INTRODUCTION
Welcome

Abbott

Design Change Control Process

CLICK THE FORWARD ARROW TO BEGIN.

INTRODUCTION
Objectives

Upon completion of this course, you will be able to:

- Explain what design change controls are and why they are important,

- Distinguish between ADC's design change control processes, and

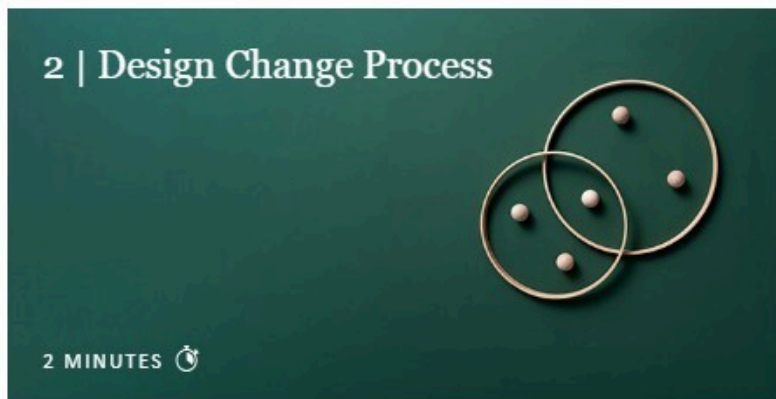- Know where to go if you have questions or concerns.

INTRODUCTION
Menu

1 | Understanding Design Change Control

Click the panel to get started.

18 MINUTES ⏱

2 | Design Change Process

2 MINUTES ⏱

3 | Knowledge Check

5 MINUTES ⏱

UNDERSTANDING DESIGN CHANGE CONTROL
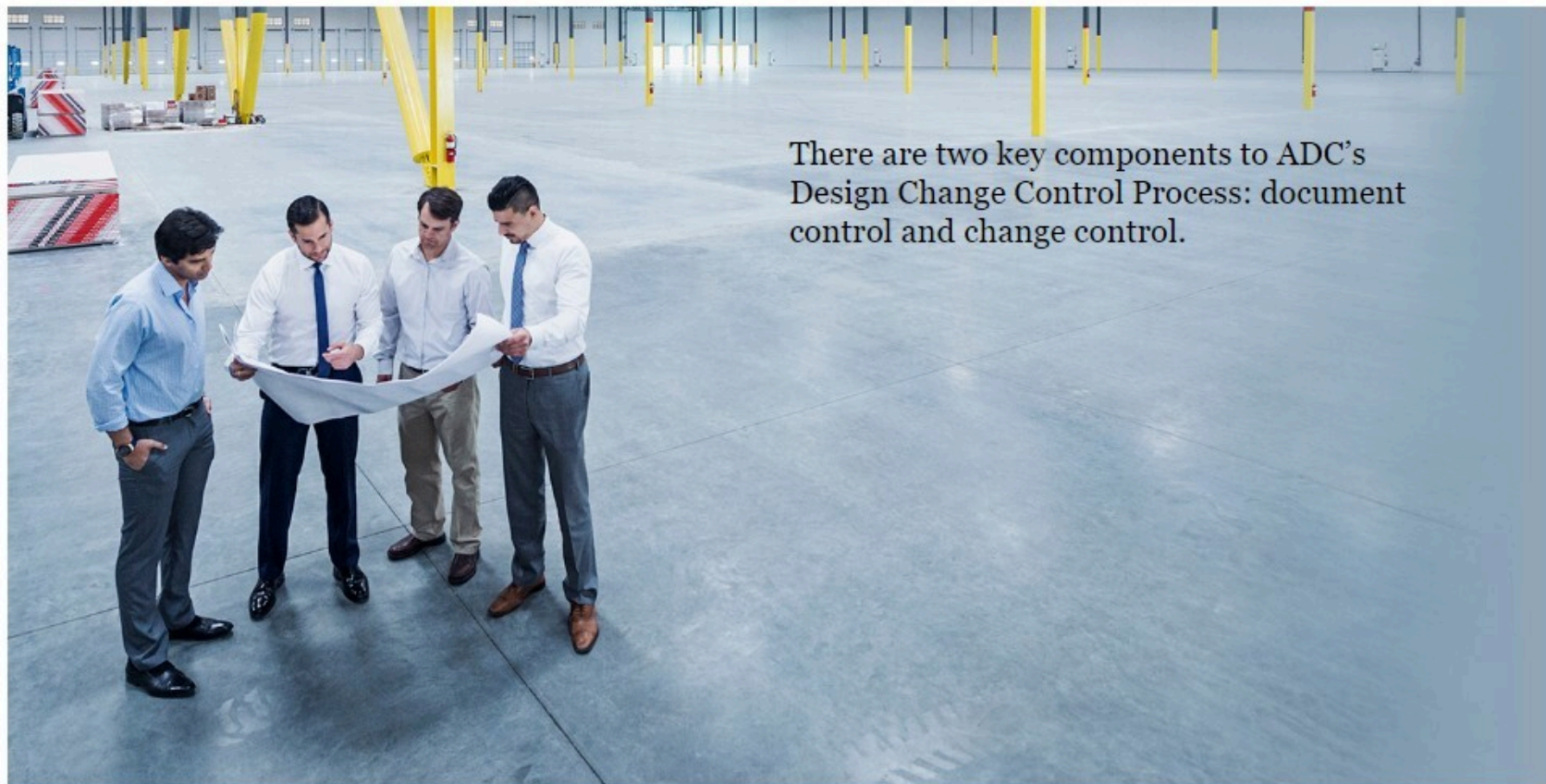
What is Design Change Control

