Process Step No.	Process Description	Resp.	Forms
01	This procedure applies to all certification related activities performed by QACA for NABCB Accreditation. The decision is performed for granting or refusing certification, expanding or reducing the scope of certification, suspension or restoring certification, withdrawal or renewing of certification. **MDQMS Specific** **When QACA has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, there is no need to repeat the audit for conformity with the elements of ISO 13485 previously covered, provided it is demonstrated that all of the requirements of this document have been complied with.** **Note: Typical regulatory schemes that include or go beyond the requirements of ISO 13485 are European Medical Device Directives and Regulations:** **i) Medical Device Regulation (MDR)** **ii) In-Vitro Diagnostic Devices Directive (IVD)** **iii) Active Implantable Medical Devices Directive (AIMD)** **Other jurisdictions include: i) Canada – Health Canada, Canadian Medical Devices Conformity Assessment System (CMDCAS) ii) Australia – Therapeutic Goods Administration, Therapeutic Goods Regulations** **Additionally, other countries are adopting or considering adopting ISO 13485 into their Medical Device Regulations** **Where higher risk medical devices (e.g. GHTF C and D) are concerned, the stage 1 should be performed on-site.**	**Executive Director**	
	Initial/Recertification audits		
02	After the completion of the stage 2/recertification audit, the audit team send in all the audit documents for review and these documents include: 1. Stage 1 – stage 1 audit plan, stage 1 report and any relevant data. 2. Stage 2 – stage 2 audit plan, stage 2 report, non-conformities (if any), NC Action Plan, evidences to support the same (in case of major NCs or if requested by auditor) and the auditor's recommendation. 3. Follow up Audit (as applicable) – audit plan, audit report, non-conformities (if any) and related corrective actions, evidences to support the same and the auditor's recommendation. 4. Recertification - audit plan, recertification report, non-conformities(if any), check sheets and related corrective actions, evidences to support the same and the auditor's recommendation	**Planning Team**	All reporting, operational documents
03	**Report Review (Level 1 Review)** The report pack is then forwarded to the approved reviewer based on the NACE competence matrix so that the reviewer performs a review for all these documents to ensure that all requirements	**Risk & Compliance Team & Planning Team**	NACE Competence Matrix; Certification

	have been fulfilled before a certification decision is then granted. To review an audit pack the following must be available: 1. Audit reports – stage 1 & stage 2, PDV, Proposal, IOFO and Major or Minor NC (if any). For recertification, only recertification report may be applicable plus the proposal, PDV **and closure response / action plans / objective evidences for** Major or Minor NCs (if any). 2. Recommendation of the audit team in the report. **Certification Decision (Level 2 Review):** **After the report is reviewed and cleared, the certification decision is finally taken by the Executive Director.** This is demonstrated by cross checking the entire audit package independently, maintaining objectivity and impartiality to the whole process. QACA shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process. Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person. **The effective date of Certification shall not be before the date of Certification decision.**	**Executive Director**	Decision Form, **Report review check sheets**
04	Surveillance Audits: After the surveillance audits are performed, the complete audit pack (audit plan, report, NCs if any; Correction Action Plan) are reviewed by the approved reviewers and the final conclusion is captured in the certification decision form. If, a major non-conformity or any other situation is identified by audit team which may lead to suspension or withdrawal of certification, team leader would inform the QACA that an independent review (both Level1 & Level 2) is required and same would be recommended in audit report. Review would be carried out by competent reviewer and decision would be taken about suspending/withdrawing/maintaining the certification.	Team Leader, Report Reviewer(s)	All operational documents
05	**Recertification/Transfer Audits:** These are performed in line with the initial audit review audit pack. It is mandatory to follow the current version of the applicable guideline of the IAF during these transfers or recertification audits. During the recertification, the audit team has the responsibility to check and report all the recent past cycle data of certification of the specific client and any complaints received from users of certification, report these in the observations. For transfer case, sufficient information is obtained for the client for taking decision on certification. This information must contain - Validity of Existing Certificate from another CB - Audit reports of Previous/Current Certification Cycle - Non-conformities identified during last audit and evidences of its closure - Trend of customer complaints		

