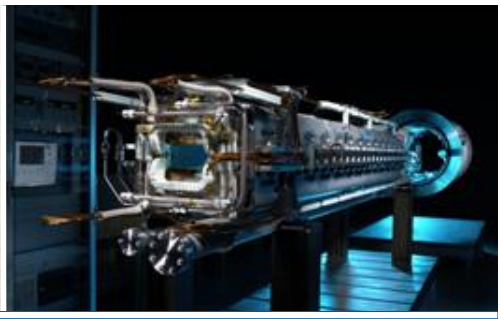
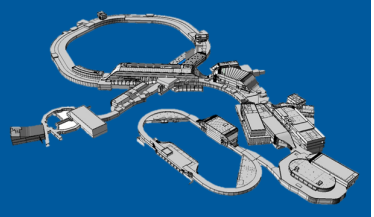
Добро пожаловать на семинар по обеспечению качества!





2nd joint BINP FAIR meeting

Quality Assurance Training:
Agenda for May 21, 2019



Major Quality Gates and QUA Training Modules

Milestone/ Activity	Description
M3	Specifications / TDR are approved
M4	Contract is signed
M5	Schedule and Q-Plan accepted
M6	CDR accepted
M7	FDR accepted
M8	Pre-series/prototype accepted
M9	FAT accepted
M10	SAT Aa&Ab accepted
M11	SAT Ba accepted
M12	SAT Bb accepted

Agenda

- ***09:00*** ***Welcome & Opening***
- 09:05 Quality Assurance Overview
- 09:15 Conducting Design Reviews (CDR & FDR)
- 09:45 Performing Acceptance Tests (FAT & SAT A)
- ***10:15*** ***Coffee Break***
- 10:45 Dealing with Nonconformities (NCRs)
- 11:15 Required Documents
- 11:30 Lessons Learned and Discussion
- ***12:00*** ***Tentative End***

Motivation

- This training course provides a short and comprehensible overview of the most important quality assurance processes for the FAIR Accelerator Project
  - → Starting point for Newbies
  - → Booster for Experts

- This training is addressed primarily to all work package leaders (incl. their deputies)

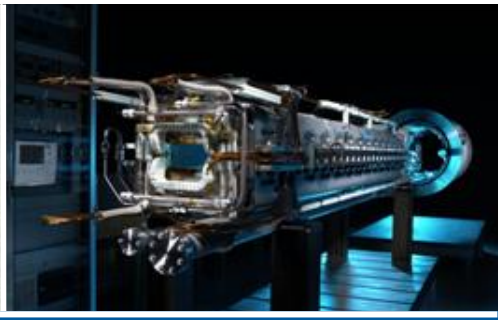
General Remarks

- This training material is for information only, in doubt the released procedures are binding

- All Training Modules have a similar structure

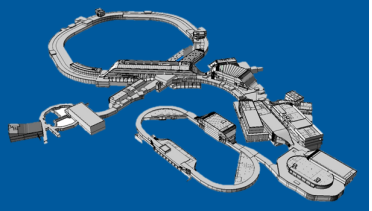
- The given presentations will be distributed afterwards





2nd joint BINP FAIR meeting

Training Module:
Quality Assurance Overview



Tuesday, May 21, 2019

FAIR

Motivation for Quality Assurance

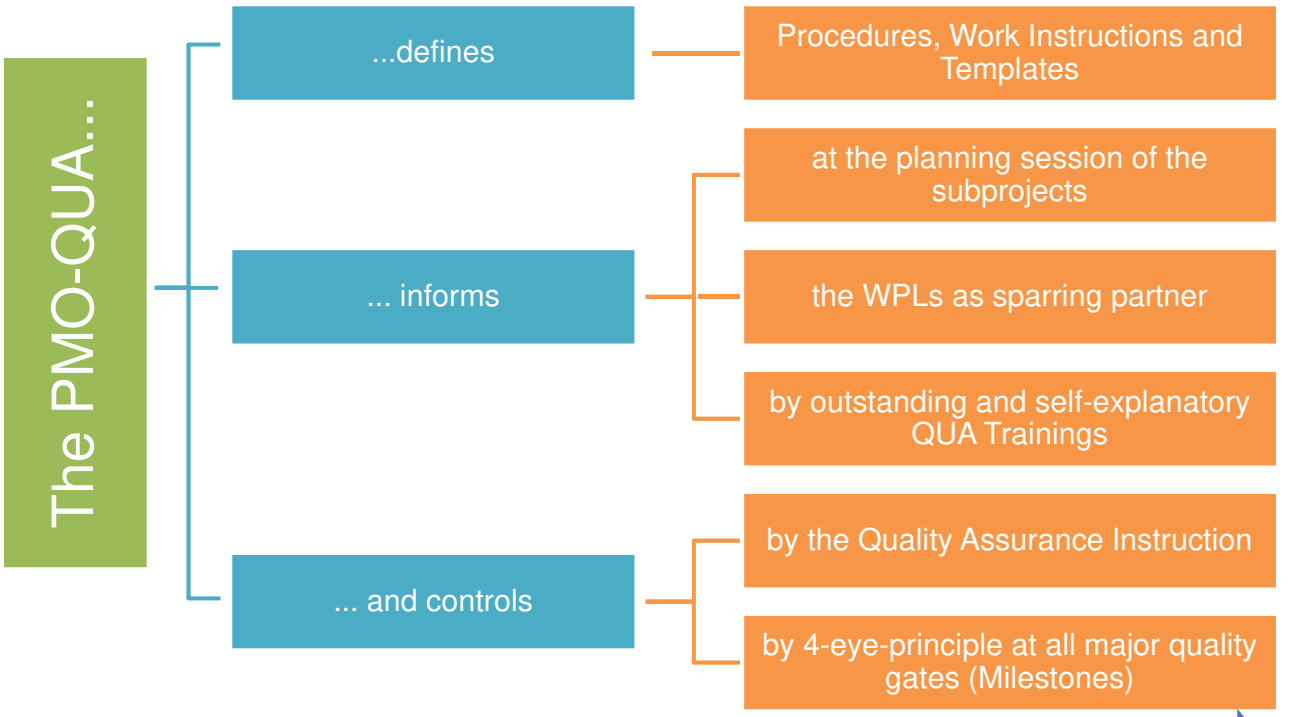
Objectives of Quality Assurance

Quality Assurance for FAIR Accelerator

Responsibility of PMO-QUA

- The quality assurance (QUA) is within the FAIR project responsible for reliably stating whether the components for the new accelerator machine are fulfilling their specific requirements
- Involvement of QUA already starts with the specification of these accelerator components
- Quality assurance accompanies the whole production process of the component from its development up to its certification and release and, later on, its operation up to the end of its service life

Tasks of FAIR Quality Assurance



Conclusion: Aim of Quality Assurance is to save time and costs

QUA Intranet & Instruction

Information page of Quality Assurance

This page is the entry point of QUA and offers a collection of information.

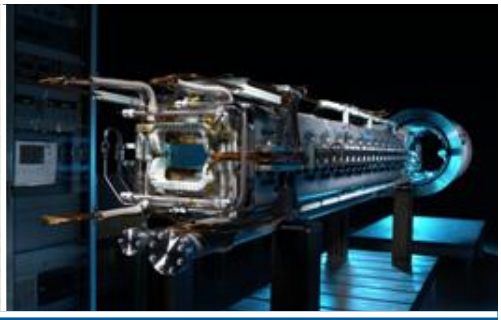
Quick access: www.gsi.de/qa → Information page of Quality Assurance

- **Employees**
- **QUA Glossary**
- **QUA Training Modules**
- **Procedures and Templates**
- **Management of Test Equipment**
- **Directives and Standards**
- **QUA Instruction with Certificate**

Certificate: http://instruct-guest.gsi.de → Instruction „Quality Assurance“

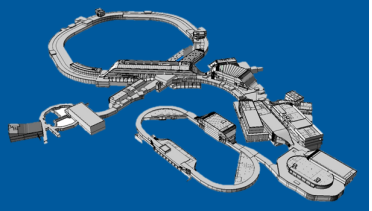
Спасибо за внимание!





2nd joint BINP FAIR meeting

Training Module: Design Reviews



Tuesday, May 21, 2019

FAIR

Agenda

1. Introduction
2. Documents
3. Processes & Methods
4. Experiences & Tips
5. Summary

Motivation

ISO 9001:2015, Chapter 8.3.4:

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

a) the results to be achieved are defined;

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

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

Focus of this training

Introduction

- F-GS-F-01e (General Spec) defines ***milestones***:
  - ...
  - **M6 = CDR** (conceptual design review) accepted
  - **M7 = FDR** (final design review) accepted
  - ...

- Q-VA-QA-0006: **Concept** phase, **design** phase, and **preparation of production** for a component or module (...) shall be verifiably closed by different ***design reviews.***

Agenda

Documents

- Procedure (VA): **Q-VA-QA-0006 Design Reviews**
  - and documents mentioned therein
- F-GS-F-01: **General Spec**
  - and documents mentioned therein
- BGI/GUV-I 5139: **Manufacturing and operation of equipment designed for research purposes**
  - and documents mentioned therein
- F-TG-MDS-en-KRL: **Design Guideline for Mechanical Design**

Agenda

Different Design Reviews

- F-GS-F-01e (General Spec) defines **CDR** and **FDR** only
  Currently, however, there are more terms used:
  - **CDR** = conceptual design review
  - PDR = preliminary design review; used if the CDR covered a very early concept, or instead of CDR
  - **FDR** = final design review
  - MDR = manufacturing design review; used if designer and manufacturer are different organizations
  - And many others like PPDR, PFDR, ...

