Statutory and Regulatory Requirements

Anticipating expectations within a Quality Management System (ISO 9001) audit

Please note:

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- Please type your questions in the "Question" section of the dashboard – we will take questions at the conclusion of this presentation.
- Please note that copies of today's presentation will be available for download shortly.
- This webinar (and all other past PJR webinars) will also be available for re-viewing on our website under "Previously Recorded Webinars."

Today's presentation will cover:

- What are Statutory and Regulatory Requirements?
- Why is PJR auditing Statutory and Regulatory Requirements in an ISO 9001 audit?
- Where does ISO 9001:2008 address these requirements?
- Where does ISO 9001:2015 address these requirements?
- Examples of Statutory and Regulatory requirements
- Conclusion/Questions

What are Statutory and Regulatory requirements?

- From ISO 9000:2015:
  - Statutory Requirement: Obligatory requirement specified by a legislative body.
  - Regulatory Requirement: Obligatory requirement specified by an authority mandated by a legislative body.

Understanding the difference

- The main difference between statutory and regulatory requirements is simply from where the requirements come.
  - Statutory requirements come from statutes; in other words, these are legal requirements that come from laws passed by State or Federal Government (e.g., Congress).
  - Regulatory requirements come from regulations; such as EPA Requirements, OSHA Regulations, Regulations provided by the FDA, FAA, FCC, DOT, etc.
    - Regulations are generally rules issued by an Agency to which the Government has given the authority to regulate some industry or to do something and can often be found in the Code of Federal Regulations (CFR).

Example

- The Food and Drug Administration (FDA) is statutorily authorized to regulate food and drug safety through the Food, Drug and Cosmetic Safety Act.

- However, specific labeling and packaging requirements are found in Title 21 of the CFR, the regulations issued by the FDA in order to help them fulfill their statutory authority to regulate.

Can we simplify this a bit?

- Basically, a statute is the law – and is often general;
- Regulations are the rules developed to interpret the law and ensure that we stay within it – and are often more specific.

Example

- A statute may say that "excessive levels of certain pollutants shall not be permitted in or near major bodies of water" or something similar.

- The Environmental Protection Agency (EPA) might issue regulations that determine what "excessive levels" and "major bodies of water" are, as well as its plan for enforcement of what Congress intended in passing the statute.

Why does PJR audit Statutory and Regulatory Requirements in an ISO 9001 audit?

- PJR is held accountable to a number of requirements in our work as a certification body.
- Among the many requirements that PJR is held accountable to are those found in ISO 17021:2015.
- This standard includes a clause that reads (in part):
  - *"(Auditing shall include) the client's management system ability and its performance regarding meeting of applicable statutory and regulatory requirements."*

Where does ISO 9001:2008 address these requirements?

- ISO 9001:2008 including reference to Statutory and Regulatory requirements in the following auditable clauses:
  - 5.1A – Establishes a requirement for management to provide communication to the organization at large about the importance of meeting Statutory and Regulatory requirements;
  - 7.2.1C – Establishes a requirement for inclusion of Statutory and Regulatory requirements among the items determined by the organization during the contractual phase with the organization's customers; and
  - 7.3.2B – Establishes a requirement for inclusion of Statutory and Regulatory requirements among the design inputs.

Where does ISO 9001:2015 address these requirements?

- ISO 9001:2015 including reference to Statutory and Regulatory requirements in the following auditable clauses:
  - 5.1.2A – Places a particular responsibility on top management to ensure that Statutory and Regulatory requirements are determined, understood, and consistently met;
  - 8.2.2a1 – Establishes a requirement for inclusion of Statutory and Regulatory requirements among the items determined by the organization during the contractual phase with the organization's customers;
  - 8.2.3.1D – Establishes a requirement that Statutory and Regulatory requirements be reviewed prior to committing to supply a product or service to a customer;

Where does ISO 9001:2015 address these requirements? (continued)

- ISO 9001:2015 including reference to Statutory and Regulatory requirements in the following auditable clauses:
  - 8.3.3C – Establishes a requirement for inclusion of Statutory and Regulatory requirements among the design inputs;
  - 8.4.2c1 – Establishes a requirement for the Organization to ensure that External Providers do not adversely effect compliance to Statutory and Regulatory requirements;
  - 8.5.5A – Establishes a requirement for the Organization to ensure that Statutory and Regulatory requirements are included in determining the extent of applicable post delivery activities.

How has Perry Johnson Registrars approached this requirement?

- We have created a special grid that appears in the audit report for recording our assessments of Statutory and Regulatory Requirements.

- We have instructed our auditors to ensure that they are sampling applicable Statutory and Regulatory Requirements at every audit.

What are some common examples of Statutory and Regulatory requirements?

- Occupational Health and Safety (OSHA)
  - These requirements typically pertain to personal protective equipment (PPE), ergonomics, safety training, and related considerations.
- International Traffic in Arms Regulations (ITAR)
  - These requirements often manifest in areas such as controlled access to the facility or its records.
- Safety Data Sheets (SDS, formerly MSDS)
  - These requirements often apply to the handling, use, disposal, etc. of chemical based products. Common examples include product cleaners, product packaging, and raw materials.

How will the auditors determine what requirements apply?

- Many of the things already subject to review in the audit process are going to be helpful in determining what is applicable. These items include:
  - Customer contracts/purchase orders;
  - Product blueprints and specifications;
  - The organization's website.

The limits of our assessment

- We have emphasized to our auditors the importance of ensuring that the audit process is limited to a confirmation that the auditee has effective processes for identifying and complying with relevant statutory and regulatory requirements.

- PJR auditors will not sample individual provisions of these requirements for compliance.
  - We are not OSHA auditors, EPA auditors, etc.

Audit Report Example

Statutory/Regulatory Requirement (be as specific as possible)	Effectiveness of Implementation (if not effective, summarize correction/corrective actions being taken as needed)
OSHA	Confirmed appropriate postings, as well as safety content within training records.
ITAR	Confirmed a sign in protocol at the front desk, and locks on the cabinets holding ITAR sensitive records. No ITAR regulated product in house at today's audit.
DFARS	Confirmed that all suppliers used for raw materials and finishing services are domestic sources.

Will PJR issue a nonconformance?

- It is certainly conceivable that an auditor will find a disconnect between an implemented process and an applicable Statutory or Regulatory Requirement, but whether or not a nonconformance is issued requires a bit of considered discretion:
  - Does this issue impact customer satisfaction or the attainment of a quality objective?
  - Does this issue impede the organization's ability to manufacture it's product or render it's service?
- If a nonconformance is warranted, the auditor must ensure that the requirements cited include the appropriate clauses from either ISO 9001:2008 or ISO 9001:2015 standard.

Conclusion

- Perry Johnson Registrars wants to ensure that we provide our clients with a value added audit while meeting all applicable requirements.
- It is our hope that you will use the points of this presentation to develop an even better understanding of what our expectations are for Statutory and Regulatory Requirements.

Please tune in for one of our other webinars

- *"ISO 9001 2015 Approaching Your Transition With Confidence"* is presented on a semi-monthly basis.
  - This new and updated webinar provides an in depth review of the ISO 9001:2015 standard. It also provides valuable feedback from PJR's first year of auditing ISO 9001:2015, as well as lessons learned from the new ISO 9002 guidance standard.
- *"Non-Applicable Clauses, Permissible Exclusions, Exemptions - Developing a better understanding of what can and what cannot be excused in an audit assessment"* is presented on a quarterly basis.
  - This webinar explores the critical topic of exemptions and the right approach to take in determining which apply to you.
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