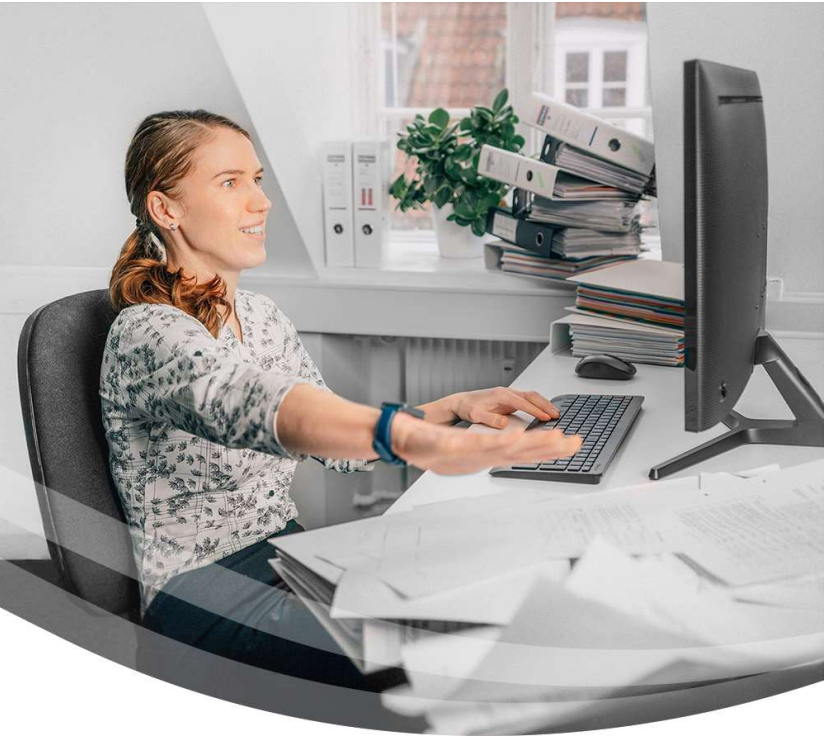


SimplerQMS

Workflows in SimplerQMS

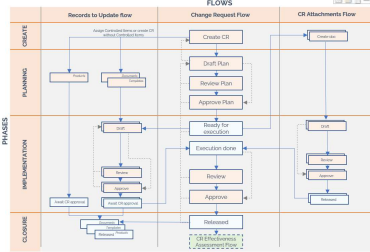


SimplerQMS workflows

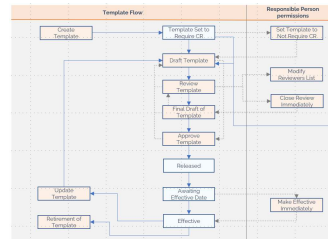
Tailored for processes in Life Science companies



