

Veeva&U Quality User Community

March 05, 2019



Agenda

Tuesday, March 5th

15:30 – 15:45

Welcome

Neelam Sidhu: Customer Success Manager, Veeva

15:45 – 16:05

Forms Working Group: Controlled Issuance of Forms

Mike Holland: Customer Success Manager, Veeva

16:05 – 16:35

Controlled Copy Trace Implementation

Olivier Melis: Process Data Owner for SourceCD, TrackWise & TSL (a.i.) Digital QA, GxP Solutions, UCB

16:35 – 17:05

Controlled Copy Enhancements and Use Cases

Chris Boschen: Senior Product Manager, Veeva

17:05 – 17:15

Wrap Up

Neelam Sidhu: Customer Success Manager, Veeva



Customer Success New Member

Customer Success Contact:



Mike Holland

R&D Customer Success Manager

- 20+ Years industry experience
- Project Management, Requirements Gathering, Change Management, Business Analysis, Validation, QA, Migrations
- Veeva Vault, FirstDoc, Documentum, FirstPoint, SharePoint
- **Quality, RIM, Submissions, eTMF**

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Vault Quality User Meeting - Remote
5th March 2019
15:30 – 17:30 CET

Vault Quality User Meeting at Summit (Onsite Only)
13th June 2019
13:00 – 15:00 CET



Community Meeting Objectives

Foster *customer success* by ...



Creating opportunities for **customer interaction**

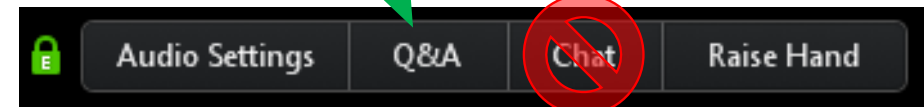


Providing a forum to **share practices**



Promoting **product education**

Please use
'Q&A' to ask a
question



Veeva R&D

SUMMIT

Europe

Register
Now

400+

attendees from
life sciences

90+

life science
companies

Unify & Connect | 11 – 13 June 2019 | Barcelona, Spain

Join our European
R&D Community



Develop New
Industry Partnerships



Share Best Practices



Network with Peers



**SAVE THE
DATE**



**Clinical
Operations**



Regulatory



Quality



**Vault
Platform**

19R1 Release

April

12, 19

April 12th: General Release POD **VV1-2**, and all Limited Release PODs

April 19th: All **remaining** General Release PODs

March

19 - 22

Validation docs available in ComplianceDocs Vault

QMS: Executed OQ docs available by 3/22

March

18 - 19

Pre-Release Vaults Available (Production Config Copied 2/15)

March

13 - 20

Quality Webinars

http://go.veeva.com/19R1_quality



Community Tools

Support Portal



- **Users:** Veeva customers – IT and business administrators
- **Purpose:** Helpdesk / customer support ticketing system for Vault issues
- **Example:** Why do I not see document actions when I click on the 'gear' for a document?

Community Vault



- **Users:** Veeva customers – working group members and reviewers
- **Purpose:** Community developed content
- **Example:** Risk-based change management of GxP systems whitepaper

LinkedIn Group



- **Users:** Veeva customers and ex-customers, and industry leaders
- **Purpose:** Connect with other quality peers and ask non-support questions
- **Example:** How do you manage forms? Does anyone manage lab books in Vault QualityDocs or Vault QMS?



LinkedIn Veeva Quality Community Group

<https://www.linkedin.com/groups/13680559/>

Group Description

- **Group name:** Veeva Quality Community
- **About this group:** Connect with peers within the Veeva Quality Community and ask, share, or learn about best practices and approaches, Veeva news and events, or other quality information that will improve the life of members.
- **Group rules:** Please do not post product support questions here. For issues with Vault Quality products, please log a ticket in the Veeva Support Portal.

Select privacy *

☐ Standard
Group visible in search results. Members can invite other members to join.

☒ Unlisted
Group does not appear in search results. Only group owners and managers can invite members to join.



Next Steps

<https://www.linkedin.com/groups/13680559/>

Getting Community Online

1. Please go to URL above to request access to the LinkedIn group
2. Start 'posting' your questions, or sharing your learnings

Management

- Veeva will moderate posts
- Only customers/quality community members will be allowed to join
- Evaluate usefulness of the LinkedIn group by next Quality Community meeting

Benefits

- Global group
- Connect with other Veeva quality customers
- Crowd sourcing to help solve problems
- Participation from Veeva customers, customer success managers, market owners
- Stay up-to-date on key information



Controlled Issuance of Forms

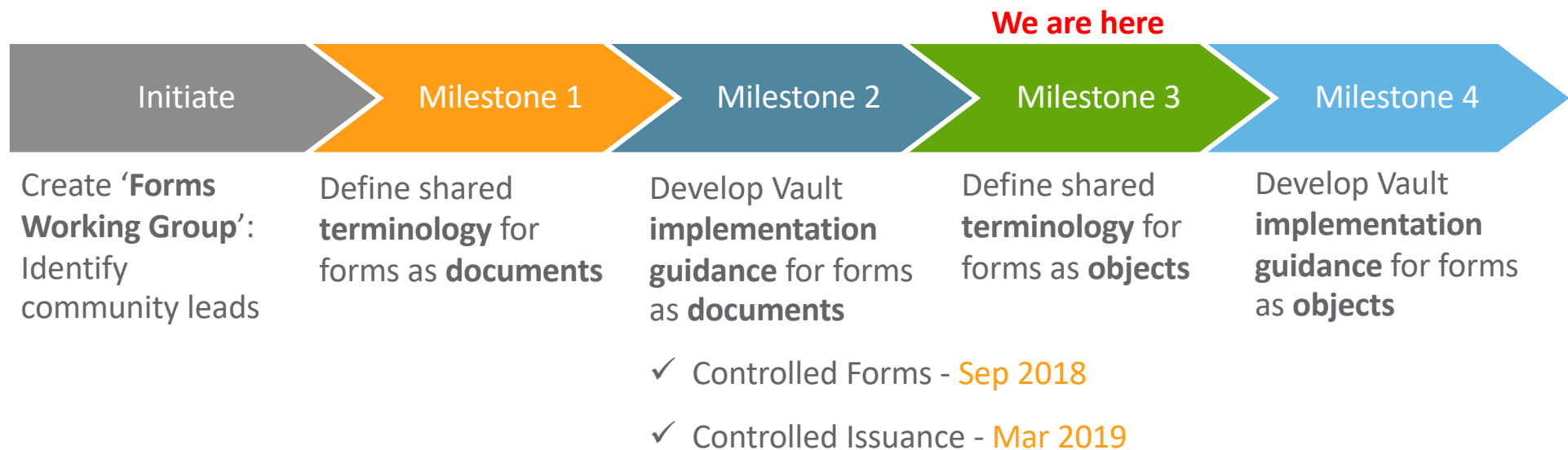
Mike Holland

Customer Success Manager, Veeva



Forms Working Group Objective

- Define a shared terminology for forms that describes how they are used **in relation** to Vault Quality
- Provide guidance on how to develop, manage, and use forms now; and suggest product enhancements



Controlled Copy

- The process of authorizing a controlled document for physical printing or download
 - Overlays identify the controlled issued copy
 - Unique identifier provides tracking capabilities

Doc #: SOP-00107 Version #: 1.0 Status: Effective Effective Date: 11/5/2018 Controlled Copy #CC-SOP-00107-1-0-0001	
	Standard Operating Procedure: Controlled Copies
Document No.: SOP-00107	Department: Quality Assurance

1. PURPOSE

The purpose of this document is to outline the procedure for requesting, issuing and recalling controlled copies.

