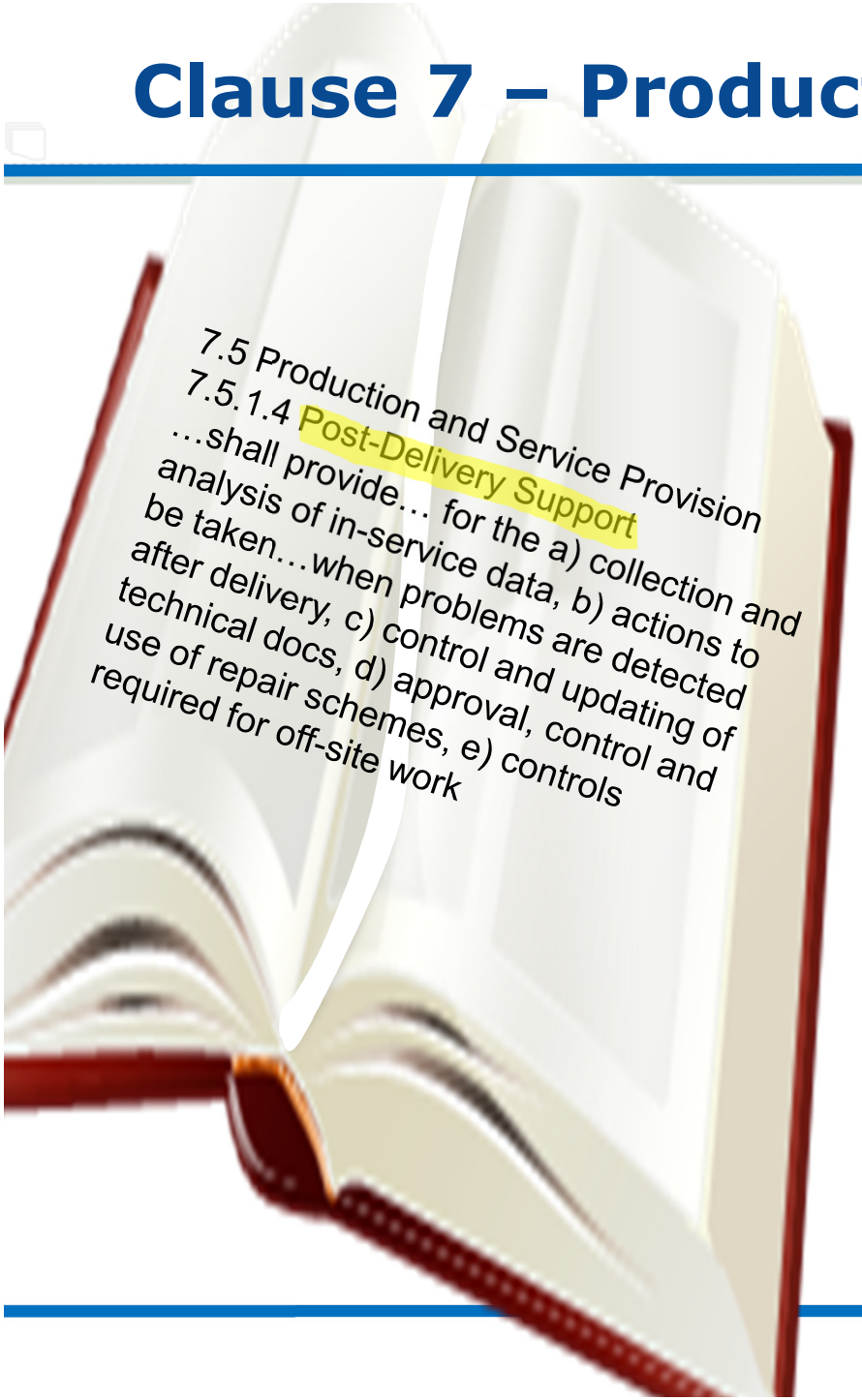

- **No evidence that a Production Process Verification (First Article Inspection) has been performed.**
- **No FAI performed since a process/tooling change.**
- **Errors on the FAI reports**

