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## **PCN DOCUMENT QS1 Issue 6**

# **GUIDANCE FOR ORGANISATIONS SEEKING BINDT QUALITY MANAGEMENT SYSTEMS CERTIFICATION FOR THE PROVISION OF NON-DESTRUCTIVE TESTING SERVICES (INTERPRETATIONS OF ISO 9001:2008 FOR NDT)**

### **ASSOCIATED DOCUMENTS**

- QS2 PROCEDURE FOR PCN ASSESSMENT AND CERTIFICATION**
- QS3 QUALITY MANAGEMENT SYSTEM ASSESSMENT INSTRUCTIONS AND CHECKLIST  
(CONFIDENTIAL TO PCN ASSESSORS)**
- QS4 APPLICATION FOR ASSESSMENT AND REGISTRATION**
- PSL/35 CHARGES FOR PCN CERTIFICATION SERVICES**



The British Institute of Non-Destructive Testing is an accredited certification body offering personnel and quality management systems assessment and certification against criteria set out in international and European standards through the PCN Certification Scheme.



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## 1. INTRODUCTION

Where appropriate, this document provides a specific interpretation of the requirements of BS EN ISO 9001: 2008 (hereafter referred to as "The Standard") for organisations offering Non-Destructive Evaluation (NDE) or Non-Destructive Testing (NDT) services. The present document is referred to hereafter as 'This Specification'.

This Specification is applicable to all NDT applications, including material and product testing at manufacture, in-service inspection of components plant and structures, training and qualification of personnel and manufacture of NDT equipment.

For the purposes of This Specification, the terms Non-Destructive Evaluation (NDE) Non-Destructive Inspection (NDI) and Non-Destructive Testing (NDT) are considered to have the same meaning.

The Standard extends the requirements of its earlier edition to now "enhance customer satisfaction". Its companion document, BS EN ISO 9004 provides "Guidelines for performance improvement" and contains many useful interpretations of BS EN ISO 9001 requirements. The single most obvious change in the new standard is the requirement to "identify the processes and determine their sequence and interaction as well as monitoring, measuring and analysing them." Most small to medium companies have based their previous quality system documents on their actual activities (processes). These processes are often described in procedures or flow charts drawn up to address

the older editions of the Standard and these have been revised after surveillance visits to accurately reflect continuing effectiveness. Some extra criteria have been included in the new Standard and these now need to be included where applicable.

Further, ISO9001:2008 introduces an extension of the overall scope of the standard, that can be specified at the discretion of the certification body (CB), to include 'assessment of the organisations ability to meet statutory requirements' (requirements specified by legislative Acts; **i.e. legal requirements**), not just customers and regulatory requirements. Many issues from legislative Acts are already incorporated into PCN audit procedures, such as Health and Safety, Fire egress, PAT testing of electrical equipment etc. Therefore the inclusion of assessment of compliance to statutory requirements in ISO9001:2008 at the discretion of the CB, in this case BINDT, is an auditable requirement in QS3.

The PCN Scheme for the assessment and certification of quality management systems is controlled and operated so as to ensure, amongst other things, that it is impartial. The PCN Certification Management Committee (CMC), which is widely representative of industry and of the stakeholders in the PCN Schemes, requires that decisions taken and implemented at all levels, including management and committees, are free from commercial or other pressures that may prevent the objective provision of certification services. In order to ensure that the desired impartiality is provided, the CMC maintains an overview of the implementation of its policies to ensure impartiality, which includes (at least) an annual internal audit to confirm that impartiality is maintained.

## **2. REQUIREMENTS & CONDITIONS FOR CERTIFICATION**

Where This Specification is used as a basis for third party certification, requirements and conditions are given in separate documents (see associated documents).

## **3. SCOPE**

### **3.1 General**

NDT service providers seeking certification of their Quality Managements Systems for compliance with The Standard through BINDT Certification Services may adopt the interpretations provided in this specification, although it is not mandatory for them to do so since BINDT will accept alternative interpretations which can be demonstrated to comply with The Standard.

This Specification does not duplicate the criteria of The Standard, but should be read in conjunction with it.

The Standard specifies requirements for a quality management system where an organisation needs:

- a) to demonstrate its ability to provide consistently, products that meet customer and applicable regulatory and statutory requirements, and
- b) to address customer satisfaction through the effective application of the system, including processes for continual improvement and prevention of non-conformities.

NOTE. Monitoring of customer satisfaction, as stated in b) requires the evaluation of information relating to customer perceptions of whether or not the organisation has met customer requirements.

The requirements specified in The Standard are generic and applicable to all organisations, regardless of type, size and product provided.