→ If possible, CDR and FDR shall suffice

- If other reviews are used, they must be defined and clearly differentiated from the CDR and FDR

Review Process [1/2]

- **Prepare** the review (responsible = WPL):
  - Get the required documents well in advance (min. 2 weeks)*
  - Invite participants, i.e. WPL, SPL, QUA, and contractor;
    - optional: further relevant departments (ENMD, ENMI, SSBV, CSTI, ...)
  - Make the documents accessible for all participants asap
  - Compose a list of all test criteria applicable (from the contract and its co-applicable documents – e.g. GS, CS, DS, KRL, TGs)
- **Conduct** the review (responsible = WPL):
  - Check all test criteria as listed (i.e. all requirements)
  - Compare with the achievements, agree on each criterion checked (accepted or rejected) and record the decisions (base of minutes)
  - The review will be passed straightly if all criteria are fulfilled

*) The contractor itself stores those documents into EDMS

Review Process [2/2]

- **Close** the review (responsible = WPL):
  - Fill in the “Acceptance Record” and write the minutes
  - Get the signatures of all participants and scan the record
  - Store both documents in EDMS and set them to “Released”*
  - Update MS Project plan
- **What if <u>not all</u> criteria are fulfilled?**
  - Obviously, the review failed and must be rejected**
  - Though – don’t panic!
  - If a review fails, it shall be simply finalized as soon as the required amendments are completed

*) supported on request by Wolfgang Gallus, Andrea Lopèz or Klaus Höhne

**) It may be “conditionally accepted” with <u>minor</u> shortcomings

Content of CDR

- CDR
  - Release of an proper 3d-model or an functional structure of the object to built with its required documents according our VA „Design reviews“ and documents mentioned therein.
  - Needed documents:
    - » concept
    - » finalized risk assessment
    - » draft of production plan
    - » draft of test and inspection plan
    - » calculations and/or simulation for its dimensioning
    - » …

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

- Q-FO-QA-0013_Required_Documents

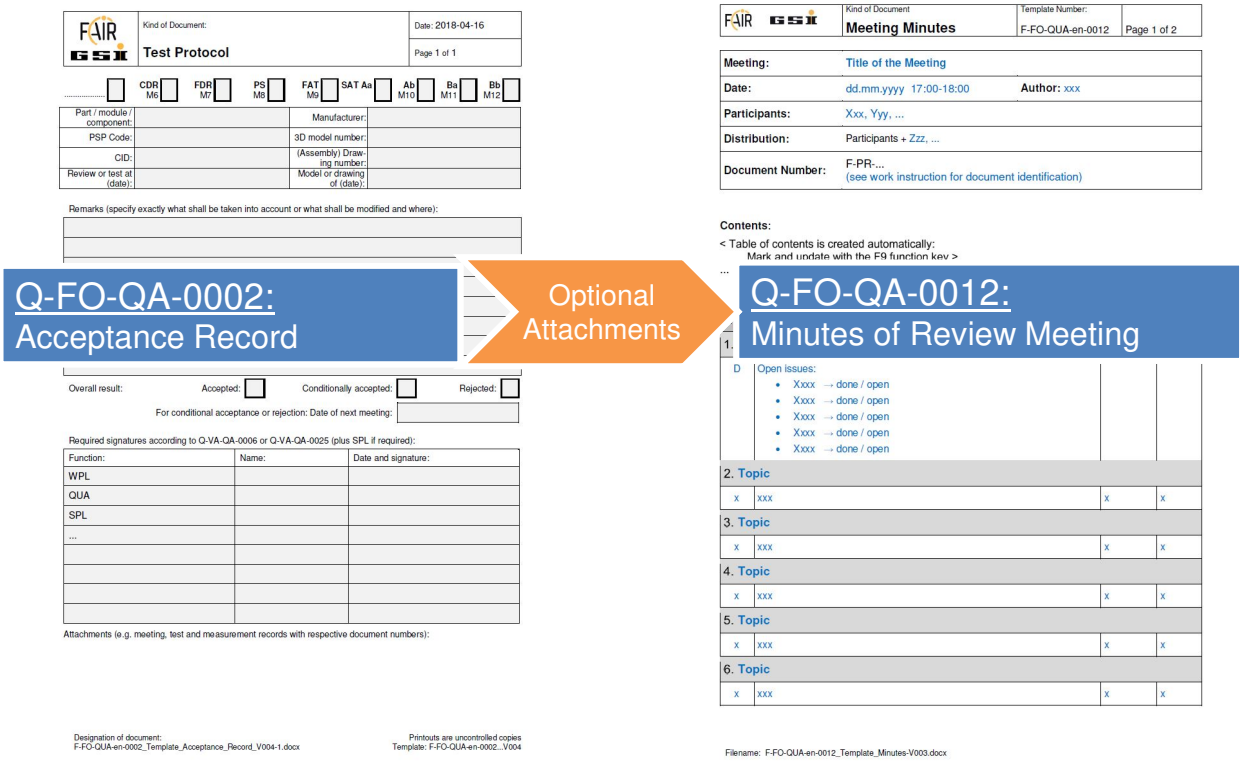
Content of FDR

- FDR
  - Release of all needed drawings to manufacture the object and the complete final documentation
  - Needed finalized documents:
    - » production plan
    - » test and inspection plan
    - » work and test instructions
    - » set of production drawings and parts list
    - » complete documentation (user manual, …)
    - » …

The Template „Required Documents“ may help to finalize the required documentation:

- Q-FO-QA-0013_Required_Documents

Templates for Documentation



Agenda

- Introduction
- Documents
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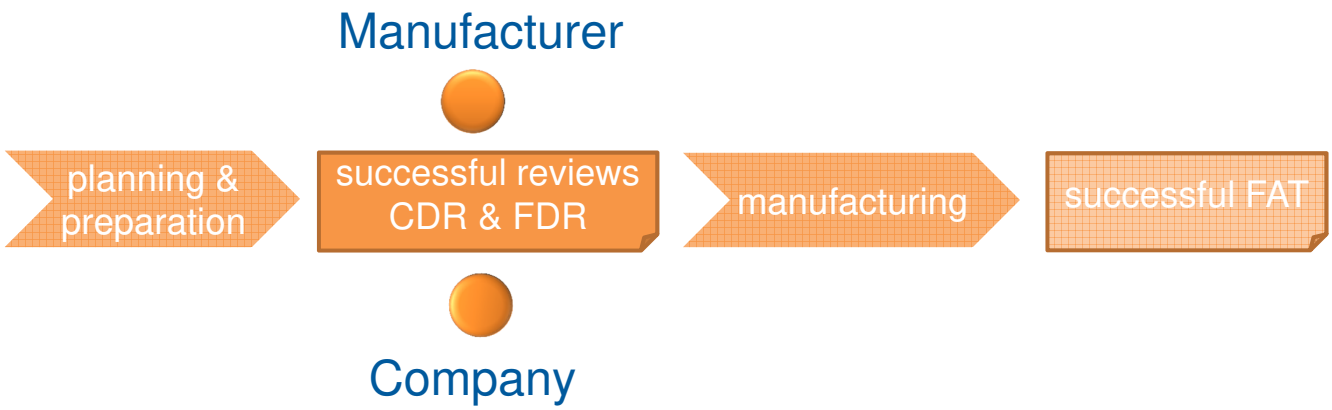
- Summary

Experiences & Tips

- Read the related procedure and documents
  (Clarify questions with the authors in advance of the review)
- Get the required documentation well in advance a review meeting
  (do not cut time for proper checking!)
- Be prepared and organized (list of criteria!) to have an easy review
- Cut the emotions – no drama if a review fails!
  - Go for agreement on the remaining open points
- No work is done till the paperwork is done
  - Take care of the record and get it signed by the participants
    (done best immediately after the review)
  - Scan and store it together with the minutes in EDMS

Experiences & Tips

Reviews are Preconditions for Manufacturing:



A successful CDR is mandatory for preparing the FDR

Conclusion: Well prepared Reviews guide to good products!

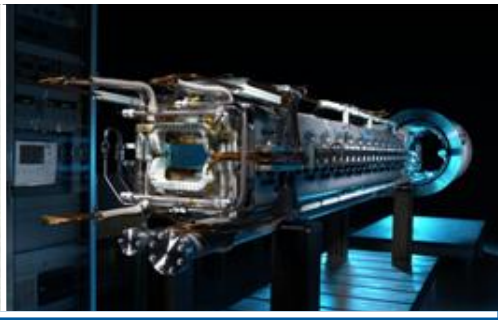
Agenda

Summary

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

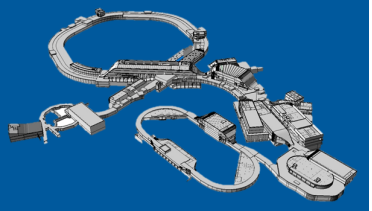
Спасибо за внимание!





2nd joint BINP FAIR meeting

Training Module:
Acceptance Tests
FAT & SAT Aa/Ab



Tuesday, May 21, 2019

FAIR

Agenda

1. Introduction
2. Documents
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Motivation

Each component or system must undergo acceptance tests during and after production

=

FAT (Factory Acceptance Test)

After delivery of a component or system, repeated or additional acceptance tests will be performed.