Design change control is the process we use to identify, document, verify or validate, review, and approve design changes to products.

UNDERSTANDING DESIGN CHANGE CONTROL

What is Design Change Control

There are two key components to ADC's Design Change Control Process: document control and change control.

UNDERSTANDING DESIGN CHANGE CONTROL

What is Design Change Control

Document control is the process we use to enumerate design documents, and track their status and revision history.

The term "document" is inclusive to mean all design documents, drawings, and other items of design input or output which characterize the design or some aspect of it.

UNDERSTANDING DESIGN CHANGE CONTROL

What is Design Change Control

Change Control is the process we use to enumerate changes following a standardized set of procedures, which identify the documents to be revised with a summary and justification of the changes.

UNDERSTANDING DESIGN CHANGE CONTROL

What is Design Change Control

If a proposed design change impacts any part of an on-market or in development device master record or a manufacturing process, ADC requires following the Design Change Control Process.

UNDERSTANDING DESIGN CHANGE CONTROL

What is Design Change Control

The aim of the Design Change Control Process is to review, approve, and document design changes, the impact of those changes, the change plan, and deliverables before the change is made.
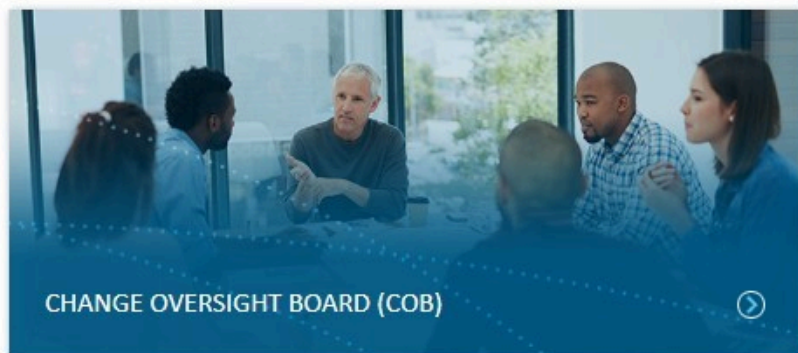
UNDERSTANDING DESIGN CHANGE CONTROL

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE RESPONSIBLITIES OF THOSE INVOLVED IN THE DESIGN CHANGE CONTROL PROCESS.

CHANGE INITIATOR

CHANGE TEAM

CHANGE OVERSIGHT BOARD (COB)

OTHER KEY FUNCTIONS

UNDERSTANDING DESIGN CHANGE CONTROL

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE RESPONSIBLITIES OF THOSE INVOLVED IN THE DESIGN CHANGE CONTROL PROCESS.

CHANGE INITIATOR

The Change Initiator is the individual responsible for identifying a change and providing a summary and justification for it. The Change Initiator collaborates with the Change Team, as needed, to determine the appropriate change management methods and requirements. Once identified, the Change Initiator is responsible for managing and verifying the completion of the activities associated with the change.

In the case of product changes, the Change Initiator is typically the Research and Development Program Manager.

CHANGE I

CHANGE OVERSIGHT BOARD (COB)

OTHER KEY FUNCTIONS

UNDERSTANDING DESIGN CHANGE CONTROL

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE RESPONSIBLITIES OF THOSE INVOLVED IN THE DESIGN CHANGE CONTROL PROCESS.

CHANGE TEAM

The Change Team is responsible for evaluating and documenting the impact of the change. The Team may include members from multiple functional areas (such as Regulatory Affairs, Quality Assurance, Research and Development, and Operations), as well as individuals representing multiple ADC sites.

CHANGE I...

CHANGE OVERSIGHT BOARD (COB)

OTHER KEY FUNCTIONS

UNDERSTANDING DESIGN CHANGE CONTROL

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE RESPONSIBLITIES OF THOSE INVOLVED IN THE DESIGN CHANGE CONTROL PROCESS.