# Clause 7 – Product Realization (Cont'd)



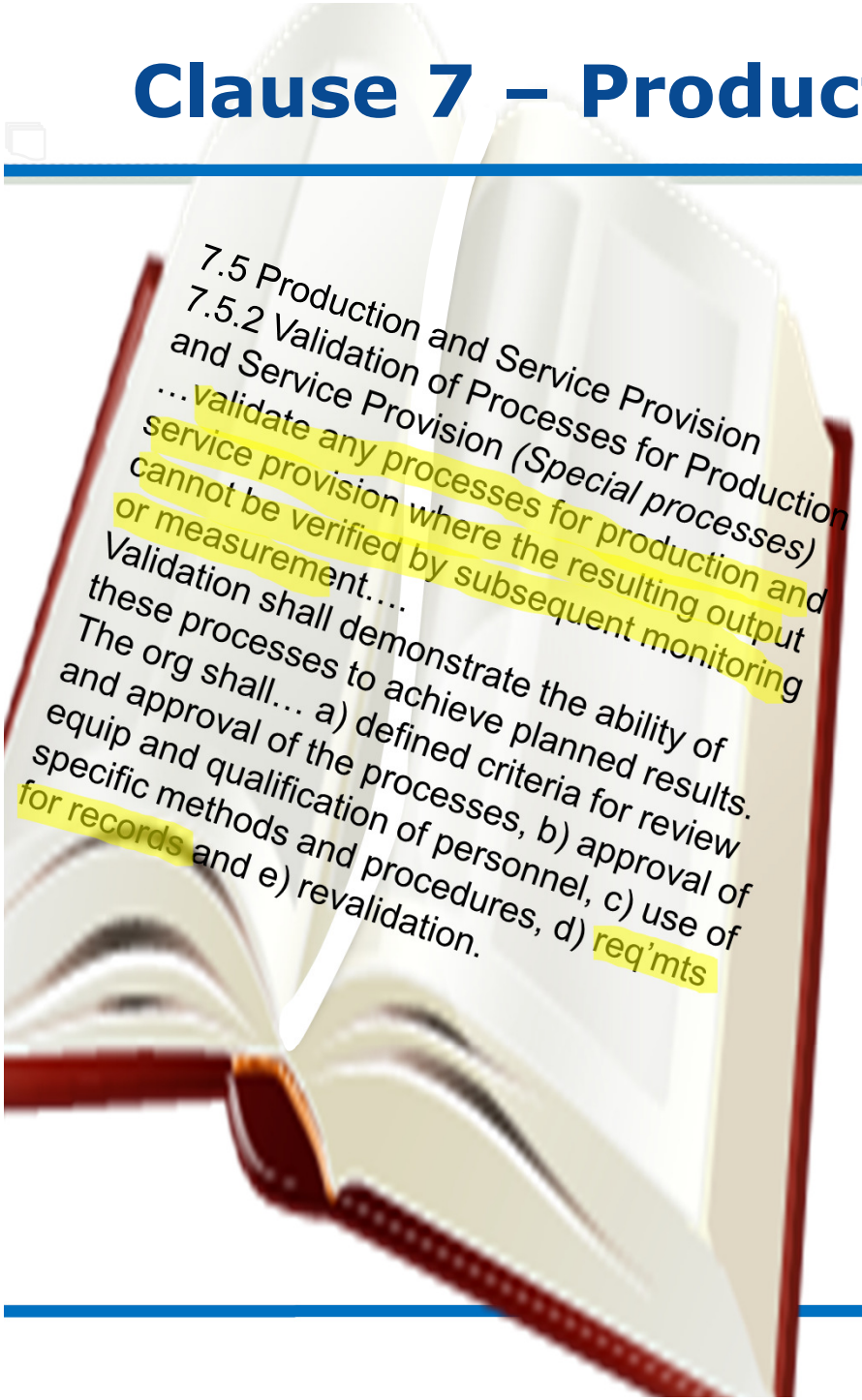

- **Personnel authorized to make planning changes not identified.**
- **Authorized changes to planning.**
- **No evidence that stored production equipment or tooling is being periodic checked.**

# Clause 7 – Product Realization (Cont'd)



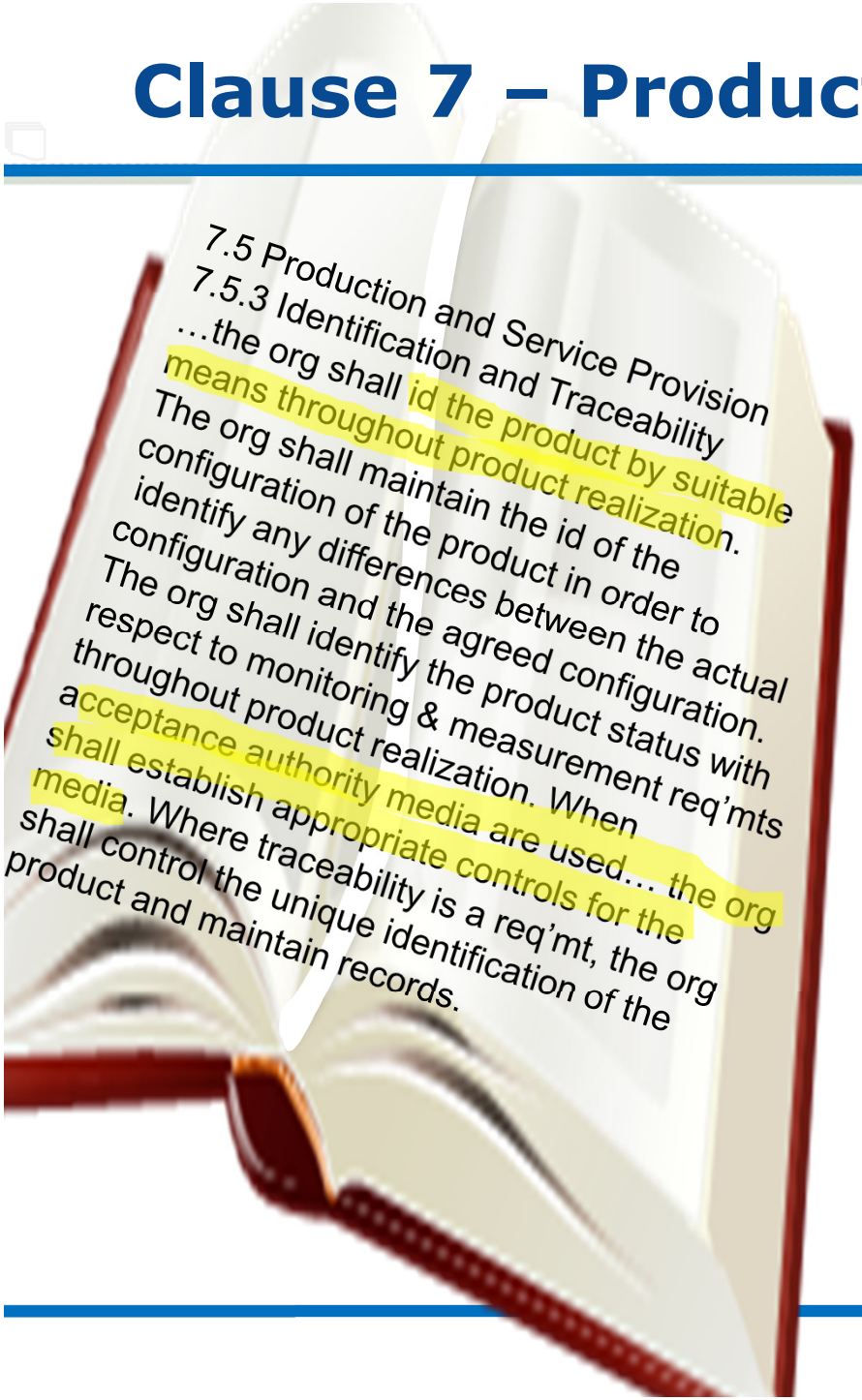

- **Post Delivery Support is often times excluded**
- **Applicable to companies that perform post-delivery support (e.g. service contracts for repair, in service training, field service support, warranty provisions, etc)**