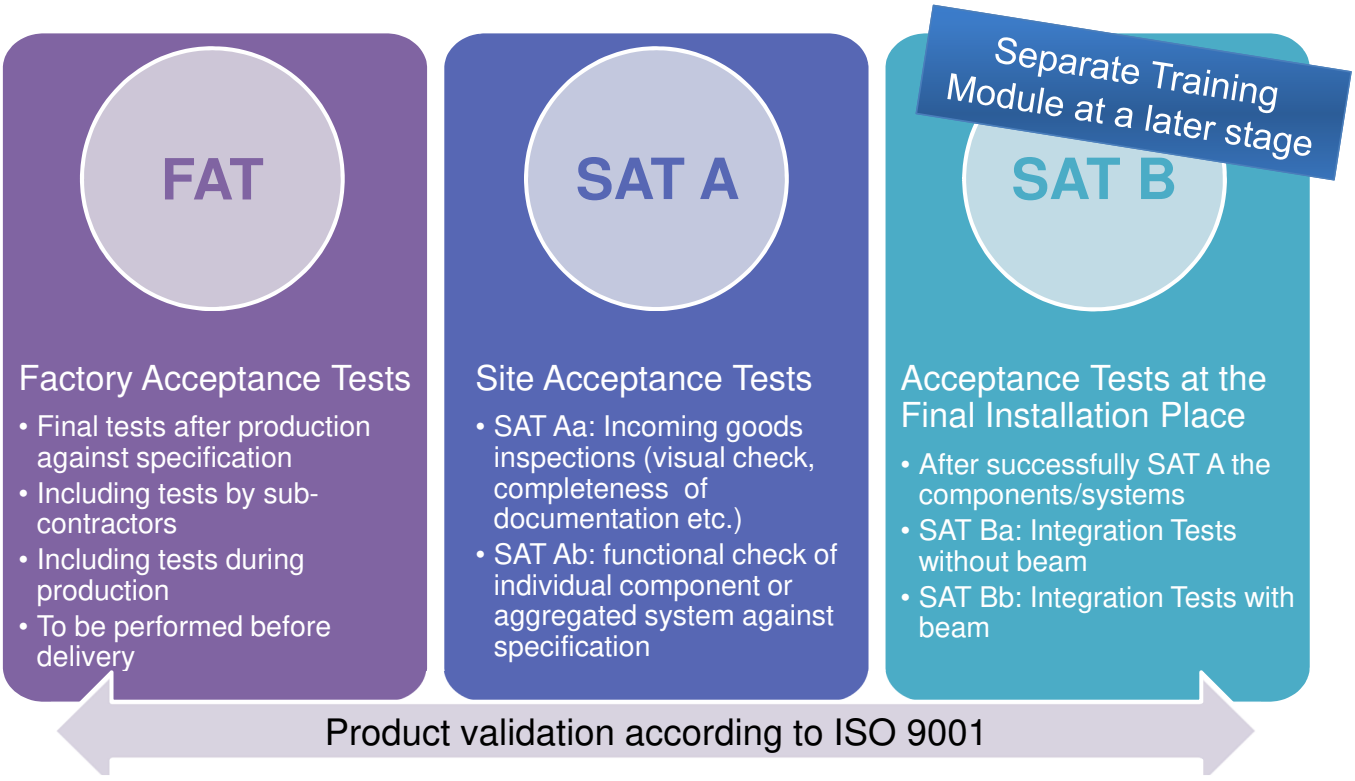
=

SAT (Site Acceptance Tests)

It must be determined

- what needs to be monitored and measured
- the method of monitoring, measurement, analysis and evaluation
- when to perform the monitoring and measurement
- when the analysis and evaluation of the results is carried out

FAT / SAT Overview



All components that will be productively used must pass through all acceptance tests
→ Prototypes for evaluation purposes are not relevant from quality assurance perspective

Agenda

Applicable Documents

- Procedures
  - **Q-VA-QA-0025 (Performing FAT or SAT)**
    https://edms.cern.ch/document/1514174
  - F-VA-QUA-en-0030_Nonconformities-V002
    https://edms.cern.ch/document/1503121

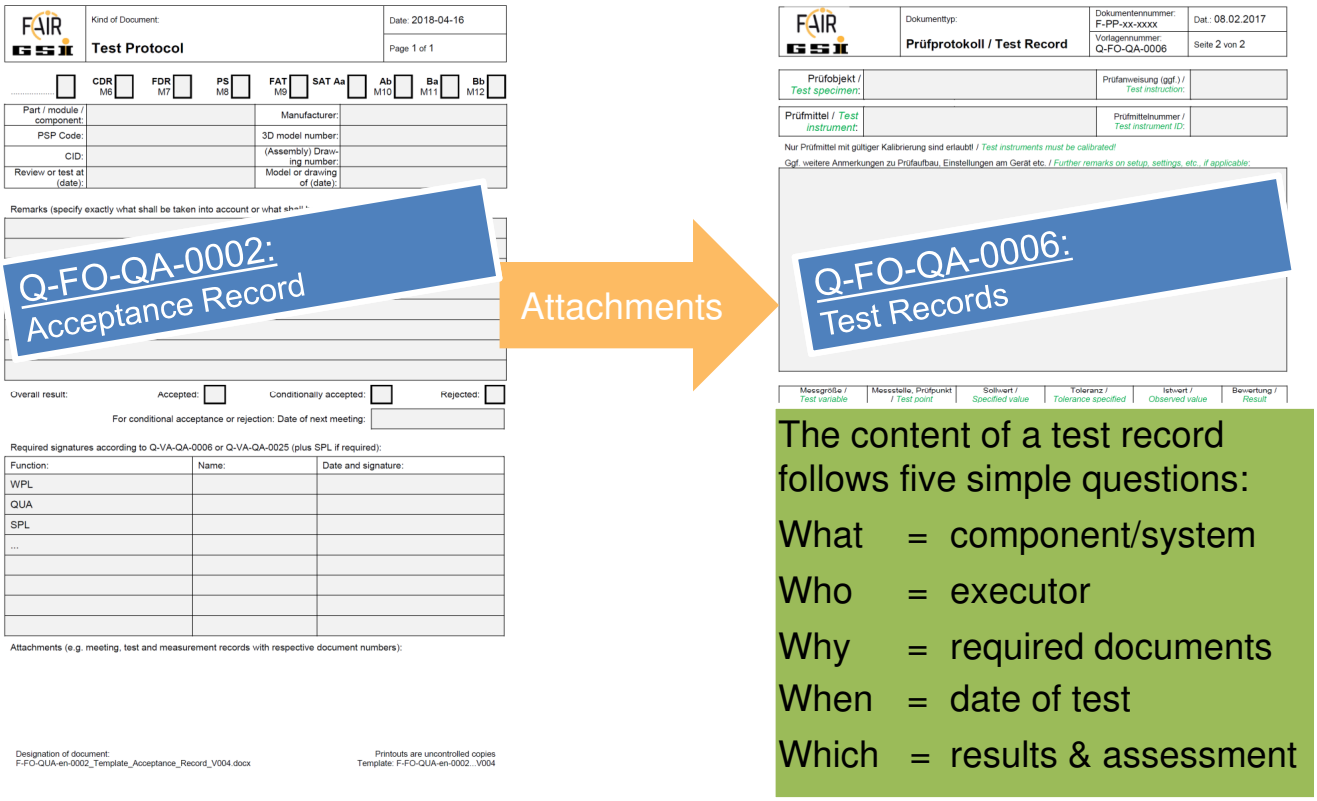
- Templates
  - **F-FO-QUA-bl-0007 (Inspection Plan)**
    https://edms.cern.ch/document/1810648
  - **Q-FO-QM-0010 (Test Instruction)**
    https://edms.cern.ch/document/1512546
  - **Q-FO-QA-0006 (Test Record)**
    https://edms.cern.ch/document/1517696
  - **Q-FO-QA-0002 (Acceptance Record)**
    https://edms.cern.ch/document/1458121
  - **Q-FO-QA-0008 (for SAT Aa)**
    https://edms.cern.ch/document/1517431
  - F-FO-QUA-bl-0003_NCR-V0002
    https://edms.cern.ch/document/1503137
  - F-FO-QUA-0004_Stoppage Card-V002
    https://edms.cern.ch/document/1503140

Examples on next pages

Required documentation

- Planning
  - Inspection plan
  - Test instruction
  - Template test record acc. test instruction
- Documentation of results
  - SAT Aa - incoming inspection
    - Incoming inspection protocol (Template Q-FO-QA-0008)
    - Acceptance protocol (Template Q-FO-QA-0002) for the fulfillment of the milestone
  - Sat Ab – functional test
    - Test records
    - Acceptance protocol (Template Q-FO-QA-0002) for the fulfillment of the milestone

Standard Templates for FAT/SAT Documentation



The content of a test record follows five simple questions:

What = component/system

Who = executor

Why = required documents

When = date of test

Which = results & assessment

Legal acceptance

- **FAT and SAT are no acceptance or partial acceptance within the meaning of § 640 BGB**
- **A Legal Acceptance protocol is necessary <u>in addition</u> to FAT and SAT protocols**

Process owner is:

PMO RTO (Reporting & Processes)

Template for Incoming Goods Inspection

Qualitätsmanagement	Dokumenttyp:	Dokumentennummer: F-PP-xx-xxxx	Datum: 28.04.2016
FAIR GSI	**Prüfprotokoll / Test Record**	Vorlagennummer: Q-FO-QA-0008	Seite 1 von 1

Ware / *Item*:		Lieferdatum / *Date of delivery*:	
Hersteller / *Manufacturer*:		Anlieferort / *Point of delivery*:	
Lieferant / *Supplier*:		Component ID:	
Bestellnummer / *Order no.*:		PSP Code:	
Einkaufswagennummer / *Shopping cart no.*:		Bezeichnung / *Nomenclature*:	

Wareneingangsprüfung / *Incoming inspection*:

