

PCN DOCUMENT QS2 PROCEDURE FOR ASSESSMENT AND REGISTRATION

Issue 9 – dated 1st October 2019

ASSOCIATED DOCUMENTS:

- QS1 BS EN ISO 9001: 2015 - GUIDANCE FOR ORGANISATIONS SEEKING BINDT QUALITY MANAGEMENT SYSTEMS CERTIFICATION
- QS3 QUALITY MANAGEMENT SYSTEM ASSESSMENT INSTRUCTIONS AND CHECKLIST (confidential to assessors)
- QS4 APPLICATION FOR ASSESSMENT AND REGISTRATION
- PSL/35 CHARGES FOR CERTIFICATION SERVICES
- CP14 BINDT AUDIT PROCEDURE AND REPORT FORMS

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ANNEXES

- A Initial application form (QS2A)
- B Extension to scope application form (QS2B)

1. INTRODUCTION

- 1.1. This document provides information and guidance to organisations seeking PCN registration as complying with BS EN ISO 9001: 2015 as interpreted in PCN document QS1.
- 1.2. It is recommended that QS1, QS4 and this document are read carefully by applicant organisations in order to avoid unnecessary effort and delay in the assessment and registration process.
- 1.3. An organisation may apply to be registered as providing one or more of a number of services. These are detailed in document QS4 under Certification Available.
- 1.4. Should a certificated organisation wish to apply to extend its scope of certification, an application will be made on form QS2B (Annex B).

2. APPLICATION FOR ASSESSMENT AND REGISTRATION

- 2.1. The first step towards gaining BINDT registration is the submission of a completed application form QS2A (Annex A). This will enable BINDT to evaluate the nature of your company's business, the activities that support it and whether BINDT has the relevant expertise to undertake the assessment. A controlled copy of the organisation's documented quality system must be supplied to BINDT with the application. Following this, BINDT will send you a quotation and a contract. If you wish to go ahead with assessment, receipt by BINDT of the signed contract will initiate the assessment process.
- 2.2. BINDT will appoint a lead assessor to carry out a pre-assessment visit to your premises on a mutually agreeable date, during which your quality system documentation will be briefly reviewed in the context of your facilities and business. At this time, the BINDT lead assessor will form an initial opinion as to the extent that the proposed quality system and organisation meet the applicable requirements, and will advise on readiness for initial assessment.

3. PREPARATION FOR INITIAL ASSESSMENT

- 3.1. Providing the pre-assessment visit and a formal desk-top review of the application and supporting documentation proves satisfactory, BINDT will liaise with you to establish a mutually agreeable date for the initial assessment.
- 3.2. The applicant organisation will be sent an audit assessment programme, format of the assessment and areas of responsibility.
- 3.3. The Lead Assessor will inform the representative of the auditee that the assessment is to ensure compliance with specified requirements and the organisation's own quality management system against the scope of approval or certification sought by the organisation concerned.

4. THE ASSESSMENT

- 4.1. The auditee must afford any assistance which BINDT or its agent(s) may reasonably need to facilitate an assessment. This will include undertaking, at the request of BINDT or its agent, any reasonable checks, calibrations or inspections to demonstrate the effectiveness of the Organisation's facilities (such access shall by no means come into conflict with the rules for confidentiality of work for the Organisation's clients).
- 4.2. The auditee must afford any assistance which BINDT or its agent(s) may reasonably need to facilitate an assessment. This will include undertaking, at the request of BINDT or its agent, any reasonable checks, calibrations or inspections to demonstrate the effectiveness of the Organisation's facilities (such access shall by no means come into conflict with the rules for confidentiality of work for the Organisation's clients).
- 4.3. The purpose of the assessment is twofold, first to determine the suitability of the company's general administration in respect of systems, records, security arrangements, facilities and staff structure. Secondly to technically assess the capability of your organisation with regard to facilities, equipment and technical expertise within the scope of the application.

- 4.4. The assessment will begin with an introductory meeting between the assessment team and your company's representatives. At this meeting the lead assessor will introduce the assessment team and confirm the assessment programme, the format of assessment and areas of responsibility. Arrangements will be made for a member of your staff to accompany BINDT assessment team members during the assessment to confirm the correctness of any observations recorded.
- 4.5. The opening meeting also provides an opportunity for the assessing team to answer questions on any aspect of the assessment (Please note that BINDT assessors are not permitted to offer any advisory or consultancy services).
- 4.6. The assessment team will audit the organisation against the requirements of ISO 9001: 2015, as interpreted and supplemented by BINDT document QS1, and the organisations own quality management system against the scope of approval or certification sought by the organisation concerned. The scope includes that defined for initial assessments. Each assessor will review the activities of the department to which he is assigned, and his appraisal will consist of on-the-spot observations of the organisation, documentation and activities defined by the organisation's quality system and procedures. Any other department within the organisation, which interfaces directly or indirectly with the scope of certification sought, may be audited for compliance with BS EN ISO 9001: 2015 if its function affects the compliance within the scope of certification sought.