# Clause 7 – Product Realization (Cont'd)



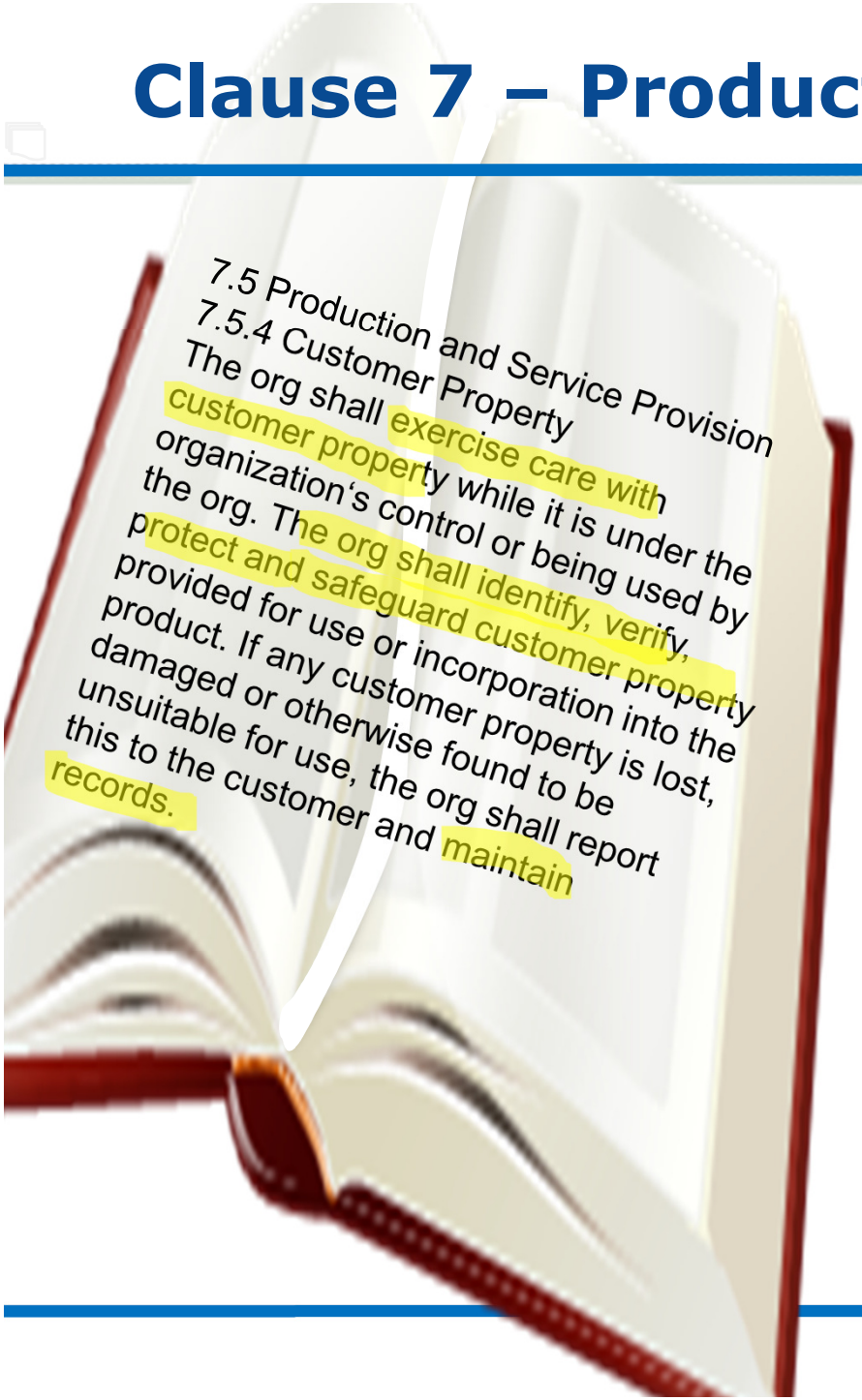

- **Special Processes not defined as such by the company.**
- **No records of special process validations and/or re-evaluations.**