Prüfung / *Test*:	ok	n. ok	Bemerkung, Prüfprotokoll, QAB / *Remark, record, NCR*	Prüfer / *Inspector*	Datum / *Date*:	Unterschrift / *Signature*:
Identprüfung / *Identity check*:						
Stückzahl / *Amount*:						
Transportschäden / *Transport damage*:						
Transportsensoren / *Transport sensors*:						
Verpackung / *Packaging*:						
Dokumentation vorhanden / *Documentation present*:						
Weitere Prüfungen oder Bemerkungen / *Further tests or remarks*:						

Gesamtbewertung der Ware / *Overall result*: Freigegeben / *Accepted*: ☐ Gesperrt / *Rejected*: ☐

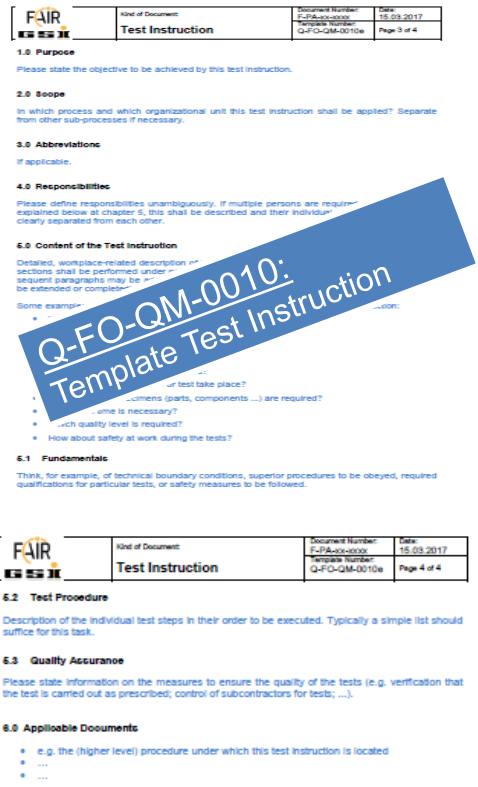
Funktion / *Function*:	Abt. / *Dptmt.*:	Name in Druckbuchstaben / *Name in print*:	Datum / *Date*:	Unterschrift / *Signature*:
Fachverantwortlicher / *FV*				
Qualitätssicherung / *QA*	QA			

Anlagen / *Attachments*: Lieferschein, ...

Ausgefülltes Protokoll inkl. Anlagen im EDMS ablegen / *Please store the filled in record incl. attachments in EDMS*

<u>Q-FO-QA-0008:</u>
Incoming Inspection Record (SAT Aa)

Template for Test Instructions



Content of test instructions:

- Description of test set up
- Definition of all requirements (set values, units, tolerances)
- Definition of applicable documents and regulations (e.g. AD2000)
- Reference to test documentation (e.g. templates for test records)
- The test equipment must be named and suitable for the planned tests
- The required qualification of the testing staff must be defined

Example for a completed test record

Qualitätsmanagement	Dokumenttyp:	Dokumentennummer: Q-PP-xx-xxxx	Dat.: 16.12.2015
FAIR GSI	**Prüfprotokoll / Test Record**	Vorlagennummer: Q-FO-QA-0006	Seite 1 von 1

Prüfobjekt / *Test specimen*:	Vacuum chamber, CID ######	Prüfanweisung (ggf.) / *Test instruction*:	ohne
Prüfmittel / *Test instrument*:	1. / 2. Messschieber 3. Haarlineal	Prüfmittelnummer / *Test instrument ID*:	1./2. PM0033 3. PM0586

Nur Prüfmittel mit gültiger Kalibrierung sind erlaubt! / *Test instruments must be calibrated!*

Ggf. weitere Anmerkungen zu Prüfaufbau, Einstellungen am Gerät etc. / *Further remarks on setup, settings, etc., if applicable*:

Zu prüfende Positionen:
1 Drill-hole Ø 15,1 -0 / +0,1mm
2. Drill-hole Ø 20,1 -0 / +0,1mm
3. Flatness flanges (allowed deviation ≤ 0,2mm)

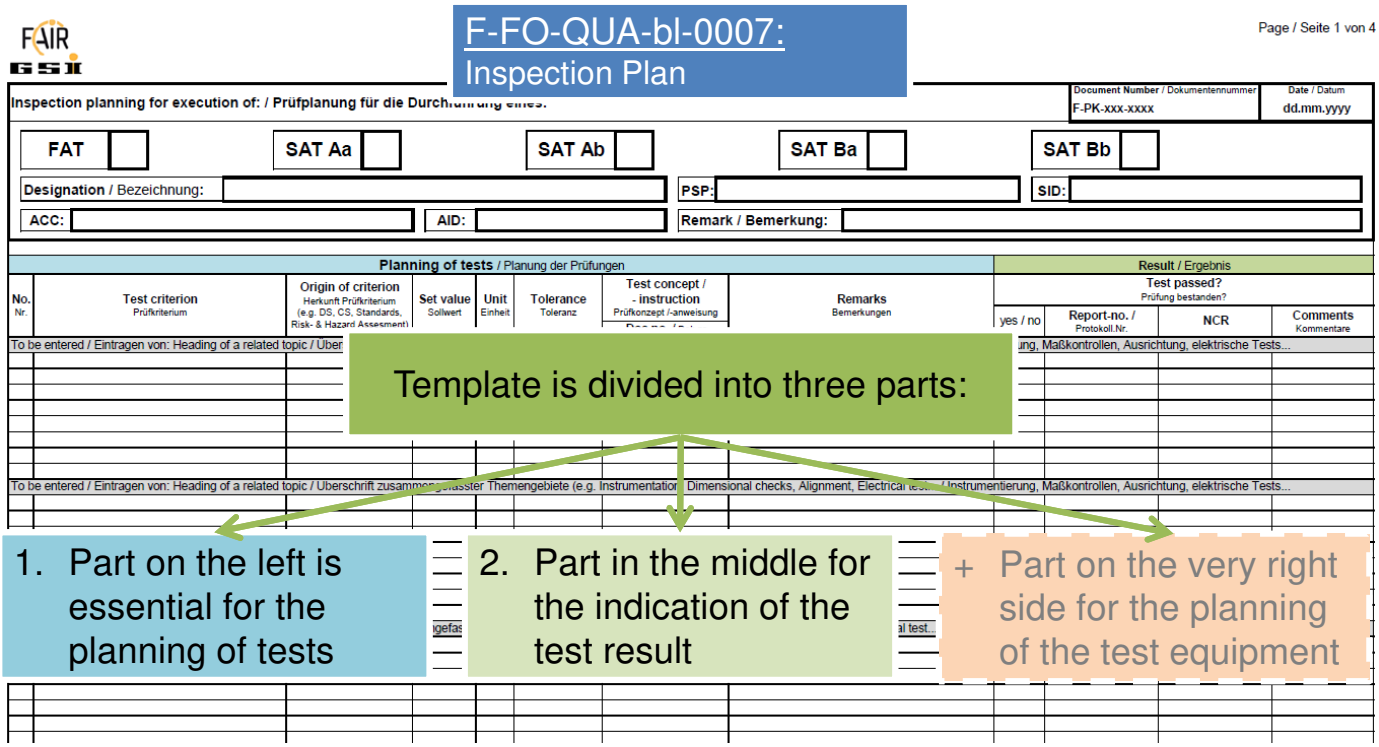
Prüfpunkt / *Test point*	Sollwert / *Specified value*	Messgröße / *Test variable*	Toleranz / *Tolerance specified*	Istwert / *Observed value*	Bewertung / *Result* ok	Bewertung / *Result* not ok
1.	Ø 15,1	mm	-0 / +0,1mm	15,2 mm	X	
2.	Ø 20,1	mm	-0 / +0,1mm	19,9 mm		X
3.	Flatness	Mm	≤ 0,2mm	0,1mm	X	

Gesamtbewertung / *Overall result*: Freigegeben / *Accepted*: ☐ Unter Vorbehalt freigegeben / *Conditionally accepeted*: ☐ Zurückgewiesen / *Rejected*: X

Funktion / *Function*:	Abt. / *Dept.*:	Name in Druckbuchstaben / Name in print:	Unterschrift / *Signature*:
Prüfer / *Inspector*	XX	Mustermann	xxxxxxxxxx

