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| --- | --- | --- | --- |
| Code |  | Onscreen Text | Graphics |
| Audio plays as soon as user lands on page. |
|  |  | IntroductionWelcome | STObjectives | FMenu | HNo Description | x minutes |  |
| 0.1.1 | No VO | Understanding Design Change ControlWhat is Design Change Control | F,S,F,FRoles and Responsibilities | P4Categories of Design Change | F,F,AReview | CDescription | x minutes | Full screen  |
|  |  | Design Change ProcessStandard Change Process | A,A,A, A,A,A,AEmergency Change Process | A,A,A,AMinor Change Process | A,A,AIn-Development Change Process | A,F,FExempt Changes | FImplementation Activities | RPlaying Your Part | LReview | CDescription | x minutes |  |
|  |  | Knowledge CheckIntroduction | IAssessment | TFeedback | EAssess your understanding of the key concepts and principles of this course. | 5 minutes |  |
|  |  | ResourcesResources | K |  |
| User selects forward arrow to move to next screen. |

INTRODUCTION

###  Welcome

Page 1 of 1

|  |  |  |  |
| --- | --- | --- | --- |
| Code |  | Onscreen Text | Graphics |
| Audio plays as soon as user lands on page. |
| 0.1.1 | No VO | Design Change Control ProcessCLICK THE FORWARD ARROW TO BEGIN. | Full screen  |
| User selects forward arrow to move to next screen. |

INTRODUCTION

### 0.2 Objectives

Page 1 of 1

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| --- | --- | --- | --- |
| Code |  | Onscreen Text | Graphics |
| Audio plays as soon as user lands on page |
| 0.2.1 | Before starting this course, take a moment and review the course 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.
 |  |
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| Code |  | Onscreen Text | Graphics |
| menu |
| 0.2.1 |  |  |  |
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# 1.0 Understanding Design Change Control

Understanding Design Change Control

### 1.1 What is Design Change Control

Page 1 of 4

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | Design change control is the process we use to identify, document, verify or validate, review, and approve design changes to products. | Full screen |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.1 What is Design Change Control

Page 2 of 4

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | There are two key components to ADC’s Design Change Control Process: document control and change control. | Sliding Screens – 3 |
| User selects forward arrow to move to next section of screen.  |
|  | VO mirrors onscreen text | 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. |  |
| User selects forward arrow to move to next section of screen.  |
|  | VO mirrors onscreen text | 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. |  |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.1 What is Design Change Control

Page 3 of 4

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |  |  |  |
|  | VO matches onscreen text. | 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. | Full screen |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.1 What is Design Change Control

Page 4 of 4

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |  |  |  |
|  | VO matches onscreen text. | 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. | Full screen |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.2 Roles and Responsibilities

Page 1 of 3

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| --- | --- | --- | --- |
| Code |  | Onscreen Text | Graphics |
|  |
|  | VO matches onscreen text. | 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.  | 4 Panel |
| *User clicks the* **Change initiator** thumbnail. Popup opens and text reveals. |
|  | NO VO | CHANGE INITIATORThe 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. |  |
| *User clicks the* CHANGE TEAM thumbnail. Popup opens and text reveals. |
|  | NO VO | CHANGE TEAMThe 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.  |  |
| *User clicks the* **CHANGE OVERSIGHT BOARD (COB)** thumbnail. Popup opens and text reveals. |
|  | NO VO | 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.
 |  |
| *User clicks the* **OTHER KEY FUNCTIONS** thumbnail. Popup opens and text reveals. |
|  | NO VO | OTHER KEY FUNCTIONSThe 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. |  |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.3 Categories of Design Change

Page 1 of 3

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | At ADC, design changes fall into one of four categories:* Standard Change,
* Emergency Change,
* Minor Change, or
* In-development Change.
 | **Full screen** |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.3 Categories of Design Change

Page 2 of 3

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| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text | 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.  | **Full screen** |
| User selects forward arrow to move to next screen. |

Understanding Design Change Control

### 1.3 Categories of Design Change

Page 3 of 3

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  | **A diagram of a product  Description automatically generated** |
| User selects forward arrow to move to next screen. |

Design Change Controls

### 1.4 Review

Page 1 of 1

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| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text |  |  |
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# 2.0 Design Change Process

Design Change Process

## 2.1 Standard Change Process

Page 1 of 6

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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. | **Slide 1** |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 2 of 6

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 3 of 6

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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
 | Fintan – just change the text |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 4 of 6