# Clause 7 – Product Realization (Cont'd)



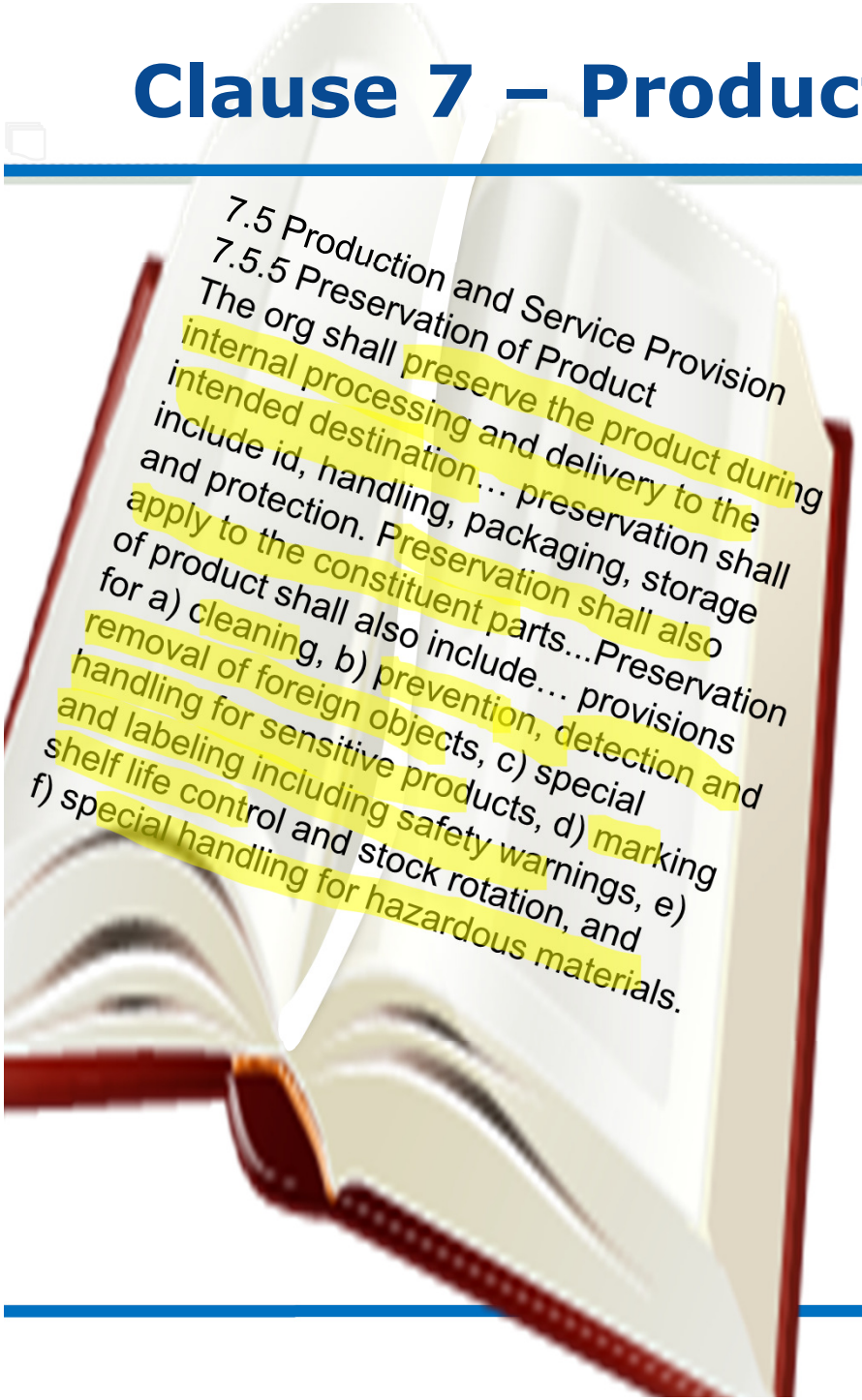

- **Inadequate stamp controls**
- **Parts in-work without product identification and/or planning paperwork.**

# Clause 7 – Product Realization (Cont'd)



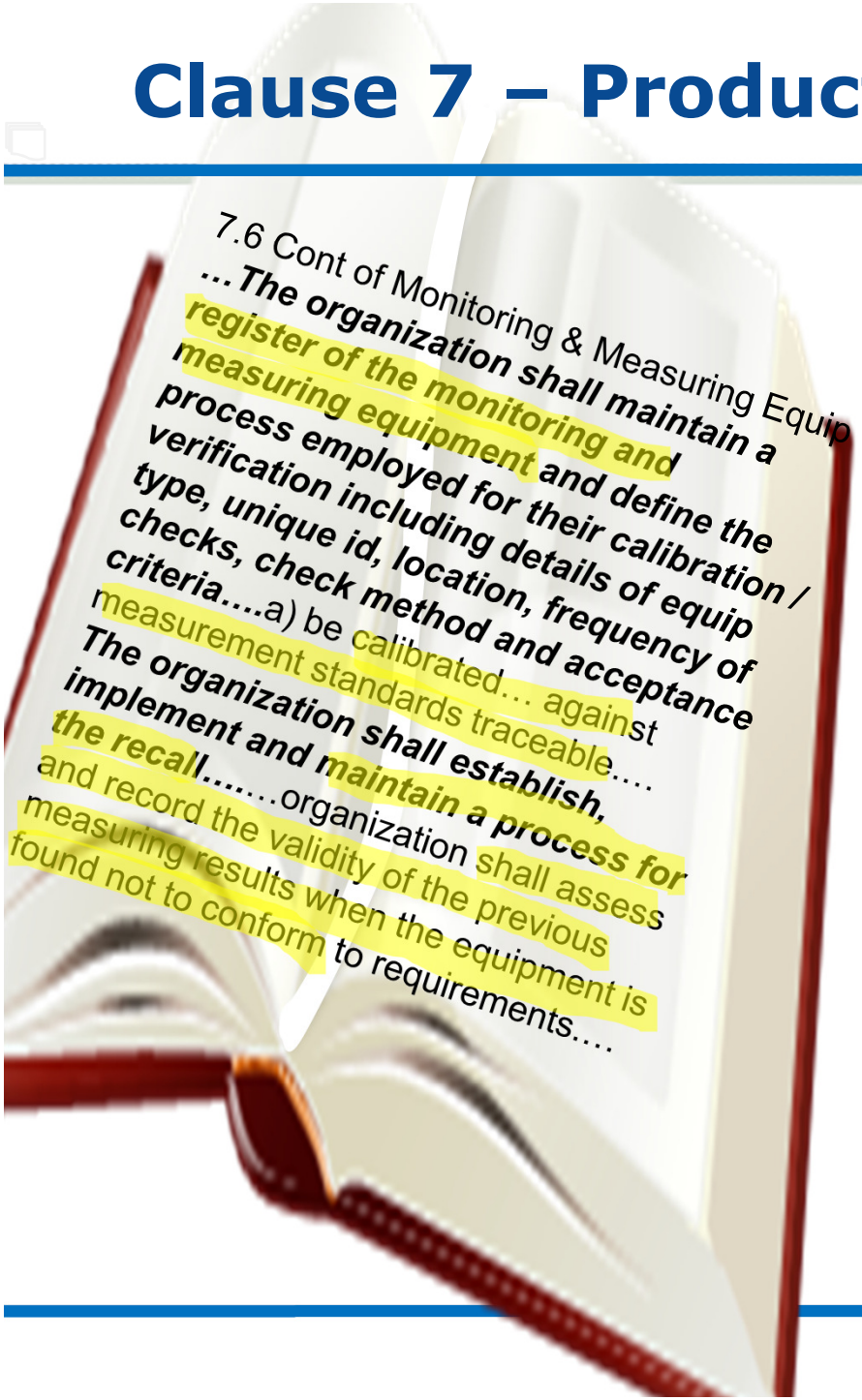

- **Inadequate control of customer property (e.g. comingling, protection against damage, etc.)**