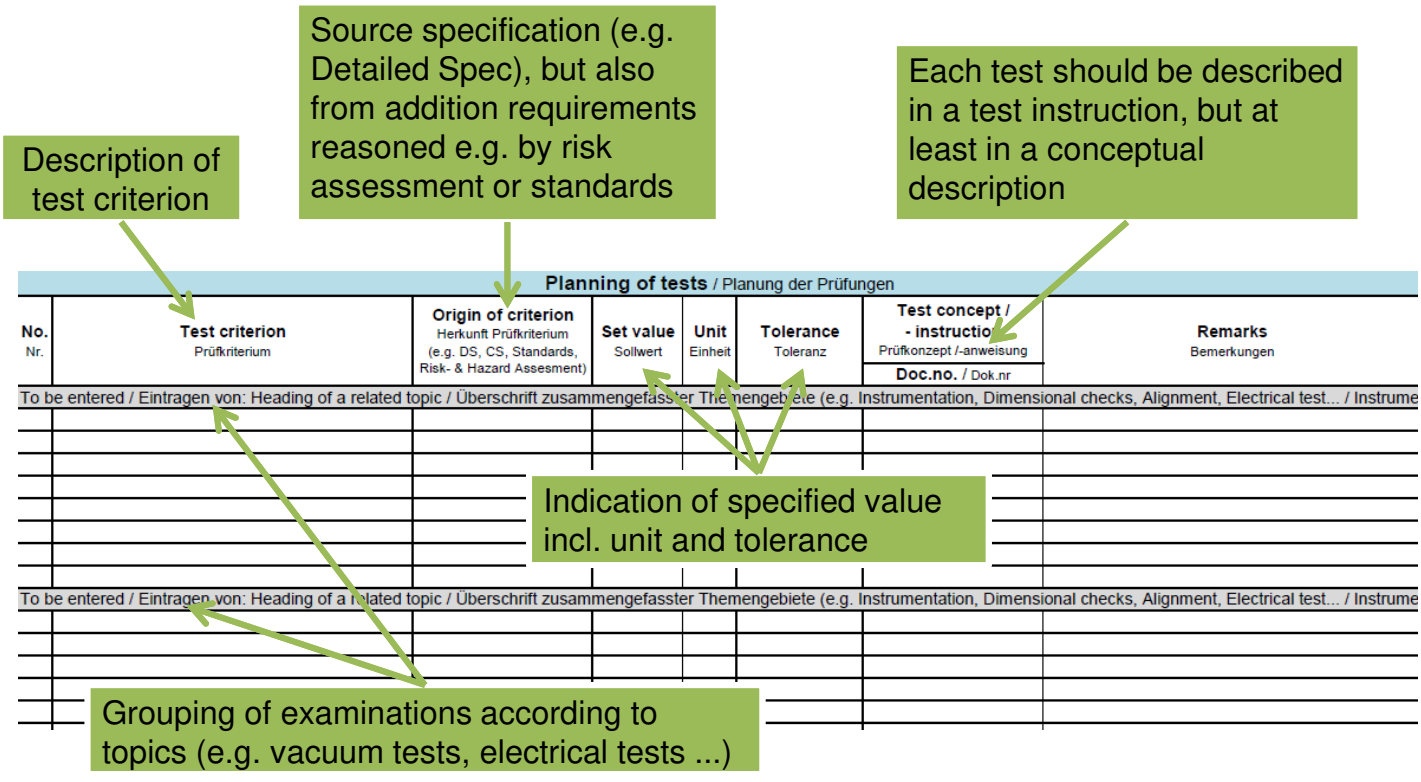
1. Adopt the template Q-FO-QA-0006 to your needs if necessary
2. Fill in the header
3. Add test positions
4. Perform the tests
5. Inspector's signature (follow-up action will be defined in the acceptance record)

Template for Inspection Plan



Template Inspection Plan

Planning of tests / Planung der Prüfungen



Template Inspection Plan

Result / Ergebnis

The part “Result / Ergebnis” can be used as cover sheet for the acceptance tests

You get an immediate overview whether an test passed or failed

Result / Ergebnis			
Test passed? Prüfung bestanden?			
yes / no	**Report-no. /** Protokoll.Nr.	**NCR**	**Comments** Kommentare
ntierung, Maßkontrollen, Ausrichtung, elektrische Tests...			

Number of the NCR that belongs to this test if it was not passed

Number of protocol

Template Inspection Plan

Planning of test equipment

FAIR GSI

Inspection Plan
Prüfplan

Page / Seite 2 von 4

Inspection planning for execution of: / Prüfplanung für die Durchführung eines:				**Document Number** / Dokumentennummer F-PK-xxx-xxxx	**Date** / Datum dd.mm.yyyy
FAT	**SAT Aa**	**SAT Ab**	**SAT Ba**	**SAT Bb**	
Designation / Bezeichnung:		**PSP:**		**SID:**	
ACC:	**AID:**	**Remark / Bemerkung:**			

Planning of test equipment / Prüfmittelplanung

No. Nr.	Test criterion Prüfkriterium	Test equipment designation Prüfmittel	Fabricator Hersteller	Required tolerance geforderte Toleranz	Measuring inaccuracy Messungenauigkeit	Measuring uncertainty Messunsicherheit	Order required Bestellung notwendig: Order-No. Bestell-Nr.	Order required Bestellung notwendig: Delivery Date Liefertermin	available? vorhanden? yes / no	PM-No. Test equipment no. Prüfmittelnr.
To be entered / Eintragen von: Heading of a related topic / Überschrift zusammengefasster Themengebiete (e.g. Instrumentation, Dimensional checks, Alignment, Electrical test... / Instrumentierung, Maßkontrollen, Ausrichtung, elektrische Tests...										
To be entered / Eintragen von: Heading of a related topic / Überschrift zusammengefasster Themengebiete (e.g. Instrumentation, Dimensional checks, Alignment, Electrical test... / Instrumentierung, Maßkontrollen, Ausrichtung, elektrische Tests...										

Test criterion from test plan (filled in automatically)

Test equipment (description, accuracy, availability, equipment no., etc.)

Agenda

- Introduction
- Documents
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Main Responsibility

- The work package leaders have the superior quality responsibility for their components / systems
- Important is a systematic monitoring and controlling of all responsibilities which are delegated (e.g. contractor)

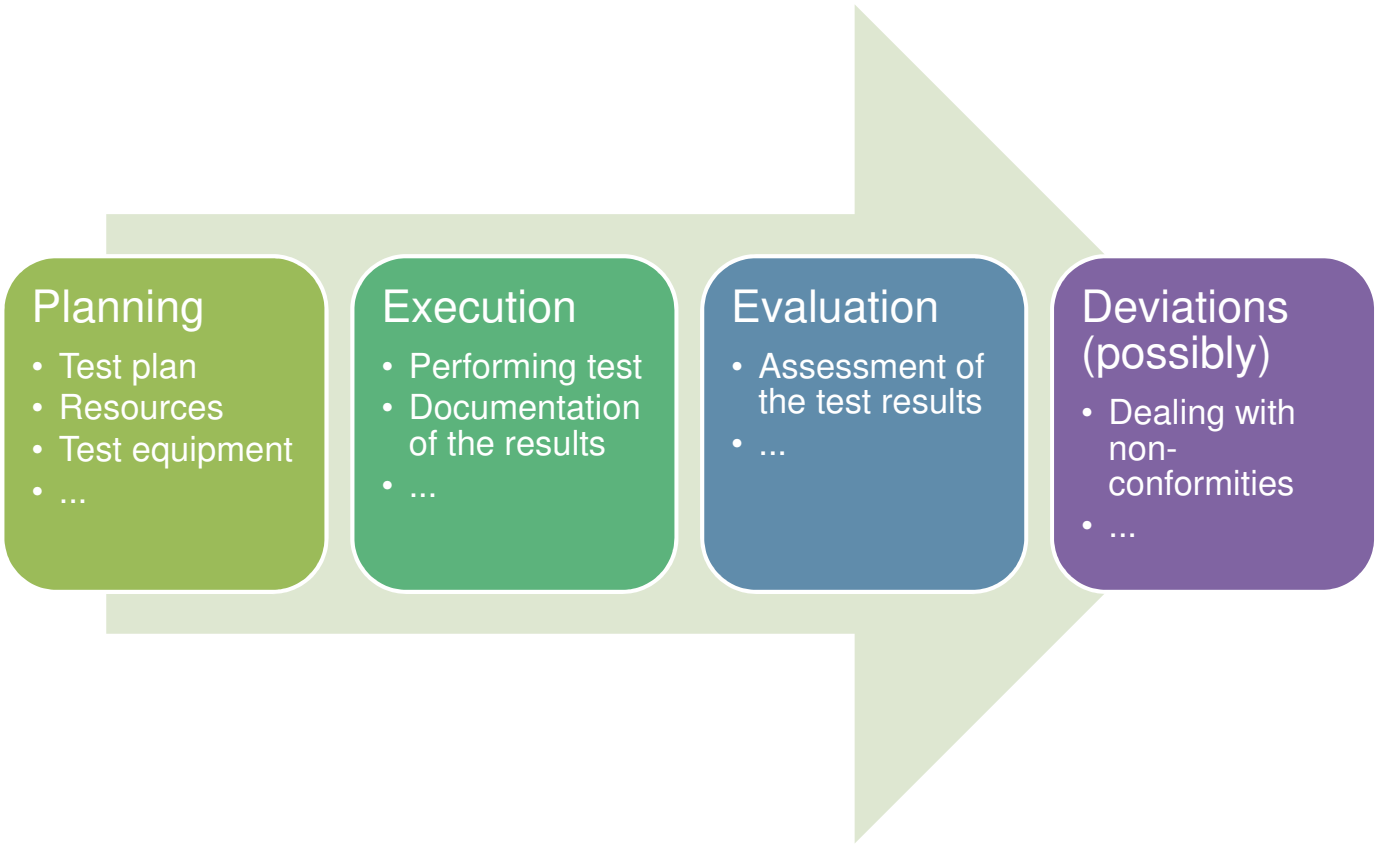
Preparation, execution and evaluation of the acceptance tests are within the responsibility of the Work Package Leader (WPL)* The WPL shall involve QA in these process steps

*) or respective „Anlagenverantwortlicher“ (cf. „Betriebsordnung“)

Q-VA-QA-0025

- Maintenance and update of the MS Project plan

Acceptance Test Phases



Overview of Responsibilites

	Planning	Execution	Evaluation & Release	Deviations
FAT	Contractor (acceptance during CDR/FDR)	Contractor	**WPL**	Contractor
SAT Aa	WPL/ Contractor*	WPL/ Contractor*	**WPL**	Internal: WPL External: Contractor
SAT Ab	WPL/ Contractor*	WPL/ Contractor*	**WPL**	Internal: WPL External: Contractor

*** Attention:** the proper responsibility is stipulated in the contract together with the referenced specifications! (In accordance to the current General Spec the contractor is in charge for the SAT A)

Timeline

FAT

- **Test & production planning**
  - **Draft version at CDR** - **Final version at FDR**
- **Required Documentation** (material certificates, personal certificates, test records, filled execution plans ...)
  - The already finished documents must be checked at FAT
  - The required documentations must be delivered to FAIR/GSI, latest together with the component/system itself
    - It must be controlled at SAT Aa

SAT A

- **Test planning (Inspection Plan)**
  - **Final version at FDR**
    (Otherwise a timeline must be determined!)
- **Execution planning, test instructions, templates of test records**
  Must be available at latest 8 weeks before scheduled delivery of component or module

Requirements for Planning

A detailed test planning is mandatory!