2. SCOPE

The scope of this document is related to all SOPs that may be issued for inclusion



Controlled Issuance

- The process of authorizing a controlled form for physical printing or download
 - Overlays identify the controlled issued copy
 - Unique identifier provides tracking capabilities
 - Often linked to a batch or lot number
- Issuance is restricted to the Effective or Approved document version
- Who can issue may be restricted

Doc #: FRM-00022 Version #: 1.0 Status: Effective Effective Date: 2/20/2019 Issued Copy #IC-FRM-00022-1-0-0001 Batch/Lot: 1000 Location: Pleasanton	
Date of Test:	Click or tap to enter a date.
Sterile Water for Irrigation Batch Number:	Click or tap here to enter text.
Expiry Date of Water:	Click or tap to enter a date.
1. Examine samples and purified water in vials:	<input type="checkbox"/>
2. Hold vials 10 cm apart below a light source:	
a. Examine vials against a white background	<input type="checkbox"/>
b. Examine vials against a black background	<input type="checkbox"/>
3. Gently swirl vials and observe color and clarity.	<input type="checkbox"/>



When is Issuance Needed?



Operator needs to execute a protocol and record data during an instrument qualification



Team Lead prints for reference in a team meeting



Operator needs to follow a procedure on the manufacturing floor



Manager prints procedure for reference during presentation



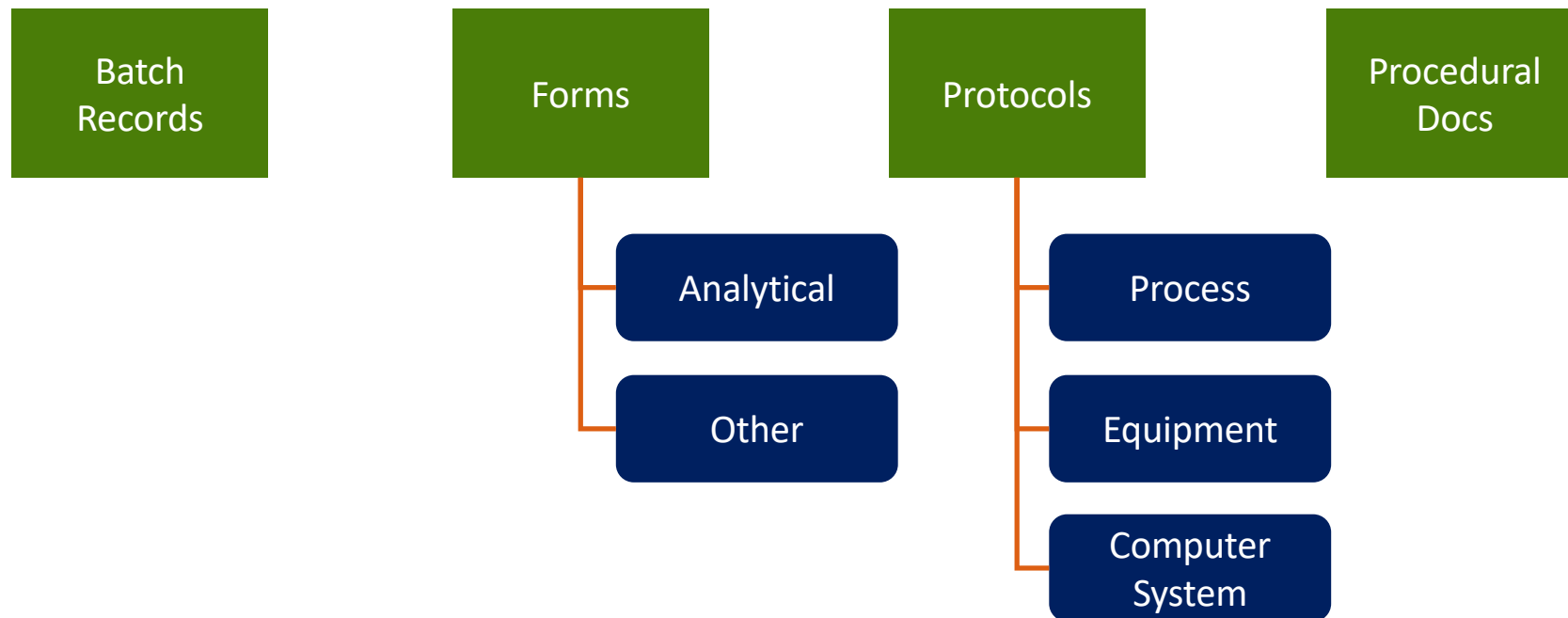
Analyst need to complete a form to record original data during test execution.



Individual prints system access request form to complete and submit

Issuance Types

- Refers to the way an organization groups document classifications with similar Controlled Issuance requirements



Issuance Types – Who Can Issue?

Analytical Master
Forms



Any
User

All
Other Forms



Authorized Controlled
Issuance Users

Forms
Issuance
Type



Issuance Types – Data Collected at Issuance

Analytical Master Forms

- **Issuance ID** – identifies batch or material being tested
- Prevent issuance if the **Issuance ID** specified was already used for the selected master form version

All Other Forms

- **Issuance ID** – Unique issuance number generated by system, not entered by user to identify a batch/sample

Common data collected from a user at issuance includes such things as Recipient, Location Used, Reason for Issuance

Forms
Issuance
Type



Issuance Types - Metadata for Tracking

Controlled Copy User Input

▼ Details

Controlled Copy User Input Type Issued Copy

Vault Document [Appearance Testing Form \(v1.0\)](#)

Manufacturing Facility*

Batch / Lot*

Reason for Issuance*

Issued To*

Requested By* Bob Kenney

Name*

▼ System Information

User Action Label* Download Issued Copy



Controlled Copy Traces >

Issued Copy: IC-FRM-00022-1-0-0001 ★ ISSUED

► Workflow Timeline

▼ Details

Controlled Copy Trace Type Issued Copy

Vault Document [Appearance Testing Form \(v1.0\)](#)

Released From Vault Yes

Number of Copies in Package 1

Requested By Bob Kenney

Manufacturing Facility [Pleasanton](#)

Batch / Lot 1000

Reason for Issuance Sample Testing

Issued To [Bob Kenney](#)

Lifecycle State Issued

Lifecycle Controlled Copy Trace Lifecycle

Forms
Issuance
Type



Issuance Types – Copy Handling

- Sample: **ABC**
 - # copies: 3
 - System creates 3 issued copies of doc FRM-3456 v5.0 with the following issued copy numbers and trace records for each:
 - IC-FRM3456-50-**ABC**01
 - IC-FRM3456-50-**ABC**02
 - IC-FRM3456-50-**ABC**03
- Sample: **ABC, DEF, GHI**
 - # copies: 3 (one for each sample)
 - System creates 3 issued copies of doc FRM-3456 v5.0 with the following issued copy numbers and trace objects for each:
 - IC-FRM3456-50-**ABC**
 - IC-FRM3456-50-**DEF**
 - IC-FRM3456-50-**GHI**

Forms
Issuance
Type



Issuance Types - Reconciliation

Analytical Master Forms



- Any User + QA Oversight
- Person reconciling an issued copy record cannot be the person that issued the copy