CHANGE OVERSIGHT BOARD (COB)

The COB is a cross-functional team that provides review and approval of the change plans. All COB members are responsible for:

- Confirming that impacted product lines are correctly selected,
- Confirming how the change is to be managed including documentation of regulatory / compliance impacts to change implementation.
- Confirming that all actions are complete or a method to track remaining actions is identified.

CHANGE I

CHANGE OVERSIGHT BOARD (COB)

OTHER KEY FUNCTIONS

UNDERSTANDING DESIGN CHANGE CONTROL

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

CLICK EACH OF THE PANELS TO LEARN ABOUT THE RESPONSIBLITIES OF THOSE INVOLVED IN THE DESIGN CHANGE CONTROL PROCESS.

OTHER KEY FUNCTIONS

✕

The R&D team is responsible for evaluating the impact of the change on all elements of the design history file and ensuring all technical input is considered during the assessment.

Operations team members assist with the evaluation of the impact on design transfer activities or the manufacturing process.

Quality Assurance is responsible for determining the change impact on product compliance and ensuring Quality Assurance requirements are addressed, including external partner notifications, economic partner notification, and verifying that the DHF and DMR have been updated.

Regulatory Affairs is responsible for ensuring Regulatory approval of the proposed change, including assessing the impact on regulatory submissions, technical files, and product registrations.

CHANGE I...

CHANGE OVERSIGHT BOARD (COB) ⊙

OTHER KEY FUNCTIONS ⊙

UNDERSTANDING DESIGN CHANGE CONTROL

Categories of Design Change

At ADC, design changes fall into one of four categories.

Each category of change requires the Change Initiator and the Change Team to follow a different process when identifying, documenting, reviewing, approving and reporting on the impacts of the change.
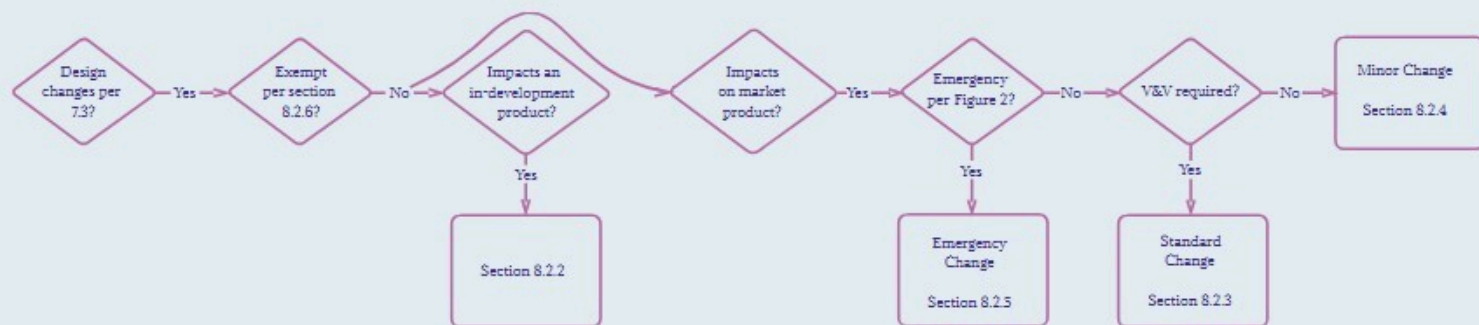
Abbott

1. Standard Change.
2. Emergency Change.
3. Minor Change.
4. In development Change.

Categories of Design Change

The flow-chart onscreen is a job aid that can be used to determine the category of change required.

Change Teams are encouraged to carefully consider the scope of any change and its impact in order to correctly determine the category of design change required. As you will learn in the next section, each change category has a different set of requirements.

UNDERSTANDING DESIGN CHANGE CONTROL

Review

Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.

UNDERSTANDING DESIGN CHANGE CONTROL

Review

Design Change Control Defined

Design change control is the process we use to identify, document, verify or validate, review, and approve design changes to products.

UNDERSTANDING DESIGN CHANGE CONTROL

Review

Roles and Responsibilities

Depending on the nature of the change, and where and when in the process it occurs, the Design Change Control Process requires varying degrees of effort, and input from a variety of functions across the organization.