This includes the whole process (manufacturing and tests) which is necessary to ensure the required product quality.

Content:

- Planning of tests
- Planning & allocation of test equipment.
- Definition of needed documentation (test instructions, templates for test records, work instructions...)
- Planning of resources (qualified and certified test staff)
- Planning, organization and documentation of work that has to be performed (execution plan...)

Execution and Evalutation

- **Executing**

  The requirements taken from the test instructions will be checked step by step. The results of each test step must be recorded (Q-FO-QA-0006 Test Record)

- **Evaluation**
  - Each result will be compared with the corresponding required value and will be rated
    - The **acceptance test is passed** if all included checks and tests were passed = all results are within the required tolerances
    - It is **failed** if one or more test result is rated unacceptable
  - All **nonconformities** and the handling of them must be properly documented

→Separate Training Module „Non-Conformities“

Agenda

Experiences & Tips [1/2]

- Make sure that all the requirements and **acceptance criteria are already listed within the Detailed Specification** in a clear and comprehensible manner (best in tabular form)

- **Each test shall be described in a separate test instruction**
  - A technical guideline isn´t a test instruction

- **All acceptance tests should be performed as early as possibly (better within FAT then SAT A and so on)**

Experiences & Tips [2/2]

- Tests from the FAT should not be repeated during the SAT Ab

  → **Be aware that the tests during FAT are comprehensive**

- If additional milestone **„Storage“** is applicable, it must be decided when it takes place (e.g. between SAT Ab and SAT Ba)
  - Possibly some inspections must be repeated

- **Involve QUA staff** as early as possible in all quality related issues
  - Use also the experiences in technology and measuring systems of QUA

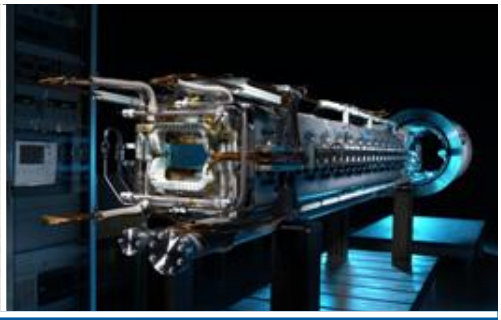
Agenda

Summary

- Take care of responsibilities, especially for SAT A (see Contract, Detailed Spec, General Spec)
- Also prototypes / pre-series which are provided for assembly in the tunnel must undergo and pass all acceptance tests
- A detailed test and execution planning is mandatory
  - For FAT at FDR in a final version
  - For SAT Aa/Ab at FDR preferably in a final version, latest after FAT
- Besides the functional acceptance tests the accompanying documents are just as important
- Documentation within EDMS (test results / nonconformities)
- Maintenance of MS Project plan
- Be aware that FAT and SAT are no Legal Acceptance

Спасибо за внимание!





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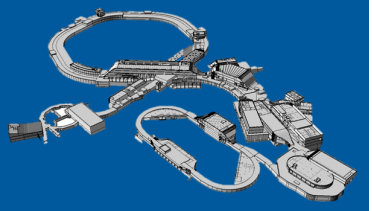
Training Module:
Dealing with Nonconformities



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FAIR

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- Introduction
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Motivation by ISO 9001

- *„The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.“*
- *„The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services”*

(clause 8.7.1)

Conclusion: A nonconformity is a non-fulfillment of a requirement.
A requirement is a need or expectation that is stated, generally implied or obligatory.

Introduction

- Nonconformities may appear in manufacturing processes (be it at contractors or in our own responsibility) as well as in (external or internal) commissioning
- Nonconformities must be documented in a suitable form
- For the uniform handling of nonconformities, it is necessary to establish a unified system
- The most important terms are:
  - **Mistake:** is the non-performance of a defined requirement (from specifications, technical guidelines, contracts, drawings)
  - **Repair:** is a measure of a defective product, to make it suitable for the intended use
  - **Corrective Action:** is a measure to eliminate the cause of an already occurred error, with the aim that this no longer occurs

Definition of Nonconformities which are Subject for Obligation of Documentation

A nonconformity observed during production or assembly process or in a subsequent examination (e.g. SAT Ab, SAT Ba/Bb) **has to be documented** when:

- It is a critical area or part

  (Interpretation e.g. according to high pressure directive/AD2000, radiation protection, high load by forces)
- The nonconformity occurred shall be left
- The repair requires a significant overhead (time and money)
- Through repairing the appearance will change with respect to the drawing (e.g. additional weld)

Agenda

Documents

- Procedure (VA):
  F-VA-QUA-en-0030_Nonconformities
  https://edms.cern.ch/document/1503121
- Templates
  F-FO-QUA-bl-0004 (Stoppage Card)
  https://edms.cern.ch/document/1503140
  F-FO-QUA-bl-0003_NCR (Template for NCR)
  https://edms.cern.ch/document/1503137
- Take also note:
  Procedure: Q-VA-QA-0006 Design Reviews
  https://edms.cern.ch/document/1514206

Stoppage Card

If the necessary repair or rework cannot be executed immediately, QUA will attach a stoppage card to the part of said component where the nonconformity was found.

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Internal & External Nonconformities

- **INTERNAL NONCONFORMITY**
  Nonconformity caused by work that has been carried out by FAIR or GSI
- **EXTERNAL NONCONFORMITY**
  Nonconformity caused by work of a contractor.
  This also applies to work which was performed after delivery to FAIR

The following steps have to be met always for creating an internal or external Nonconformity Report (NCR):

- Define measures (repair and if necessary corrective actions & additional test)
- Carry out a review and approval process (via EDMS!)
- After approval of the NCR, start the implementation of measures
- If all the measures are done, release the NCR (close the stoppage card if existing)

Definition of Minor and Major Deviations

Minor	▪ No condition is fulfilled requiring its classification as a “major” nonconformity ▪ Neither the functionality of the component or system nor requirements given by EU guidelines, regulations (e.g. AD2000), or specified standards are affected ▪ The defect can be eliminated quickly, easily, and at low cost ▪ It is an isolated event (no recurring nonconformity!)
Major	▪ The nonconformity causes restrictions or deviations from specified requirements or features, leading to reduced functionality ▪ Repair will change the look compared to the drawing (e.g. by additional welding) ▪ The amount of rework foreseen (regarding costs and time) will be major ▪ There will be consequences for the progress of the entire project ▪ A complaint at the AN is required