5. RECORDING OBSERVATIONS

- 5.1. The audit team members will record any areas of potential non-compliance (finding) or any areas for potential improvement (Observation) at the time of discovery. The auditee guide/representative shall be made aware verbally of any such instances at the time of discovery and asked to verbally acknowledge such. There will be no attempt to designate the category of any identified potential issue at this time. The audit team member shall report such instances to the Lead Assessor and they shall be discussed and final decisions made at the audit team private meeting(s).
- 5.2. The Lead assessor shall ensure that all recordable findings and observations are entered on to a CP14D Findings matrix, quoting the reference from the relevant criteria. These are for presentation at the closing meeting and will provide the objective evidence upon which the lead assessor will base any subsequent recommendations to BINDT.
- 5.3. The lead assessor inform the auditee's senior representative that all staff involved in the assessment should attend the final closing meeting, at which time the findings of the team will be presented.

6. CATEGORISATION OF FINDINGS

- 6.1. Identified issues may be categorised as a non-compliance or observation after consultation with the audit team.
- 6.2. An observation would indicate that, although there is no evidence that a non-compliance has been observed, the company should review the area indicated in order to improve quality.

7. THE SUMMARY REPORT

- 7.1. After the assessors have completed their individual assignments they will hold a private meeting to coordinate the team results. The lead assessor will collate all identified issues, ensuring that the correct document reference has been allocated, and categorise each finding as a non-compliance or observation.
- 7.2. The Lead Assessor will then complete the CP14D Findings summary matrix, taking into account the assessment team's agreed findings and categorisations. The SR will not re-iterate the statements on the detail reports but will present an overall impression of the organisation.
- 7.3. Based upon the findings/observations raised and audit team general opinions the Lead assessor shall compile a summary audit report (BINDT CP14C form) for presentation at the closing meeting.

8. CLOSING MEETING

- 8.1. In order to conclude an assessment, a closing meeting will be held at which the Audit team will deliver the findings and report to the auditee representative(s), including any recommendation regarding the scope of approval sought. The meeting will be chaired/controlled by the Lead assessor.
- 8.2. It shall be emphasised that the assessment is a sampling process and will not necessarily cover every aspect of the company's quality system and, therefore, where no non-compliances were reported it does not follow that none exist.
- 8.3. All findings/observations will be detailed such on a CP14D Findings matrix, quoting the reference from the relevant criteria.
- 8.4. The information recorded on the DR will include the following:-
 - 8.4.1.1. Details of the Finding or observation - using clear and concise terminology
 - 8.4.1.2. Reference to the applicable section or clause within the controlling standard(s)
 - 8.4.1.3. Details of any reference material involved (Objective evidence)
- 8.5. The lead assessor will deliver the findings (non-compliance with requirements) and observations (minor anomalies or potential improvement opportunities) in such a way that they are clearly understood by the auditee representative(s) (Assistance from the audit team may be employed where necessary). The audit team shall not offer any advice that may be construed as consultancy (which, in third party assessments, is prohibited under the terms of UKAS accreditation). A finding/observation may be withdrawn if a satisfactory explanation is offered during the closing meeting or a finding may be downgraded to an observation on the same basis.
- 8.6. The auditee's representative will be asked to agree any finding/observation at the assessment closing meeting. This agreement (or otherwise) is recorded in the assessment report documentation (CP14C). Where a finding cannot be agreed or acknowledged by the auditee it shall remain on the CP14D matrix and the auditee shall be advised of the BINDT appeals process through which a final decision can be reached.
- 8.7. The Lead assessor and senior auditee representative shall agree timescales for the submission of cause analysis and any proposed corrective actions. The auditee will be asked to enter the required details on to the CP14D matrix and return the updated matrix to the lead assessor within the agreed timescales. The use and compilation of the CP14D matrix will be explained during the closing meeting. Any agreed timescales may be amended during the corrective action process through auditee application to, and with the agreement of, the lead assessor;
- 8.8. The summary report shall conclude with the lead assessor's recommendation on the scope of approval(s) sought. The lead auditor recommendation will normally be in the form of one of the four guidance clauses given below or a variation thereof. These conclusions are given for Lead Auditor guidance only. The Lead auditor may record other approval recommendations at his/her discretion.