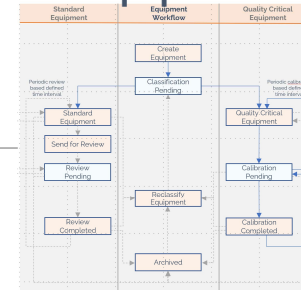
Change Requests



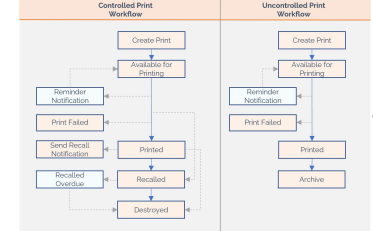
Templates



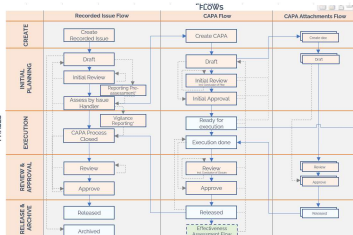
Equipment



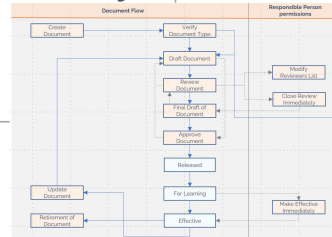
Controlled Printing



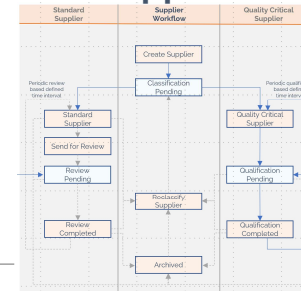
Recorded Issues & CAPAs



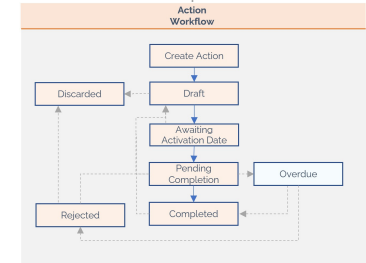
Quality Documents



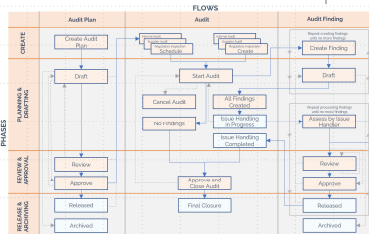
Suppliers



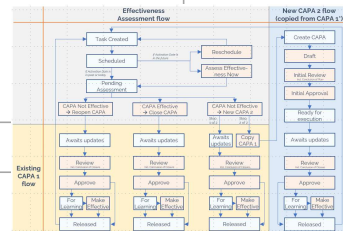
Actions



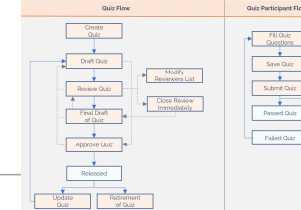
Audits



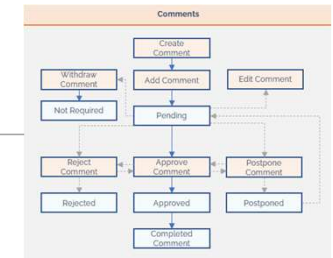
CAPA Effectiveness



Quizzes



Comment





Workflow overview

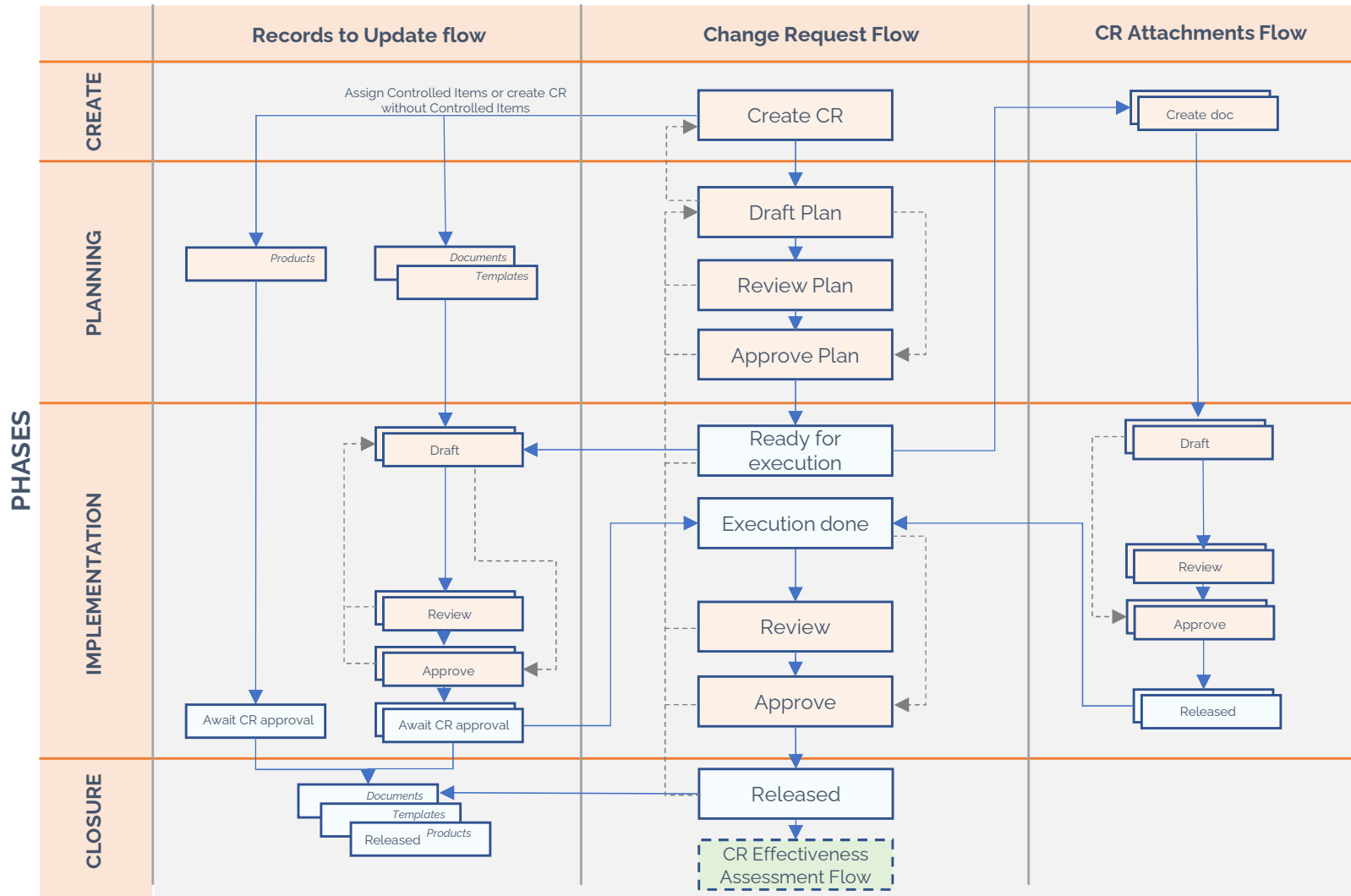
Slide	Workflows	Work Instructions
4	Change Requests	WI-00035 Managing Change Requests
5	CR Effectiveness Assessment	WI-07120 Assessing Effectiveness of Change Request
6	Recorded Issues & CAPAs	WI-00046 Managing Recorded Issues and CAPAs
7	CAPA Effectiveness Assessment	WI-00047 Assessing Effectiveness of CAPA
8	Quality Documents	WI-00037 Managing Quality Documents
9	Templates	WI-00036 Managing Templates
10	Training - Quizzes	WI-01055 Creating and Managing Quiz WI-01056 Quiz Participation
11	Audits incl. Plans & Findings	WI-00045 Managing Audits
12	Equipment	WI-00042 Managing Equipment
13	Suppliers	WI-00041 Managing Suppliers
14	Controlled & Uncontrolled Printing	WI-02238 Controlled Printing
15	Action	WI-00039 Actions, Periodic Tasks and Reminder Rule
16	Comments	WI-06044 Released Document Commenting

