Assessing Document Control for Conformance

Document Control Procedure

Assess the implementation of a written document control procedure to ensure it addresses the following requirements:

- Reviewing an internal controlled document.
- Approving an internal controlled document.
- Identify authorized personnel to review internal controlled documents.
- Identify authorized personnel to approve an internal controlled document.
- Distribution of controlled documents. (internal and external)
- Ensuring documents are current and fit for use.

Authorized Personnel

- Are there authorized personnel assigned to approve internal controlled documents prior to issue?
- Are correct personnel authorized in accordance with procedures?
- Is there a method defined that verifies internal controlled documents are reviewed and approved by authorized personnel prior to issue? (signature, electronic signature, other methods)

Reviewing (reviewer and approver may be the same person)

- Are there authorized personnel assigned to review internal controlled documents prior to issue?
- Is there objective evidence the internal controlled documents are reviewed prior to issue? (signature, electronic signature, other methods)
- Are revisions of internal controlled document reviewed in the same manner as the original document?
- Are there any internally controlled documents in use that have not been reviewed?

Approving (reviewer and approver may be the same person)

- Are the authorized personnel assigned for approving documents prior to issue?
- Is there objective evidence the internal controlled documents are reviewed prior to issue? (signature, electronic signature, other methods)
- Are revisions of internal controlled documents approved in the same manner as the original document?
- Are there any internally controlled documents in use that have not been approved?
Distributing

- Are documents distributed at the location of the prescribed activity?
- Is there a master list or equivalent document control procedure to determine where the documents are distributed and how many copies at each location? Are required documents of external origin included?
- Are the correct revisions of controlled documents distributed to the location of the prescribed activity?

Current and Fit for Use

- Is there a master list or equivalent document control procedure to determine if the correct revisions of controlled documents are being used? (internal and external documents)
- Are the correct versions or revisions of controlled documents being used by the state?
- How are expired/obsolete documents controlled to prevent unintended use when revisions are made?