Title:	**Design Reviews (CDR and FDR)**
Purpose:	Systematic, verifiable closing of the various design phases and of the preparation of production
Organizational unit:	Quality Assurance (QUA)
Valid for:	FAIR Accelerator Project
Key performance indicators:	

Document history:

Version	Created, date	Reason for modification
V 1.0	W. Bonin, 10.6.2015	Original
V 1.1	W. Bonin, 2.10.2015	Changed one word
V 2.0	W. Bonin, 7.11.2016	Updated due to restructuring, refined details
V 2.1	A. Froehlich, 16.1.2017	Focus on FAIR Accelerator
V003	D. Freire, 30.10.2019	Adoption to new document designations. Update Risk Assessment in CDR and FDR
V004	D. Freire, 11.11.2019	Included the DARL in CDR and FDR
V005	D. Freire, 11.03.2020	The responsible for approving an Acceptance Record is the SPL
V006	D. Freire, 08.06.2021	General improvements to wording, update of templates and references.

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1 Purpose

The individual development phases of a system, component, or assembly (generally called “product” below) shall be verifiably closed by different design reviews (cf. *ISO 9001*, par. 8.3.4). The CDR (M6) closes the concept phase, the FDR (M7) the development phase and preparation for production. Thereafter, manufacturing of the product may be started.

CDR and FDR are required by the GS and must be executed for every product. If the WPL thinks of additional reviews being necessary for individual cases, he is free to do so but shall specify their positions in the project plan as well as their purposes and scopes.

2 Definitions and Abbreviations

Abbreviation	Explanation
AN	Contractor
CDR	Conceptual Design Review (M6): The objective of the CDR is releasing the concepts, models, and draft drawings of the product, so they can be detailed
DARL	Data Exchange Guideline
DMS	Document Management System
FAT	Factory Acceptance Test (M9)
FDR	Final Design Review (M7): The objective of the FDR is releasing all documents (i.e. instructions, drawings, etc.) required for production of the product
GS	General Specification
KRL	Design Guideline
M3 – M12	Milestone according to GS
PSP Code	Project Structure Plan Code
QUA	Quality Assurance
SPL	Sub-Project Leader
WPL	Work Package Leader

3 Responsibilities

The WPL is responsible for the review, i.e. for its preparation, execution, and finalization. Besides him, at least one member of QUA must participate in a CDR and FDR.

Additionally, the SPL and representatives of further departments involved should participate (e.g. respective members of design department, mechanical integration, media supplies, electronics, control, vacuum, cryogenics, transport, the safety expert, the electrically qualified person responsible).

If needed for the explanation of the documents supplied, the contractor may be invited to the review meeting – though he must not be an assessor.

Anyway, the WPL is responsible for a verifiable participation of all relevant functions; they shall take part in the meeting or deliver their opinion in writing well in advance (such texts shall be distributed to all participants).

The SPL is responsible for the approval and release of the Acceptance Record. However, the SPL may delegate this task to the WPL.

4 Description of the Procedure

A review is a systematic check of all relevant development results for the product against previously specified criteria; its objective is a release for the next process steps.

Preparation: Basically, the development results required for the check shall be received by the WPL two workweeks ahead of the review meeting. The WPL shall make them accessible for all review participants (see par. 3) immediately (following the valid document management system). The review meeting shall be scheduled allowing the participants sufficient time for checking the documents before.

The applicable test criteria result from

- the valid specifications for the product (Detail, Common, and General Specifications; in the GS, especially par. 4 applies to those development phases),
- contractual requirements,
- including the applicable documents mentioned in the contract and specifications – e.g. legal requirements (see Annex I of the GS), guidelines, and Technical Guidelines; a list of applicable standards for the product is one result of the design phase,
- Read more about test criteria in par. 4.1.

Expediently, the WPL compiles the test criteria in a list. In addition, the departments involved may have their own specific lists of criteria. It is recommended to include these lists into the *Meeting Minutes* (see *F-FO-QUA-en-0012*); this facilitates the verification of the processed topics. The *Acceptance Record* (template *F-FO-QUA-bl-0002*) can be filled out in advance, except for the overall result; expediently, it contains a reference to the corresponding minutes for details. In addition to the SPL and the QUA, the participants required to release the milestone have to be also specified.

All participants check the available development results against "their" test criteria in the time before the review meeting and provide a summary with a final evaluation. Requirements from the specifications that cannot be tested in the FAT must be identified as such in the FAT test plan and adopted in the SAT A test plan. Anyone who cannot attend the meeting must submit their comments in advance by email to the WPL.

Execution: During the review meeting, all test criteria will be questioned. The individual results of the checks shall be recorded in the *Meeting Minutes* (see *Preparation*). Wherever particular test criteria are not or not completely fulfilled, corrective measures must be decided, scheduled, and recorded.