	- Reason for Transfer		
06	Generally, a certification decision for grant/refusal is to be made is case of - Initial Certification - Re-certification - Scope Expansion/Reduction - Site Addition/Deletion - Transfer of certification **Certification may be refused** in case of non-availability of scope, scheme, major non-conformities from previous CB (in case of transfer clients), etc. In addition, a decision may be required to suspend or withdraw the certificate in certain scenarios, e.g., suspension due to non-conduct of due surveillance further resulting into either restoration or withdrawal of certification. The certification decision is made by different competent personnel from those who carried out the audit. These persons will be employed by QACA. In case, the need for an expert arises, an external resource may be used but his role in decision making would be limited to technical inputs only. A contract agreement would be signed with the expert and competence evaluation must be completed before he is used. The person(s) [excluding members of committees assigned by QACA to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either QACA or an entity under the organizational control of the certification body. The persons employed by, or under contract with, entities under organizational control shall fulfill the same requirements of this part of ISO/IEC 17021 as persons employed by, or under contract with QACA. The reviewer confirms prior to making a decision, that a) the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification; b) he has reviewed, accepted and verified the effectiveness of correction and corrective actions, for all major nonconformities that represent 1) failure to fulfill one or more requirements of QMS/ EMS/OHSMS (example – legal compliances) or 2) a situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs; c) he has reviewed and accepted the client's planned correction and corrective action for all minor nonconformities. d) confirmation that the audit objective has been achieved Exceptionally the Certification Body may still grant certification but shall seek objective evidence to confirm that the organization's OH&SMS: A) is capable of achieving the required compliance through full implementation of the above implementation plan within the due date,	**Executive Director**	Certificate Decision form

	B) has addressed all hazards and OH&S risks to workers and other exposed personnel and that there are no activities, processes or situations that can or will lead to a serious injury and/or ill-health, and C) during the transitional period has put in place the necessary actions to ensure that the OH&S risk is reduced and controlled. Records of certification decision are maintained.		
07	In an event implementation of corrections and corrective actions have not been able to get verified for any major nonconformity within 6 months after the last day of stage 2, stage 2 will be conducted again prior to recommending certification.		
08	QACA has maintained a Executive Directory of all certified clients to include all preliminary details of the clients	**Planning Team**	Executive Directory of certified clients
09	A draft certificate is then prepared and sent to the client for approval **in soft copy**. Once the approval is granted the final certificate is printed and sent to the client **in hard copy**. **This hard copy is then couriered to the client.** **QACA shall precisely document the scope of certification. It shall not exclude part of processes, products or services (unless allowed by regulatory authorities) from the scope of certification when those processes, products or services have an influence on the safety and quality of products.**	**Planning Team**	Draft Certificate and Final Approved Certificate
10	Each certificate has the following: a) the name and geographic location of each client whose management system is certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification); b) the dates of granting, extending or reducing scope and renewing certification; c) **Initial Issue Date, Current Issue Date,** the expiry date or re-certification due date consistent with the re-certification cycle; d) **a unique identification code. This shall be abbreviated as "IND/Scheme/Year/Region-Sr. No." Where IND stands for INDIA, Scheme may be either QMS, EMS, OHSMS, MDQMS, EOMS. Year will be on going calendar year and Region will be either North (N), South (South), East (E) or West (W).** **If an ISO 9001:2015 certificate if to be issued for North region in the Year 2023 and this is the 60th client of QMS, then its unique identification no will be IND/QMS/2023/N/060.** **If an ISO 14001 and ISO 45001 certificate is to be issued for North region in the year 2023 and this is the 15th client of EHS, then its unique identification no for EMS certificate will be IND/EMS/2023/N/015 and for OHSMS certificate will be**	**Planning Team**	Final Certificate

	IND/OHSMS/2023/N/015. e) the standard and/or other normative document, including issue number and/or revision, used for audit of the certified client; f) the scope of certification with respect to type of activities, product (including service), process, etc., as applicable at each site without being misleading or ambiguous g) the name, address and certification mark of the certification body; other marks (e.g. accreditation symbol, client logo) may be used provided they are not misleading or ambiguous; h) any other information required by the standard and/or other normative document used for certification; i) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents. **While mentioning the "Issue No." in case of transfer from another accreditation, the number of certificates issued under previous accreditation shall be checked and kept in client folder and next "Issue No." shall be allocated while issuing the NABCB Certificate.** J) **Certification documentation shall include the signature or other defined authorization of person (s) of the CB assigned such responsibility, which will be the Executive Director.** **K) *An annexure is issued only in cases of multi-site certification.* Where annexure for multiple sites are issued, it shall include in the main certificate:** **1. Name and address of the main site /central function (that it is the management system of the whole organization which is certified)** **2. Certificate Registration Number (traceability with the main certificate, e.g. a code)** **3. Date /dates of Site Addition** **4. Scope / scopes of Site Added (the activities performed for that specific site / legal entity which are covered by this certification)** **5. A statement saying "This Annexure is only valid in connection with above-mentioned certificate".** **6. Certificate to each site may be granted based on client's written request through mail during draft approval stage. In all other cases, certification documents will comprise of main certificate and an annexure listing all site details. *Wherever a certificate to each site is requested by the client, specific certificate format stating a unique registration number linked with the main certificate and a statement quoting 'The validity of the qualityaustriacentralasia certificate will be maintained by surveillance audit every year and depends on the validity of the main certificate.' shall be issued.*** **Under no circumstances, can this annexure be issued to the**		

