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**VOLUME 0 INTRODUCTION  
AND GENERAL  
REQUIREMENTS**  
**SECTION 2 GENERAL GUIDANCE**

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**PART 1 GD 2/16**

**QUALITY MANAGEMENT SYSTEMS FOR  
HIGHWAY DESIGN ACTIVITIES**

**SUMMARY**

This document gives the requirements of the Overseeing Organisations of England, Scotland, Wales and Northern Ireland in respect of quality management systems applicable to the design of highways, including construction and maintenance works. It provides interpretation and guidance on BS EN ISO 9001 for highway designers including requirements and advice for the development and use of project specific quality management plans.

**INSTRUCTIONS FOR USE**

This document is to be incorporated into the Manual.

1. This document supersedes GD 02/08
2. Remove Content pages from Volume 0 dated May 2008.
3. Insert GD 2/16 into Volume 0, Section 2, Part 1
4. Archive this sheet as appropriate.

Note: A quarterly index with a full set of Volume Contents Pages is available separately from The Stationery Office Ltd.



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Llywodraeth Cymru  
Welsh Government

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WELSH GOVERNMENT**



**DEPARTMENT FOR INFRASTRUCTURE  
NORTHERN IRELAND**

# Quality Management Systems for Highway Design Activities

## SUMMARY

This document gives the requirements of the Overseeing Organisations of England, Scotland, Wales and Northern Ireland in respect of quality management systems applicable to the design of highways, including construction and maintenance works. It provides interpretation and guidance on BS EN ISO 9001 for highway designers including requirements and advice for the development and use of project specific quality management plans.

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**PART 1**

**GD2/16**

**QUALITY MANAGEMENT SYSTEMS  
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# 1. INTRODUCTION AND SCOPE

## Background

- 1.1. The Overseeing Organisation relies on careful preparation of design work carried out on its behalf by Designers for the successful delivery of the Overseeing Organisation's new highways and for upgrading and maintaining the existing network.
- 1.2. This standard is aligned and structured with BS EN ISO 9000 series of standards within a framework of UK, European and International standards and legislation.
- 1.3. This standard uses the convention according to GD 1, Introduction to the Design Manual for Roads and bridges (DMRB), clause 1.41, where the use of the terms 'must' or 'shall' indicates a requirement.

## Scope and Purpose

- 1.4. This standard applies to all organisations carrying out Design Activities on behalf of the Overseeing Organisation.
- 1.5. The Overseeing Organisation's quality management requirements relating to Design Activities, additional to those in BS EN ISO 9001, are summarised in Chapter 3. Specific additional requirements and guidance is stated in Chapters 4-9.

## Mutual Recognition

- 1.6. Where there is a requirement in this document for compliance with any part of a "British Standard" or other technical specification, that requirement may be met by compliance with the mutual recognition clause in GD1.

## Implementation

- 1.7. This standard supersedes GD 2/08 and shall be implemented in accordance with GD 1.

## Feedback and Enquiries

- 1.8. Users of this document are encouraged to raise any enquiries and/or provide feedback on its content and usage to the dedicated Highways England team. The email address for all enquiries and feedback is: [DMRB\\_Enquiries@highwaysengland.co.uk](mailto:DMRB_Enquiries@highwaysengland.co.uk).

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## 2. DEFINITIONS, ACRONYMS AND ABBREVIATIONS

### General

- 2.1. For the purposes of this standard, the terms and definitions given in BS EN ISO 9000 apply unless defined and redefined below.

### Definitions

- 2.2. “Designer” means any part of the supply chain contracted to the **Overseeing Organisation** to carry out the duties of a designer as defined in the Construction (Design and Management) Regulations (CDM). For the avoidance of doubt, this includes both individuals and organisations.
- 2.3. “Design Activities” means design, development and associated activities undertaken by the Design Organisation in delivering products and services to the **Overseeing Organisation**.
- 2.4. “Design Organisation” means any party undertaking Design Activities or procuring others to undertake Design Activities on their behalf.
- 2.5. “Quality Plan” means documented information in which the Design Organisation defines project, framework or contract quality objectives and sets out the processes to be used to achieve them.

