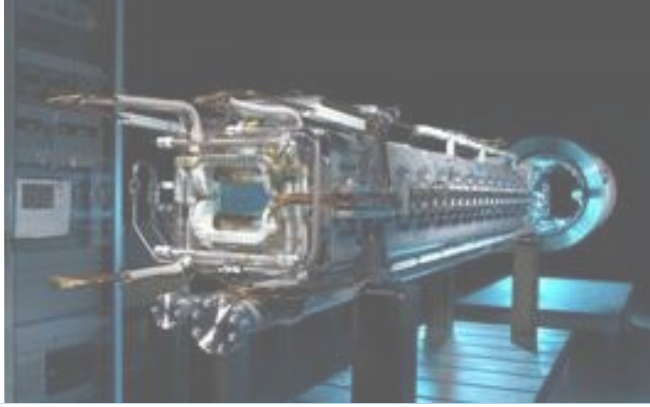
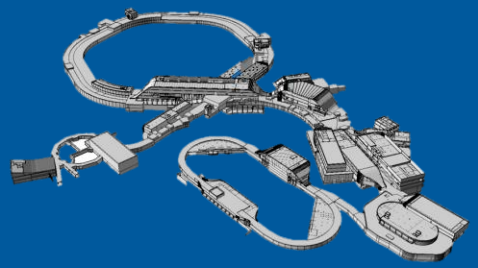




Training Module:
Design Reviews



December 5, 2019

Agenda

- Introduction
- Documents
- Processes & Methods
- Experiences & Tips
- Summary

Motivation

ISO 9001:2015, Chapter 8.3.4:

The organization shall apply controls to the design and development process to ensure that:

a) results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

Focus of this training

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements.

Introduction

- F-GS-F-01e (General Spec) defines ***milestones***:
  - ...
  - **M6 = CDR** (**C**onceptual **D**esign **R**eview) accepted
  - **M7 = FDR** (**F**inal **D**esign **R**eview) accepted
  - ...

- F-VA-QUA-en-0006: **Concept** phase, **development** phase, and **preparation of production** for a component or system (...) shall be verifiably closed by different ***design reviews.***

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Documents

- Procedure (VA): **F-VA-QUA-en-0006 Design Reviews**
  https://edms.cern.ch/document/1514206
  - and documents mentioned therein
- F-GS-F-01: **General Spec**
  https://edms.cern.ch/document/1365092
  - and documents mentioned therein
- F-TG-MDS-en-KRL: **Design Guideline for Mechanical Design**
  https://edms.cern.ch/document/1229367
- F-TG-ET-01e: **Electrical Design Rules and Regulations**
  https://edms.cern.ch/document/1172862
- DGUV 202-002: **Manufacturing and operation of equipment designed for research purposes**
  https://publikationen.dguv.de/dguv/pdf/10002/202-002eng.pdf

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Review Process [1/2]

- **Prepare** the review (responsible: WPL)
  - Get the required documents well in advance (min. 2 weeks)*
  - Make the documents accessible for all participants (in DMS)
  - Invite participants, i.e. WPL, SPL, QUA, contractor (optional: further relevant departments)
  - Compile a list of all applicable test criteria (from the contract and its co-applicable documents – e.g. GS, CS, DS, TGs)
  - All participants check the documentation against “their” test criteria
- **Execute** the review (responsible: WPL)
  - All test criteria as listed will be addressed (requirements)
  - All results and decisions shall be recorded in the Meeting Minutes and Acceptance Record
  - After mutually completing the review of all relevant aspects and criteria of the component, the participants shall agree on an overall result

*) The contractor itself stores those documents into DMS

Review Process [2/2]

- **Finalize** the review (responsible: WPL):
  - Accepted (if all test criteria are fulfilled),
  - Conditionally accepted (if minor modifications are considered necessary and can be closed quickly), or
  - Rejected (else).
  - Fill the result in the “Acceptance Record”
  - Upload documents (acceptance record, meeting minutes, etc.) in DMS and start the release process
- **What if <u>not all</u> criteria are fulfilled?**
  - If there was a rejection, reschedule the review meeting.
  - If there was a conditional acceptance, the Contractor has to make the updates and the review shall be repeated for said topics
  - If a review fails, it shall be simply finalized as soon as the required amendments are completed

Content of CDR

The objective of the CDR is releasing the concepts, 3D models, and draft drawings of the product, so they can be detailed

- Needed documents:
  - Concept,
  - a schematic sketch of the component,
  - calculations and simulations for ist dimensioning,
  - Risk assessment,
  - draft of production plan,
  - draft of test and inspection plan,
  - …

The Template „Required Documents“ may help to identify additional required documentation:

- F-FO-QUA-bl-0013_Required_Documents
  https://edms.cern.ch/document/1732710

Content of FDR

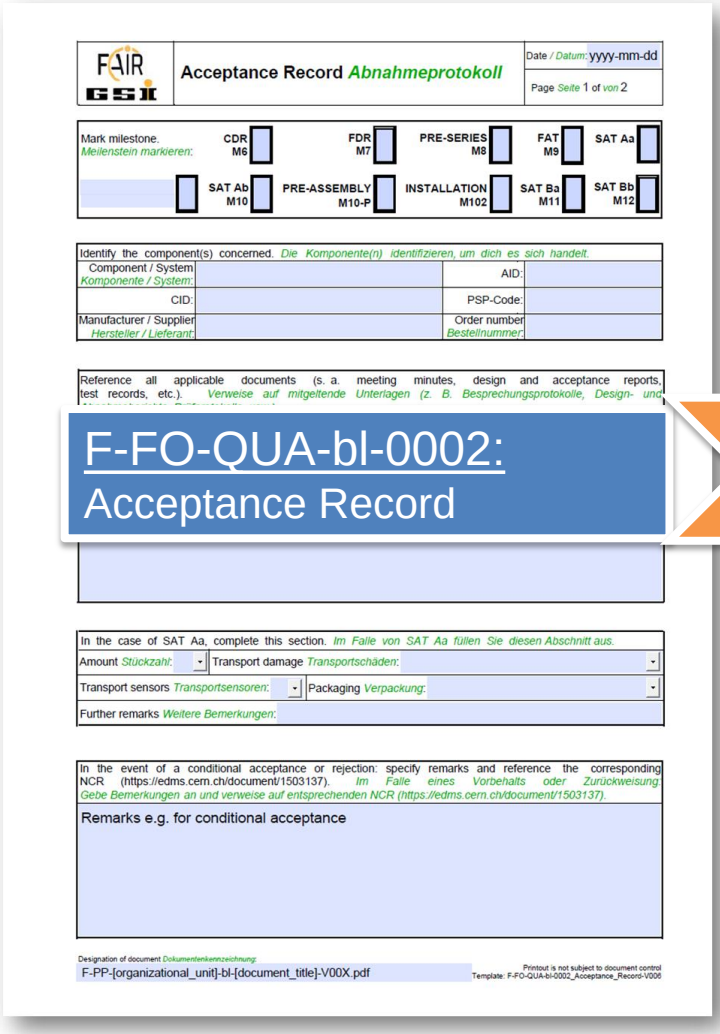
The objective of the FDR is releasing all documents (i.e. instructions, drawings, etc.) required for production of the component.

- Needed documents:
  - » complete production documents (user manual,…)
  - » test and inspection plan,
  - » work and test instructions,
  - » list of manufacturing and test equipment,
  - » set of production drawings and parts lists
  - » Updated risk assessment (if applicable)
  - » …

The Template „Required Documents“ may help to identify additional documentation:

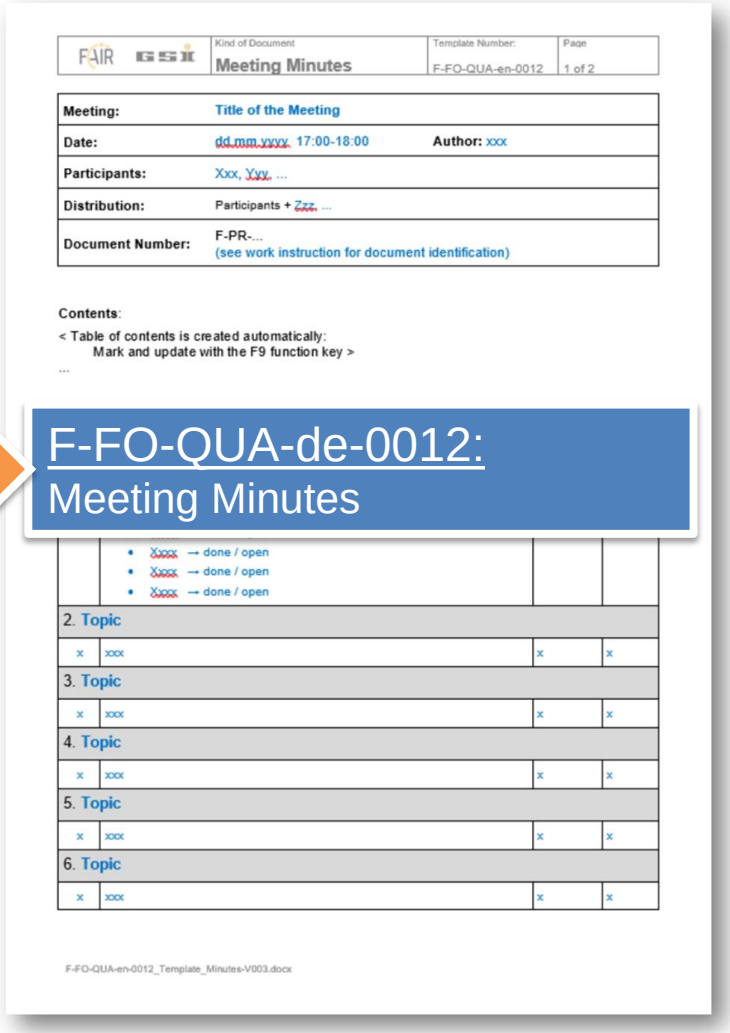
- F-FO-QUA-bl-0013_Required_Documents
  https://edms.cern.ch/document/1732710

