

Process Step No.	Process Description	Resp.	Forms
01	<p>Receive submitted quotations of clients from Sales along with filled “Information for Offer Making” of the concerned client. It is ensured that these documents are complete in all respects and are signed/stamped (mail approval may also be considered) as evidence of approval from the client.</p> <p>For BMWfw Accreditation, all Quality Austria templates as designated in the WIS System are to be used, however this same document is also applicable for NABCB purposes.</p>	Planning Team	- Information on Making Offer Form - QACAPL-Quotation
02	<p>Review these documents for completeness. Re-verify the technical aspects like capability to deliver, resources, mandays, Scope, NACE, EAC, Logistical arrangements, any specific requirements, tentative audit planning dates or any other requirements.</p> <p><u>If after the calculation, the result is a decimal number, the number of days should be adjusted to the nearest half day (e.g.: 5.3 audit days becomes 5.5 audit days, 5.2 audit days becomes 5 audit days).</u></p>	Risk & Compliance Team/ Planning Team	PDV
03	<p>Review the “Competence Matrix” for the ability to deliver and select from in house resource or external resource. Consult line manager as applicable. It is ensured that the selected resource must have the necessary competence in the audit team. Where such options are not available, a technical expert is selected from the “Competence Matrix” so as to ensure that the audit team has atleast one person with the necessary NACE/EAC. During this process, the critical aspect of “Scope” is also validated in correlation to the NACE/EAC. For all audits only the specific NACE allocated auditor shall be scheduled for the audit, this applies for Stage 2, Surveillance and Recertification. It is preferred that the Stage 1 be done by the NACE holder however its not deemed mandatory, prior approval via the PDV is required.</p> <p>In deciding the size and composition of the audit team, consideration shall be given to the following: a) audit objectives, scope, criteria and estimated audit time; b) whether the audit is a combined, joint or integrated; c) the overall competence of the audit team needed to achieve the objectives of the audit; d) certification requirements (including any applicable statutory, regulatory or contractual requirements); e) language and culture.</p> <p>MDQMS specific The audit team shall have the competence for the Technical Area (Annex A in conjunction with relevant knowledge and skills as defined in Annex B of IAF MD9 (latest version) for the scope of audit. If the audit is performed for an organization that only parts and services (see Table A.1.7 of IAF MD9:2017), , the audit team does not have to demonstrate technical competence at the same level as that for a manufacturer producing medical devices. To include devices that are sterile or intended for end-user sterilization, the audit team shall be competent according to sterilization</p>	Risk & Compliance Team/ Planning Team	NACE Competency Matrix

	process detailed in Table 1.5 of Annex A.		
04	If the necessary competence is not available with the organization either the same is researched afresh or the client is then regretted for delivery of the assignment. The Scheduler shall then communicate to the responsible Sales personnel/function. Sales shall in turn maintain all such records where necessary.	Sales/ Planning Team	
05	Once the team is selected, communications and confirmations between the selected members is then initiated and finalized. QACA shall provide the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client to object to the appointment of any particular audit team member and for QACA to reconstitute the team in response to any valid objection. The CV of the audit team is sent across to the client for eliminating any possible conflicts.	Planning Team	Pre-delivery Verification (PDV)
06	The “Pre-delivery Verification” form is then filled up in full detail, approvals taken by the Executive Director or other designated personnel. The approval is recognized only after sign off from the designated authority.	Planning Team	Pre-delivery Verification Format (PDV)
07	This PDV is the formal approval for the audit team which shall elaborate the NACE/EAC, Mandays for stage 1, stage 2, Surveillances, relevant standard etc.	-	Pre-delivery Verification Format (PDV)
08	The client in question is then allocated dates which may be negotiated to suit both parties. Eventually, the dates are finalized and formal communications done.	Planning Team	Emails/Tele
09	In all such communications the audit team is informed or kept in loop to enable complete knowledge of the client, contact details and any other specific requirements. A descriptive mail communication shall be sent to auditors which will include vital information like complexities, justifications, exclusions, site specific conditions, deliverable mandays for particular schemes and accreditation, etc. The same shall be communicated to auditors atleast 7 days in advance from the audit date. It shall also be verified whether the audit team leader, in consultation with the audit team, has assigned to each team member, responsibility for auditing specific processes, functions, sites, areas or activities or not. This will be verified with a call verification to the audit team members and audit plan as finalised by the Lead Auditor.	Planning Team/Risk & Compliance Team	Emails/Tele
10	The entire scheduling/planning is done in a Excel File called “Planning Sheet” which is in constant updation, communications to all concerned.	Planning Team	Planning Sheet/Scheduler
11	When any changes occur the communications are sent across to concerned. There are color codes used to designate confirmed/tentative audits and this is reflected in the scheduler. Yellow – Tentative confirmed Green – confirmed Blue – Leave/not available Pink – Training White – Leave	Planning Team	Planning Sheet/Scheduler
12	The entire planning sheet is also in line with those audits done	Planning Team	Planning