Finalization: After mutually reviewing all relevant aspects of the product and checking all criteria, the SPL is responsible to approve the overall result. It can be:

- Accepted (if all test criteria are fulfilled),
- Conditionally accepted (if minor modifications are considered necessary by the participants in the review, which can be closed quickly), or

- Rejected (else).

The overall result is recorded on the acceptance report (see Preparation). The WPL uploads the acceptance protocol to the DMS and invites the participants to approve it. If everyone agrees to the approval, the WPL releases the document in the DMS.

Post-processing: The WPL ensures that the approved acceptance protocol, the detailed Meeting Minutes and all documents used for the review are saved and released; only then can the milestone be confirmed in the MS project plan.

Hint: When updating the MS project plan, insert within the field “Notes” the link to the acceptance record.

- If there was a rejection, the respective review must be rescheduled in due time.
- If there was a conditional acceptance, a due date must be set for closing the shortcomings; and the review shall be repeated for said topics (adapting the list of participants, if applicable).
- If, after successfully passing an FDR, the prototype or pre-series of this product will not be accepted at M8, then the respective production documents must be modified and will be subject of a new FDR . Likewise, after the documents are released and fixed, any necessary changes after the FDR have to be done using the Change Management Process (see *F-VA-CMD-en-0011*).

Any such case will result in new review records bearing new document numbers.

4.1 Test Criteria for Design Reviews

4.1.1 CDR

For the **CDR** the product documentation shall include:

- its concept description,
- a schematic sketch of the product (or of its individual technological parts, i.e. mechanics, electronics, vacuum, hydraulics, cryogenics, etc., if applicable),
- calculations and simulations for its dimensioning (cf. e.g. *KRL*, par. 10.2, the requirements of the Pressure Equipment Directive, requirements of particular technological systems, etc.),
- the risk assessment (see e.g. *KRL*, par. 7.1),
- a draft of its production plan,
- a draft of its test and inspection plan (“test plan” according to GS). This test plan must include the tests required by applicable laws, regulations, and standards. The template "*F-FO-QUA-bl-Template_Inspection_Plan_and_Results*" can be used as a planning tool.
- for mechanical components (or products with a mantle at least): its 3D model e.g. for checking collisions with and interfaces to neighbouring assemblies (see DARL Part 1 and 2),
- for components including electrical or electronic parts: functional documents, i.e. block wiring diagrams, schematic circuit diagrams, or signal simulations,
- for components containing soft- or firmware: documents referring to functionality and dialogues, i.e. flowcharts incl. the graphical user interface (GUI), if applicable.
- for required mandatory and supporting documents, the template “*F-FO-QUA-bl-0013 Required Documents*” serves as a planning tool

4.1.2 FDR

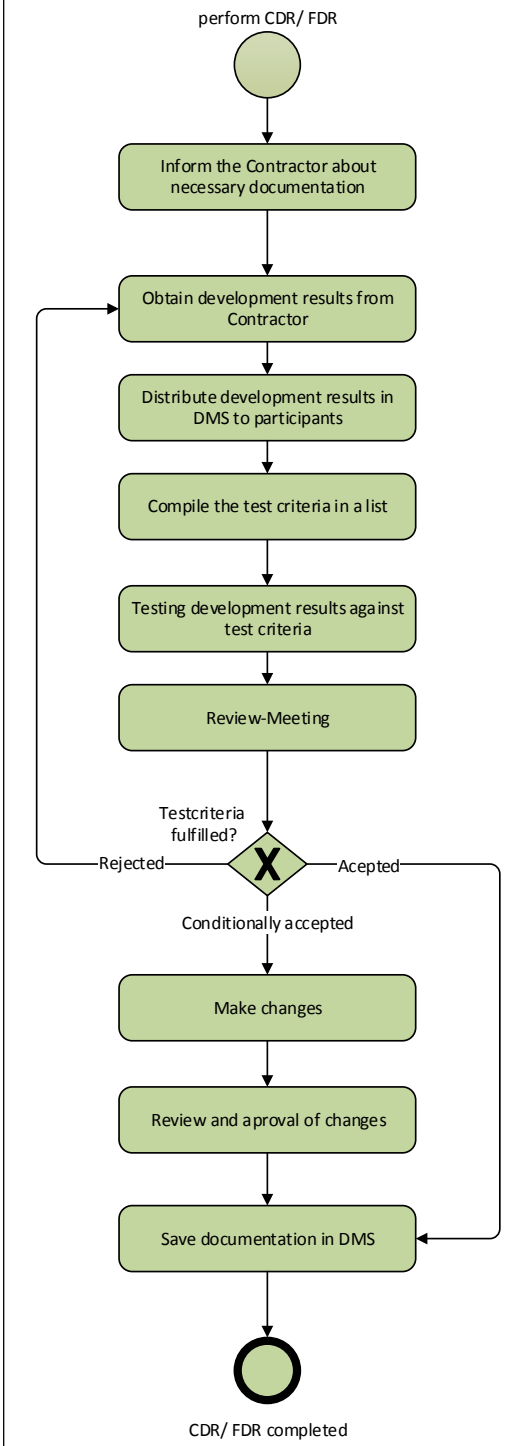
For the **FDR** the product documentation must include (in addition to the records of a successfully passed CDR):