UNDERSTANDING DESIGN CHANGE CONTROL

Review

Categories of Change

At ADC, design changes fall into one of four categories:

- Standard Change
- Emergency Change
- Minor Change
- In-development Change

UNDE

Re

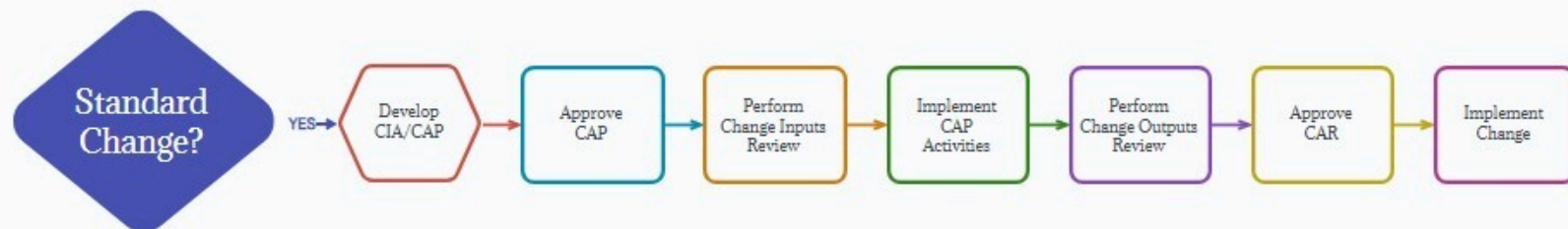To check your progress, click the Menu button

You have completed section 1 of 3

CLICK THE FORWARD ARROW TO CONTINUE LEARNING

DESIGN CHANGE PROCESS

Standard Change Process

Standard Change? → YES → Develop CIA/CAP → Approve CAP → Perform Change Inputs Review → Implement CAP Activities → Perform Change Outputs Review → Approve CAR → Implement Change

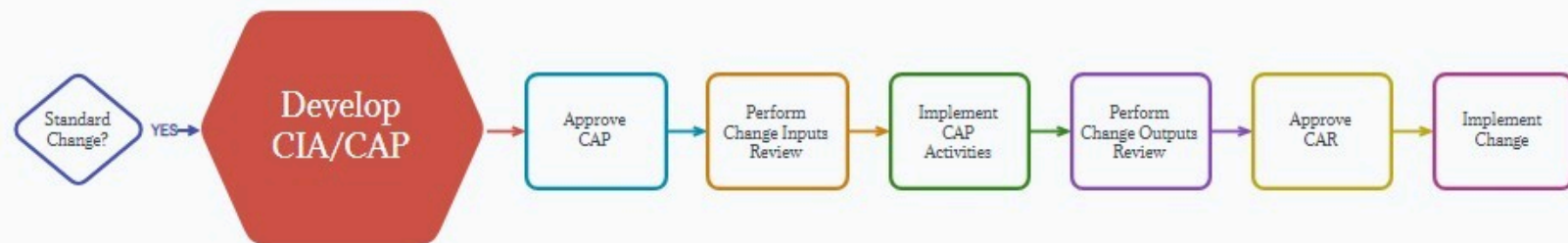## The Standard Change Process is used whenever a change is determined to:

- Impact on-market products, and
- Require the completion of design verification or validation.

If a change does not require completion of design verification or validation, it may be categorized as a minor change.

DESIGN CHANGE PROCESS

Standard Change Process

The first step in the Standard Change Process is the development of a change action plan (CAP).

The CAP outlines:

- The scope of the change,
- The justification for the change,
- All impacts of the change, and
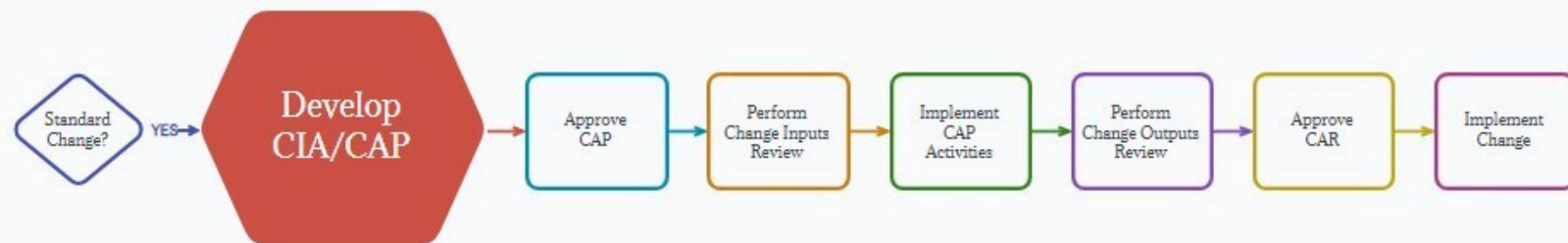- Activities to be completed before the change is implemented.

The CAP may also outline a phased implementation of the change, or may identify coordination required with other in-process CAPs.

A template is available to support the creation of the CAP – see 7.3W06 for details.