All Other Forms



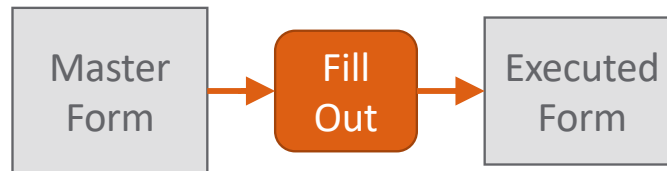
- Authorized Controlled Issuance Users
- No business process constraints on reconciliation of other forms

Forms
Issuance
Type

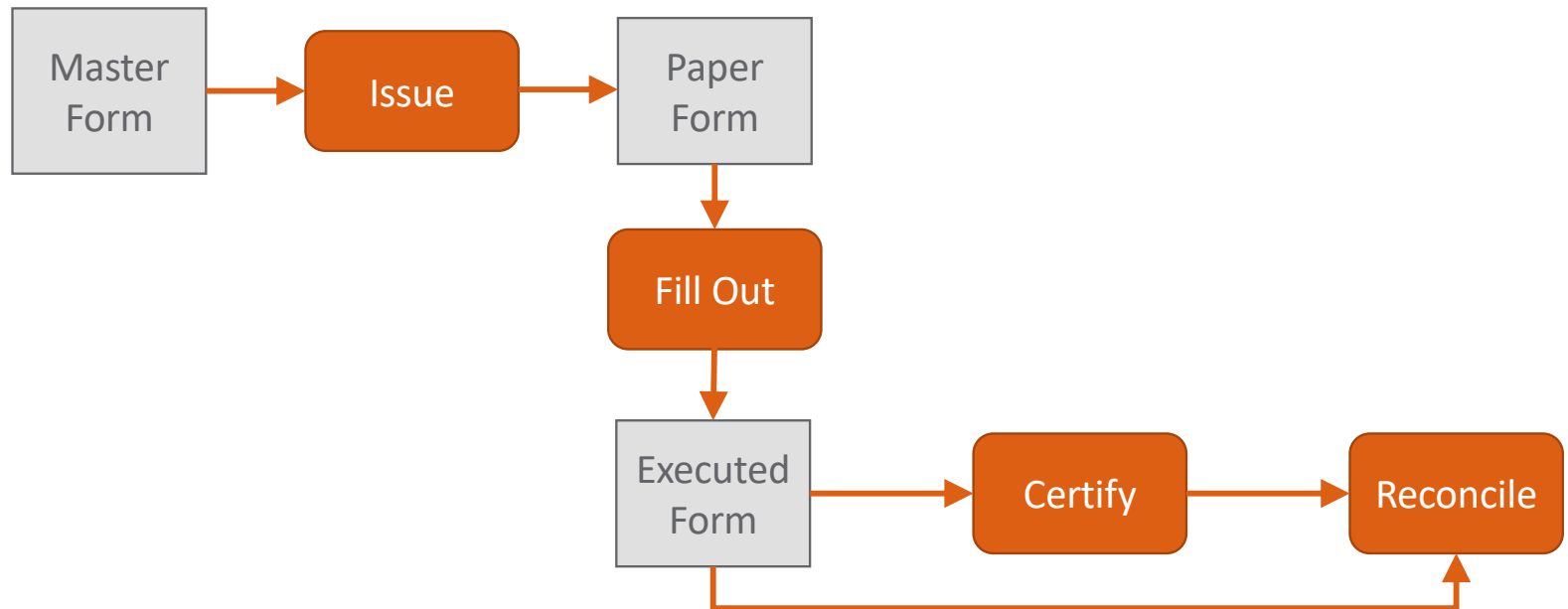


Controlled Forms/Controlled Issuance & Reconciliation

Controlled Form



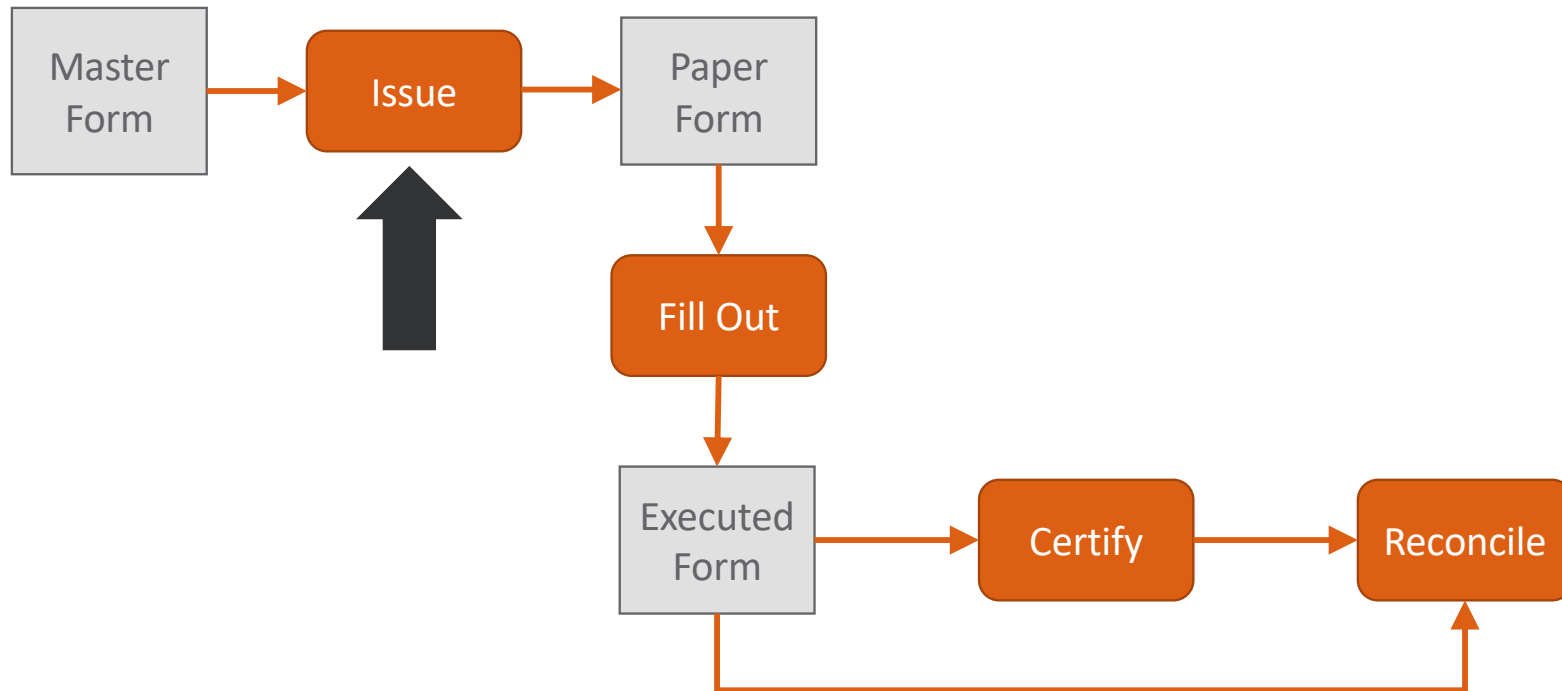