### Abbreviations

- 2.6. CDM, Construction (Design and Management).
- 2.7. QMS, Quality Management System.

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## 3. OVERSEEING ORGANISATION REQUIREMENTS

### Quality Management

- 3.1. Designers shall operate a Quality Management System (QMS) complying with BS EN ISO 9001 that includes third party assessment by bodies accredited in accordance with BS EN ISO/IEC 17021 by the United Kingdom Accreditation Service (UKAS) or equivalent European Accreditation Organisation, which is party to a multi-lateral agreement (MLA) with UKAS or any equivalent International Accreditation Forum (IAF) MLA signatory. The scope of accreditation of third party assessment bodies shall include the highway design activities undertaken.
- 3.2. Designers shall prepare a project specific Quality Plan, appropriate to the scale and characteristics of the project, which shall be submitted during initiation of the project for future audit and inspection by the Overseeing Organisation. It shall complement the Design Organisation's QMS, to define all the processes, products and services that will be undertaken to deliver Design Activities. Guidance for Quality Plans is included in Annex A.
- 3.3. The requirements for processes to be contained in the Quality Plan can be met by references to processes in Design Organisation's QMS where they exist.
- 3.4. Chapters 4-9 shall be read in association with correspondingly numbered chapters in BS EN ISO 9001.

### Top Management

- 3.5. No additional requirements.

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## 4. CONTEXT OF THE ORGANISATION

### Understanding the organisation and its context

4.1. No additional requirements.

### Understanding the needs and expectations of interested parties

4.2. The Quality Plan shall contain:

- (i) information about interested parties, including relationships such as those illustrated in Table 4.2 below, and other contextual information or references to information sources relevant to the project; and
- (ii) processes for updating and communicating information to interested parties and project teams.

**TABLE 4.2: SUPPLY CHAIN RELATIONSHIP**

Supplier	Organisation	Customer	Interested Party
Sub consultants, survey companies, etc.	Designer	Generally the Overseeing Organisation but can include contracting organisations or other designers	Road users, road neighbours, interested parties and the Overseeing Organisation in circumstances where they are not the customer
Designer	Overseeing Organisation	Road users, road neighbours, interested parties	Customers and other organisations within the supply chain

4.3. Where not incorporated within QMS, Design Organisations shall include processes within the Quality Plan to manage and undertake Design Activities in which the requirements for products and services emerge from interactions between multiple interested parties and sources of information.

### Determining the scope of the quality management system

4.4. No additional requirements.

### Quality management system and its processes

4.5. Processes incorporated in Quality Plans shall be reviewed, developed and improved.

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## 5. LEADERSHIP

### Leadership and commitment

5.1. No additional requirements.

### Quality policy

5.2. No additional requirements.

### Organisational roles, responsibilities and authorities

5.3. The Quality Plan shall identify role or position of the individual with the assigned responsibilities in BS EN ISO 9001.

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## 6. PLANNING FOR THE QUALITY MANAGEMENT SYSTEM

### Actions to address risks and opportunities

- 6.1. Design Organisations shall assess risks to project specific quality objectives and review the sufficiency of the Design Organisation's QMS in respect of identified project risks. The Quality Plan shall include any additional processes necessary to manage such risk.

### Quality objectives and planning to achieve them

- 6.2. No additional requirements.

### Planning of changes

- 6.3. No additional requirements.

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## 7. SUPPORT

### Resources

7.1. No additional requirements.

### Competence

7.2. The Quality Plan shall identify the role or position of the individual with the assigned responsibility for assessing competency and for assigning competent individuals to project specific Design Activities.

7.3. The assessment shall include a review against the DMRB, NHSS, EU and UK legislation during the determination of staff competence requirements.

### Awareness

7.4. No additional requirements.

### Communication

7.5. No additional requirements.

### Documented Information

7.6. In addition to any documentation required by the Design Organisation's QMS, the Overseeing Organisation requires Quality Plans to document the boundaries and applicability of the Quality Plan.

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## 8. OPERATION

### Operational Planning and Control

- 8.1. The project specific Quality Plan shall detail how the quantity, timing and quality of the work is managed and controlled during the execution of the work, including:
- (i) setting requirements, including acceptance criteria, for products and services;
  - (ii) establishing and monitoring performance against resource and competence requirements;
  - (iii) taking control action in accordance with criteria;
  - (iv) managing scope of work, programme and budget;
  - (v) managing change; and
  - (vi) control of outsourced processes.