It is intended that all requirements of The Standard be applied. However, certain requirements may be excluded in particular situations (see below)

### **3.2 Permissible exclusions**

The organisation may only exclude quality management system requirements that neither affect the organisations ability, nor absolve it from its responsibility to provide a product that meets customer and applicable regulatory requirements. These exclusions are limited to those requirements listed in clause 7 , and may be due to the following:

- a) inapplicability to the organisation's product or service.
- b) inapplicability to the process
- c) customer specified requirements.

Where permissible exclusions are exceeded, conformity to The Standard should not be claimed. This includes situations where the fulfilment of regulatory and statutory requirements permits exclusion that exceed those allowed by The Standard.

***BINDT Guidance:***

*Where adequately documented and justified, certain elements of The Standard (limited to clause 7 criteria) may be omitted from the quality management system. Such omissions must be justified. Additional guidance is offered in QS3.*

### 3.3 Terms and Definitions

For the purposes of This Specification, the terms and definitions given in The Standard, together with the following, apply.

Product (service)- the result of a process.

***BINDT Guidance:***

*For the purposes of This Specification, the product shall be regarded as NDT, which may fall into any one of the above categories as shown in the following examples:*

- a) Hardware: may cover the design, manufacture or repair of NDT related (test) equipment.*
- b) Services: the provision of in-house or on-site NDT testing, training, examination etc.*
- c) Software: preparation, authorisation and control of NDT procedures, techniques, reports development of computer software for control of NDT equipment or applications.*
- d) Processed materials: in-house management, control and testing of a product (which may be customer supplied).*

***Note.*** *The above are only examples and do not preclude Organisations or Assessors from making their own interpretations.*

## 4. QUALITY MANAGEMENT SYSTEM

### 4.1 General requirements

The organisation shall:

- a) identify the processes needed for the quality management system and their application throughout the organisation
- b) determine the sequence and interaction of these processes
- c) monitor, measure and analyse these processes
- d) implement actions necessary to achieve planned results and continual improvement of these processes.

**BINDT Guidance:**

Processes referenced in the QMS manual should include all those activities which are described in the procedures or process maps referred to, whilst addressing the requirements of clauses 5 to 7 of the standard. The main, or core processes, will be those activities which describe how the NDT service is provided. For example, the enquiry/quotation/order/acknowledgement process of setting up a contract interacts with the preparation of inspection instructions. The setting up of inspection instructions interacts with the provision of suitably certified personnel, using approved inspection procedures, together with suitably calibrated equipment and correct consumables.

## 4.2 Documentation requirements

### 4.2.1 General

The QMS documentation shall include

- a) documented procedures required by this Standard
- b) documents needed by the organisation to ensure the effective planning, operation and control of its processes.

**BINDT Guidance:**

It is up to the organisation to decide which documented procedures it requires over and above those specified in the standard – providing they relate to relevant processes throughout the organisation.

### 4.2.4 Control of quality records

Records required for the quality management system shall be controlled. Such records shall be maintained to provide evidence of conformance to requirements and of effective operation of the quality management system. A documented procedure shall be established for the identification, storage, retrieval, protection, retention time and disposition of quality records.

***BINDT Guidance:***

*NDT personnel records should be retained for a specified period beyond termination of employment.*

*NDT instructions and procedures shall be designated as quality records.*

## 5. MANAGEMENT RESPONSIBILITY

### 5.4 Planning

#### 5.4.1 Quality objectives

Top management shall ensure that quality objectives including the need to meet requirements for product (service) are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy.

**BINDT Guidance:**

With respect to the words relevant functions and levels – the organisation must decide which activities can have “personal performance indicators” introduced into the procedures/process flow charts. These indicators can then be monitored by the personnel or their supervisors to decide whether that part of an overall process is being undertaken successfully and consistently; e.g.: NDT reports accurately completed and sent to client within X working days. Consideration may then be given to whether the activity can be improved.

Similarly, overall measurable quality objectives need to be developed for RELEVANT processes so that measurements can be undertaken (e.g. at internal audit) and processes can be improved, based on factual evidence, instead of management feel. An example might include the supply and return of client questionnaires per month to judge client feedback – all with acceptable marking.

## 5.5 Responsibility, authority and communication

### 5.5.2 Management representative

Top management shall appoint member(s) of the management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- a) ensuring that processes of the quality management system are established and maintained;
- b) reporting to top management on the performance of the quality management system, including needs for improvement;
- c) promoting awareness of customer requirements throughout the organisation.

NOTE The responsibility of a management representative may include liaison with external parties on matters relating to the quality management system.