Change Request (CR) and CR Attachments



SimplerOMS

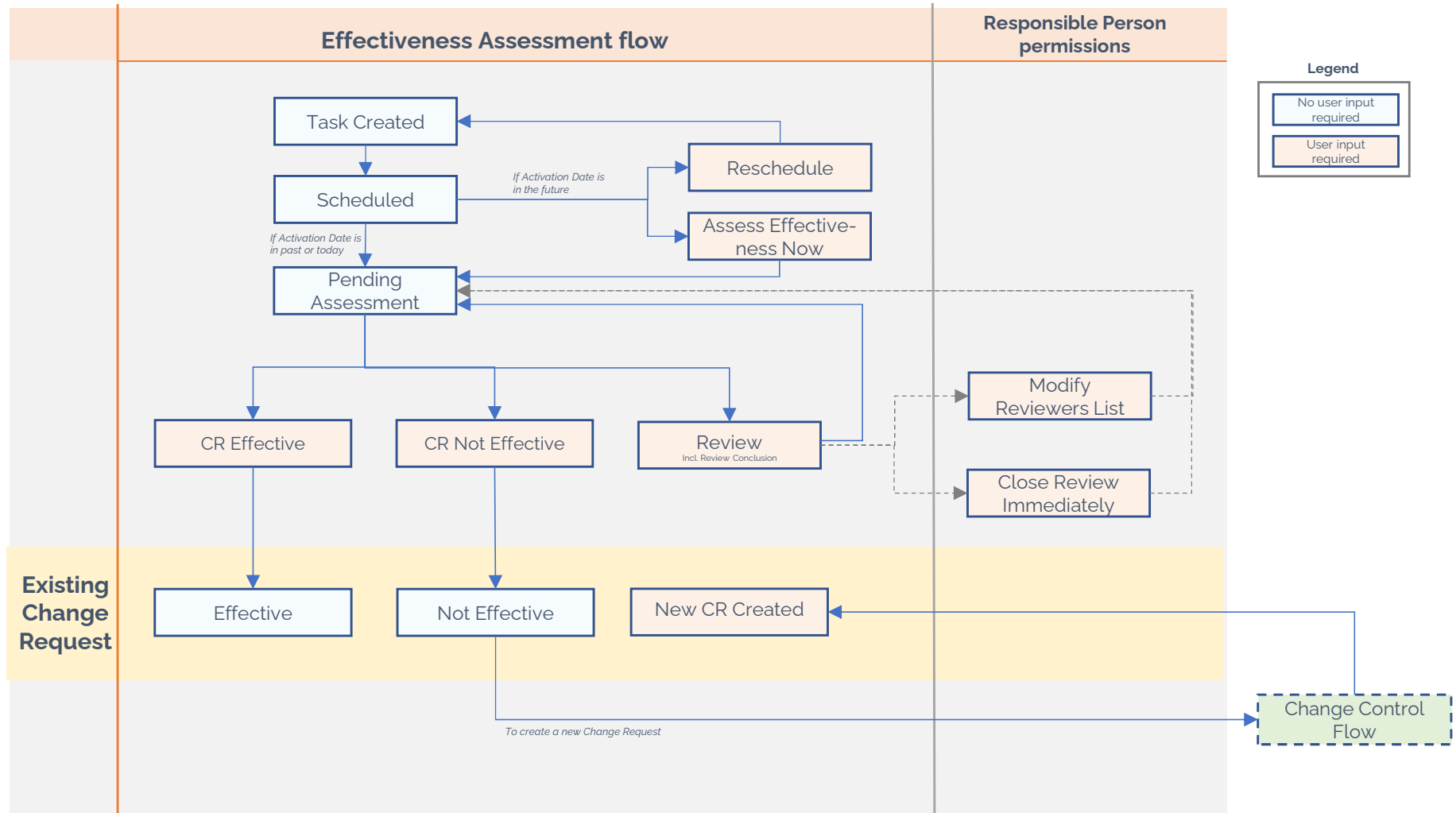
FLOWS



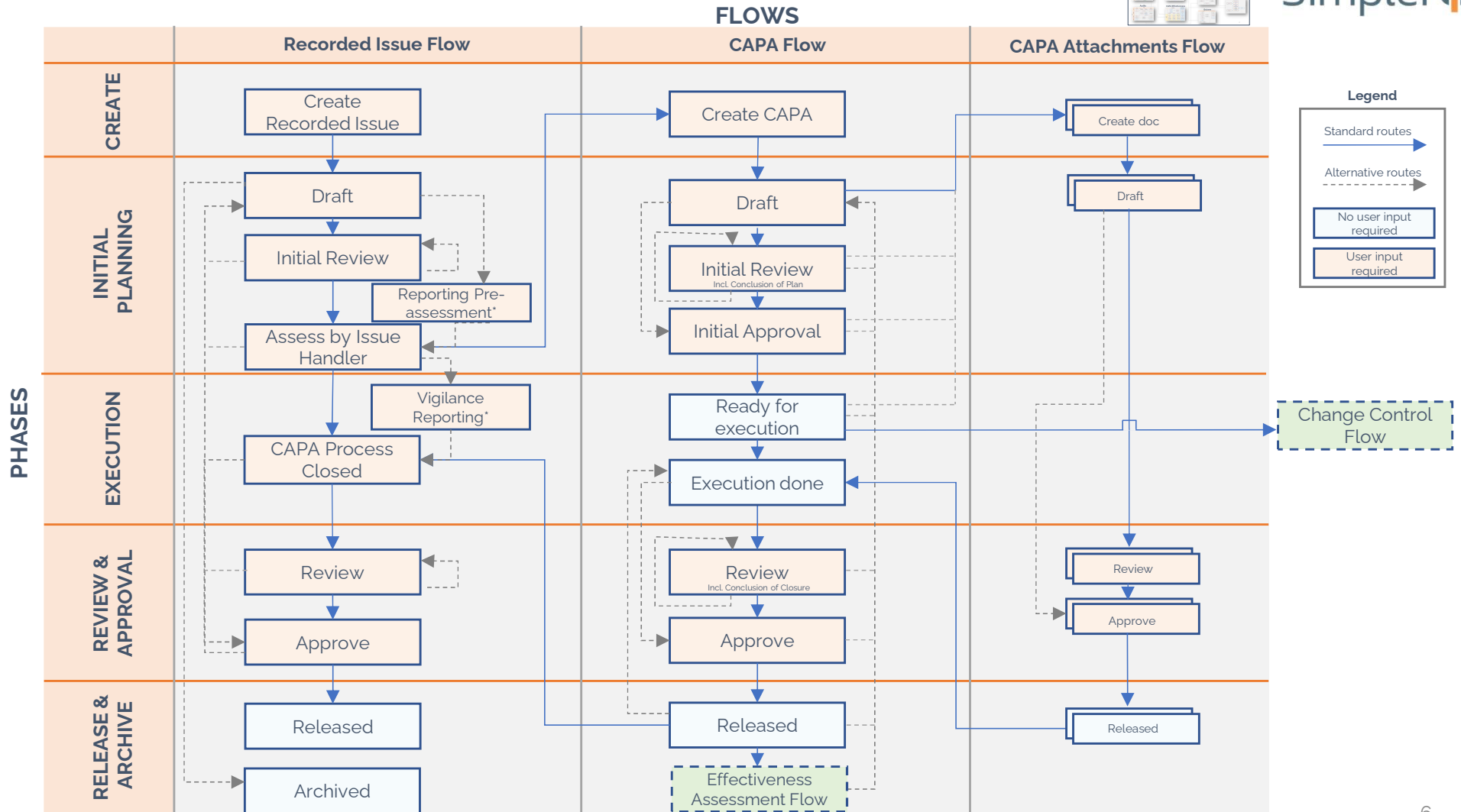
Effectiveness Assessment of Change Request



SimplerOMS



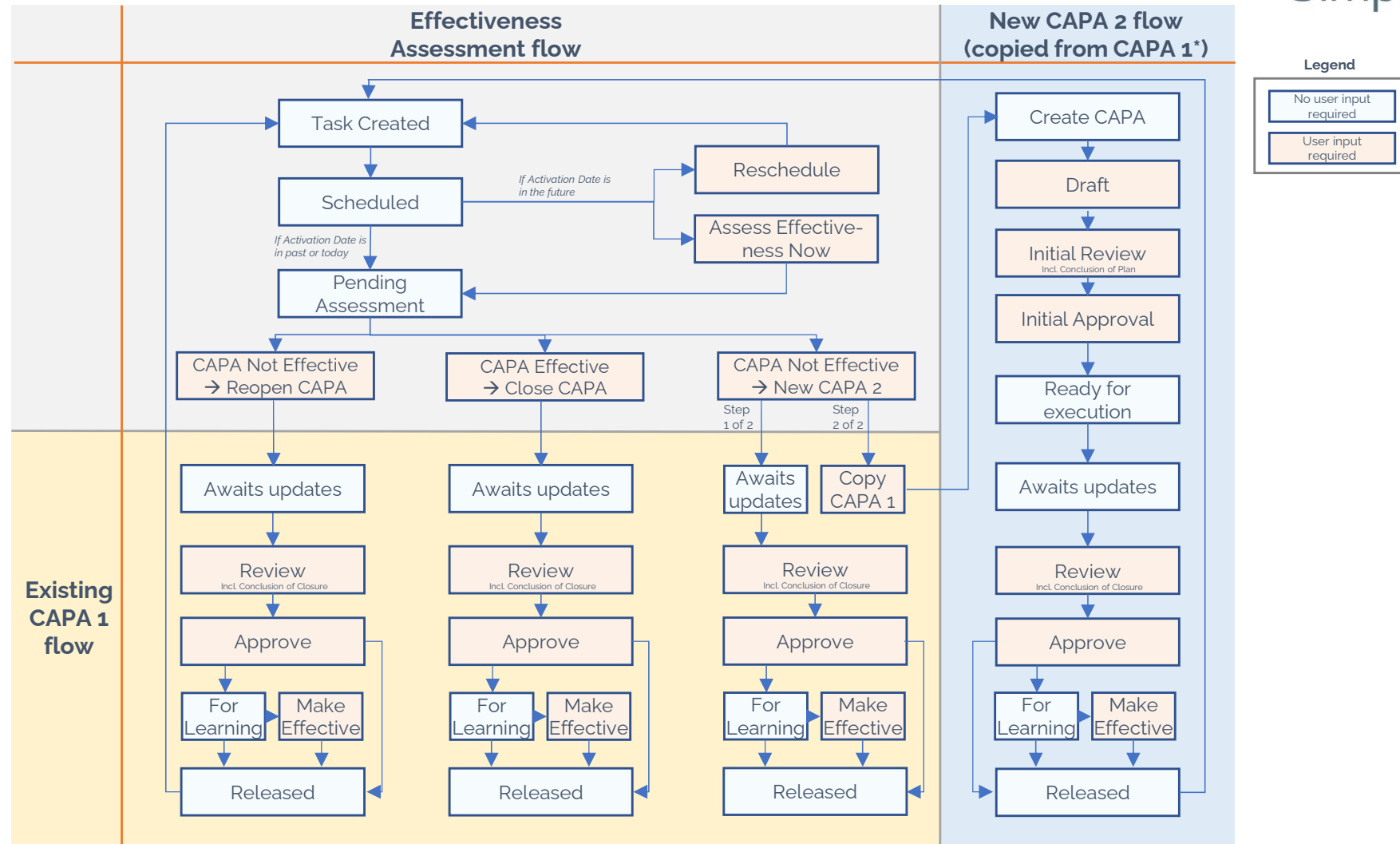
Recorded Issues** with CAPAs and CAPA Attachments