### Determination of requirements for products and services

- 8.2. The Quality Plan shall identify the arrangements for communicating with the Overseeing Organisation on a project specific basis, including details of customer and interested party contacts and communication protocols.
- 8.3. Quality Plans shall set out project specific requirements for products and services:
- (i) specified by the Overseeing Organisation;
  - (ii) necessary to meet those specified by the Overseeing Organisation;
  - (iii) to comply with statute and regulation critical to the project;
  - (iv) that need to be established in detail; and
  - (v) to incorporate relevant Overseeing Organisation management processes, for example to coordinate the timing programme and expenditure monitoring.
- 8.4. The Quality Pan shall set out project specific arrangements for the review of requirements.

### Design and Development of products and services

- 8.5. The Quality Plan shall set out design and development processes to be used to establish requirements for products and services on projects for which requirements are not stated by the customer, but are necessary for the specified or intended use, when known. This shall include identifying the involvement of the interested parties including the Overseeing Organisation.

### Control of externally provided products and services

- 8.6. The Quality Plan shall identify externally provided products and services together with project specific processes for selection and management of providers.
- 8.7. The Quality Plan shall include processes for managing and controlling externally provided products and services.

### Production and Service Provision

- 8.8. The Quality Plan shall set out the project specific operational processes for production and service provision and the control processes to be used:
- (i) for measurement criteria and monitoring methodologies;
  - (ii) for review, verification and validation of output conformity to design production input requirements;
  - (iii) for validation to be carried out by third parties or regulatory authorities;
  - (iv) for documented information or other evidence that design production has met requirements;
  - (v) for issue, including authorisation, of information and products to the Overseeing Organisation and other interested parties;
  - (vi) to assure competencies of people involved in operation and in validation;
  - (vii) for use of specific equipment and information; and
  - (viii) for review and validation of operational processes.
- 8.9. The Quality Plan shall include control processes:
- (i) to ensure identification and traceability of products;
  - (ii) to identify changes and the current revision and status of documents;
  - (iii) to identify personnel responsible for preparation, verification and approval of products and services; and
  - (iv) for issue, retention and disposal of documented information.

### Release of products and services

8.10. No additional requirements.

### Control of nonconforming process outputs, products and services

8.11. The Quality Plan shall set out project specific processes to control non-conforming products and services and to document action taken.

## 9. PERFORMANCE EVALUATION

### Monitoring, measurement, analysis and evaluation

- 9.1. Quality plans shall set out project-specific processes for undertaking monitoring, measurement, analysis and evaluation, including:
- (i) format, schedule and sequence of design reviews;
  - (ii) characteristics to be reviewed or verified at each point;
  - (iii) responsibilities and competencies of people involved in reviews and verification;
  - (iv) reviews or checks to be carried out by third parties or regulatory authorities; and
  - (v) requirements to prepare, report, communicate and retain documentary records of monitoring, measurement, analysis and evaluation.
- 9.2. The Quality Plan shall incorporate Overseeing Organisation processes for performance measurement to determine customer satisfaction as appropriate.

### Internal Audit

- 9.3. The Design Organisation shall set out project specific audit requirements in the Quality Plan in accordance with needs identified by risk assessment, reference paragraph 6.1.1 above, including:
- (i) the scope and frequency of audits to be undertaken; and
  - (ii) how the results are to be used to correct and prevent recurrence of nonconformities that affect products and service provision.

### Management review

- 9.4. No additional requirements.

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## 10. IMPROVEMENT

### General

10.1. Quality plans shall identify project specific improvement initiatives, including initiatives sponsored by the Overseeing Organisation, and how they will be managed, resourced and controlled.

### Nonconformity and corrective action

10.2. The Quality Plan shall set out the project specific processes to comply with BS EN ISO 9001.

### Continual improvement

10.3. The Quality Plan shall set out the process for periodic review, update and change of the Quality Plan. The Quality Plan shall include a process for feeding back the review results to top management and the Overseeing Organisation, as appropriate.