#### ***BINDT Guidance:***

*The Organisation should nominate a person holding appropriate level 3 certification to be responsible for the overall technical quality of NDT activities. Where the nominated person is not a full time employee, the Organisation should demonstrate equivalent technical control through the documented use of external level 3 services.*

*In addition, a person should be nominated as responsible for ensuring compliance with statutory and customer specific requirements on all matters concerned with Health and Safety, including Ionising Radiations Regulations, environmental statutes, where applicable. As part of his duties the nominated person shall be responsible for providing and maintaining:*

- (i) documented procedures specifying safe working practices and actions to be taken in the event of accidents involving personnel or equipment, and*
- (ii) compliance with local safety rules and regulations.*
- (iii) compliance with applicable environmental rules and regulations*

*An appropriate number of persons should also be appointed to provide supervision of other activities, including site operations.*

*The Organisation shall define and document its organisation and the responsibilities, terms of reference, and the essential qualifications of all key staff within it.*

## 5.6 Management review

### 5.6.1 General

Top management shall review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall evaluate the need for changes to the organisation's quality management system, including quality policy and quality objectives.

### 5.6.2 Review input

Inputs to management review shall include current performance and improvement opportunities related to the following:

- a) results of audits;
- b) customer feedback;
- c) process performance and product conformance;
- d) status of preventive and corrective actions;
- e) follow-up actions from earlier management reviews;

- f) changes that could affect the quality management system.

***BINDT Guidance:***

*Management reviews shall include: Reference to changes in legislation that are applicable to NDT, such as the Ionising Radiations Regulations and COSHH and environmental requirements in respect of chemical used in NDT processes and changes, or pending changes to national or international standards and their potential affect on the Organisation.*

## **6. RESOURCE MANAGEMENT**

### **6.2 Human resources**

#### **6.2.2 Competency, awareness and training**

The organisation shall:

- identify competency needs for personnel performing activities affecting quality-;
- provide training to satisfy these needs;
- evaluate the effectiveness of the training provided;
- ensure that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- maintain appropriate records of education, experience, training and qualifications (see 5.5.7(a1))

***BINDT Guidance:***

*The Organisation should document how it recognises and provide staff training requirements.*

*Where (NDT) training is to be conducted "in house" the organisation shall provide suitable facilities, a competent trainer, syllabus, training notes and carry out documented assessments of trainees throughout the training course.*

*Where training leads to examination qualification in accordance with a nationally or internationally recognised employer based certification schemes, the Organisation shall fully document the processes to be used and demonstrate its compliance with the scheme.*

*Where NDT training is sub contracted to an external training agency the Organisation shall develop a documented procedure for assessing the suitability of the agency and the training provided.*

*Organisations shall monitor the ongoing competence and ability of its NDT personnel to provide testing services to the required standard. This should be carried out by appropriately qualified and include (but not be limited to) checking and approving inspection reports, random re-inspections and monitoring of staff.*

*Monitoring should :*

- a) *be conducted in accordance with a documented procedure;*
- b) *be conducted for each authorised inspection employee at a maximum of a yearly interval;*
- c) *include all NDE methods which the inspection employee is authorised to apply;*
- d) *be carried out by senior personnel who currently hold and have held a minimum of Level 2 in relevant NDE sectors and methods for at least two years*

## **7. PRODUCT REALISATION**

### **7.2 Customer-related processes**

#### **7.2.3 Customer communication**

The organisation shall identify and implement arrangements for communication with customers relating to:

- product information;
- enquiries, contracts or order handling, including amendments;
- customer feedback, including customer complaints.

***BINDT Guidance:***

*The Organisation should establish a procedure for conducting a sufficiently extensive and timely review of the specified requirements of each service enquiry to ensure that:*

- Orders received by verbal means are confirmed in writing by the customer and translated into written instructions which should be retained as a contractual record.*
- Customer requirements are adequately recorded at the tender or enquiry stage and reviewed to ascertain availability of the necessary resources to carry out the work to the standard required within the indicated time scales.*

*The organisation is required to measure and demonstrate that its NDT services satisfy customer requirements and relevant legislation (PED, IRR99, COSHH etc).*

### **7.3 Design and/or development**

#### **7.3.5 Design and/or development verification**

Design and/or development verification shall be performed to ensure the output meets the design and/or development inputs. The results of the verification and subsequent follow-up actions shall be recorded (see 5.5.7). [a2]

***BINDT Guidance:***

*Newly developed NDT procedures, techniques and equipment shall be verified in accordance with written procedures and relevant standards, using representative validation samples (see 7.5.6[a3]). Document reference CEN/TC 138 WG9 N47 (Report on Methodology for Qualification of Non-Destructive Tests) dated 20.05.2001 may be useful to organisations embarking on qualification of NDT.*

### **7.4 Purchasing**

#### **7.4.3 Verification of purchased product**

The organisation shall identify and implement the activities necessary for verification of purchased product. Where the organisation or its customer proposes to perform verification activities at the supplier's premises the organisation shall specify the intended verification arrangements and method of product release in the purchasing information.