# Clause 7 – Product Realization (Cont'd)



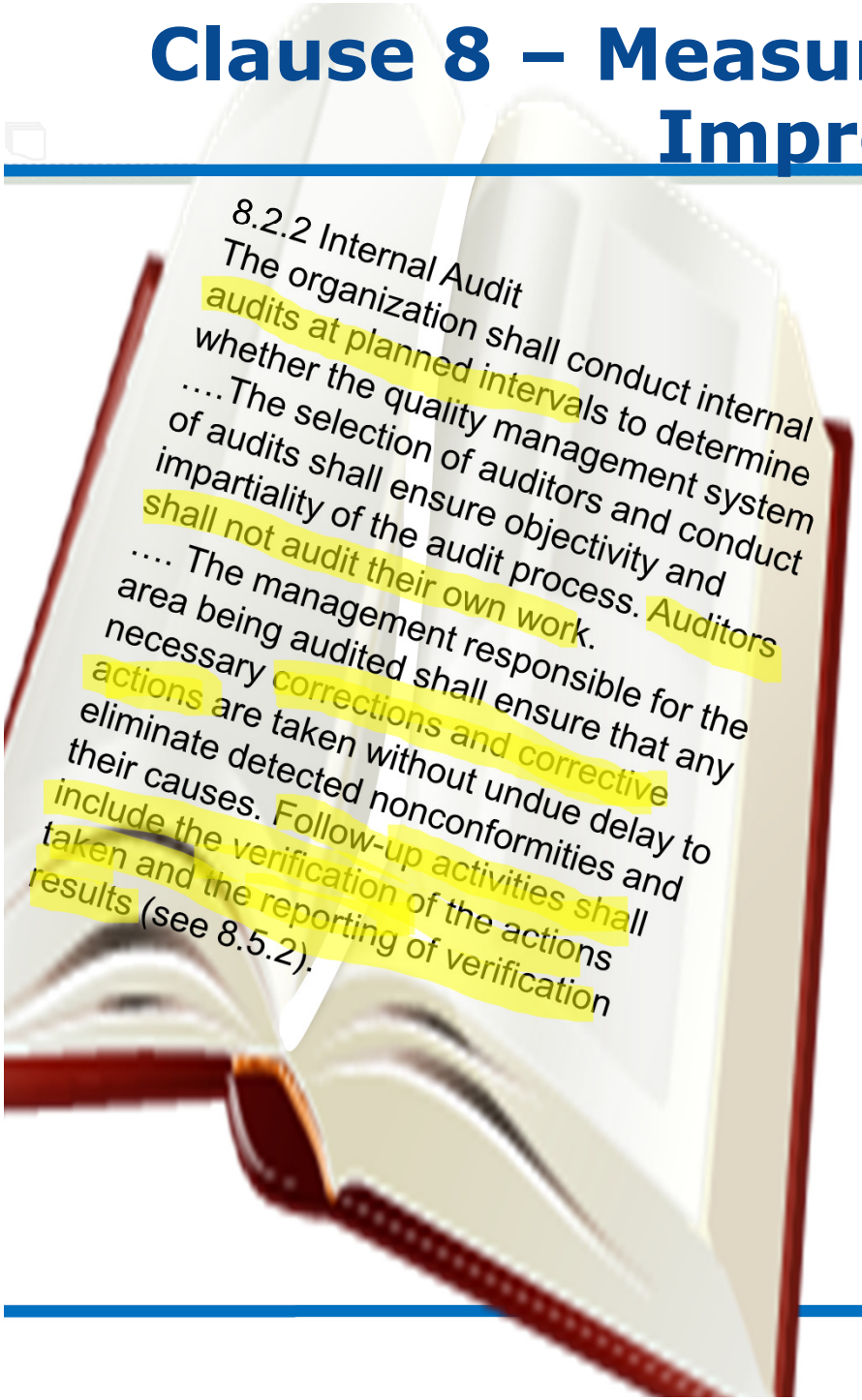

- **No provision for FOD controls in-place.**
- **Expired shelf life materials.**
- **Inadequate handling of hazardous materials.**
- **Inadequate environmental controls for stored or warehoused materials and/or parts.**

# 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)**

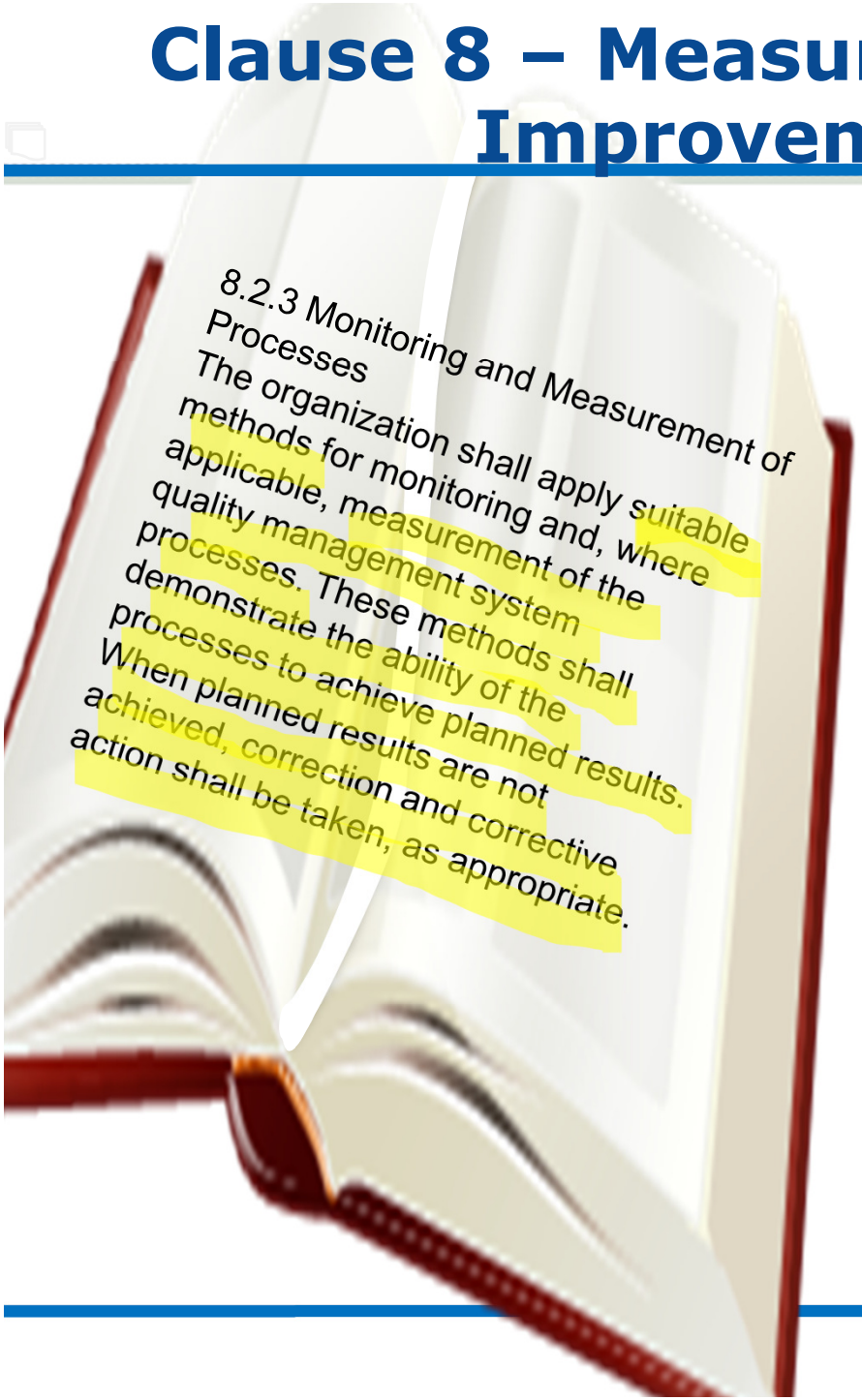
# Clause 8 – Measurement, Analysis And Improvement