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# 11. NORMATIVE AND INFORMATIVE REFERENCES

## Normative References

11.1. The following documents, in whole or in part, are normative references for this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- (i) BS EN ISO 9000, Quality management systems – Fundamentals and vocabulary;
- (ii) BS EN ISO 9001, Quality management systems – Requirements.

## Informative References

11.2. The following documents, in whole or in part, are informative references for this document and provide additional guidance. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- (i) Design Manual For Roads and Bridges (DMRB);
- (ii) National Highway Sector Schemes (NHSS);
- (iii) BS EN ISO 9004, Managing for the sustained success of an organization – A quality management approach; and
- (iv) BS EN ISO 10018 Quality Management - Guidelines on people involvement and competence;
- (v) BS EN ISO 14001, Environmental management systems – Requirements with guidance for use;
- (vi) BS OHSAS18001 Occupational health and safety management systems – Requirements; and
- (vii) CDM Regulations.

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## 12. ENQUIRIES

Approval of this document for publication is given by:

Highways England  
Woodlands  
Manton Lane  
Bedford  
MK41 7LW

C BROOKES  
Chief Highway Engineer

Transport Scotland  
8th Floor, Buchanan House  
58 Port Dundas Road Glasgow  
G4 0HF

R BRANNEN  
Director, Trunk Road and Bus Operations

Welsh Government  
Transport  
Cardiff  
CF10 3NQ

S HAGUE  
Deputy Director  
Network Management Division

Department for Infrastructure  
Clarence Court  
10-18 Adelaide Street  
Belfast  
BT2 8GB

P B DOHERTY  
Director of Engineering

All technical enquiries or comments on this Document should be sent to [DMRB\\_Enquiries@highwaysengland.co.uk](mailto:DMRB_Enquiries@highwaysengland.co.uk)

### Notification under 2015/1535/EU

This document was notified in draft to the European Commission in accordance with Technical Standards and Regulations Directive 2015/1535/EU

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# ANNEX A – GUIDANCE FOR QUALITY PLANS

## Introduction

- A1 The purpose of the Quality Plan is to tie the specific requirements of a project to the existing generic integrated QMS of the Designer. The Quality Plan may require documented procedures to be produced, over and above those that may already be in existence as part of the QMS.
- A2 Much of the necessary Quality Plan documentation will normally exist as part of the QMS documentation. The Quality Plan need only refer to this documentation and show how it is to be applied to the specific situation in question. Where an element of such documentation does not exist but is required, the Quality Plan should identify it and also identify when, how and by whom it will be prepared and approved.
- A3 The contents of the Quality Plan should be based on BS EN ISO 9001, this Standard and the Design Organisation's QMS. The elements described in the following sub-clauses should be addressed, where relevant to the requirements of the product or service being provided.
- A4 The scope of the Quality Plan should be defined and include, but not be limited to:
- (i) The product or service, or service and product combination to which it is to be applied;
  - (ii) The scope of the project to which it is to be applied;
  - (iii) The product/service quality objectives;
  - (iv) Specific exclusions; and
  - (v) The conditions of its validity.
- A5 The following provides a typical content of a Quality Plan, as an example for guidance.

### 1.0 Purpose

### 2.0 General Project Description

- 2.1 History
- 2.2 Location
- 2.3 Performance criteria
- 2.4 Project benefits

### 3.0 Project Strategy

- 3.1 Key outcomes and outputs for the Overseeing Organisation
- 3.2 Interested parties
- 3.3 Communication plan

### 4.0 Roles, Responsibilities & Processes

- 4.1 Overseeing Organisation's responsibilities
- 4.2 Project management team
- 4.3 Externally provided products and services

**5.0 Key Processes**

- 5.1 Quality management
- 5.2 Health & safety management
- 5.3 Environmental management
- 5.4 Risk management
- 5.5 Management of interested parties
- 5.6 Communications management
- 5.7 Contract & scope management
- 5.8 Project controls & period reporting
- 5.9 Document control
- 5.10 Configuration management
- 5.11 Change control
- 5.12 Surveys, analysis & reports
- 5.13 Design control
- 5.14 Internal approvals and authorisation
- 5.15 Customer acceptance

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