* If Reportability on the Recorded Issue Type is set to Yes

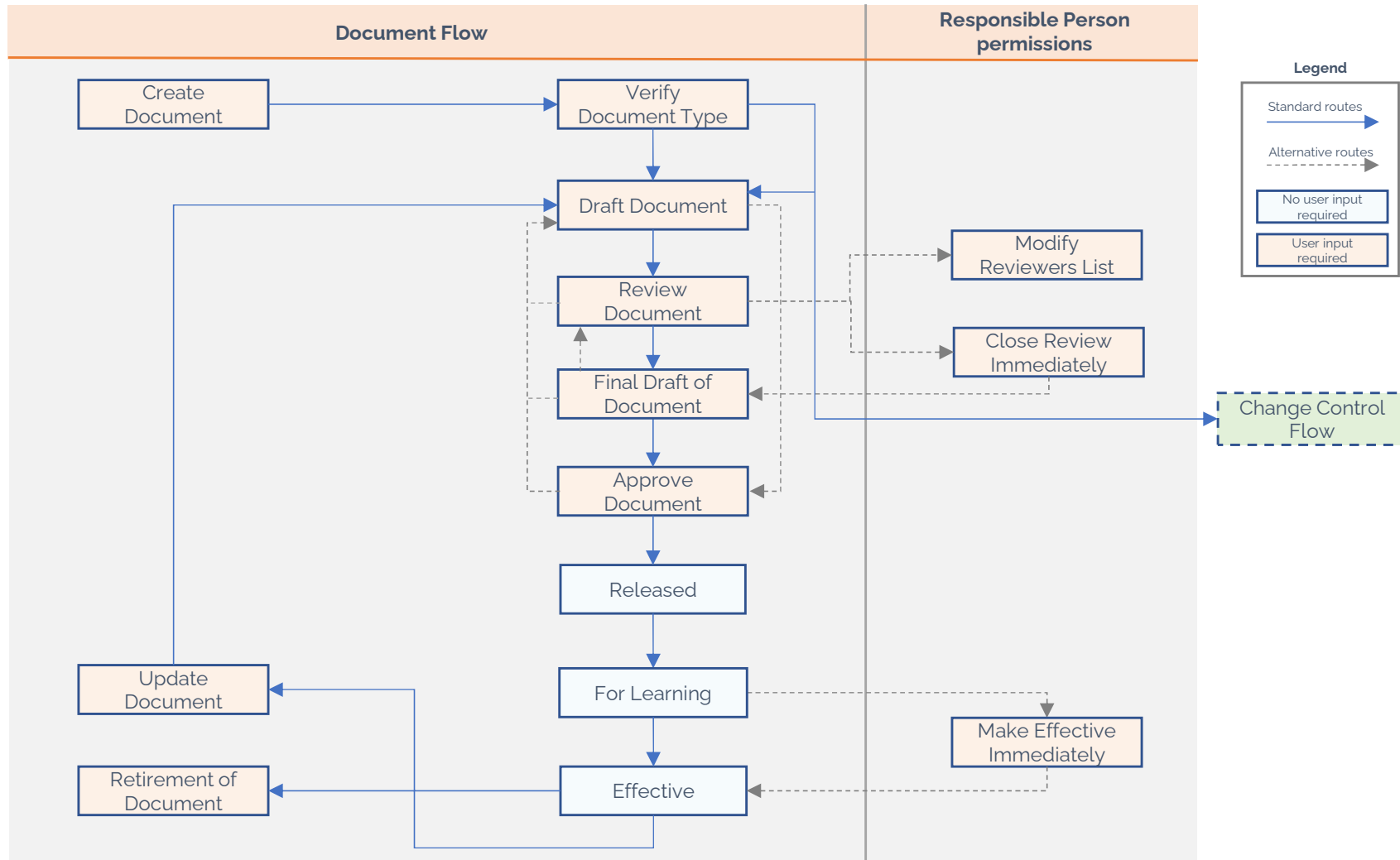
**Recorded Issues include Complaints, Nonconformances, Supplier Issues and Continuous Improvements