	name of the site/legal entity or suggest that this site/legal entity is certified (the one certified is the client organization), nor shall it include a declaration of conformity of the site processes/activities to the normative document. ***On the application of a new site to join an already certified multi-site organization, the site shall be audited before being included in the certificate, in addition to the planned surveillance in the audit programme. After inclusion of the new site in the certificate, it shall be cumulated with the previous ones for determining the audit time for future surveillance or recertification audits.*** Note 1: In no circumstances the issue date of the certificate is to exceed 30 days from the stage 2/recertification audit NC closure. The issue date of the certificate will be only after the certification decision has been made. Note 2: The original certification date may be kept on the certificate when a certificate lapses for a period of time but: — the current certification cycle start and expiry date would be clearly indicated; — the last certification cycle expiry date would be indicated along with the date of recertification audit.		
11	If the client requires, QACA would put their company logo on the certificate along with QACA Logo, NABCB and IAF Logo.	**Planning Team**	
12	Periodically, QACA will be sharing the Executive Directory of the certified clients to NABCB for evaluation purposes	**Executive Director**	Executive Directory of certified clients
13	QACA website has a link in public domain, that if any person wishes to check the certificate validity for a client, then can do so by visiting the web site and requesting for this information.	**Executive Director**	Executive Directory of certified clients
14	This website also has detail information about the activities of QACA and the road map for achieving certification**. Information includes Certification Scheme & evaluation process, for certification granting, maintaining, extending, suspension, withdrawal etc. A description of rights and duties of the applicants & clients, including requirements of use of CB's name, certification mark & certificate**. Also there are marketing collaterals and power point presentations which are sent to prospective clients for their information as to the procedure/process of achieving certification. **Where it is required by law or by relevant Regulatory Authority, QACA shall provide the information about certifications granted, suspended or withdrawn to the Regulatory Authority.**	**Executive Director**	QACA Website
15	SUSPENSION involves to restrict the client to actively advertise or promote its certification of its Management System by Quality Austria Central Asia Pvt. Ltd. - Suspension – can occur in situations of surpassing surveillance audit defined cycle, serious complaints/conflicts, non-closure of the NC in the defined	Lead Auditor or **Executive Director**	Letter, Actions, Plans, Minutes

	time scales, client voluntarily requests, commercial aspects eg non-payment of audit fees as per contract etc. - The client is normally sent reminders prior to reaching the above situation, these are in the form of emails, letters clearly mentioning the violation and the deadline for the same. - If there is no response, then the client is reached over phones so that the contact is established. All the above activities is done prior to the deadline of expiration of the dates ie minimum 90 days prior to the deadline. - Incase the reasons given for the delay are genuine eg renovation in the site/construction activities/no orders leading to no production then these needs to be supported by suitable evidences and records kept. - An analysis of the situation is done by the concerned and a decision to suspend or not to suspend is taken in 45 days maximum from the due date of the assessment/concern. - During the suspension period the certificate shall remain temporary invalid - During suspension, the client organization shall not advertise its continued certification in any form, recall the claims in any form of media and any such activity which misleads the situation - After the condition of suspension is removed, the designated shall verify the implemented effective corrective actions on site or off site within the next 10 days. Where required, a special audit may also be planned. - Reinstate the certificate after the above is successful. The overall time from suspension to reinstatement shall not exceed 180 days from the date of the original condition/concern/communication. In extraordinary cases, where adequate justification is available, suspension period can be increased to 1 month. In any case, there can't be more than 3 such extensions. - Examples - A major non-compliance is raised during a Special Surveillance, which indicates that insufficient action was taken by the client to clear raised non-conformities; Improper use of the Quality Austria Central Asia Pvt. Ltd. logo has been discovered and has not been resolved effectively by the Client after notification by Quality Austria Central Asia Pvt. Ltd. - Information on incidents such as a serious accident, or a serious breach of regulation necessitating the involvement of the competent regulatory authority, provided by the certified client or directly gathered by the audit team during the special audit, shall provide grounds for QACA to decide on the actions to be taken, including a suspension or withdrawal of the certification, in cases where it can be demonstrated that the system seriously failed to meet the OH&S certification requirements. The same has been addressed in proposal cum agreement for client understanding.		