DESIGN CHANGE PROCESS
# Standard Change Process

The CAP also contains the change impact assessment (CIA), which assess the impacts to product lines, all 7.3 (design control deliverables), regulatory registration or submission, and several other considerations, including:

- Other products, processes, or sites
- External partners
- Economic operator verification
- Data privacy
- Materials
- Quality management system
- Clinical and post-market surveillance plans

DESIGN CHANGE PROCESS
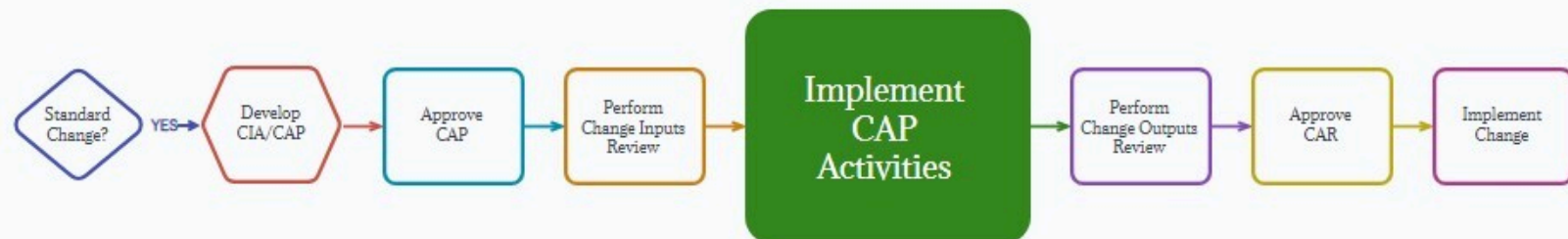
Standard Change Process
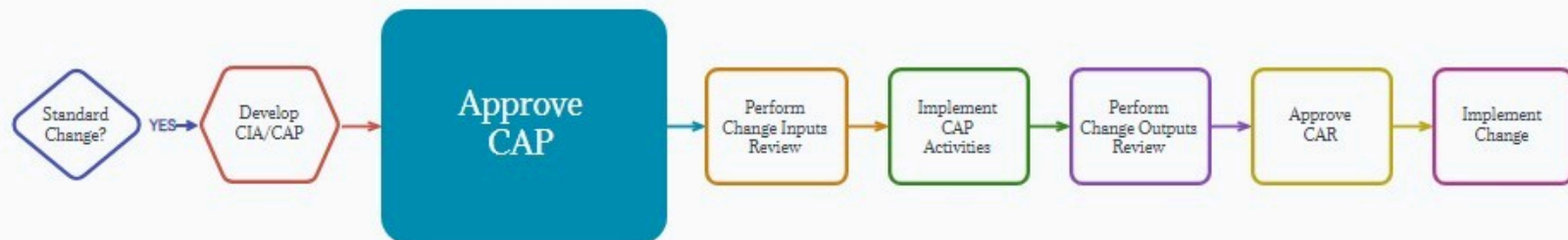
Once all activities required to implement the change have been documented in the CAP, the Change Oversight Board (COB) reviews and approves the CAP.

The COB confirms that all impacts of the change have been documented and that the strategy and activities identified are sufficient to manage the change.

Standard Change Process

## Once approved, the Change Initiator collaborates with the Change Team to implement the CAP activities.

Activities may include:

- The execution of V&V test cases or protocols and the obtaining of test results.
- Regulatory submissions, changes to product registrations, or updates or technical files.
- Updates to labelling.
- Updates to design outputs.
- Change input review (as required).
- Change output review.

Standard Change Process
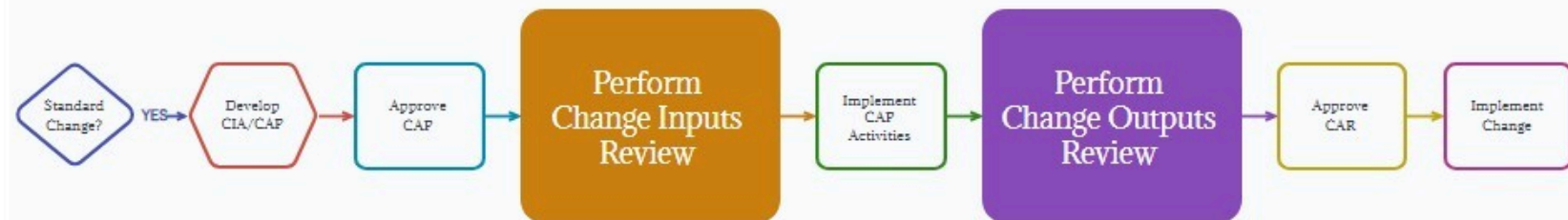
Two change reviews may be held as activities of the change action plan.

The change inputs and outputs reviews are conducted by a cross-functional team.