Effectiveness Assessment of CAPAs

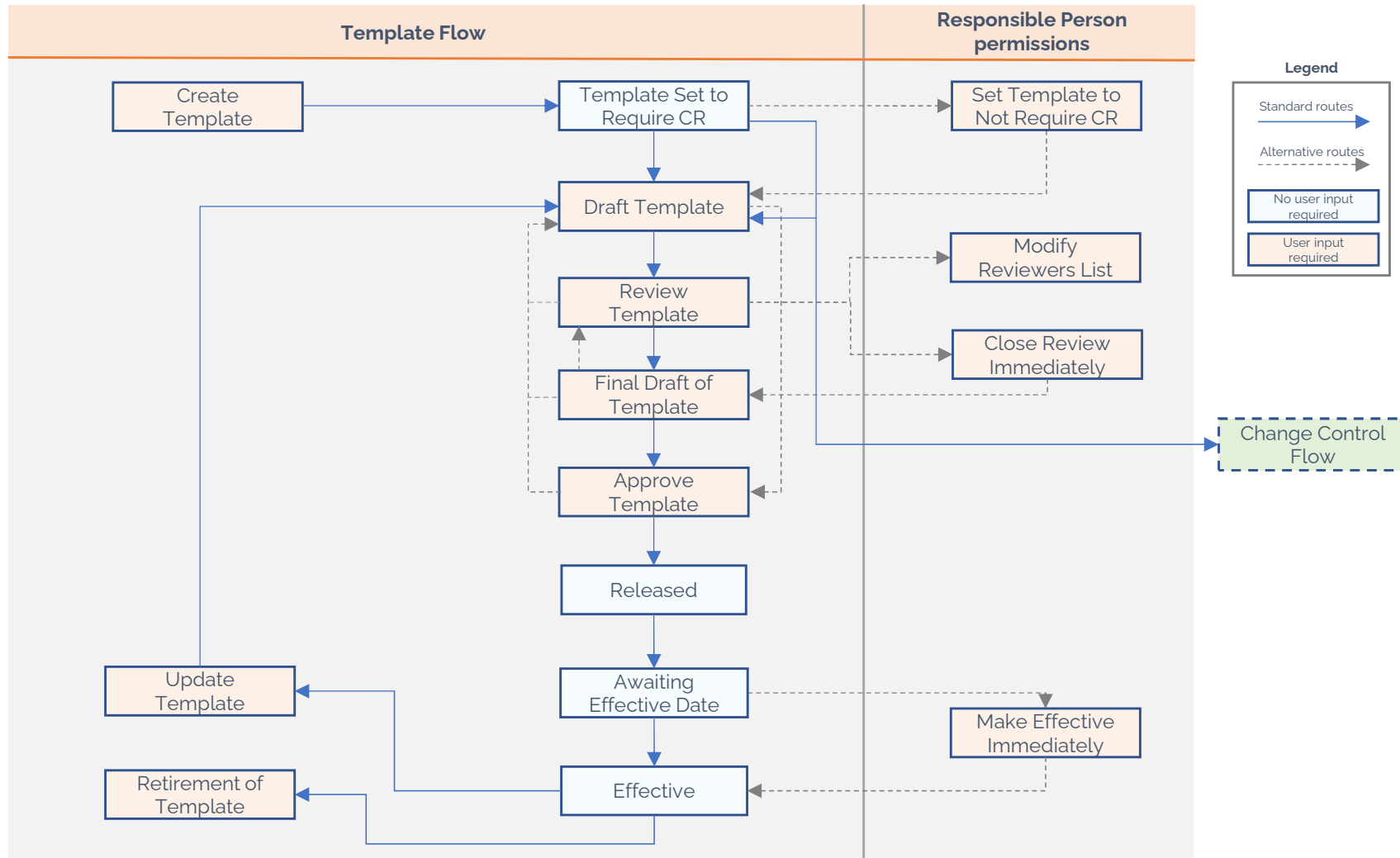


*Go to the workflow "Recorded Issue" flow with CAPA and CAPA attachments flow" to view the full CAPA workflow incl. CAPA Attachments

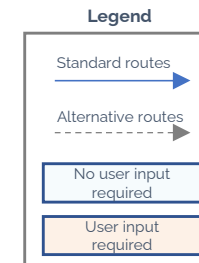
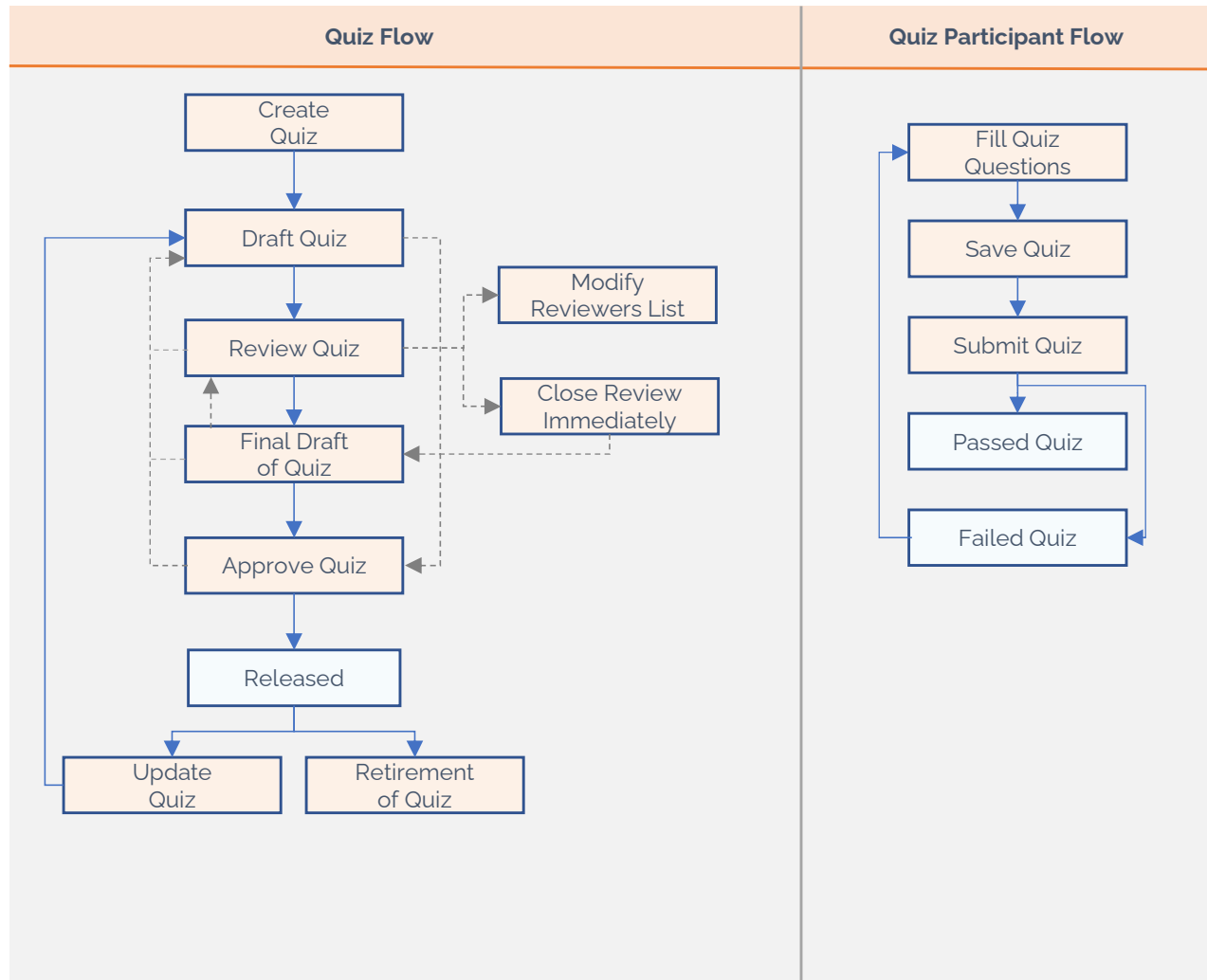
Quality Documents without Change Requests



