MWEA Laboratory Practice Committee:

Standard Operating Procedure (SOP) Writing Techniques

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Agenda

- Personal Introduction
- ‘Need’ (Requirement) for Standard Operating Procedures (SOPs)
- Value Proposition of Standard Operating Procedures (SOPs)
- How to Construct Efficient and Effective SOPs

Personal Introduction

Current Role w/ NSF-ISR:

- Overall technical responsibility for all management system registration programs including QMS (ISO 9001, ISO/TS 16949, AS 9100, ISO 13485, ISO 22000, ISO 20000, ISO 27001) as well as EMS (ISO 14001, GHG, RC/RCMS, SFI, ATFS, OHSAS) program offerings

- Primary interface with Accreditation Bodies/Oversight Bodies (ANAB, ANSI, IAOB) on all related accreditation matters for NSF-ISR

Previous Life (Industry):

- Responsible for the final implementation of an EMS (ISO 14001) and two QMS system (ISO 9001:2008 and ISO/TS 16949) implementations/upgrades at a major heavy-truck engine supplier (3 million ft^2 facility, 2500+ employees, two facility locations, approximately twelve production machining/assembly lines and over ninety processes)

- QMS responsibility for product certification and other unique system requirements with groups such as the US Government, Underwriters Laboratory, Germanischer Lloyd, Bureau Veritas, American Bureau of Shipping and Det Norske Veritas

- Facility representative for global lead roles on related QMS projects within larger multinational, Fortune Global 20 parent company

Accreditations/Trainings:

- Certified Quality Auditor (CQA) and Certified Manager Quality/Organizational Excellence (CMQ/OE) through ASQ; IRCA auditor (QMS) as well as various LEAN trainings (office and shopfloor)

‘Need’ (Requirement) for Standard Operating Procedures (SOPs)

ISO 9001:2008:

- Requires an organization to document various production and service provisions under controlled conditions (ref. ISO 9001:2008, 7.5.1):

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,
a) the availability of information that describes the characteristics of the product,
b) ***the availability of work instructions, as necessary,***
c) – f)…

- These documentation requirements are in turn required to support some additional requirements (ref. 4.2.3):

Documents required by the quality management system shall be controlled…

A document procedure shall be established to define the controls needed
a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents are legible and readily identifiable,
f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution list controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Value Proposition of Standard Operating Procedures (SOPs)

Some 'key' items of consideration as to when something should be documented (in possible order):

1) Is the work instruction or standard operating procedure 'customer-related'?
2) Is the work instruction or standard operating procedure required per the standard?
3) Could an absence of the work instruction or standard operating procedure lead to a possible failure, defect or undesirable outcome?
4) Is there still a value-added with the work instruction or standard operating procedure ?

… Once an organization determines what is 'needed':

- The work instruction or standard operating procedure does have to be 'controlled' (ref. 4.2.3, ISO 9001:2008)

- The opportunity exists once something is documented, to better manage it (five sets of questions):
  - → Where are there variations from the intended work instruction or standard operating procedure being provided?
  - → Why are these deviations occurring? Is there insufficient documentation, too much documentation, etc.?
  - → What opportunities exist to improve the work instruction or standard operating procedure?
  - → How do we realize these work instruction or standard operating procedure improvements and when can we implement and verify its efficiency and effectiveness?

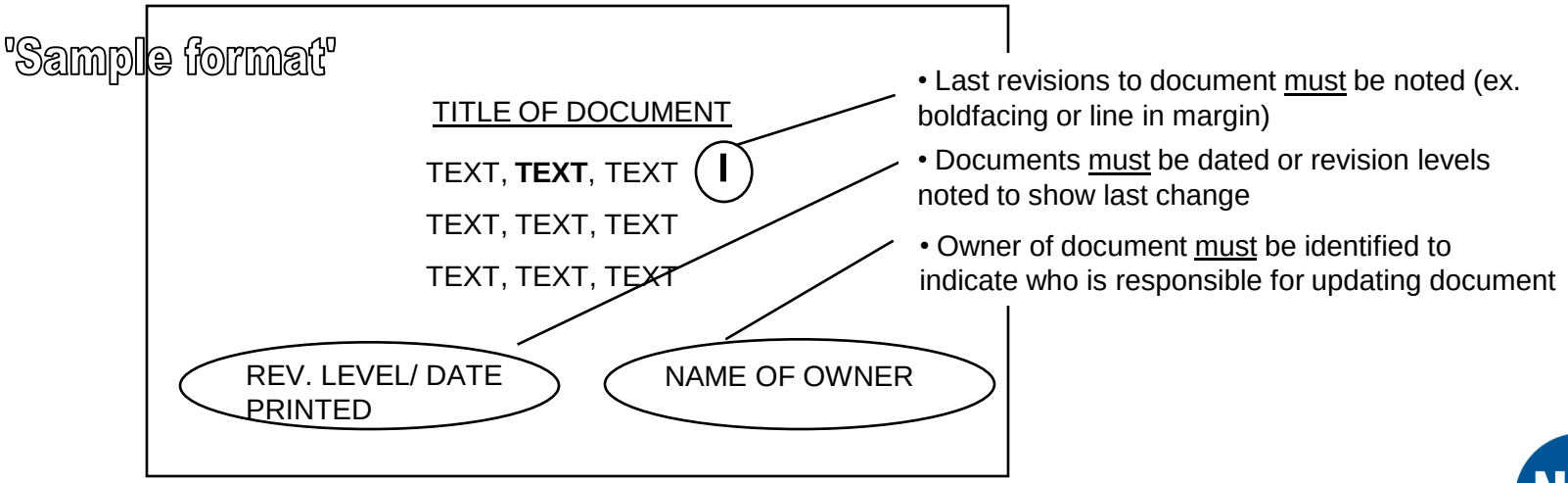
- Key consideration efficiency (time to realize an intended result) and effectiveness (the ability to realize the intended result consistently).

How to Construct Efficient and Effective SOPs

Roadmap to construction of effective and efficient SOPs:

- Once you've determined what the customer needs; what's required per the standard; considered where a lack of documentation can result in a failure, defect or undesirable outcome and even considered where value-add occurs with the presence of a standard operating procedure; the next step is constructing the document itself

- Key focus should be on making it simple
  - → Noting of approval authorities on documents
  - → Noting of issue and revision date on documents
  - → Noting of updates to documents using a consistent technique or method
  - → Identification of where all documents are to be used and verification of their access
  - → No hand written documents
  - → External origin document references are periodically reviewed for appropriateness
  - → Removal of obsolete documents immediately



Miscellaneous 'Tips' on Particular SOP Writing Styles and Materials

Back-Up

Different styles of procedures for different industries ('generally speaking'):

- Medical device procedures are much more specific and generally requires two or more sign offs
- Military or government procedures are long and extremely detailed (i.e. many still based on the "MIL" requirements)
- Laboratory procedures should include any applicable equipment references (DE #s, gages, calibration requirements) and reference external documents, where appropriate

Still for any procedure, the following items should be kept in mind:

- Brief is always better, make procedures succinct and direct while minimizing long literary descriptions and always reference any other related documents
- Procedures can be flow charts, pictures, and or include representative examples (i.e. picture always helps)
- Policy documents and procedures are different- policies typically tell the 'what' a company does or goes into brief detail into 'how' they do it while procedures focus on the underlining 'how' steps and provide further instruction