During change inputs review, reviewers confirm that the change plan identifies the impacted design inputs and outputs.
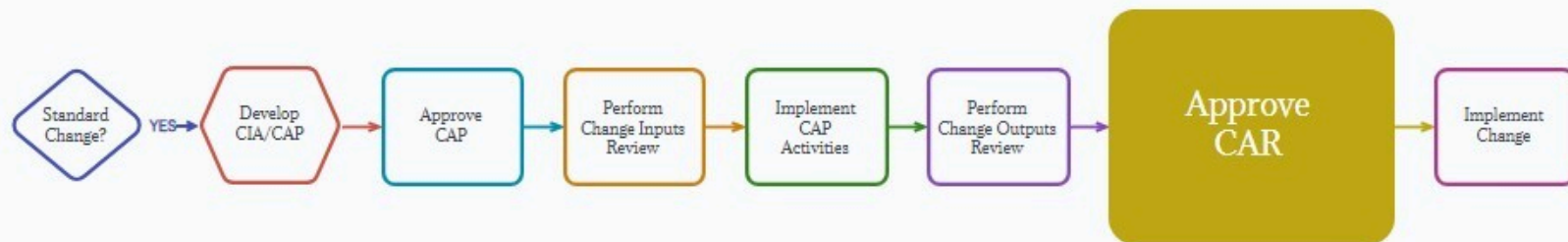
During the change outputs review, the reviewers confirm, based on objective evidence, that all activities are complete or that a method is in place to track any outstanding activities.

The Reviews are approved by executive management. A CIR is required when there are changes to the design inputs.

Standard Change Process

The final step is the approval of the CAR.

The CAR describes the results of the implementation activities described in the CAP. The CAR includes, amongst other things:

- Objective evidence that the actions identified in the plan have been completed,
- Rationales for any modifications from the change action plan,
- A description of how the change will be implemented into production, and
- Identification of any implementation regulatory / compliance requirements.

The CAR should also state if subsequent revisions will be necessary to document additional activities to support the phased implementation of the change outlined in the CAP.
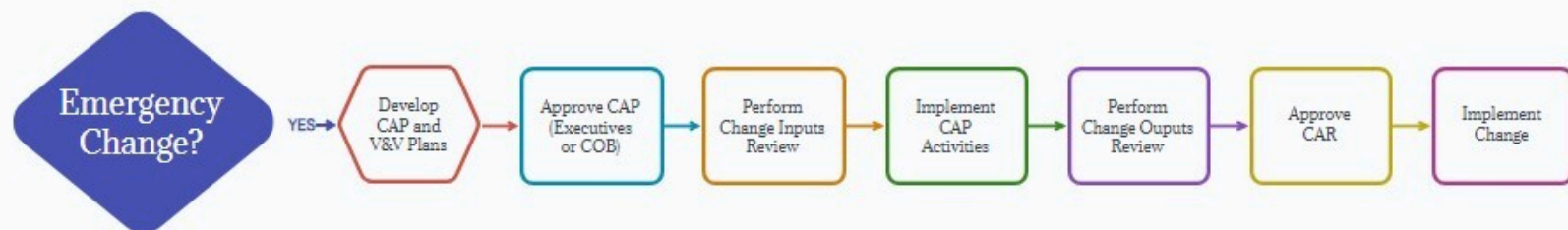
DESIGN CHANGE PROCESS

Emigrency Change Process

Design changes that address outages, immediate customer impacts, or significant business or user risks in on-market products are defined as emergency changes.

These changes are assessed and managed following ADC's Emergency Change Process.

Emergency Change Process

The goal of the Emergency Change Process is to expedite implementation and approval in order to get a fix into the field in as short a timeframe as possible, while still remaining compliant.

It is important to note that emergency design changes are compliant because there is a process in place to identify, document, verify or validate, review, and approve the change before it is implemented in the product.

DESIGN CHANGE PROCESS

Emergency Change Process
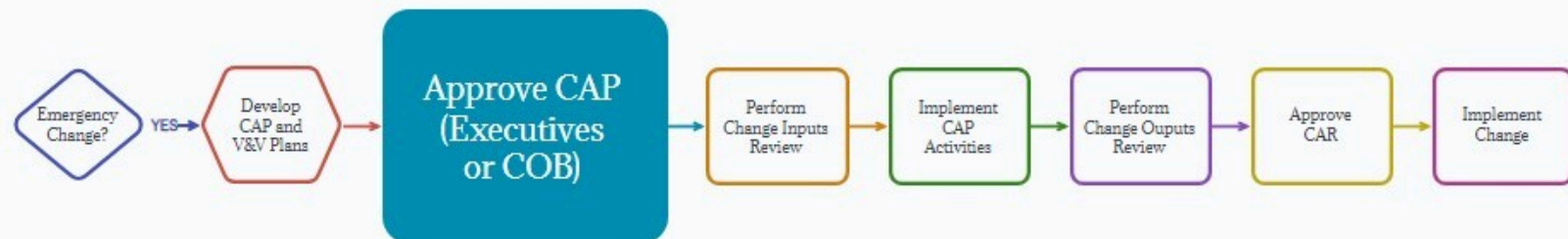
The Emergency Change Process is similar to the Standard Change Process but with two key differences.