Controlled Issuance



Note: Process based on issuing and filling out a paper form

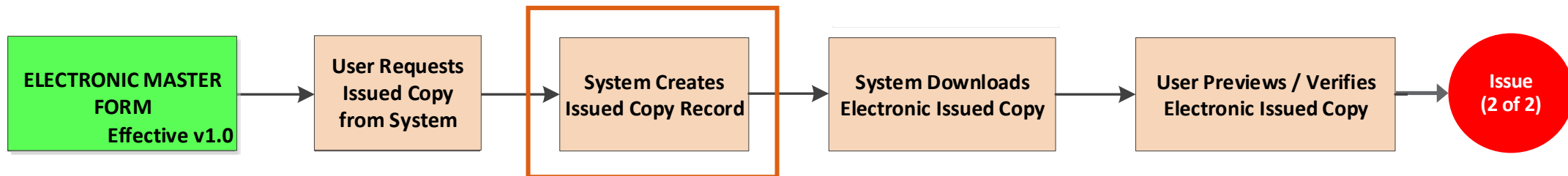


Controlled Issuance – Form Issuance Type



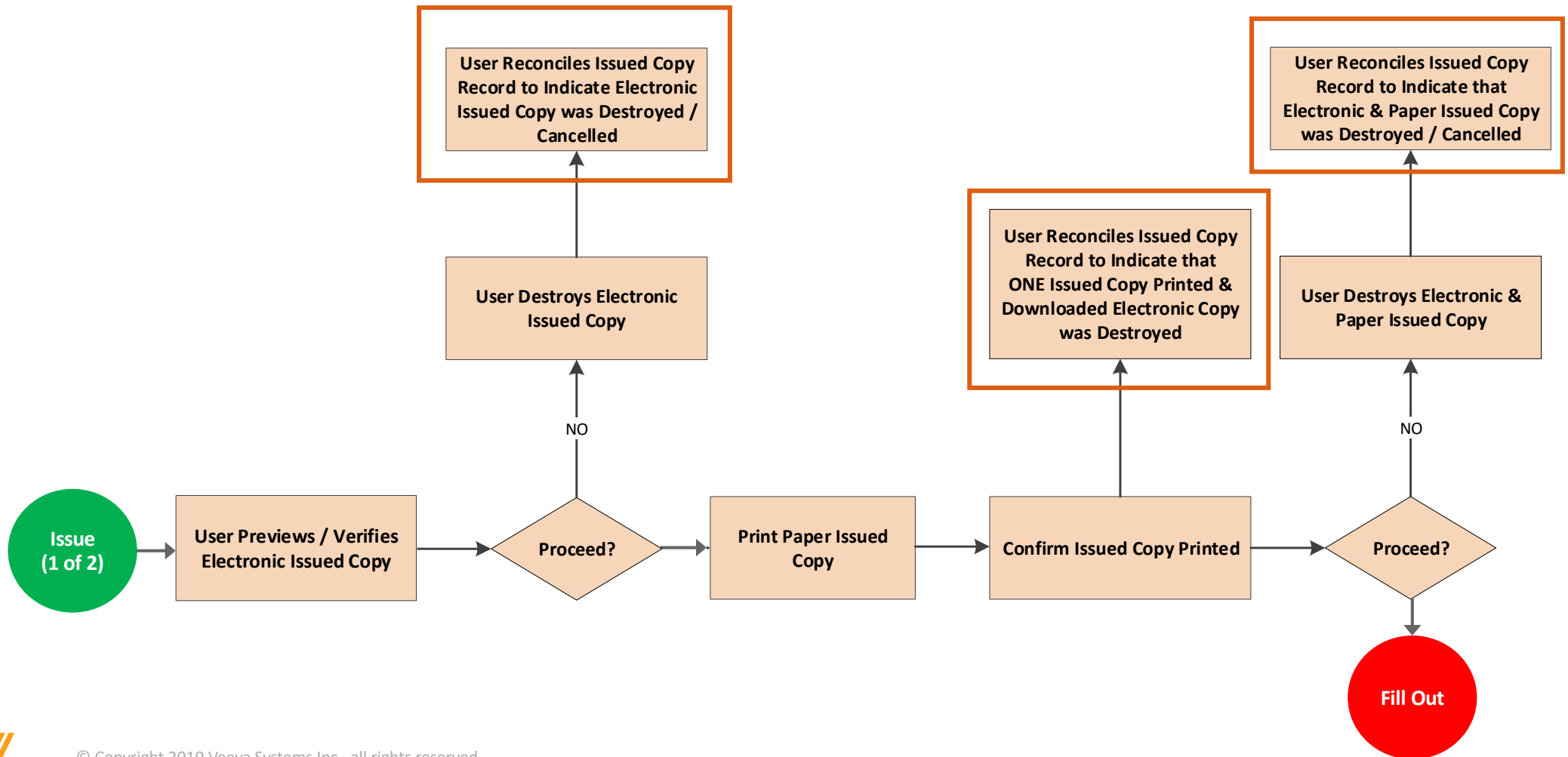
Controlled Issuance Process

Issue
(1 of 2)

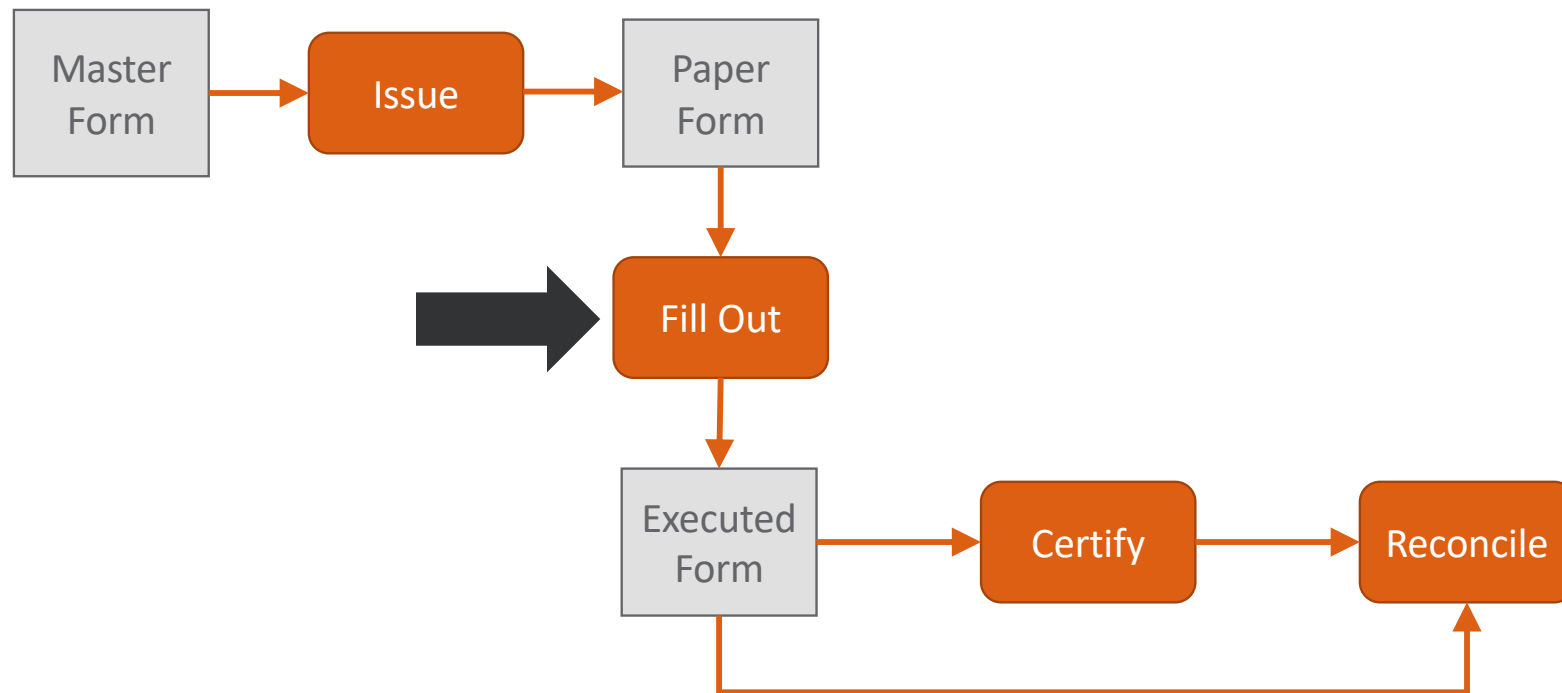


Controlled Issuance Process with Reconciliation

Issue
(2 of 2)