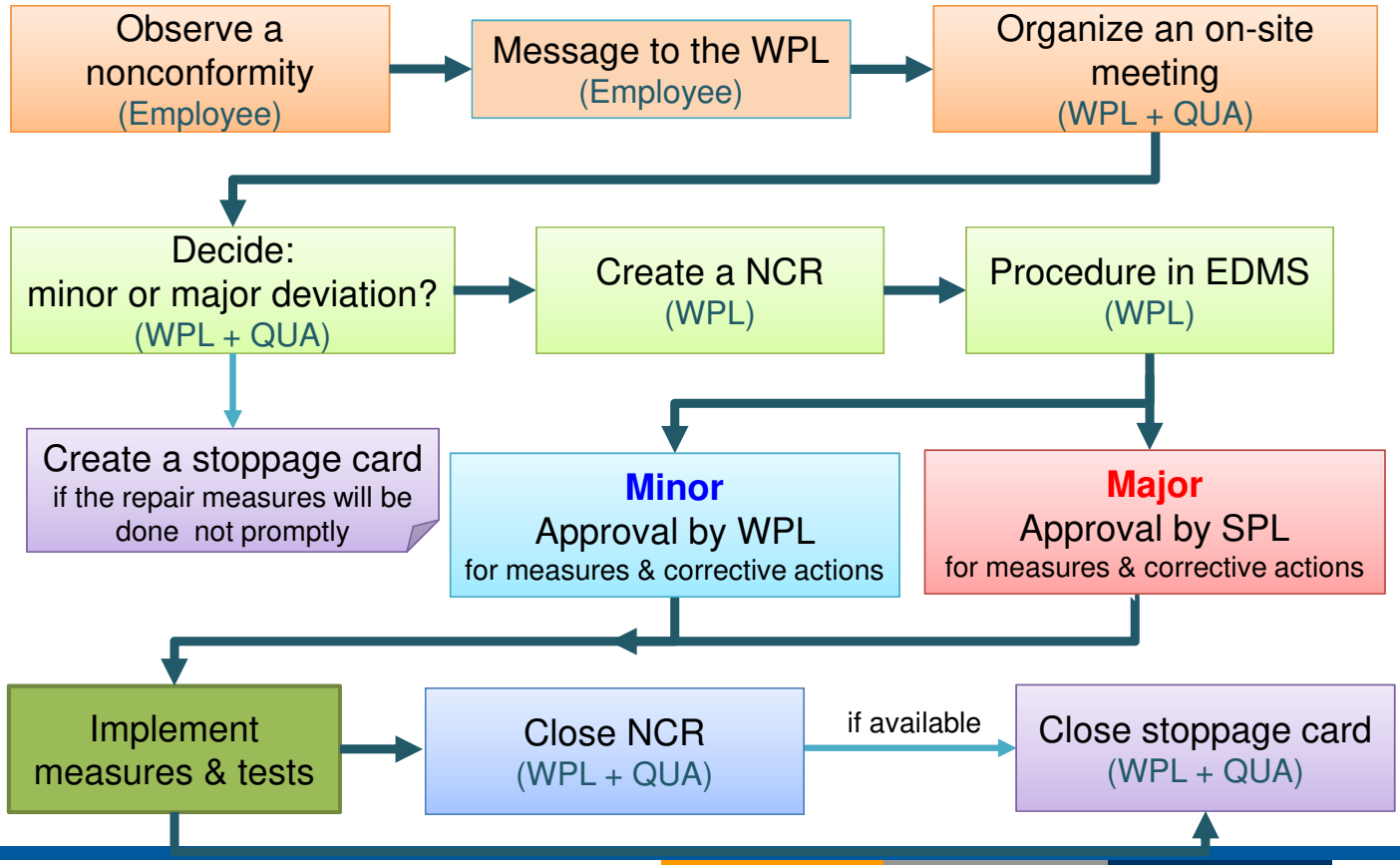
Short description of procedure

- The announcement of a nonconformity is given directly to the WPL
- The WPL informs the responsible QUA employee and organizes an on-site meeting if necessary. He has to monitor that an NCR is created. The causative principle applies to the creation of a NCR
- After creating the Nonconformity Report (NCR), the process is handled via the EDMS (Engineering Check & Approval)

  There are no more paper signatures (handling via EDMS)
- There is a strict distinction between “major and minor” deviations
- The NCR template has been simplified and can also be used by contractors
- A stoppage card will be used as a marker and will be issued if the repair measures are not promptly

Internal Nonconformities – General procedure

(see chapter 4 of F-VA-QUA-en-0030_Nonconformities):



Important Note

If the nonconformities are attributable to the manufacturer or supplier, they should be notified and given the opportunity to eliminate them!

Note the contractual agreements concerning warranty and guarantee.

External Nonconformity Report

All companies working according to ISO 9001 must have a system for the treatment of nonconformities
→ If it is not available, it must be developed and agreed by FAIR/GSI

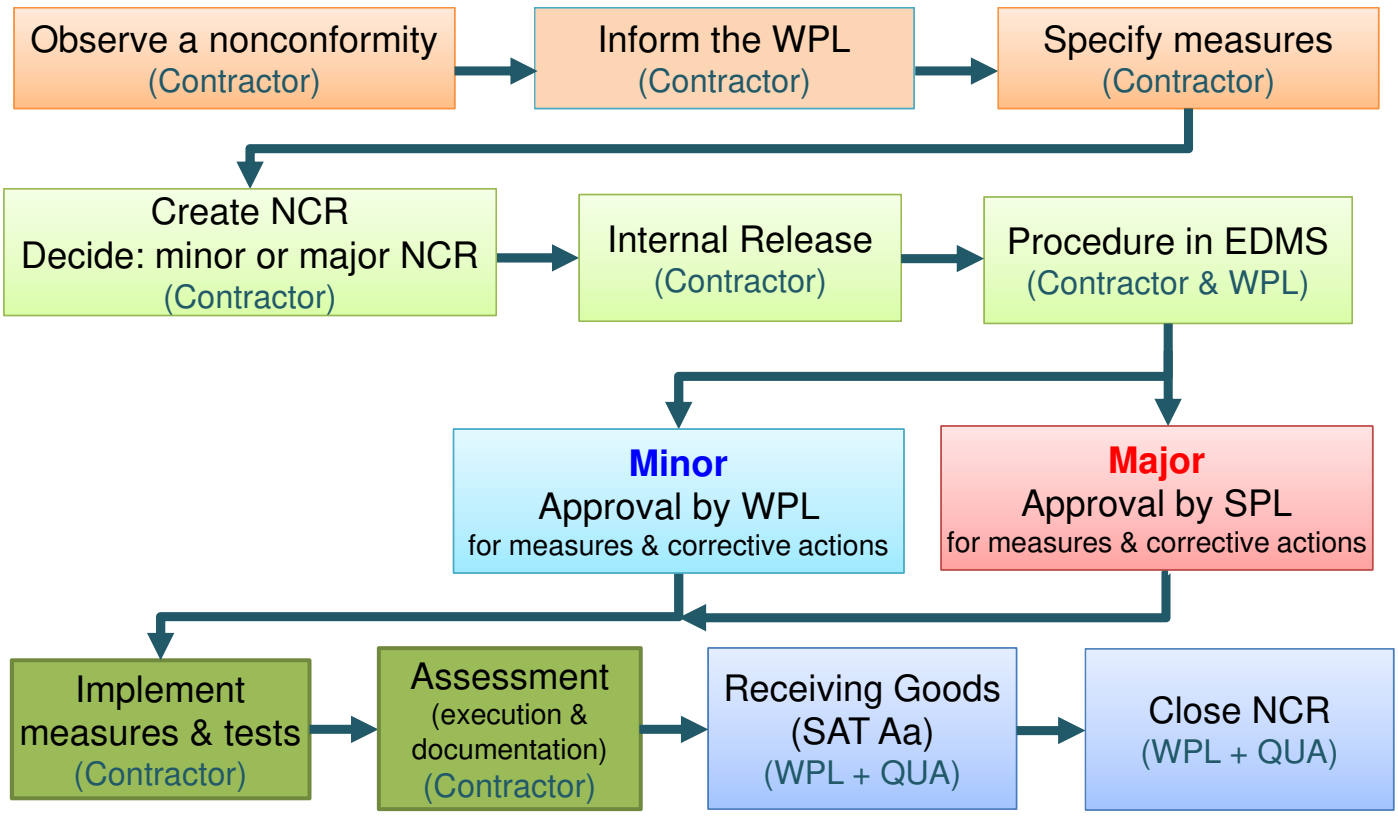
If the contractor observes a nonconformity he must:

- Immediately inform the WPL (FAIR GSI)
- Develop under its commitment, possibly in corporation with the WPL and QUA, solution proposals for the necessary repairs and tests and corrective actions
- Document this in an NCR (on his own or FAIR GSI template) The approval has to be done according to „minor“ or „major“ procedure

After implementation of measures, the contractor must approve and FAIR (WPL and QUA) must confirm that the component or system meets the requirements (at least at SAT Aa)

External Nonconformities – General procedure

(see chapter 4 of F-VA-QUA-en-0030_Nonconformities):



Differences between NCR and ECR

The most important difference between a NCR (Nonconformity Report) and an ECR (Engineering Change Request) is:

- A NCR is the document that handles a deviation that has occurred on a real component
- the NCR is always CID-related
- With an NCR no module specific documentation (Specification, Drawings, Guidelines ...) can be changed

- An ECR describes changes (like IOL, Software, beam parameters, measures, tolerances…) to be made to components, assemblies, and systems which are AID related.
- The need to create an ECR can arise from a nonconformity
  - ➢ It is important that the NCR must be created at first. In the NCR the necessary change is listed as a corrective action. If possible the ECR number should be mentioned

Agenda

Experiences & Tips

- Any nonconformity must be documented, even a small one
- Use the experience of QUA for decisions, discussion, and dealing with a nonconformity observed
- Use the production and inspection plans (execution plans) also for documentation of nonconformities
  - By doing so, the incident is assigned also to a production or test step
- If applicable, update the MS Project plan
  - Closed nonconformities could lead to project progress

Agenda

Summary

All nonconformities must be identified and known

- Every employee in the project “FAIR Accelerator and Experiments” who detects a nonconformity must immediately report it to the work package leader*)
- All nonconformities which are subject to documentation obligation must be documented at least on a stoppage card
- It must be determined (e.g. by technical meetings) how critical the deviation is and how it is classified (minor or major)

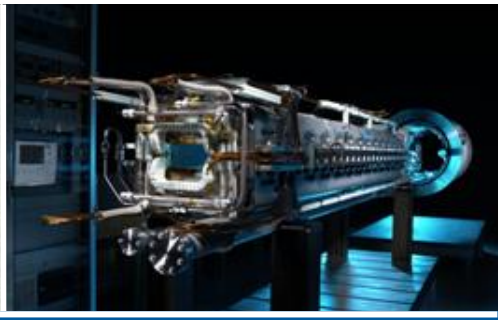
The QUA must always be involved

- QUA is responsible for monitoring compliance with the quality standards

*) *Depending on the actual project organization*

Спасибо за внимание!