First, approval of the CAP may be made by executive management (or their delegates) instead of by the full Change Oversight Board (COB).

Emergency Change Process
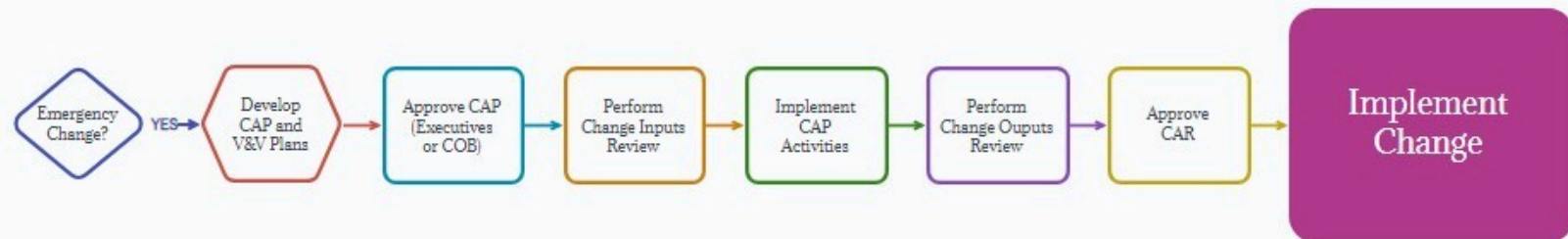
Second, a change may be implemented prior to updating all impacted design control deliverables, as long as the impacted items in the change impact assessment are identified in the CAP and the required updates to the design control deliverables are outlined in the CAP.
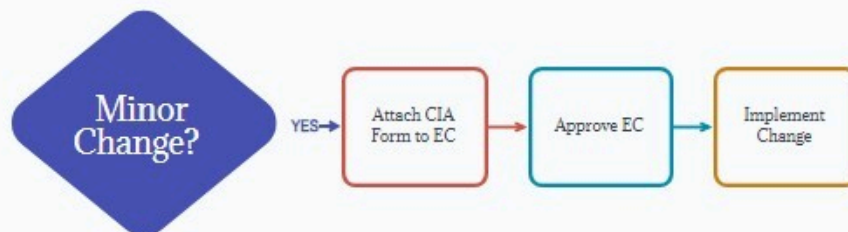
DESIGN CHANGE PROCESS

Minor Change Process

Changes that impact on-market products, but do <u>not</u> require design Verification or Validation are assessed and managed following ADC's Minor Change Process.

The Minor Change Process is a truncated version of the Standard Process.

DESIGN CHANGE PROCESS

Minor Change Process
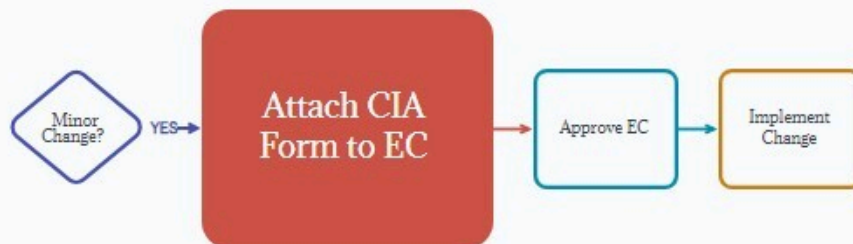
A Change Impact Assessment (CIA) form is used (in place of a CAP) to record the proposed change, its impacts, and the activities required to manage its implementation.

The details of how to append or link the CIA are documented in 7.3W06. The Change Initiator is responsible for following the procedure (and understanding the differences between the CIA form and template).

Minor Change Process

Once the CIA is approved, the change may be implemented.

DESIGN CHANGE PROCESS

In-Development Change Process

S205 Initial Design Inputs Review	S215 Detailed Design Inputs Review	S335 Initial Design Outputs Review	S445 Finished Design Outputs Review	S500 Post Market Design Review
Plans S210	Plans S180 S210 S320	Plans S180 S210 S320	Plans S180 S210 S320	Plans S180 S210 S320

In-development changes are changes identified during the development of a new product.

Specifically, they are identified after the approval of the detailed design inputs review and before approval of the finished design outputs review. These changes are assessed and managed following ADC's In-development Change Process.

		Cybersecurity S415	Cybersecurity S415	Cybersecurity S415
		Risk Management S410	Risk Management S410	Risk Management S410
		Design Inputs S170	Design Inputs S170	Periodic Monitoring Report S490
		Prototype Documentation S270	Finished Design Outputs S390 S400	Finished Design Outputs S390 S400
		Design Verification S280	Design Verification S280	
			Design Validation S370	
	Trace Matrix S420	Trace Matrix S420	Trace Matrix S420	
			Design Transfer Report S380	

DESIGN CHANGE PROCESS

In-Development Change Process

The In-development Change Process is unique in that it is managed internally by the development team.