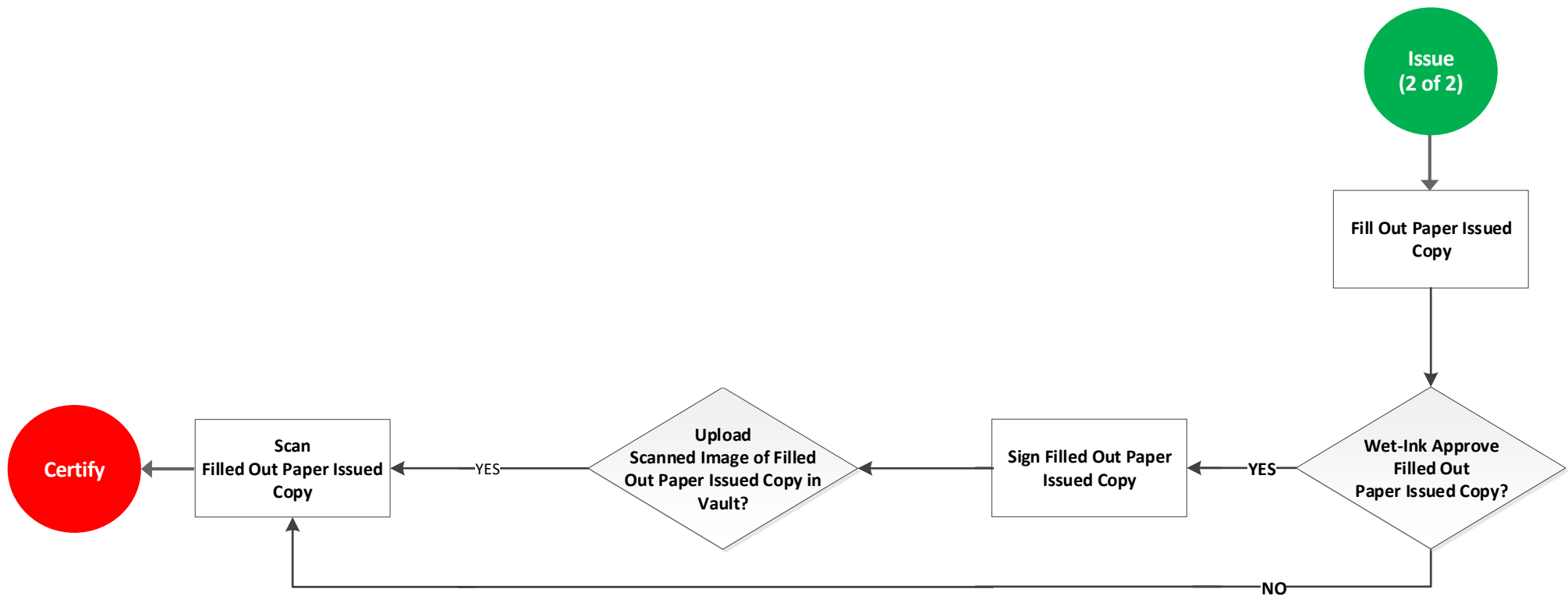


Controlled Issuance – Fill Out Form

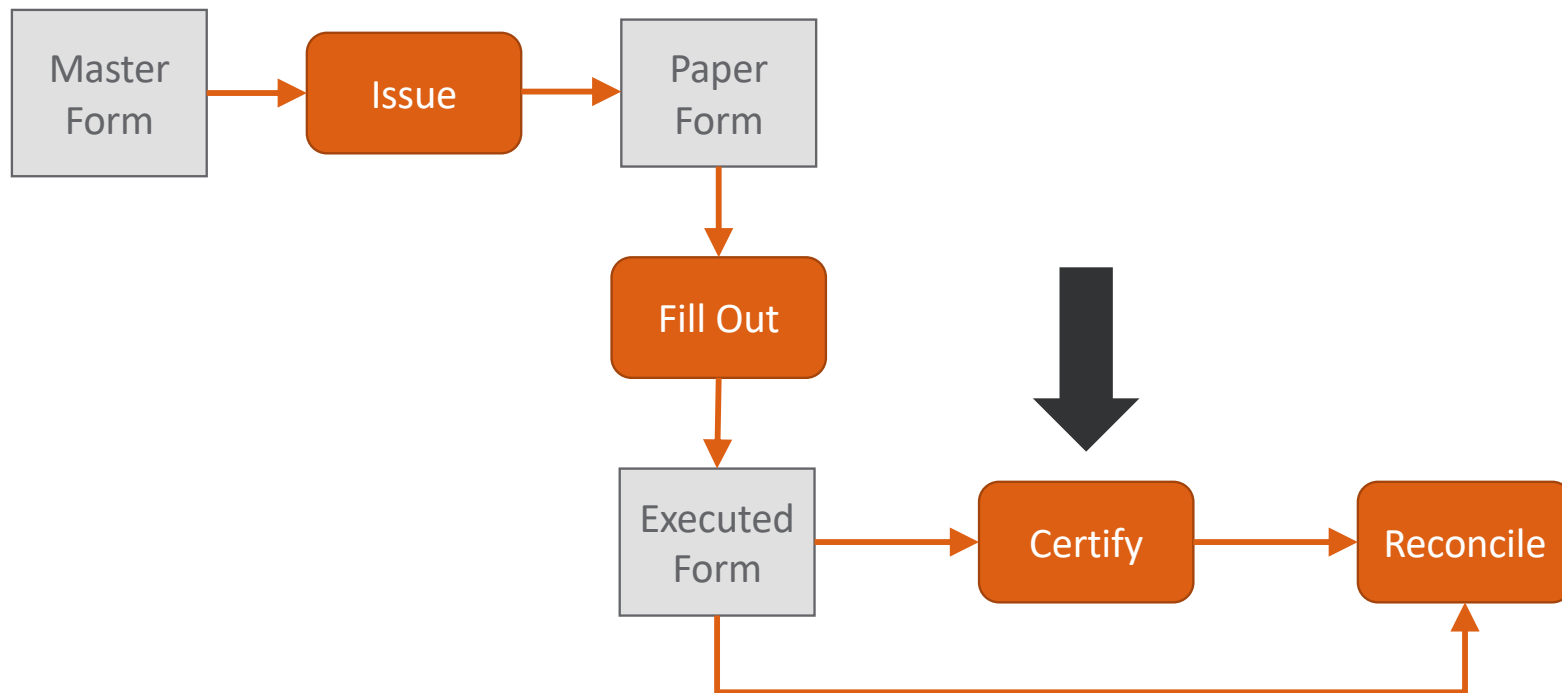


Controlled Issuance – Fill Out Form Process

Fill Out

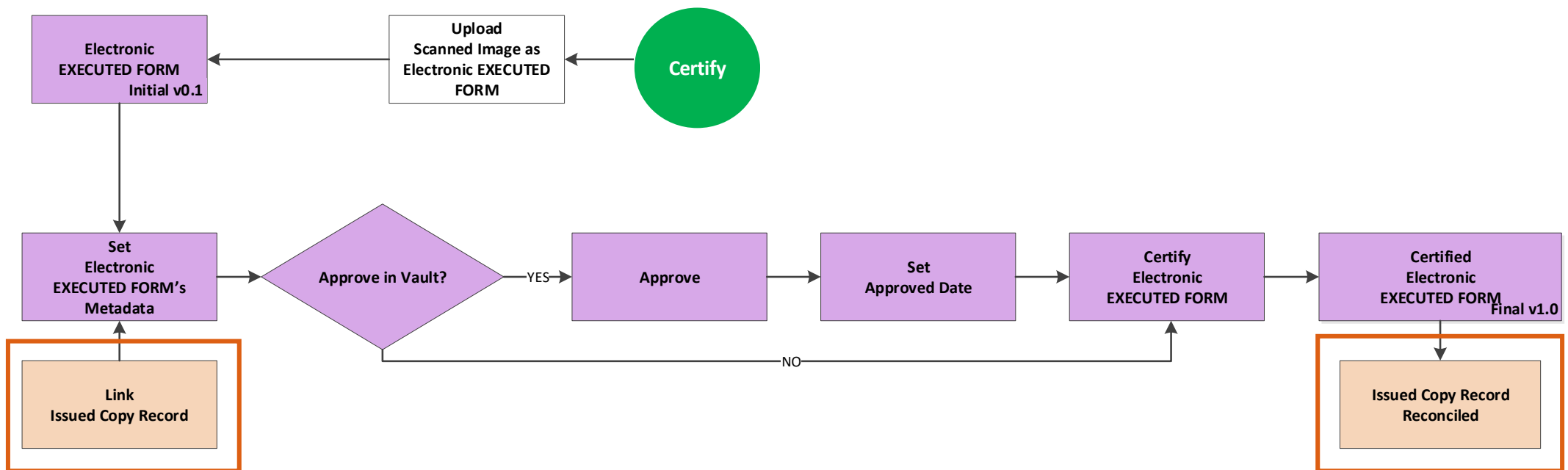