Templates for Documentation



F-FO-QUA-bl-0002:
Acceptance Record

Optional Attachments



F-FO-QUA-de-0012:
Meeting Minutes

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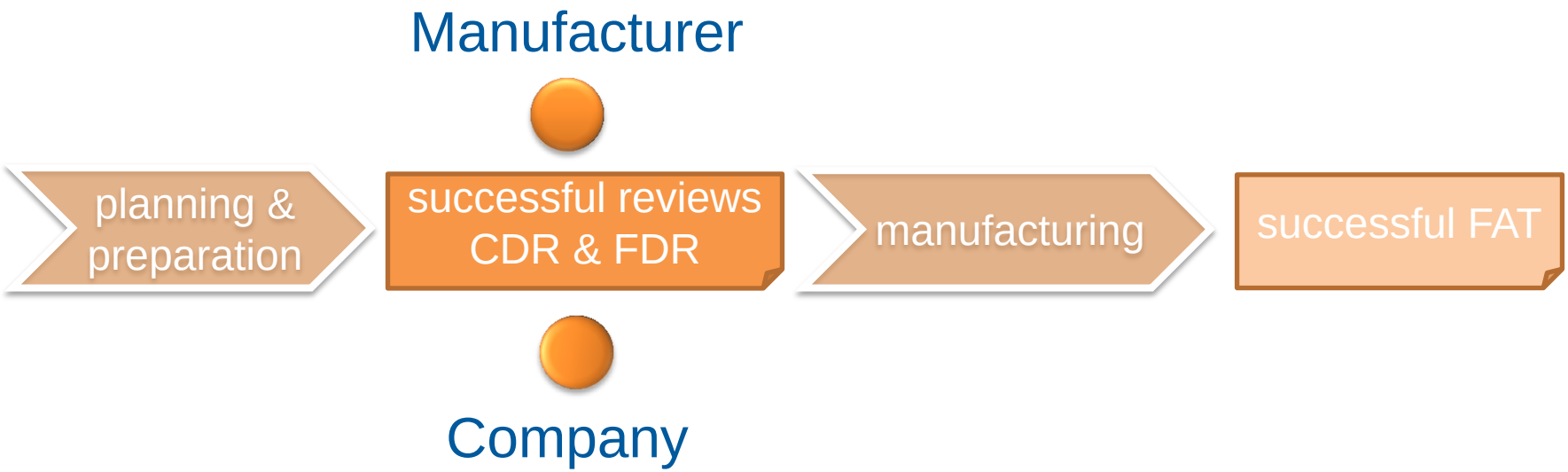
Experiences & Tips [1/2]

- Read the related procedure and documents
  (Clarify questions with the authors in advance of the review)
- Get the required documentation well in advance of a review meeting (do not cut time for proper checking!)
- Be prepared and organized (list of criteria!) to have an easy review
- No work is done till the paperwork is done
  - Take care of the record and get it approved by the participants (done best immediately after the review)
  - Store and release documents (acceptance record and meeting minutes) in the corresponding container in EDMS
- Update the MS Project plan and provide link to acceptance record in EDMS

Experiences & Tips [2/2]

Design Reviews are Preconditions for Manufacturing:



A successful CDR is mandatory for preparing the FDR

Conclusion: Well prepared Reviews guide to good products!

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Summary

- Concept phase, development phase and preparation of production for a component or system (i.e. an item) shall be ***verifiably closed*** by different ***design reviews***
- A review **compares the requirements with the achievements** at each project stage and documents the results of said comparison
- Use Acceptance Record template for each milestone
- Resulting records shall be **stored in DMS**
- Advantages:
  - ✓ Easier tracking of progress
  - ✓ Results of forthcoming steps will match expectations
  - ✓ Less unwanted surprises
  - ✓ Smoother collaboration
  - ✓ ...

Thank You!