Templates without Change Requests



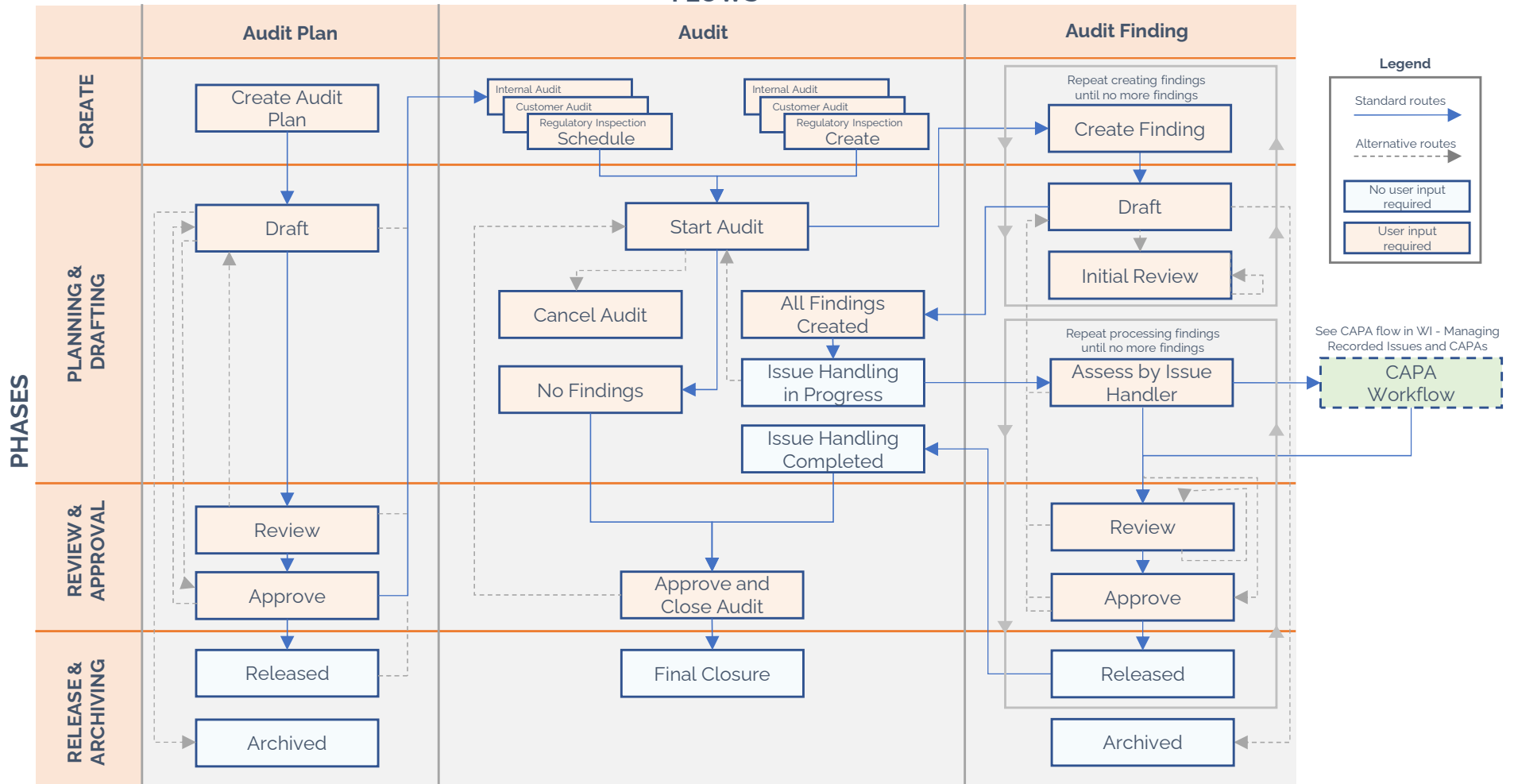
Quizzes – creating and taking quizzes



Audits including Audit Plans and Audit Findings

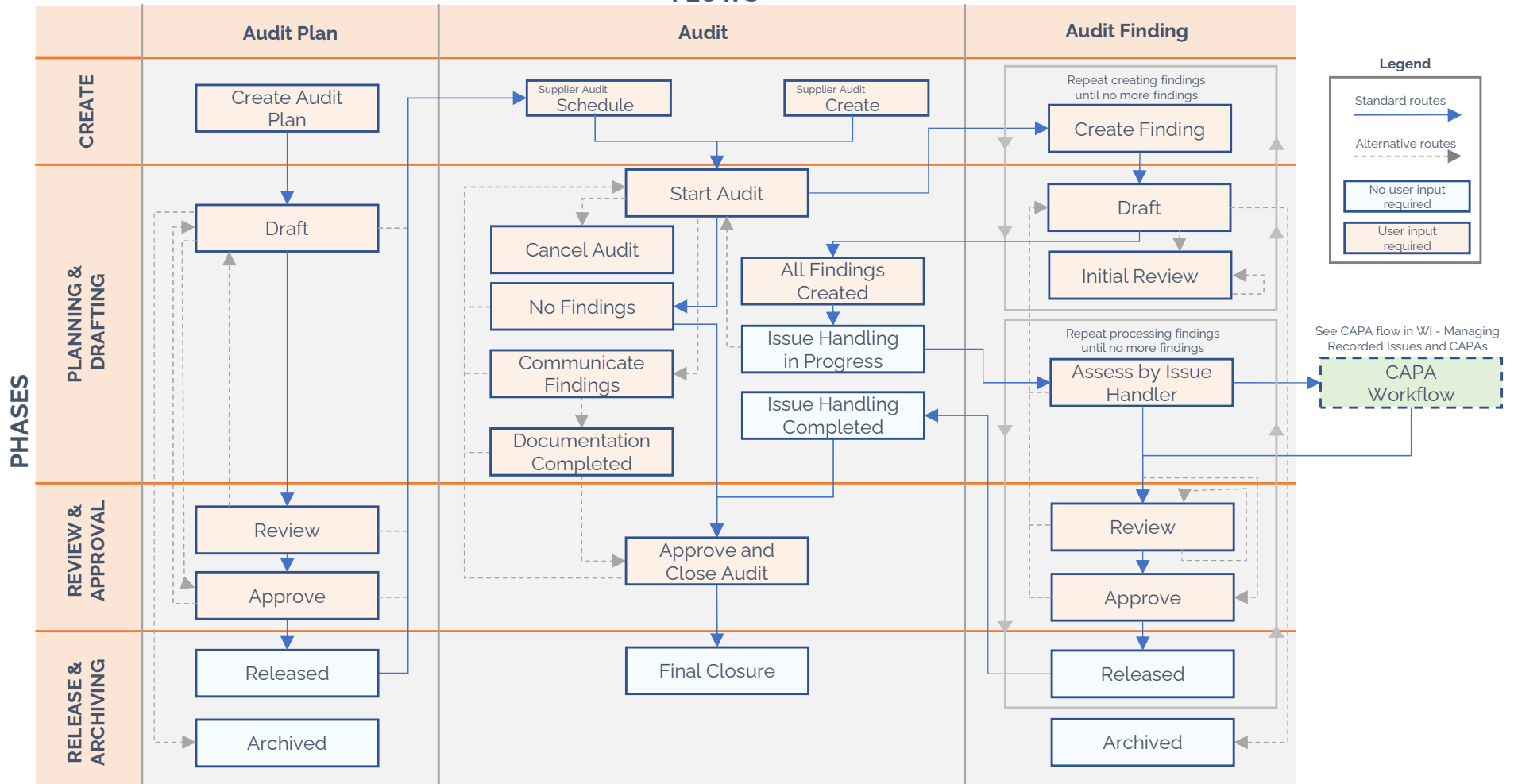


FLOWS

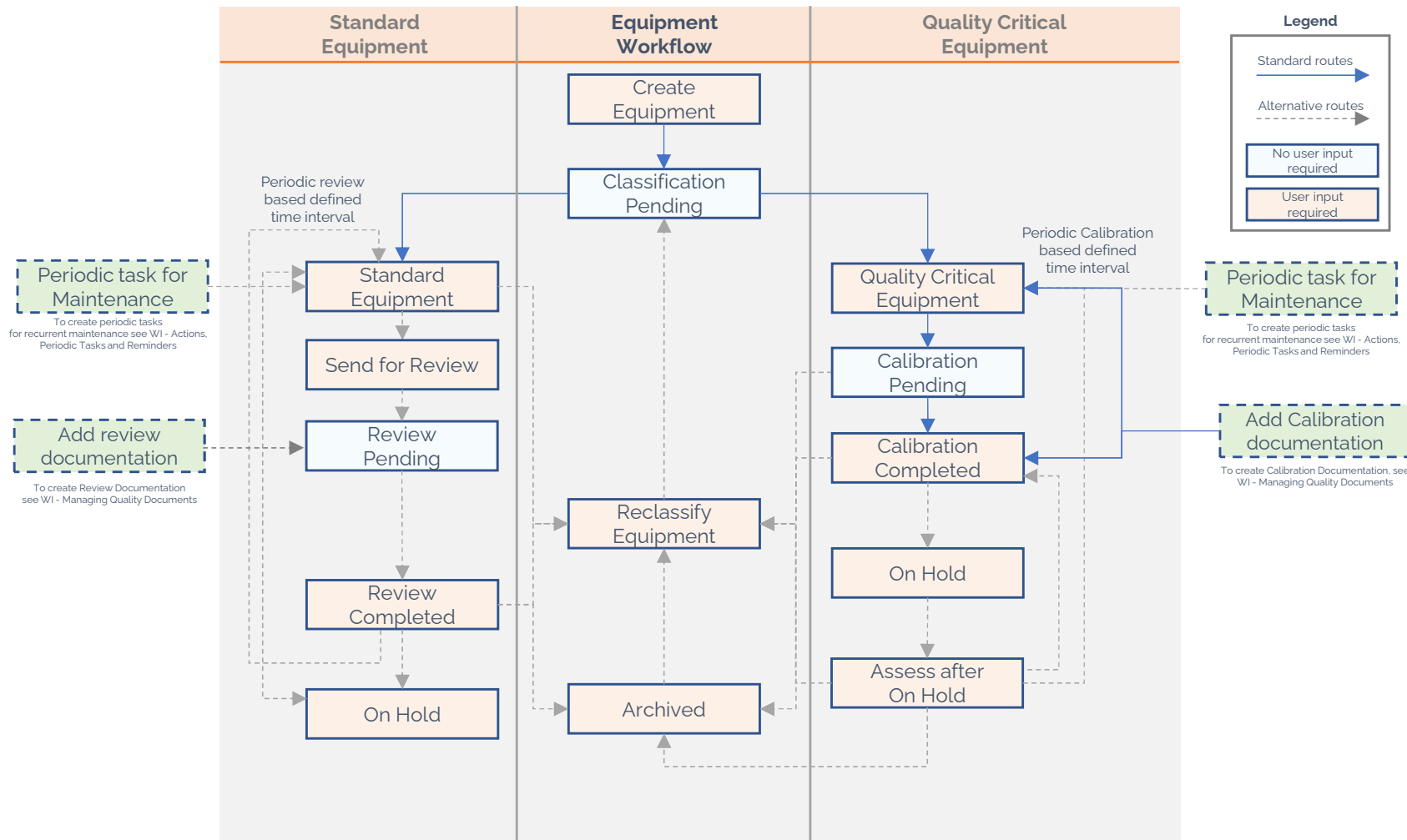


Supplier Audits including Audit Plans and Audit Findings

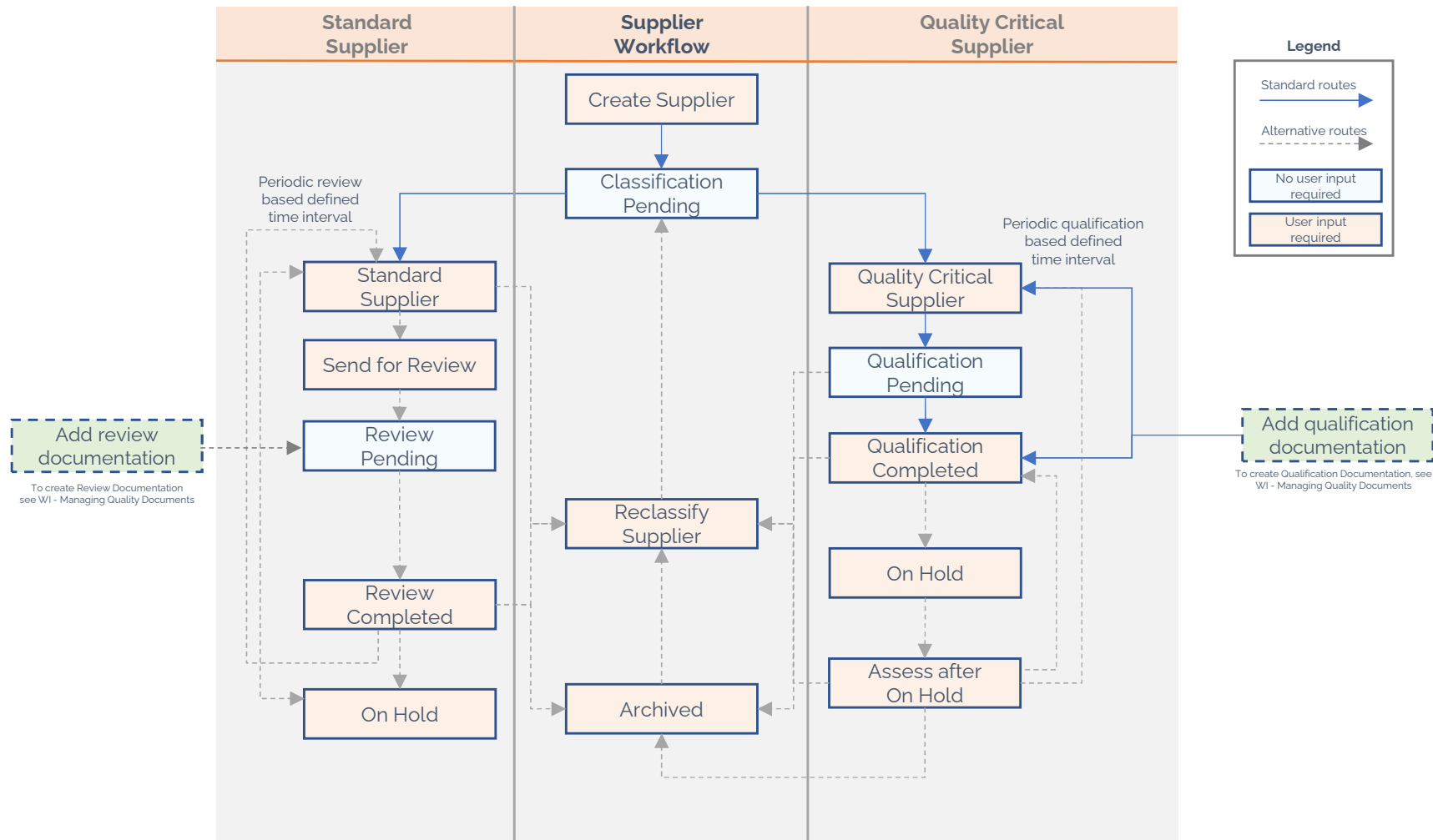
FLows



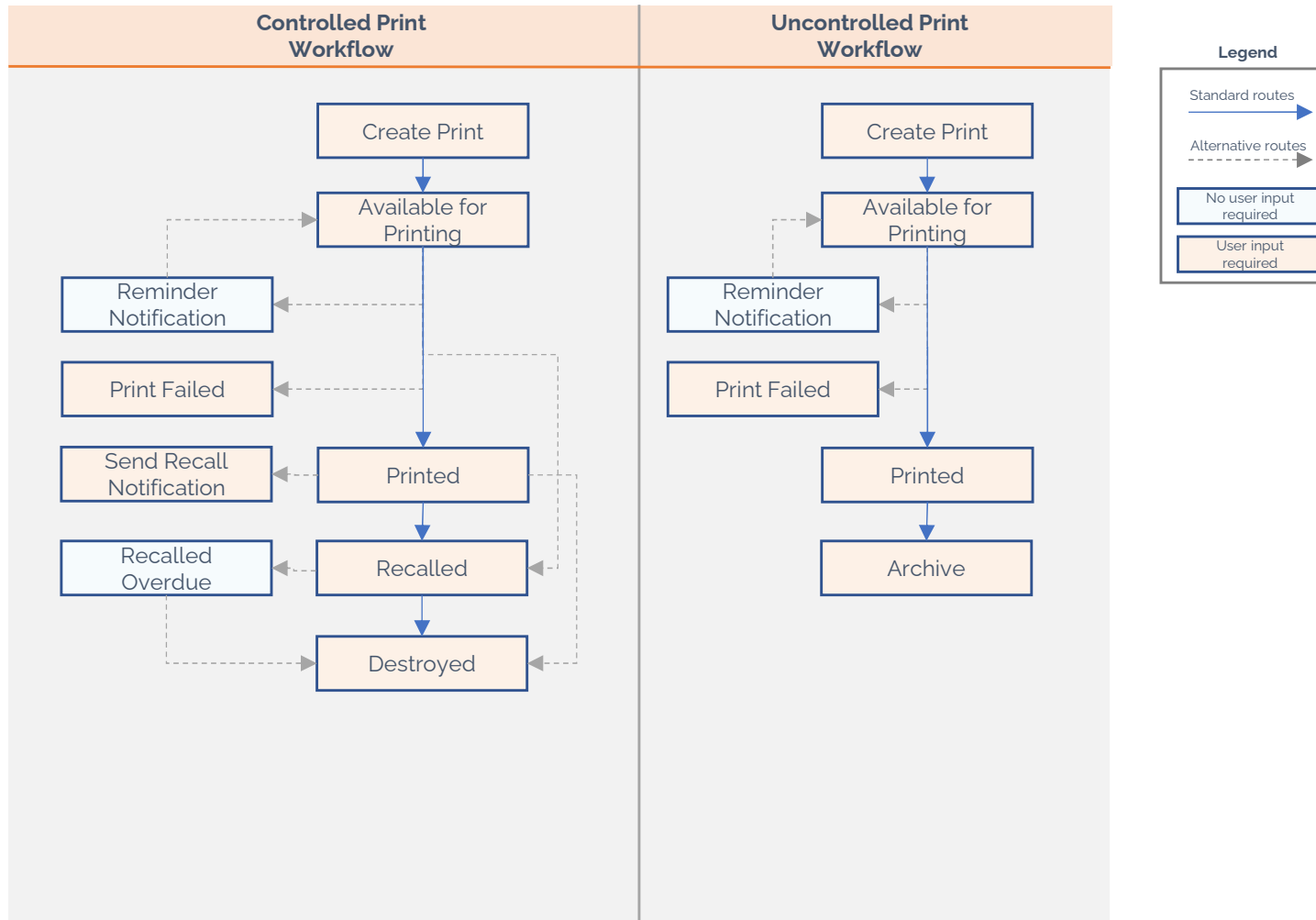
Equipment (Standard & Quality Critical)



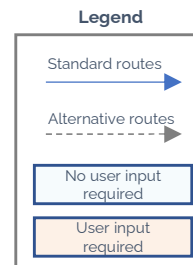
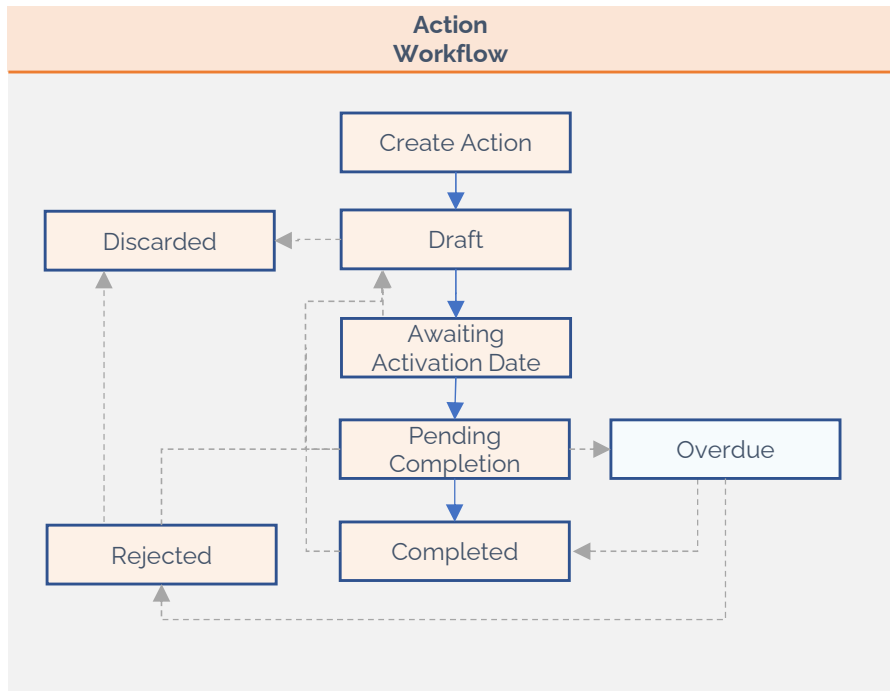
Suppliers (Standard & Quality Critical)



Controlled & Uncontrolled Printing



Action



Guide for what Task and Action feature to use

	Reminder Task	Periodic Task	Action (Replaces Assignments)
Frequency of task	Recurrent or One-time	Recurrent	One-time / ad-hoc
Assignment triggered	By document release	On Activation date based on scheduling values	On Activation date based on scheduling values
Location of feature	Create -> Periodic Task -> Reminder Task	Create -> Periodic Task -> Periodic Task	Create -> Action
Requires e-signature to complete	Yes	Yes	Determined by initiator
Mandatory for all assignees to complete	No, only one	No, only one	Determined by initiator
Examples / Use cases	Reminder task to print and replace a work instruction in a binder when a new is released	Recurrent task to calibrate equipment with a given time interval	Action to do x based on a conclusion of a CAPA
Notes		The "Periodic Document Review" and "Effective Assessment" is based on the Periodic Task	Will block CAPAs and CRs from being released until action is completed

Comments