- the complete, controlled (i.e. versioned, internally checked and released) production documents, including
  - the test and production plan (see above, especially also for the pre-series tests (M8) and FAT (M9) – see *F-VA-QUA-en-0025*),
  - the work and test instructions (including those for welding, brazing, and soldering, if applicable, as well as for inspections during manufacturing and FAT),
  - a list of the necessary manufacturing and test equipment,
  - the calculations for dimensioning the (necessary) means of locomotion (e.g. hoists, load suspensions),
  - for mechanical components or parts: the entire set of production drawings incl. parts lists (see *KRL*, par. 10.3, and DARL Part 1 and 2),
  - for electrical or electronic components or assemblies: the derived parts lists and manufacturing documents (e.g. also list of critical components, data sheets),
  - for components containing soft- or firmware: a functional description, user prompts as agreed on incl. flowcharts and parameters, mapping of hard- and software, etc.,
  - the updated risk assessment (if applicable) (see e.g. *KRL*, par. 7.1),
- Operating instructions / user manual in German; an English version can also be available. The original version must be marked as such.

All required mandatory and supporting documents have to be specified in the FDR. The template "*F-FO-QUA-bl-0013 Required Documents*" can be used as a planning tool. In the DMS are available the corresponding storage containers for these documents.

5 Process Flowchart

Input / Output, Anmerkungen	Ablaufschritte	R	A	C	I
Input: Contract; GS; CS; DS; TG; etc. **Output:** Concept description, simulations, 3D model, software, production plan, test instruction, risk assessment, etc.	Inform the Contractor about necessary documentation	WPL			AN
Input: Contractor shares documentation with the Company (DMS, email, etc.) **Output:** Documentation received	Obtain development results from Contractor	AN	WPL		
Input: Distribute documentation **Output:** Documentation available in DMS	Distribute development results in DMS to participants	WPL			Participants
Input: Contract, GS, CS, DS, TG, etc. **Output:** List of test criteria	Compile the test criteria in a list	WPL			
Input: Development results analyses **Output:** Get comments from participants	Testing development results against test criteria	WPL Participants		QUA	
Input: Test results of the participants **Output:** Decision	Review-Meeting	WPL	SPL	QUA	AN
Input: Are the test criteria fullfilled? **Output:** Result as released, conditionally accepted or rejected	Testcriteria fulfilled? X Rejected Acepted Conditionally accepted	SPL		QUA	WPL
Input: Make minor changes rapidly **Output:** Changes completed	Make changes	AN	WPL		
Input: Changes completed **Output:** Requirement and documentation met	Review and aproval of changes	WPL	SPL		
Input: The signed acceptance record, the detailed results protocol and all development results **Output:** Complete and correct documentation in DMS	Save documentation in DMS	WPL	SPL		QUA



6 Legal Requirements and Applicable Standards

The laws and regulations quoted in the GS must be observed, starting with the „Product Safety Act“. Two very useful overviews of the mandatory rules are published:

- DGUV Information 202-002: Manufacturing and operation of equipment designed for research purposes
- Helmholtz-Leitfaden Sicherheit bei Errichtung, Betrieb und Prüfung elektrischer Anlagen im Forschungsbetrieb (in German)

7 Applicable Internal Documents

- F-GS-F-01 General Specification for the FAIR Accelerator Facility Project
- F-TG-MDS-en-KRL Design Guideline
- F-FO-QUA-bl-0002 Template for an Acceptance Record
- F-FO-QUA-en-0012 Template for Meeting Minutes
- F-VA-CMD-en-0011 Change Management
- F-VA-QUA-en-0025 Performing FAT or SAT
- F-FO-QUA-bl Template Inspection Plan and Results
- F-FO-QUA-bl-0013 Required Documents
- F-TG-B-02e Data Exchange Guideline I (DARL T1)
- F-TG-B-03e Data Exchange Guideline II (DARL T2)
- „Betriebsordnung für die Beschleuniger und Experimentiereinrichtungen der GSI“ (GSI Intranet)
- Department-specific checklists for CDR and FDR