

EOTA – Business Process



Document Title:

Control of External Documents Process

Document Number

P-002 Rev 11_0304

Document Owner:

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Parent Document:

Q-001, Quality Manual

Notify of Changes:

EOTA Employees

Referenced Document(s):

REG-002, External Document Register

Revision History:

Rev.	Description of Change
A	Initial Release
11_0304	Changed revision format from alpha character to numbers; modified process to include a step directing addition to REG-002 External Document Register and changed verbiage to clarify and more accurately reflect current process.

I. Purpose

To identify the process for how external documents are identified, kept current, managed, retained, and distribution controlled.

II. Scope

This process applies to the External Document Controller and employees requiring access to external documents.

III. Responsibility

External Document Controller (EDC) / Designee – Responsible for the overall management and maintenance of the External Document process. In addition, the EDC, working with the applicable Integration Group members, will periodically schedule a review of the REG-002, External Document Register to confirm the appropriate currency of the documents.

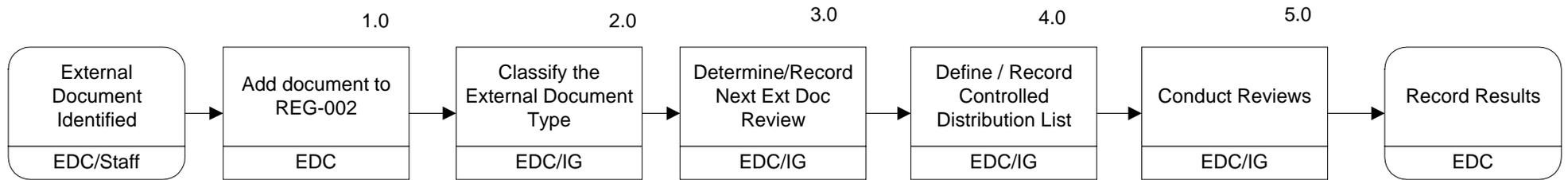
Integration Group (IG) – Working with the EDC, complete periodic reviews of the External Document Register to confirm the appropriate currency of the documents. IG members represent EOTA functional areas.

EOTA Employees/Staff – Responsible for reporting the introduction into use of any external documents not listed on REG-002, External Document Register.

IV. Definitions

External Documents – Documents of external origin whose currency/location needs to be identified and controlled to ensure ready access to the documents by employees (to carry out their activities). External Documents are identified on REG-002, External Document Register.

V. Process



1.0 Classify the External Document Type

Upon identification of an External Document, the EDC, working with the applicable Staff member and/or IG member, will determine the External Document type. The External Document type may be an electronic copy, web-based and/or a hard copy.

2.0 Add document to REG-002, External Document Register

The EDC will add the new document to REG-002, External Document Register under the appropriate heading.

3.0 Determine/Record Next External Document Review (Month/Year)

The EDC, in conjunction with the applicable IG member, will enter the External Document Review interval on REG-002, External Document Register. The Next Review Month/Year is typically within a year or less but may be extended if determined by the External Document Controller.

4.0 Define/Record the Controlled Distribution List

The External Document Controller will determine the appropriate Distribution List, if any. A Distribution list is required for an external document when multiple hard-copy “masters” are available and will require retrieval if/when a new revision is made available and added as the current external document on REG-002, External Document Register. Once established, the EDC will record the Distribution List data in the REG-002, External Document Register, as applicable.

5.0 Conduct Reviews

The External Document Controller, in conjunction with the applicable IG member, will complete an External Document Review. When the External Document requires revision/update, the EDC will remove the current document and replace it with the new External Document identified on REG-002, External Document Register. For electronic and/or web-based services or email notification update services, the EDC using REG-002, External Document Register will search for the applicable documents and replace any stock or master copies with the revised version of the external document. The EDC will ensure the review results are recorded in the Revision History section of REG-002, External Document Register.