Controlled Issuance – Certify



Controlled Issuance – Certify Form Execution Process

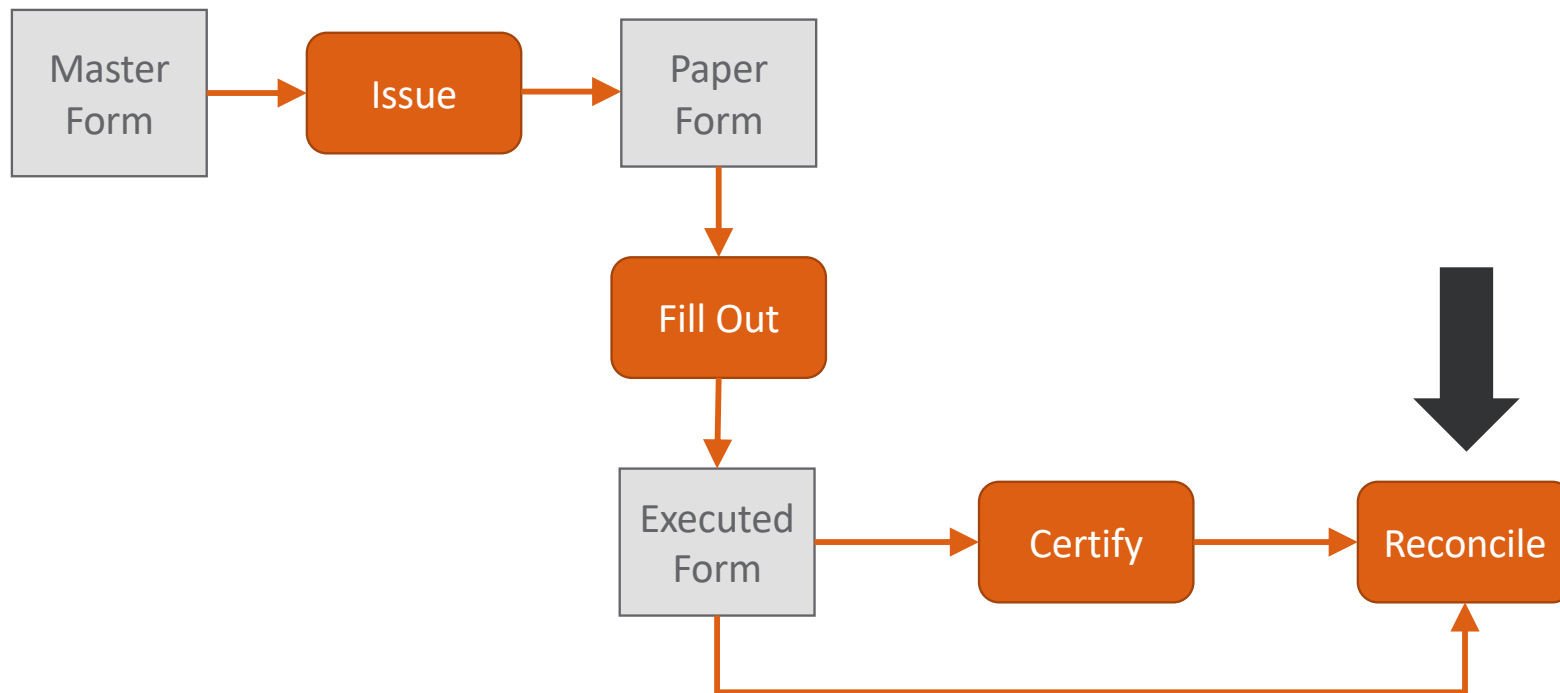
Certify



Certifying the Electronic Executed Form triggers the related Issued Copy record to be reconciled