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 5 of 6

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text | 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.
 |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 6 of 6

|  |  |  |  |
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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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. | Highlight 2 but make them smaller. |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.1 Standard Change Process

Page 7 of 7

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| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.2 Emergency Change Process

Page 1 of 4

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.2 Emergency Change Process

Page 2 of 4

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.2 Emergency Change Process

Page 3 of 4

|  |  |  |  |
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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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). |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.2 Emergency Change Process

Page 4 of 4

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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. |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.3 Minor Change Process

Page 1 of 3

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text | Changes that impact on-market products, but do not 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. |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.3 Minor Change Process

Page 2 of 3

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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).  |  |
| User selects forward arrow to move to next screen. |

## 2.3 Minor Change Process

Page 3 of 3

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | Once the CIA is approved, the change may be implemented. |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.4 In-development Change Process

Page 1 of 3

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  |  | 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. |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.4 In-development Change Process

Page 2 of 3

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.4 In-development Change Process

Page 3 of 3

|  |  |  |  |
| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.5 Exempt Changes

Page 1 of 1

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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. |  |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.6 Implementation Activities

Page 1 of 1

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  | VO mirrors onscreen text | 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 a the CIA / CAR. Implementation activities which do impact a DMR item may not occur before the CIA or CAR is approved.  | Graphic to include examples of other authorizations (e.g., authorization for shipment [AFS]) |
| User selects forward arrow to move to next screen. |

Design Change Process

## 2.7 Playing Your Part

Page 1 of 1

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| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text | 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.  |  |
| User selects forward arrow to move to next screen. |

Design Change Controls

## 2.6 Review

## Page 1 of 1

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| VO Code | Voiceover | Onscreen Text | Graphics |
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|  | VO mirrors onscreen text |   |  |
| User selects forward arrow to move to next screen. |

3.0 Knowledge Check

KNOWLEDGE CHECK

3.1 Introduction

Page 1 of 1 (Web Page with embedded movie)

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
| f\_0[Table # 50] 13 |
|  |   | The Knowledge Check that follows consists of 10 questions. You must score 80% or higher to successfully complete this course.WHEN YOU ARE READY, CLICK THE KNOWLEDGE CHECK BUTTON.  |  |
|  |

KNOWLEDGE CHECK

3.2 Assessment

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| f\_013 |
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KNOWLEDGE CHECK

3.3 Feedback

Page 1 of 1 (Web Page with embedded movie)

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| --- | --- | --- | --- |
| VO Code | Voiceover | Onscreen Text | Graphics |
| f\_11,f\_12, f\_13[Table # 52] 15 |
| f\_11 | Congratulations! You have successfully passed the Knowledge Check and completed the course.Please review your results below by clicking on each question.Once you are done, you must click the EXIT [X] icon in the course title bar before closing your browser window or browser tab. | Congratulations! You have successfully passed the Knowledge Check and completed the course.Please review your results below by clicking on each question.Once you are done, you must click the EXIT [X] icon in the course title bar before closing your browser window or browser tab. |  |
| Landing Screen (The learner is brought to this page only if they have failed to score 80% or greater on their assessment.) |
| f\_12 | Sorry, you did not pass the Knowledge Check. Take a few minutes to review your results below by clicking on each question. When you are done, click the Retake Knowledge Check button. | Sorry, you did not pass the Knowledge Check. Take a few minutes to review your results below by clicking on each question. When you are done, click theRetake Knowledge Check button. |  |
| f\_13 | No results are available, as you have not completed the Knowledge Check. | No results are available, as you have not completed the Knowledge Check. |  |
| User can review the questions. When they are done, they will click the Retake Knowledge Check button. (Once the User clicks the Retake Knowledge Check button, the 5 questions are represented in the same order.) |
| Once the user has answered all ten questions, he/she will either:* Receive a pass score of 80% or higher. In which case they are taken to the Congratulations screen.
* Fail to receive a pass score of 80% or higher. In which case they are taken back to the Feedback screen.)
 |

Button text:

Next

Retake

Resources

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| VO Code | Voiceover | Onscreen Text | Graphics |
|  |
|  |   |  Where to Get Help |  |
|  |  | http://abbottlabs-lcec.course.lrn.com/rev2015091400/course/ABB-017/en/ABB-017en/images/resources_icon_manager_up.gif Manager OR SUPERVISORIf you have questions or concerns about an activity or interaction, the best place to start is with your manager or supervisor.Design Control team to provide a full list of resources to be included here.  |  |
|  |  | Course Resources |  |
|  |  | resources_icon_pdf_up Transcript Click here for a full transcript of the course. |  |
|  |