The development team identifies the change, assesses its impact on the design control elements, and documents the activities that are required to manage the change.

In-Development Change Process

These change actions are captured in a Change Request, which is then appended to the Design and Development (D&D) Plan. See details of documenting in development design changes in 7.3W06.

The use of a Change Request allows for the recording of the change impact assessment and required actions without requiring a revision to the D&D plan. The D&D plan is updated when the actions are completed.

DESIGN CHANGE PROCESS

Exempt Changes

Some specific types of changes that may impact the device master record or manufacturing process are exempt from the Design Change Control Procedure.

See the 7.3W06 for a list of exempt changes. The Change Team may also propose changes for exemption – the Change Initiator is responsible for requesting the exemption through appropriate justification.

Implementation Activities

Finally, before implementing any change to an on-market product, you must ensure that all documentation relating to the change has been approved.

The Change Initiator is responsible for confirming that the CIA /CAR (and, as required, other authorizations) have been approved, and that implementation activities may begin.

Implementation activities vary and may or may not be gated by the approval of the CIA / CAR.

Implementation activities which do not impact a DMR item may be completed at any time during execution of the design change; these activities may occur before approval of the CIA / CAR.

Implementation activities which do impact a DMR item may not occur before the CIA or CAR is approved.

Playing Your Part

As we have seen in the short course, ADC's Design Change Control Processes help us to identify change impacts and ensure that we have a plan in place to manage these impacts.

As an ADC employee, your role is to understand and follow the processes outlined in this training. If you have any questions or concerns about design change controls or about a specific design control process, speak to your manager or check out the resources available via the Resources icon in the course menu bar.

Review

Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.

Review

Standard Change Process

The purpose of the Initial Design Inputs Review is to review, verify and approve initial plans, documents, and inputs.

Review

Emergency Change Process

Design changes that address outages, immediate customer impacts, or significant business or user risks in on-market products are defined as emergency changes.

2

DESIGN CHANGE PROCESS

Review

Minor Change Process

Changes that impact on-market products, but do not require design Verification or Validation are assessed and managed following ADC's Minor Change Process.

DESIGN CHANGE PROCESS

Review

In-development Change Process

In-development changes are changes identified during the development of a new product - specifically, after the approval of the detailed design inputs review and before approval of the finished design outputs review.

4

Review

Exempt Changes

The Change Initiator is responsible for requesting the exemption of some specific types of changes through appropriate justification.

DESIGN CHANGE PROCESS

Review

Implementation Activities

Before implementing any change to an on-market product, you must ensure that all documentation relating to the change has been approved.

To check your progress, click
the Menu button

DESIG

Re

You have completed section 2 of 3

CLICK THE FORWARD ARROW TO CONTINUE LEARNING

Introduction

The Knowledge Check that follows consists of 5 questions. You must score 80% or higher to successfully complete this course.

WHEN YOU ARE READY, CLICK THE KNOWLEDGE CHECK BUTTON.

KNOWLEDGE CHECK

KNOWLEDGE CHECK

Assessment

1 The aim of the Design Change Control Process is to review, approve, and document design changes and their impact:

1 | After the change is implemented but before it is released to production

2 | After the approval of the detailed design inputs review, but before approval of the finished design outputs review

3 | Before the change is made

NEXT

1 2 3 4 5

KNOWLEDGE CHECK
Assessment

2

During the Standard Change Process, who is responsible for reviewing and approving the CAP?

1 | The Change Initiator

2 | The Change Oversight Board

3 | Quality Assurance

4 | Executive Management

NEXT

1 2 3 4 5

Assessment

3 How does the Emergency Change Process differ from the Standard Change Process?

Check all that apply.

| 1 | Approval of the CAP may be made by executive management instead of by the full Change Oversight Board |

| 2 | The changes are identified during the development of a new product |

| 3 | The changes may be implemented prior to updating all impacted design control deliverables, as long as the impacted items are identified in the CAP |

| 4 | The changes do not require design Verification or Validation |

NEXT

Assessment

4

Which category of design change does not require completion of design verification or validation?

1 | Standard Change

2 | Emergency Change

3 | Minor Change

4 | In-development Change

NEXT

1 2 3 4 5

KNOWLEDGE CHECK

Assessment

5

Before implementing any change to an on-market product, you must ensure that all documentation relating to the change has been approved.

1	True

2	False

SUBMIT

1 2 3 4 **5**

Where to Get Help

MANAGER OR SUPERVISOR

If you have questions or concerns about an activity or interaction, the best place to start is with your manager or supervisor.

Course Resources

TRANSCRIPT

Click here for a full transcript of the course

SUBMIT

1 2 3 4 5