- **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**

PERRY JOHNSON REGISTRARS™

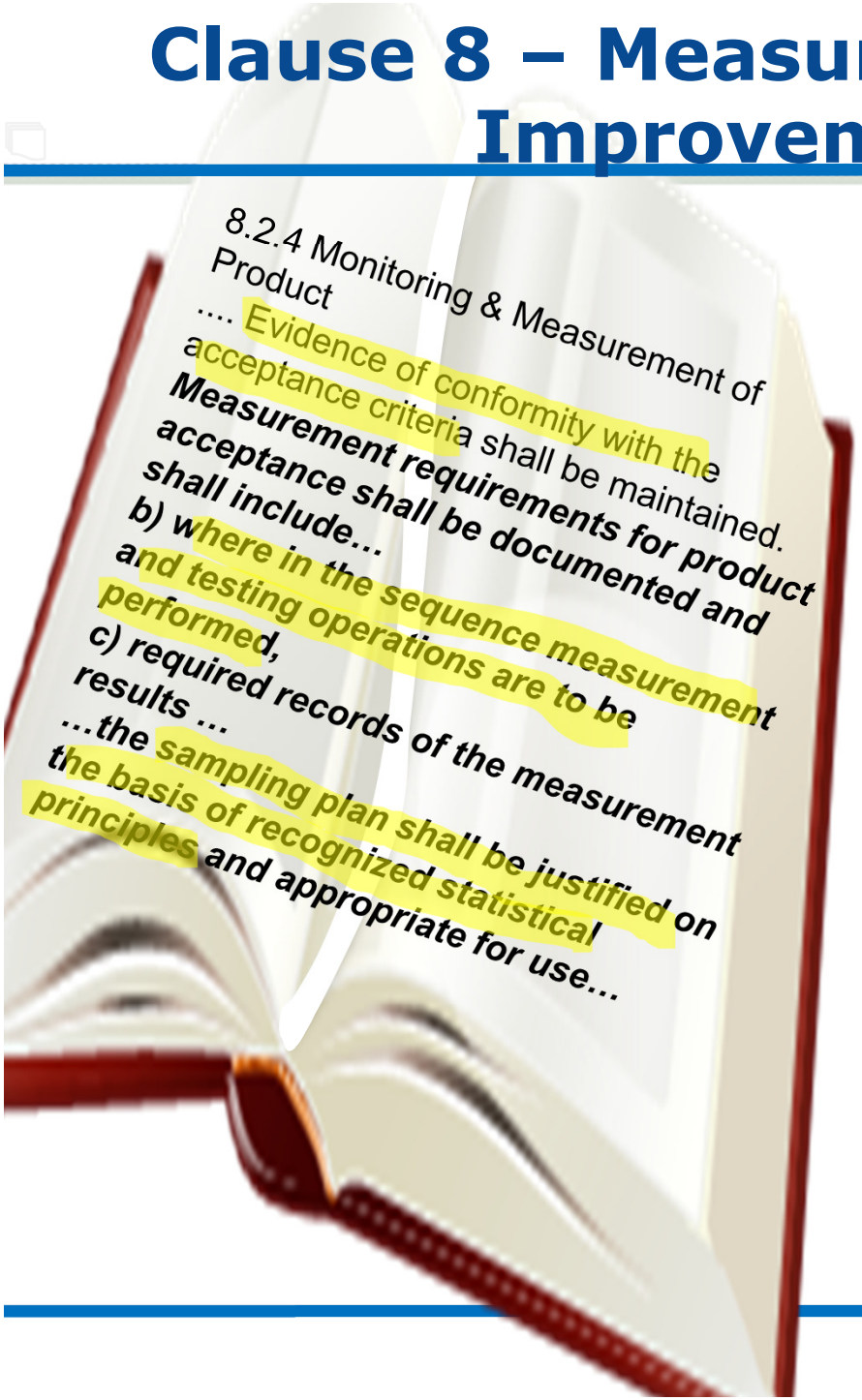
# Clause 8 – Measurement, Analysis And Improvement (Cont'd)




- **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**

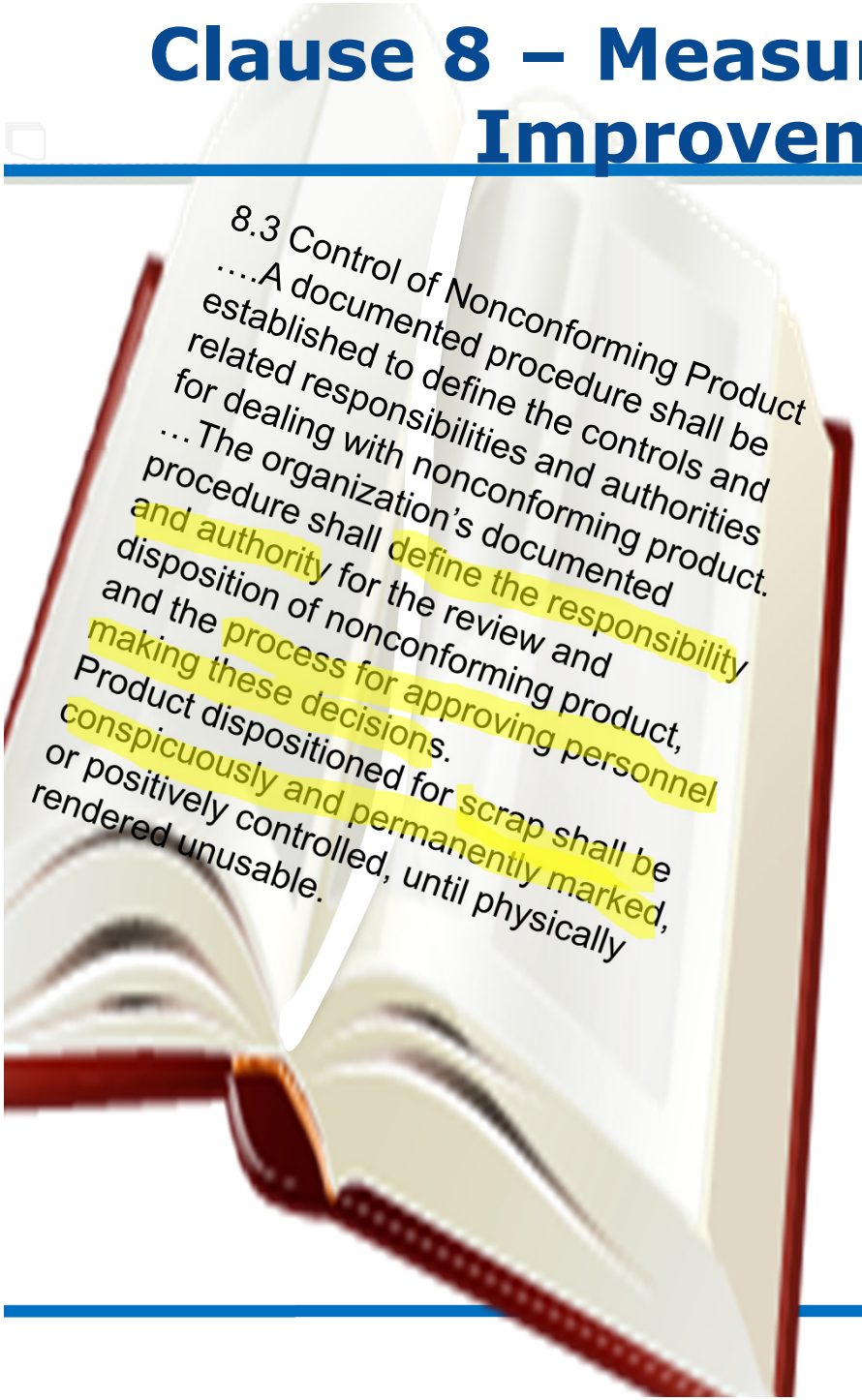
*Note: Monitors can be various methods, but must relate to the activities of the processes and demonstrate the ability of the processes to achieve planned results. (e.g. metrics, measurement devices w/controls, etc.)*