***BINDT Guidance:***

*Sub-contractors should be interpreted as encompassing both suppliers of materials, goods and services which affect the quality of NDE carried out and organisations to which the performance of NDE is sub-contracted in its entirety.*

*The Organisation should not sub-contract any part of NDE to be carried out under a contract requiring compliance with this specification without the consent of the client. Any such sub-contract should invoke the requirements of this specification. The Organisation should maintain a list of approved sub-contractors. The basis for approval and the scope of approved supply should be identified.*

## 7.5 Production and service operations

The organisation shall control production and service operations through:

- the availability of information that specifies the characteristics of the product;
- where necessary, the availability of work instructions;
- the use and maintenance of suitable equipment for production and service operations;
- the availability and use of measuring and monitoring devices;
- the implementation of monitoring activities;
- the implementation of defined processes for release, delivery and applicable post-delivery activities.

### ***BINDT Guidance:***

*The Organisation should ensure that personnel are properly authorised to carry out NDE for the Organisation and that only appropriately qualified staff are authorised to work to specific NDE Instructions and Procedures.*

***All inspection and testing should be carried out in accordance with approved NDE procedures which should be readily available to the NDE technicians. All procedures should be approved by a level 3 qualified person***

### 7.5.2 Validation of processes

The organisation shall validate any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring. This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of the processes to achieve planned results.

The organisation shall define arrangements for validation that shall include the following, as applicable:

- qualification of processes;
- qualification of equipment and personnel;
- use of defined methodologies and procedures;
- requirements for records;
- re-validation.

### ***BINDT Guidance:***

*Where the Organisation is required to develop NDT procedures, techniques or services to meet specific criteria, they shall be validated. Validation should be carried out on test pieces or samples relevant to the application and incorporate real or artificial defects representative of those to be detected. The validation procedure must be fully documented (see also 7.3.5).*

## 7.6 Control of measuring and monitoring devices

The organisation shall identify the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements.

Measuring and monitoring devices shall be used and controlled to ensure that measurement capability is consistent with the measurement requirements. Where applicable, measuring and monitoring devices shall:

- a) be calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration shall be recorded;
- b) be safeguarded from adjustments that would invalidate the calibration;

- c) be protected from damage and deterioration during handling, maintenance and storage;
- d) have the results of their calibration recorded;
- e) have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken.

NOTE See ISO 10012 for guidance.

Software used for measuring and monitoring of specified requirements shall be validated prior to use.

***BINDT Guidance:***

*Documented procedures should be used to define requirements for calibration, maintenance, pre-use and in-service checks on NDT equipment, to verify that it remains suitable for the application.*

*The Organisation should define and document methods for controlling traceability of equipment and calibration. A certificate with a UKAS logo confirms traceability to national standards providing the equipment is within the UKAS scope of accreditation. A calibration certificate with a certification body logo and a statement concerning:*

- *traceability to national standards via NPL, or*
- *via a UKAS calibration service, or*
- *similar words*

*does not confirm traceability and is meaningless without data to support it.*

*In order to ensure traceability where there is no UKAS logo to support it, BINDT policy on calibration requires the following information as a minimum:*

- a) *A master equipment/instrument reference,*
- b) *A calibration certificate number,*
- c) *The date calibrated,*
- d) *The date recalibration is due (i.e., it must be a current valid certificate)*

*It is desirable that a copy of the master certificate (with a UKAS logo) for any reference standard should accompany the calibration certificate.*

*Any item of equipment which gives suspect results, or has been shown by calibration or otherwise to be defective should be immediately identified as defective and withdrawn from service. All NDE carried out with such equipment since it was last known to be operating correctly/properly calibrated should be reviewed for validity and repeated if necessary. All equipment calibration requirements should be met before the equipment is returned to service.*

*Records of calibration, servicing and maintenance should be maintained.*

## **8. MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.5 Improvement**

#### **8.5.3 Preventive action**

The organisation shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects of the potential problems.

**BINDT Guidance:**

Organisations should determine what potential problems may possibly affect their business and plan to reduce the potential impact. Examples on loss prevention might include the protection against the loss of electronic data by organising suitable back-up systems, or having catastrophe plans available to cope with loss of buildings and other assets due to fire.