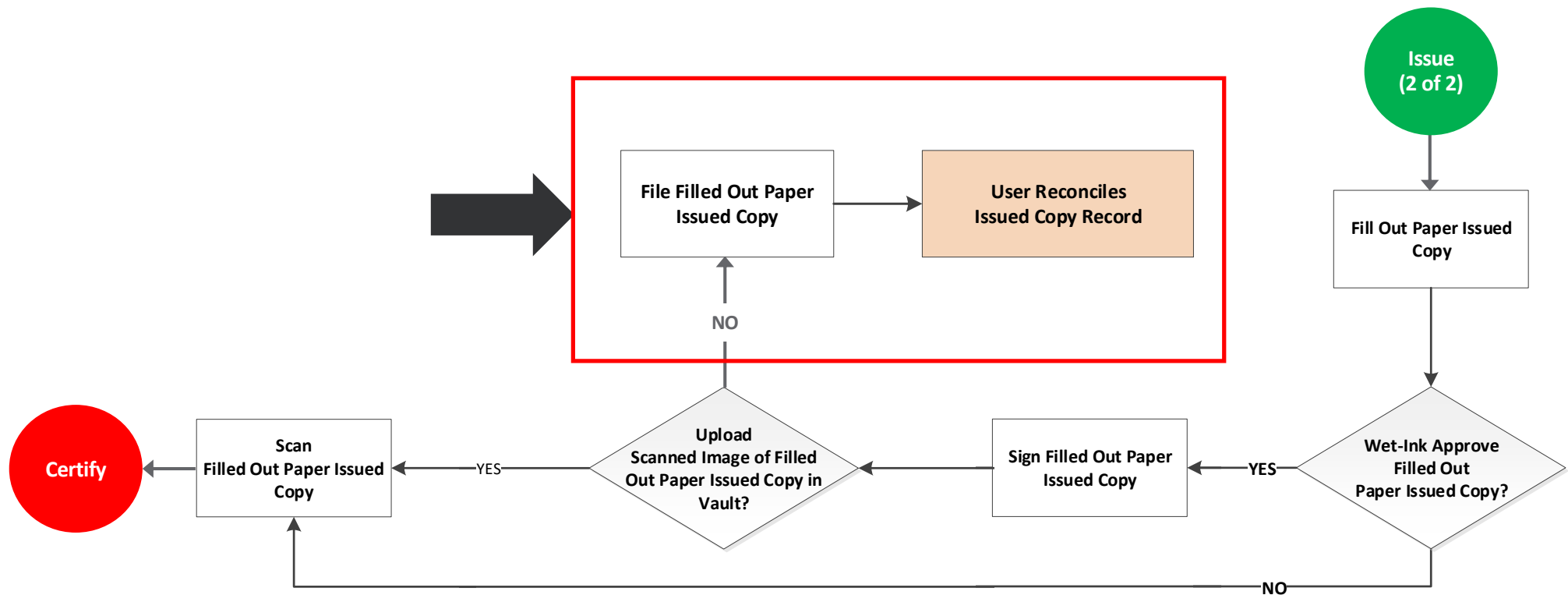


Controlled Issuance – Reconcile Paper



Controlled Issuance – Reconcile Paper

Reconcile



Next Steps

- The Forms Working Group plans to ...
 - Develop *Implementation Considerations* and *Best Practices* for the paper form issuance process described above
 - Provide content to the Quality Community for review
 - Analyze whether there is benefit to developing an issuance process for document-based forms that are filled out electronically (e.g. Word docs)
- Evaluate the case for using electronic forms (i.e. Vault objects) in QualityDocs





Controlled Copy Trace Implementation

Olivier Melis

Process Data Owner for SourceCD, TrackWise & TSL (a.i.) Digital QA, GxP Solutions, UCB



Agenda

- Controlled Copy Trace
 - Background
 - Timeline
 - First actions
 - Next steps
 - Solution
 - Solution deployment
 - Lessons Learned



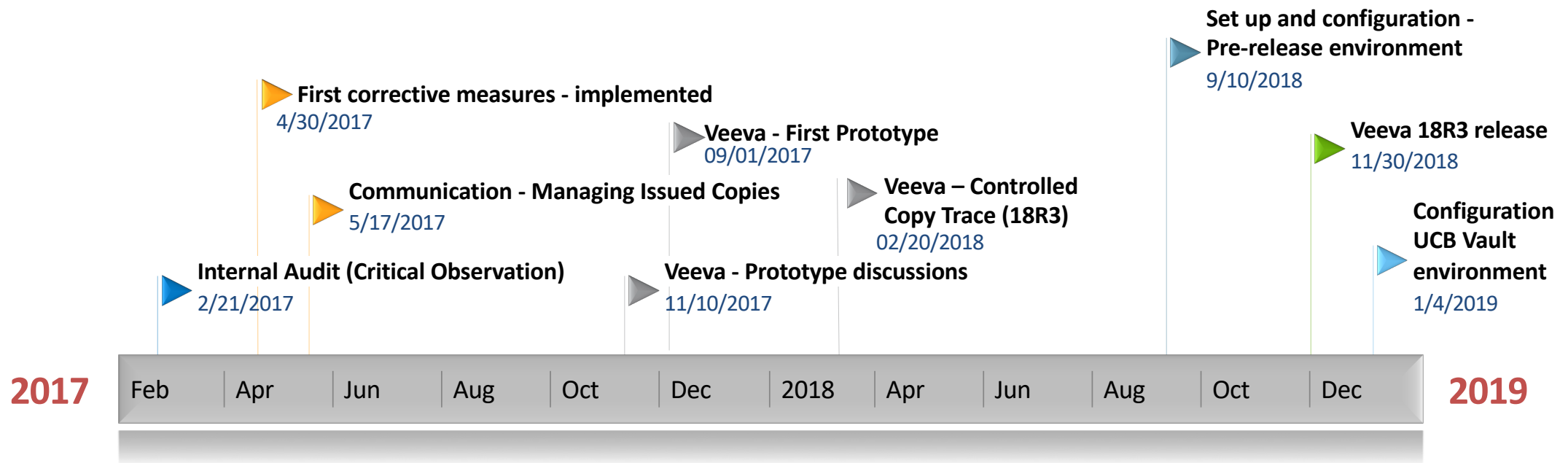
Controlled Copy Trace

Background

- Internal QC Lab GMP Audit
 - Multiple print of issued copies with the same batch number
 - Difficulties to identify the unique printed copy
 - Lack or difficulty to trace allowing possibility of falsification
 - Data integrity risk



Controlled Copy Trace – Time line



Controlled Copy Trace

First action(s)

- First measure to limit risk of duplication
 - Update applied overlay with the addition of a unique identifier for the Issued Copy
 - Creation of a Quick Reference Guide
 - Creation of an SOP, added to training profile
 - Data integrity course, added to training profile
 - Communication to distributors



Controlled Copy Trace

Next steps

- Prototype definition @ UCB
- Prototype discussion with Veeva
 - Short term enhancements
 - Enhancements for later consideration
- Review meetings and prototype alignments
- Setup up solution
- Valid for pre-release 18R3



Controlled Copy Trace

Solution

- Collaborate with Managed Services to develop & configure feature prior to 18R3 release
 - Configuration done on Clone of PreRelease
 - Project Planning
 - Weekly Meetings
 - Testing
 - Validation Documentation (provided by MS)



Controlled Copy Trace

Solution

- Controlled Copy Trace → as an object
- More control to verify manually entered reason:
 - No duplicate information allowed
 - Verification of the reason for duplication
 - No leading/trailing blanks allowed to 'force' the same value
 - No use of capital letters to 'force' the use of the same value (e.g. LOT 123 → Lot 123)

Copy Request

▼ Issued Copy Details

Requested For

Audience Details

Reason or Justification*

▼ Duplicate Copy Justification

Duplicate Justification

▼ System Information

Status* Active

User Action Label* Download Issued Copy

Requested By*

Vault Document

Cancel Continue

Controlled Copy Trace

Solution deployment

- Validation of the solution
 - Training and documentation preparation
 - Communication
-
- Still to come – Working with Product and Managed Services
 - Preparing migration of *previous* controlled copies



Lessons Learned

Not everything goes as planned

- Yes we faced difficulties, and Yes we resolved them.
- Process:
 - Numbering (we forget to start at a different number) restarted at 0001.
 - We fixed this quickly
- SDK :
 - We had not tested " ' ", fix in Vault SDK code
- Deployment / Testing
 - Security settings were not aligned. Our groups in DEV, ACC aligned, though not used in PRD.
 - Consequence, Distributors could create, but not see the list of copies.
 - Working in a clone of Pre-Release comes with challenges.
 - Not able to think of every scenario.