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



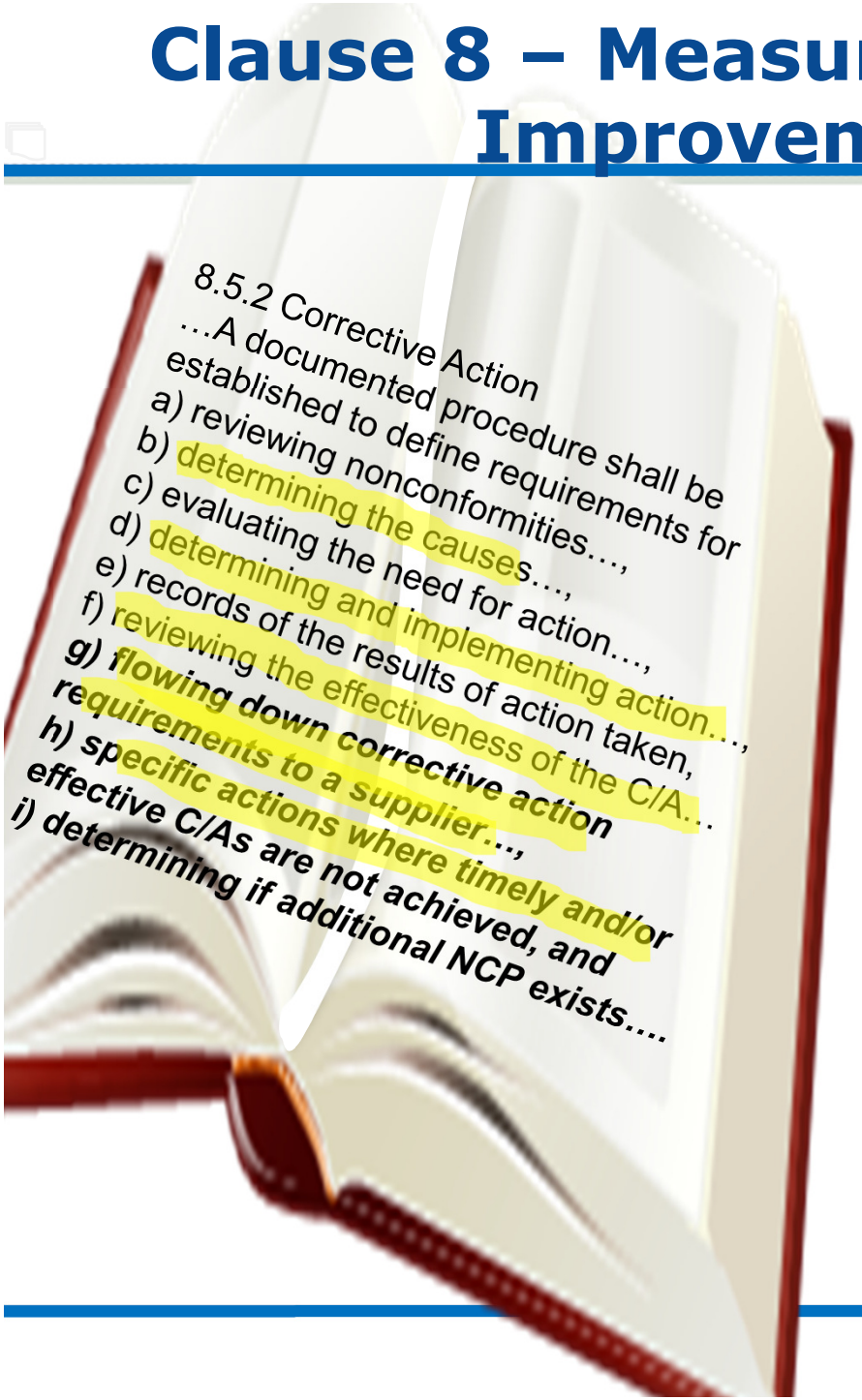

- **Common issues include:**
  - **Missing acceptance for operations (inspection and/or manufacturing)**
  - **Unauthorized planning changes**
  - **Questionable sampling plans**