13	under Austria and they follow the “WIS” system software. There is a backup entire QACA Data is taken on a monthly basis on an external hard drive. This back up data is kept for a period of two months, after which the last months’ data is over written. Records for this is maintained.	IT Incharge	Sheet/Scheduler Back Up data and Record
14	In case of BMWfw Accreditation, the details of the confirmed client is then sent across to Austria for generation of the “Commission Order Number” also known as CO Number. For NABCB Accreditation, the same process is followed except that this number is generated manually at Noida Office. This is a unique identification number for that specific application. The order number will be abbreviated as IND/Region/Sr. No. If an ISO 9001:2015 application of North region is received; then its order number will be IND/N/060.	Planning Team Risk & Compliance Team	
15	Once Audits are planned, communicated, coordinated they are then looked into if any logistical arrangements are required.	Planning Team	
16	Logistic Arrangement 1. For Local Audits Booking of Cab – Information being sent to auditor and client. 2. For Out Station Audits Air/ Train Tickets being arranged (May vary as per the contract where travel is being provided by client.) 3. Cost incurred in Travel shall be charged as actual from the client(Subject to the contract with client) For more than one day audits in Outstations Stay Arrangement either being provided by Clients or Hotel Arrangements being done and charged (Subject to Contract with Client)	Planning Team	
17	All auditors are coordinating in a centralized mechanism for all travelling/ticketing etc with Planning Team/Admin Team on a regular basis. They coordinate with the agent who does the booking and gets these completed.	Planning Team	
18	On monthly basis all the travelling statements which are invoice able to the clients are received from these agents for approval. These are then cross checked in detail and approved after which only the payments are further processed.	Planning Team	
19	Audits which are scheduled are then executed as per the relevant procedure by the concerned auditor.		
	End of Procedure		
	List of Records	Format No.	Retention Period
	Information on Making Offer Form	FO_26_01_01e	3 Years+3
	QACAPL Quotation	QACAPL/ASIA INDIA/PROPOSAL/FORM/001	3 Years+3
	NACE Competency Matrix	QACAPL/ASIA INDIA/Comp_Matrix	3 Years+3
	Pre Delivery Verification Format	QACAPL/ASIA INDIA/PDV	3 Years+3
	Planning Sheet/Scheduler	QACAPL/ASIA INDIA/Scheduler	3 Years+3

Amendment History

S.No.	Date	Nature and details	Changes	Approvals
01	1/09/2016	Reviewed as per requirements of ISO17021-1:2015	No changes	Alok Kumar
02	26/02/2020	Changes done as per EHS DRR finding of NABCB.	Requirement of clause 9.2.3.5 of ISO 17021-1 added. Para 5 amended.	Director
03	13/10/2020	Country Head replaced with Director	Para 6 amended	Director
04	04.02.2021	Changes done as per NABCB WA EHS Findings	Para 09 amended	Director
05	10/06/2021	Requirements of Clause MD 9.2.2.1 of IAF MD9:2017 added.	Para 03 amended	Director
06	10.02.2023	Changes due to annual review of documentation	Change in responsibilities	Director
07	15.05.2023	Changes done as per the NABCB EHS OA findings.	Para 14 amended. System to allocate order number to client added.	Director
08	16.01.2024	Changes done as per the NABCB OA findings.	Para 2 amended	Executive Director