

QUALITY ASSURANCE TRAINING: 2nd Joint BINP FAIR Meeting

Answers to the questions during the QA Training

Nº	QUESTIONS	ANSWERS
1	During a CDR, FDR or MDR, what happens if the Contractor does not want to show its production system due to confidentiality, know how, secrets?	There is not a problem if the Contractor does not want to show their production system. In this case they have to provide us the production procedures to ensure they are fulfilling all quality tests
2	What happens when there are different versions of CDR's? When a CDR is accepted but then a correction is present, is a Change Request needed?	A "Change Request" is needed if modifications are made after the approval of a FDR
3	What is important for the QA to check in the "Engineering check" status?	During the Engineering Check is important that the documentation provided from the Contractor fulfill a check list of QA requirements
4	What points should be inside the risk assessment document during the CDR? Is it enough with a 3D model or which proof should be presented.	In a CDR the risk assessment shall identify hazards and risk factors that have the potential to cause harm. A list of guidelines and standards to be fulfilled must be defined during CDR. The risk assessment should be marked as a "released document" (it does not have to be the final version). In the FDR the assessment should be complete
5	Is the document "Required Documents" intended for internal or external use?	This document is intended for all persons involved in a project at GSI/FAIR (WPL, Contractor, QA, etc.)
6	What are the reasons for declining or failing a design review? Technical or documental aspects?	The review will be passed straightly if all criteria are fulfilled. It may also be "conditionally accepted" with minor shortcomings. Technical and documental aspects are taken into considetion
7	Does the QA have to understand the content of the documents presented in a design review or just the format?	The QA reviews the document (content and format) according a check list of QA requirements, criteria, work experience and professional background
8	It should be clarified who is going to perform tests (FAT, SAT). Is it described in the contract?	Yes it must be clarified in the contract. Normally a FAT is performed at the Contractor's site (before shipment) and SAT at GSI/FAIR facilities. It is also important to plan a test strategie for a FAT and SAT in describe it in a "Inspection Plan". We recommend that the Inspection Plan should be planned in the milestone prior to the FAT and SAT respectively
9	Should the Contractor provide the test equipment to GSI or just protocol it?	According to our General Specification the Contractor shall be responsible for providing all necessary measurement tools/equipment and devices and also prepare a test protocol
10	SAT B will require Test protocols. Who is responsible for writing the procedures, especially which test equipment the contractors are going to use?	The final SAT B protocol will be drawn up. FAIR is responsible for creating the test plans and protocols
11	In case GSI and the Contractor have a Nonconformity report (NCR), which one should be used?	The contractor shall use their own NC template. In case of not having one available, can use the template from GSI/FAIR (by their own responsibility)
12	What are the criteria for selecting a minor or major NC? Criteria for "small" mistakes?	<p>Minor:</p> <ul style="list-style-type: none"> - No condition is fulfilled requiring it's 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!) <p>Major:</p> <ul style="list-style-type: none"> - 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 Contractor is required"
13	When the Contractor finds a NC, should they inform GSI about it?	Yes, if the Contractor observes a nonconformity he must immediately inform the WPL from GSI/FAIR. All companies working according to ISO 9001 must have a system for the treatment of nonconformities.
14	Who is the responsible for the ECRs (Engineering Chance Request)?	The WPL is the responsible for an ECR
15	In which folder should the Quality Plan be saved?	They should be saved in the CDR folder (The WPL must decide)