Guidance audit approval recommendations are given below:

- A) *Unconditional approval.*
- B) *Conditionally approved provided corrective actions to clear non-compliances are satisfactorily implemented within an agreed period. Evidence of implementation may be submitted to the Lead Auditor by **email or post***
- C) *Conditionally approved provided corrective actions to clear non-compliances are satisfactorily implemented within an agreed period. Implementation will be confirmed during a follow-up audit at a date to be decided by BINDT.*
- D) *Approval withheld, suspended or withdrawn. The audited organisation will not be approved without a further full audit.*

- 8.9. It should be noted that the Lead assessor only makes recommendations. The final decision on Approval remains with BINDT Certification panels who may or may not agree with the Lead Assessor's recommendation.
- 8.10. The lead assessor is responsible for reviewing and accepting evidence of satisfactory implementation of corrective action, for raising and maintaining a record of clearance of corrective actions, and for forwarding completed audit documentation to BINDT for review and retention.

9. SUBMISSION TO BINDT

- 9.1. The Lead Assessor will then submit the result of the assessment to BINDT and offer the following support documentation depending on the applicable recommendation identified above.
- 9.2. The initial Submitted documentation shall include the following as a minimum requirement:
- a) Completed CP14C Report form
 - b) CP14D Findings Summary matrix – at stage of completion following closing meeting
 - c) Completed QS3 assessment checklist
 - d) Any further objective evidence deemed pertinent by the Lead assessor
 - e) Copy audit plan
- 9.3. The assessment pack detailed above shall be retained in the BINDT CSD Department until such time that all observations and findings are duly closed by the Lead assessor and the final completed findings matrix accompanied by any supporting corrective action evidence are submitted to BINDT by the Lead assessor. At this time BINDT CSD Department shall marry the two sets of documentation together and submit to the Decision Making committee (CMC – certification Management Committee) or their authorised agent.

10. DECISION MAKING PROCESS AND REGISTRATION

- 10.1. Following closure of all findings/observations both sets of documents detailed in section 9 above shall be submitted to the Decision Making committee (CMC – certification Management Committee) or their authorised agent.
- 10.2. The Decision Making body/person will consider the Lead assessor's recommendation and ratify that recommendation or otherwise. Where the Lead assessor's recommendation is endorsed the Decision Maker shall authorise the issue of a certificate and defined scope of registration. Should the Lead Assessor's recommendation not be ratified a notice of rejection (or withdrawal of existing certification) shall be issued to the audited Organisation, giving reasons and advice on how to proceed to obtain or regain registration .
- 10.3. A certificate of registration is issued subject to payment in full of fees due. Your company will be invoiced for the assessment and certification fees following satisfactory assessment and clearance of any non-compliances, and prior to formal notification of the results of assessment.

11. MAINTENANCE OF REGISTRATION

- 11.1. Once an applicant Organisation receives approval, it is essential to maintain its operation to the agreed standard. To ensure this, BINDT will carry out surveillance visits at approximately twelve monthly intervals if it felt that the QMS is not to the required standard. A mutually agreeable date is always arranged; there will be no unannounced visits.
- 11.2. Every three years, the approved Organisation's entire system will be re-assessed to ensure that the quality system procedures and/or processes continue to be implemented adequately and in accordance with the requirements of ISO9001 (as interpreted by QS1). The extent of this assessment depends upon the Organisation's demonstrated ability to comply with the international standard as recorded during the annual surveillance visits. A successful review results in the issue of certification for a further three year period.

12. EXTENSION TO SCOPE OF REGISTRATION

- 12.1. An Organisation may at any time apply for an extension to its certificated scope of registration using form QS2B (Annex B).
- 12.2. Following receipt of a correctly completed form QS2B, PCN will issue an amended contract and a quotation for the assessment and, upon receipt of the signed contract, will contact you to establish a mutually convenient date for an extension to scope assessment.
- 12.3. Extension to scope assessments will be conducted the same way as an initial assessment and, if successful, an amended certificate and scope of registration will be issued for a further two year period.

13. RECORDS

- 13.1. All assessment documentation will be retained by PCN for a minimum period of seven years beyond the date that registration lapses.