	The suspended certificate will be restored by **MD or the Executive Director** if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established will result in withdrawal or reduction of the scope. MD and Executive Director are authorized for suspension and withdrawal of certificates. If the facilities and work areas are subject to closure, the OH&S risks change, as there may no longer be the same risks to employees, but there may be new risks applicable to members of the public (e.g. in case of lack of suitable maintenance and surveillance activities). The Certification Body shall verify that the management system continues to meet the OH&SMS standard and to be effectively implemented in respect of the closed facilities and work areas, and, if not, suspend the certificate.		
16	WITHDRAWAL involves the withdrawal from the client of Quality Austria Central Asia Pvt. Ltd. certification and the return of the Certificate. WITHDRAWAL usually follows, SUSPENSION, when there is no evidence of effective corrective actions taken or the deadline of maximum 180 days is not met or the client voluntarily agrees for the submission of the certificate. Withdrawal – this activity is triggered is the client crosses the suspension period or the client voluntarily surrenders the certificate or the company itself has closed down or there violations of the agreement of contract. This process is initiated within the next 10 days of the suspension. After the condition of the withdrawal of the certificate is reached, the client would need to implement the following: • Stop of media/stationery form claiming the certification • Return to QACA the original version of the certificate(s) • Remove all Logos of QACA and the Accreditation Body from all forms of communication eg letter heads, web, visiting cards etc • In case the same is not practiced within 5 working days of the withdrawal decision, QACA shall reserve the right to take a legal course of action and all expenses for the same including any liability related to this shall be on the client.		Letter, Actions, Plans, Minutes
17	Scope expansion – In case Scope of the existing certificate is to be expanded (eg. Inclusion of process (es) in the system which was earlier excluded, inclusion of new product), then following actions are initiated: • The Scope expansion audit will be conducted either as separate or combined with Surveillance / recertification. • The audit team/auditor shall send the entire set of documents and recommendations for the review and issue of fresh certificate • Incase it is deemed that based on fresh information obtained from the client, a fresh calculations for mandays are done and the process of PDV approval process is followed sequentially.	Certificate Decision taker	
18	Scope reduction – In case the scope of the existing certificate is to be reduced (e.g. parts not meeting requirements; persisting complaints; business on hold from customer), etc. then following actions are initiated: • The certification scope is reduced to that which meets the		

	current set of requirements • The audit team/auditor shall send the entire set of documents and recommendations for the review and issue of fresh certificate • In case it is deemed that based on fresh information obtained from the client, fresh calculations for mandays are done and the process of PDV approval process is followed sequentially.		
19	Termination, reduction, suspension or withdrawal of certification (ISO 17065 specific) When a nonconformity with certification requirements is substantiated, (in surveillance or otherwise), QACA shall consider and decide upon the appropriate action. NOTE Appropriate action can include: a)continuation of certification under conditions of increased surveillance; b)reduction in the scope of certification to remove NC product type; c)suspension of the certification pending remedial action by client; d)withdrawal of the certification. When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively of ISO 17065, shall be fulfilled. If certification is terminated (by request of the client), suspended or withdrawn, QACA shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, QACA to take actions as above , in order to ensure the reduced scope of certification is clearly communicated to the client & clearly specified in certification documentation & public information. If certification is suspended, QACA shall assign one or more persons to formulate and communicate the following to the client: –actions needed to end suspension & restore certification for the product(s) in accordance with certification scheme; –any other actions required by the certification scheme. These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications. Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3 of ISO 17065.		
20	**Action shall be taken to deal with incorrect references to certification status, misleading use of Certification documents, marks and audit reports. The client will be required to submit a CAP along with correction and corrective action plan along with photographic, documentary evidences. The same shall be verified during next planned audit. Failure to demonstrate the implementation of CAP may result in suspension/withdrawal of certification.**		
	End of Procedure		