Extensible Controlled Copy Enhancements and Use Cases

Chris Boschen
Senior Product Manager, Veeva



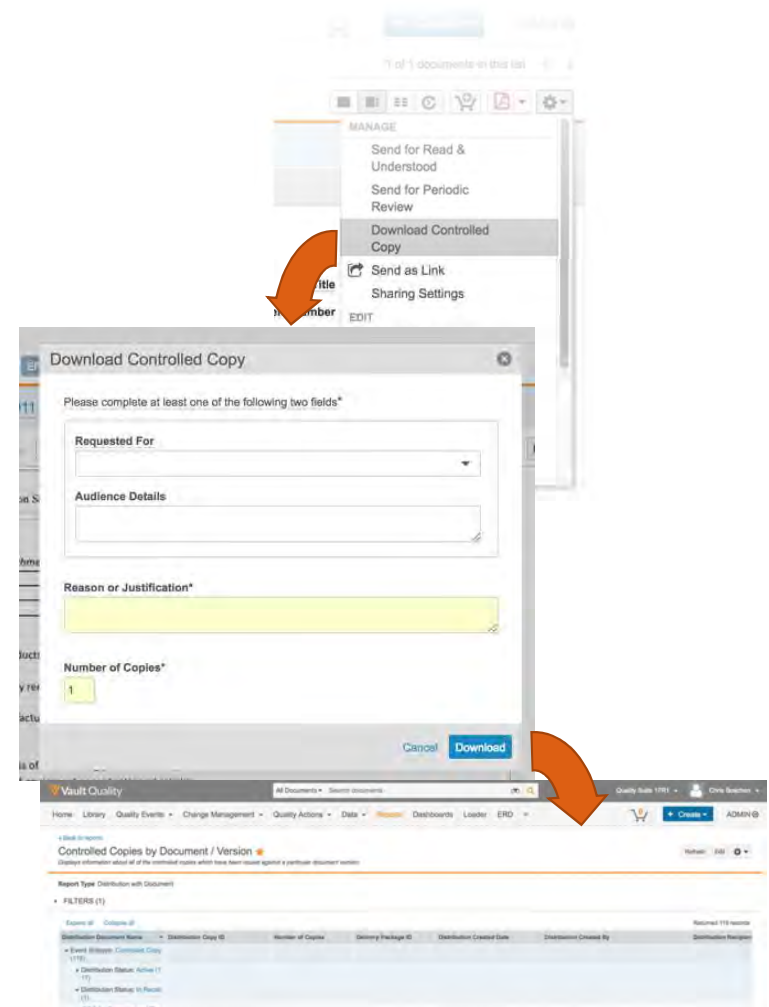
Important Disclosures

The following is intended to outline Veeva's general product direction. It is intended for informational purposes only and does not form part of any contract. It is not a commitment to deliver any specific functionality and it should not be relied upon in making purchasing decisions. Features and functions described in this document will be released commercially only when and if they become available. The development, release, and timing of the features or functionality of Veeva's products remains at the sole discretion of Veeva.



Quick Review: Vault **Legacy** Controlled Copy

- Allows configuration of who can begin the Controlled Copy
 - Leverage Vault Overlays
 - Configurable overlay definition (text, data, font, size, color, placement, images, etc.)
 - Restricted to members of specific roles
- Capture information of intended use
 - Who requests what, when? User Prompted Reason, Justification and Audience
 - System defined fields capture information
- Track, Reconcile & Report on copies
 - Dedicated Vault Report
 - Leverages Vault's Reporting (group, filter, export, etc.)



Legacy Controlled Copy vs. Extensible Controlled Copy

Functional Description	Controlled Copy (legacy)	Ext. Controlled Copy
Control who can request a Controlled Copy	✓	✓
Control the data displayed on the Controlled Copy document	✓	✓
Delivery Manifest for bulk-requested Controlled Copies	✓	✓
Control who can reconcile a Controlled Copy		✓
Configurable set of data prompted for upon request		✓
Configurable set of data available in reports		✓
Support for SDK extension of the QualityDocs function		✓
Configurable reconciliation process		✓
Automation ready via Vault Jobs		✓
Built on VOF, receives updates with each release		✓



ECC is Supported by an evolving platform

- Extensible Controlled Copies get enhancements in VOF, Reporting, Search and more in each release
- Since release, many new features have landed
 - Introduced record Validation rules, dynamic Page layout rules, new field types, live lookup field updates
 - Released SDK Enhancements
 - Enhancements to Object Workflow participant controls & task completion
 - Enhancements to Searching & Searching with Filters
 - Enhancements to Reporting Line Charts and Grouping concepts



Designs informed by a widespread team

- Thanks to working group members for industry feedback and commentary
- Good level of engagement coming from multiple geographic regions, across many organization sizes
- Early Adopter implementation feedback very beneficial



Great minds... something, something

- Many implementations, many discussions, surprising **consistency** in solutions
- Current common threads across working teams:

- **Reference Copy:** Low risk content copy.

- Content is not expected to be executed and/or returned to the vault.
- Duplicates (each with unique copy ID) are permissible



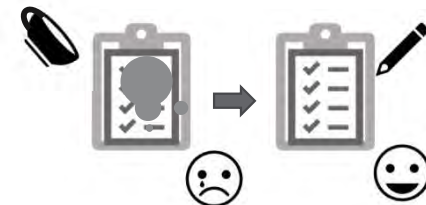
- **Issued Copy:** Medium or High risk copy.

- Copies are available to a restricted audience
- Content is expected to be executed and returned to the vault.
- Deviations from this flow should be captured in the vault.
- Duplicates (even each with unique copy IDs) should be prevented



- **Re-Issued Copy:** Medium or High risk copy duplicate

- Copies are only available to a *very* restricted audience
- Content is expected to be executed and returned to the vault.
- Deviations from this flow should be captured in the vault.
- Must be linked to original copy



So, how can one model those?

- Five points of consideration with Extensible Controlled Copies
 - **Pre-Vault planning** – the planning phase: Configure different *Types* of controlled copies, available to different audiences with different fields, behaviors, etc. Significantly more capabilities are available when leveraging Vault's java SDK.
 - **During the Copy Request Flow**: Configure copy request forms with key data and perform data validations within Vault; extend it further via java SDK
 - **The reconciliation workflow**: Full configuration control over the reconciliation workflow, states, audiences, notifications and tasks.
 - **The certification workflow**: Full configuration control over the upload of executed copies and certification lifecycle/workflow process
 - **Reporting & Dashboards**: Configure automated alerts or reports/dashboards to enable better visibility and management of outstanding copies



OK, but, how close are we today, *really*?

- Demonstration Flow
 - Request an Issued copy of an appropriate type of content
 - Reconcile that copy as destroyed / defaced / unusable
 - Request a duplicate Issued copy of an existing issued request
 - Execute that Re-Issued copy
 - Reconcile that Re-Issued copy's trace





Demonstration

So... Where to next?

- Vault is still listening, iterating & designing
- (A few) Current areas under consideration
 - **Streamlined Certification & Reconciliation** – depending on the type of content, certifying the document should be enough to automatically complete reconciliation of the *trace* record.
 - **Copy Request Approvals** – a process to allow a user to formally *request* a copy entirely within the vault
 - **Better automation** – automated kickoff of reconciliation processes when a new version of a document is released, and controlled copies of the prior version are out in use



Interested? Adoption considerations:

- Extensible Controlled Copy is available now for all Quality customers using QualityDocs
 - Discuss with your Veeva contacts to get more information & to begin the process
- This is as much a *process change* as it is a feature set or configuration change – approach it as one
 - Moving to the new model is an opportunity to get more value out of Vault – ask your Veeva contacts how you can best benefit from this feature set!
 - If your business is in the process of deploying QualityDocs, ask about ECC
 - If your business is live with *legacy* controlled copies, you have some considerations about *how* to move to ECC
 - A clean ‘cut-over’ is almost always the best approach, but not the only one available
- Feedback? Thoughts? Let us know!





Thank you