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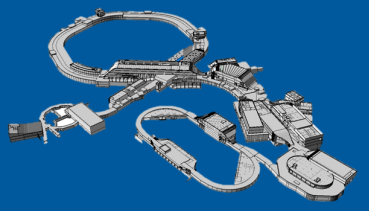
Training Module:
Required Documents



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FAIR

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Motivation

- We all must meet the requirements of the FAIR project in terms of function, reliability, safety and costs
- **Documentation and technical function have equal priority**

  → Documentation is necessary due to **legal reasons**, but also for **internal usage**
- The required documents are determined by underlying specs and regulations
- WPLs shall **plan the documentation** for their components based on the associated specifications

Agenda

Applicable Documents

General

- F-GS-F-01e (General Specification)
  https://edms.cern.ch/document/1365092
- BGI/GUV-I 5139e
  (Manufacturing and operation of equipment designed for research purposes)
  https://edms.cern.ch/document/1744719
- F-TG-MDS-en-KRL (Design Guideline for Mechanical Design)
  https://edms.cern.ch/document/1229367

Template

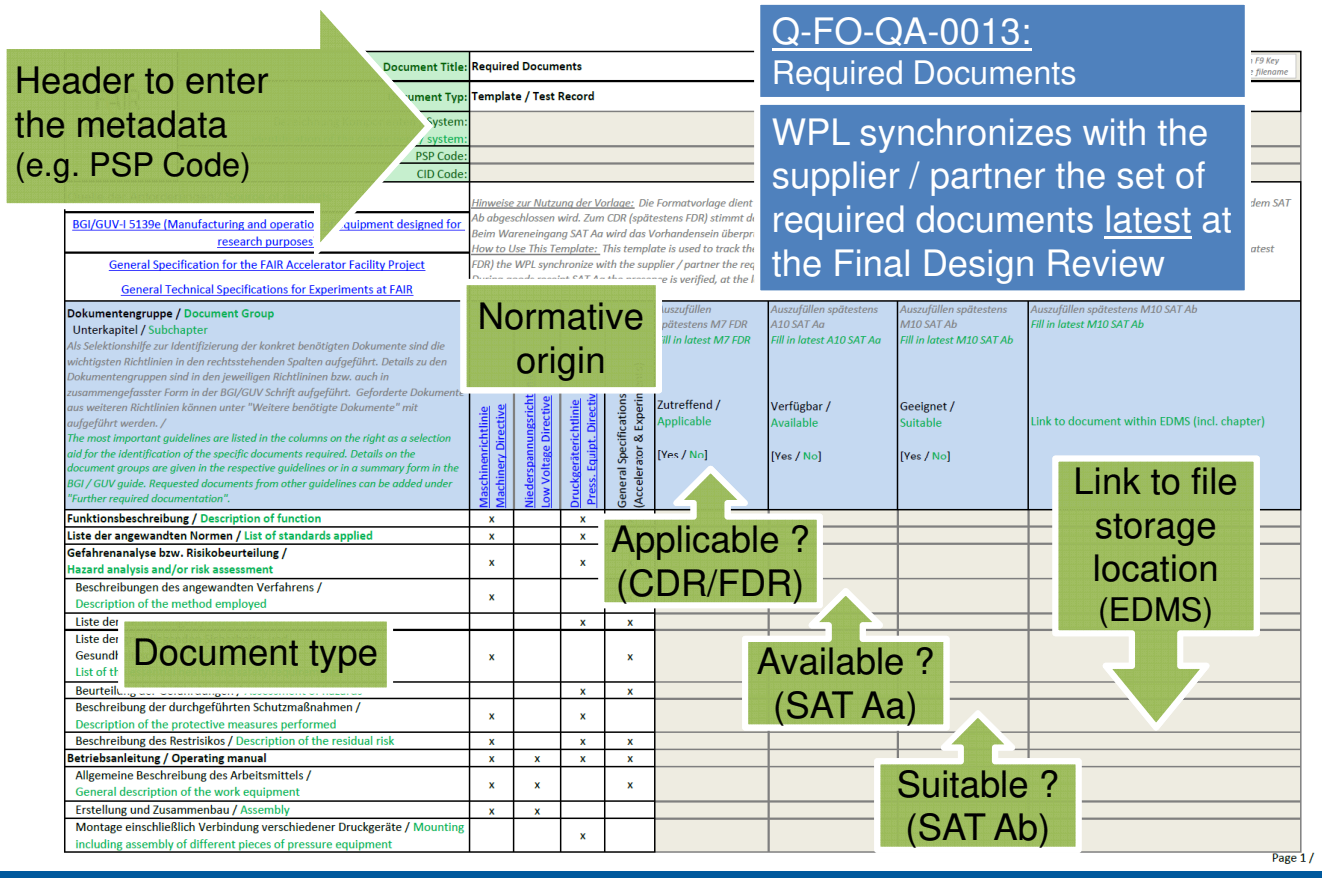
- Q-FO-QA-0013_Required_Documents
  https://edms.cern.ch/document/1732710

Agenda

Processes & Methods

- WPL has to consider in which role (s)he acts:
  - **As company**
    The company orders the design, manufacturing and commissioning (the company is the future operator of the facility)
  - **As supplier** or **provider** or **manufacturer**
  - **As contract manufacturer** (a manufacturer working with released as-built production documents)
- Check the contract: Are there any special agreements?
- With the ***safety related risk assessment*** (e.g. acc. ISO 12100) finalized, the standards to be met are defined
- Use Q-FO-QA-0013 ***Required Documents Template*** as a documentation plan for the next milestones (see next slide)

Template „Required Documents“



Agenda

Experiences & Tips

- Look for **comparable projects** of various specialist departments and get in touch
- **Ask QUA** for help
  → Examples and experiences from various projects are available
- Use the **Guideline BGI/GUV-I 5139e**
- If necessary: consult external specialists

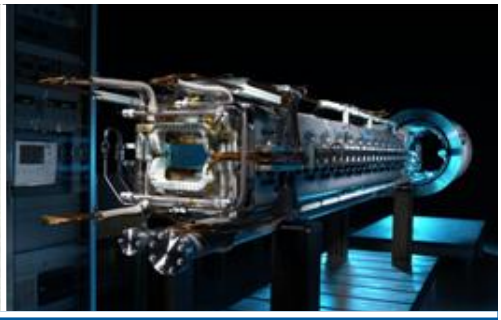
Agenda

Summary

- Underlying **specs** and **regulations** determine which documents are required
- The mandatory ***safety related risk assessment*** is prepared for the **CDR** – this **specifies many required documents**
- At the **FDR**, the WPL takes care of **the content** of the required documents being detailed
- At latest for **SAT**, the WPL takes care of these **documents being finalized** and creates a list of applicable documents and their versions
- To support this, FAIR QUA has designed a template of a **checklist for these required documents**

Спаси́бо за внима́ние!





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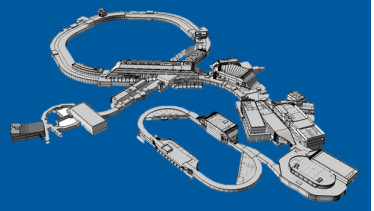
Training Module:
Lessons Learned & Discussion



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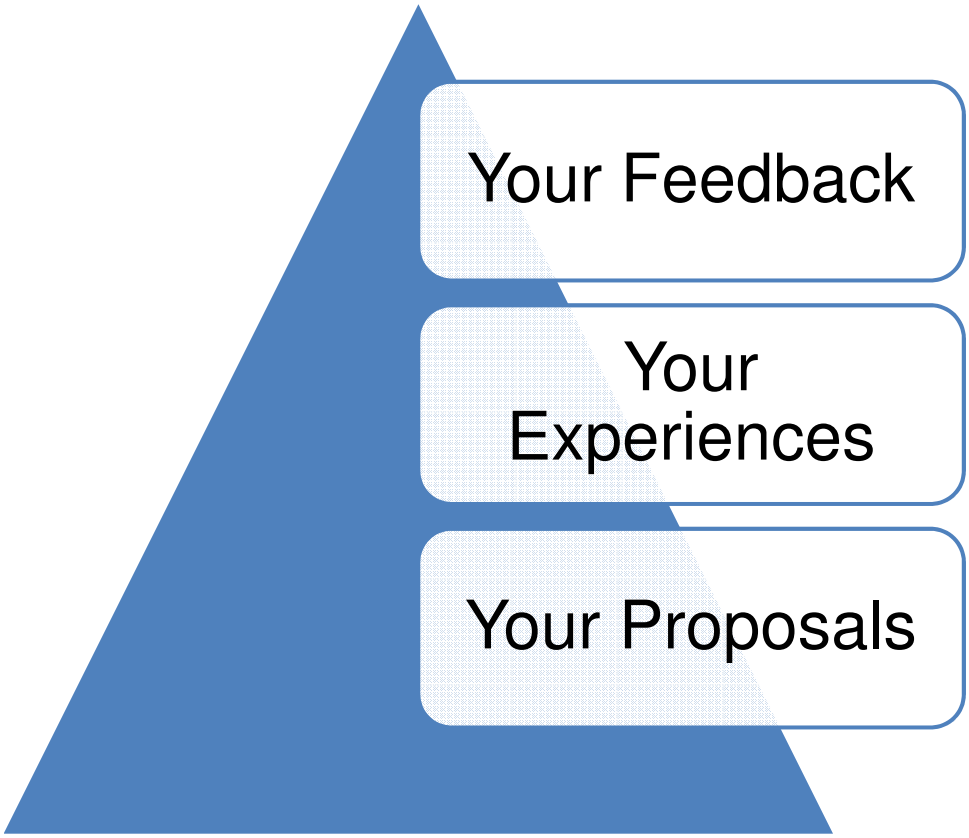
FAIR

Lessons Learned

- Quality assurance it not an additional hurdle
  → *Most quality related activities are straightforward project activities*
- The specifications and contract terms are the base of nearly most quality assurance related measures
  → *Clear and stringent formulations are needed*
  → *Any shortcuts will lead to (massive) additional efforts at a later stage*
- Difficulties and deviations from the specification are usual
  → *Dealing with Non-Conformities is an inherent topic of quality assurance*
- Verbal agreements work until something goes wrong
  → *Compliance with the specified processes, procedures and templates is essential for a successful project completion*
- Solution based flexibility is necessary
  → *But large-scale project involving many stakeholders requires compliance with processes, therefore quality assurance sometimes needs to be some kind of formal*

Discussion



Спасибо за внимание!

Responsible for quality

Every employee