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




- **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.**

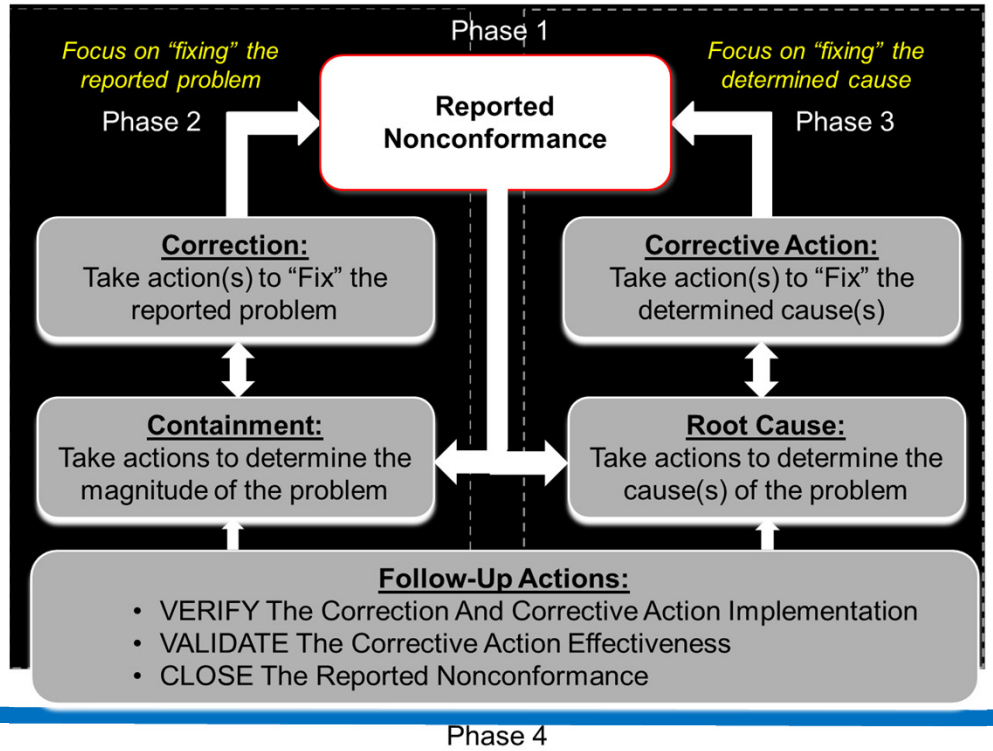
# Clause 8 – Measurement, Analysis And Improvement (Cont'd)



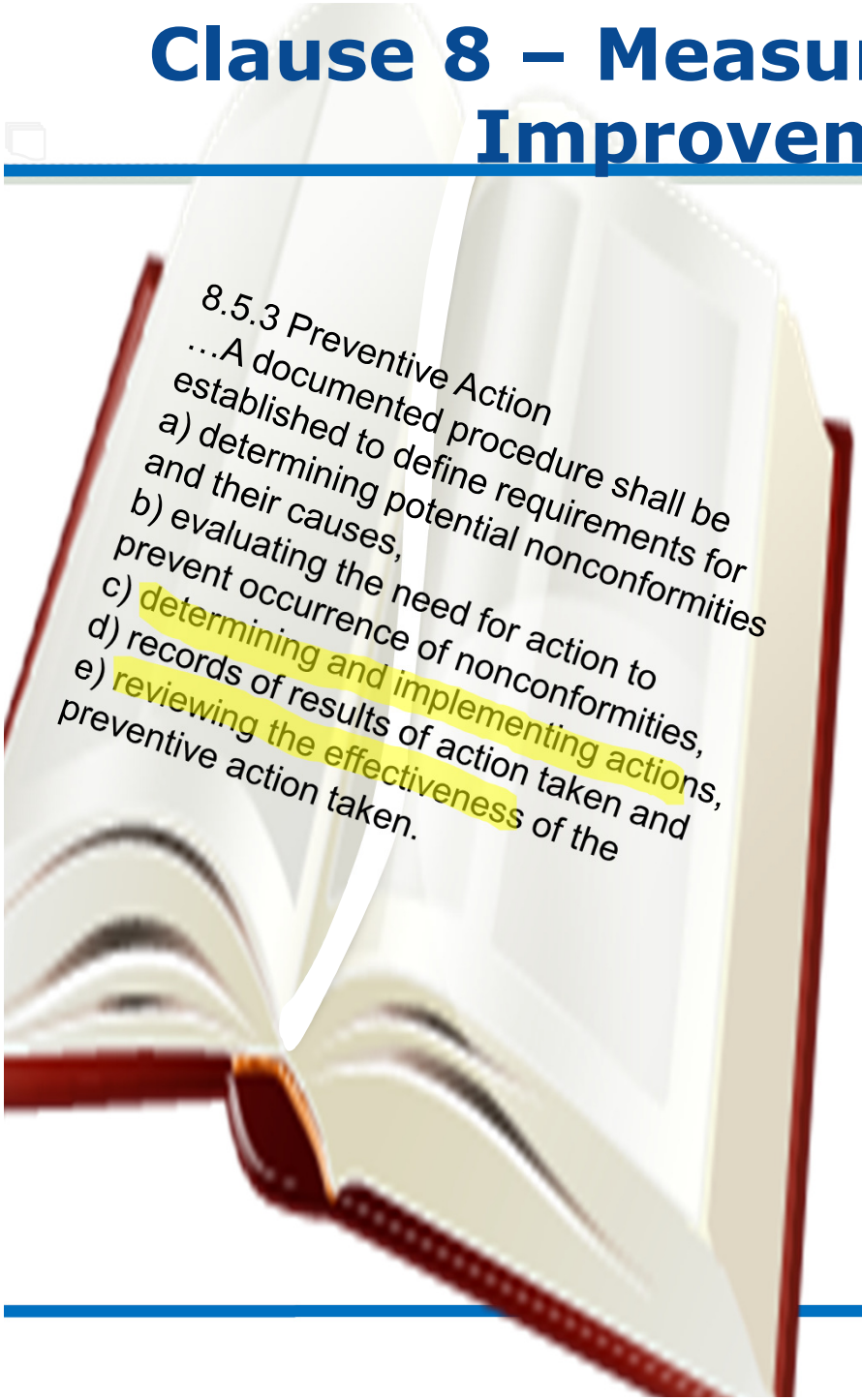

- **Common problem areas include:**
  - **Lack of good Root Cause analysis**
  - **Lack of acceptable Corrective Actions**
  - **Lack of timely implementation of corrective actions**
  - **Lack of documented follow-up activities**
  - **Lack of supplier CARs**
  - **Lack of Customer Complaint documentation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

# 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**

# 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**