	List of Records	Format No.	Retention Period
1	NACE Competence Matrix	QACAPL/ASIA INDIA/NAM_Auditors	3 Years+3
2	Certification Decision Form	QACAPL/ASIA INDIA/CDF	3 Years+3
3	Executive Directory of certified clients	QACAPL/ASIA INDIA/Client_Dir	3 Years+3
4	Certificate Copy	QACAPL/ASIA INDIA/QMS_XXXX_XXX	3 Years+3
5	Stage 1 Audit Plan	FO 27_01_030e	3 Years+3
6	Stage 1 Audit Checklist	FO_27_01_040e	3 Years+3
7	Stage 2 Audit Plan	FO 27_01_030e	3 Years+3
8	Stage 2 Audit Report	FO 27_01_032e	3 Years+3
9	Non-Conformity Format	No.: FO_27_01_033e	3 Years+3
10	Certificate Decision Form	QACAPL/ASIA INDIA/CDF	3 Years+3

Amendment History

S.No.	Date	Nature and details	Changes	Approvals
1	05/03/2016	Period of Suspension is amended	Point 15 & 16 are amended for maximum period of suspension	Country Head
2	13/02/2017	Scope expansion process added	i) Para 17 added;	Country Head
3	15/04/2017	i) Certification information amended; & ii) Information required for Transfer of certification added iii) Certification decision process amended. iv) Suspension for major non-conformity in surveillance added.	i) Para 10 amended & Note-2 added; ii) Para 05 Amended iii) Para 06 amended. iv) Para 04 amended.	Country Head
4	12/06/2017	Need for review of report and certification decision added in case of a major non-conformity or any situation identified during surveillance audit leading to suspension or withdrawal.	Para 4 amended	Country Head
5	19/07/2017	Process for Extension of suspension in special cases added.	Para 15 amended	Country Head
6	21/11/2019	Personnel responsible for restoring the certification post suspension is added as per DRR findings.	Para 15 amended	Director
7	09/12/2019	Suspension and Withdrawal authority clearly defined.	Para 15 amended	Director

8	24/02/2020	Reason of suspension/withdrawal added as per clause G 9.6.5.3 of IAF MD22:2018. Clause C.2.4 of IAF MD 22 and clause 9.5.1.3 of ISO 17021-1 added.	Para 15 amended. Para 6 amended	Director
09	02/04/2020	Changes done to meet the requirements of clause 4.6(c) of ISO 17065.	Para 14 amended	Director
10	13/10/2020	(i) Country Head replaced with Executive Director and MD (ii) Refusal provision clearly defined	Throughout the document Point 6 amended	Director
11	15/10/2020	(i) Requirements of Clause 7.4.6,7.4.7,74.8,7.4.9 of ISO 17065 added. (ii) Requirements of Clause 7.61, 7.6.2, 7.6.3 of ISO 17065 added (iii) Requirements of Clause 7.7.2 of ISO 17065 added (iv) Requirements of Clause 7.11.1, 7.11.2, 7.11.3, 7.11.4, 7.11.5 added.	Para 3 amended Para 1 amended Para 10 amended Para 19 added	Director
12	22/10/2021	Requirements of clause MD 8.1.3 and MD 8.2.1 of IAF MD9:2017 added.	Para 14 amended Para 09 amended	Director
13	10/02/2023	Changes due to annual documentation review	Responsibilities changed	Director
14	15/05/2023	Changes done as per the NABCB EHS OA findings. Process to allocate unique identification no in certificate added. Introduction of a report review check sheet	Para 10 and 3 amended.	Director
15	10/08/2023	Director replaced with Executive Director as a result of change in responsibility	Throughout the document	Executive Director
16	15/11/2023	Changes as part of DRR for Reaccreditation of ISO 17021 accreditation	Para 1, 3 & 6 amended Certification decision reviewers' designations added	Executive Director
17	12/12/2023	Changes as per DRR Findings. Date of effective certification date added.	Para 03 amended. Para 20 added.	Executive Director
18	12/01/2024	Changes as per OA 17021 RA Findings	Certificate signing authority amended	Executive Director
19	28/01/2024	Changes as per OA 17021 RA Findings	Certificate signing authority mentioned in para 10 J), Para 9 amended for specifying means of certificate issuance	Executive Director
20	16/02/2024	Changes as per OA 17021 RA Findings	Details about main certificate and annexure issued to client are added in detail on page 5	Executive Director

21	23/02/2024	Changes as per OA 17021 RA Findings	Provision of a separate certificate issuance upon request to clients is elaborated in Point 10K)	Executive Director