bsi.

DPC: 14 / 30262728 DC

#### **BSI Group Headquarters**

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000 Fax: +44 (0)20 8996 7400 www.bsigroup.com Date: 15 May 2014 Origin: European

#### Latest date for receipt of comments: 31 August 2014

Project No. 2012/01067

Responsible committee: QS/1 Quality management and quality assurance procedures

Interested committees:

| Title: | Draft BS ISC | 9000 Quality | Management S | Systems - F | undamentals and | Vocabulary |
|--------|--------------|--------------|--------------|-------------|-----------------|------------|
|--------|--------------|--------------|--------------|-------------|-----------------|------------|

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

### WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 31 August 2014

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.** 

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <a href="http://shop.bsigroup.com">http://shop.bsigroup.com</a> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <a href="http://standardsdevelopment.bsigroup.com">http://standardsdevelopment.bsigroup.com</a>

Responsible Committee Secretary: Ms Sally Swingewood (BSI)

Direct tel:

E-mail: sally.swingewood@bsigroup.com

#### Introduction

This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

#### UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

#### **Submission of Comments**

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**
- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**
- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at: http://drafts.bsigroup.com/

#### Template for comments and secretariat observations

| Date: | xx/xx/20xx | Document: ISO/DIS xxxx |
|-------|------------|------------------------|
|-------|------------|------------------------|

| 1  | 2  | (3)                                 | 4                    | 5   | (6)  | (7)  |
|----|--|-------------------------------------|----------------------|---|--|--|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/<br>Figure/<br>Table/Note | Type of com-<br>ment | Commend (justification for change) by the MB  | Proposed change by the MB  | Secretariat observations on each comment submitted |
|    | 3.1  | Definition 1                        | ed                   | Definition is ambiguous and needs clarifying.   | Amend to read 'so that the mains connector to which no connection' |  |
|    | 6.4  | Paragraph 2                         |                      | <u>*</u>  | Delete reference to UV photometer.                                 |  |
|    |  |                                     |                      | alternative cannot be supported as serious problems have been encountered in its use in the UK. |  |  |

# DRAFT INTERNATIONAL STANDARD ISO/DIS 9000

ISO/TC **176**/SC **1** Secretariat: **ANSI** 

Voting begins on: Voting terminates on:

2014-07-10 2014-10-10

## Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

ICS: 03.120.10;01.040.03

#### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number ISO/DIS 9000:2014(E)

#### **Copyright notice**

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

| 12       | Contents |   |    |  |
|----------|----------|---|----|--|
| 13       | Forev    | vord  | iv |  |
| 14       | Intro    | duction   | v  |  |
| 15       | 1        | Scope   | 1  |  |
| 16       | 2        | Quality management principles and fundamental concepts                  | 1  |  |
| 17       | 2.1      | General   |    |  |
| 18       | 2.2      | Fundamental concepts  |    |  |
| 19       | 2.3      | Quality management principles   |    |  |
| 20       | 2.4      | Development of fundamentals into a QMS                                  | 7  |  |
| 21       | 3        | Terms and definitions   | 11 |  |
| 22       | 3.1      | Terms related to person or people                                       |    |  |
| 23       | 3.2      | Terms related to organization   | 12 |  |
| 24       | 3.3      | Terms related to activity   | 14 |  |
| 25       | 3.4      | Terms related to system   | 16 |  |
| 26       | 3.5      | Terms related to requirement  | 17 |  |
| 27       | 3.6      | Terms related to process  |    |  |
| 28       | 3.7      | Terms related to results  |    |  |
| 29       | 3.8      | Terms related to data, information and document                         |    |  |
| 30       | 3.9      | Terms related to customer   |    |  |
| 31       | 3.10     | Terms related to audit  |    |  |
| 32       | 3.11     | Terms related to action   |    |  |
| 33       | 3.12     | Terms related to characteristic   |    |  |
| 34       | 3.13     | Terms related to determination  | 33 |  |
| 35       | Anne     | x A (informative) Methodology used in the development of the vocabulary | 35 |  |
| 36       | Biblio   | ography   | 51 |  |
| 37<br>38 | Alpha    | abetical index  | 52 |  |

#### **ISO/DIS 9000**

#### **Foreword**

39

45

48

49

51

52

53

54

- ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies 40
- 41 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO 42
  - technical committees. Each member body interested in a subject for which a technical committee has been
- 43 established has the right to be represented on that committee. International organizations, governmental and 44
  - non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the
  - International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.
- 46 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.
- 47 The main task of technical committees is to prepare International Standards. Draft International Standards
  - adopted by the technical committees are circulated to the member bodies for voting. Publication as an
  - International Standard requires approval by at least 75 % of the member bodies casting a vote.
- 50 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
  - rights. ISO shall not be held responsible for identifying any or all such patent rights.
  - ISO 9000 was prepared by Technical Committee ISO/TC 176, TC Quality management and quality
  - assurance, Subcommittee SC 1, SC Concepts and terminology.
  - This fourth edition cancels and replaces the third edition (ISO 9000:2005).

55

#### Introduction

56

- This International Standard provides the fundamentals and terminology of quality management systems. It is the foundation of other ISO quality management system standards and serves as the normative reference for many of them. It will help the user to understand the principles, systems model and terminology of quality management in order to more effectively and efficiently implement a quality management system and realize value from other ISO quality management system standards.
- This management standard for quality makes the case for a well-defined quality management system based on a framework that integrates established quality fundamental concepts, principles, processes and resources to help organizations realize their goals Its aim is to make top management aware of their duties and commitment in achieving their customers and stakeholders needs, expectations and satisfaction with their products and services.
- The terms and definitions are arranged in conceptual order according to ISO/IEC Directives. Annex A provides information on how this works, including the set of diagrams of the concept systems that form the concept ordering. An alphabetical list is provided at the end of the document to aid location of entries.

#### 70 Quality management systems — Fundamentals and vocabulary

#### 71 **1 Scope**

- 72 This International Standard describes the fundamental concepts, principles and vocabulary of quality 73 management, and defines related terms, which are universally applicable to the following:
- organizations seeking sustained success through the implementation of quality and other management systems;
- 76 customers seeking confidence in organization's ability to provide satisfactory products;
- 77 organizations seeking confidence in their supply chain that their product requirements will be met;
- 78 those interested parties seeking to improve communication through a common understanding of the terminology used in quality management;
- 80 organizations performing conformity assessments against the requirements of ISO 9001;
- 81 those providing training in quality management;
- 82 developers of related standards.

#### 2 Quality management principles and fundamental concepts

#### 84 **2.1 General**

83

- The quality management concepts and principles described in this standard give management the capacity to
- meet challenges presented by an environment that is profoundly different from that of just a few decades ago.
- 87 The context in which the 21<sup>st</sup> century organisation works is characterised by accelerated change, globalisation
- of markets, limited resources, and the emergence of knowledge as a principal resource. Society has become
- 89 better educated and more demanding, making interested parties increasingly more powerful. This clause
- 90 provides a way of thinking about the organisation more broadly, by providing fundamental concepts and
- principles to be used in the development of a Quality Management System.

#### 92 2.2 Fundamental concepts

#### 93 **2.2.1 Quality**

- 94 Quality focused organizations embrace a culture that inspires and drives behaviour, attitude, actions and
- 95 processes in order to deliver value through fulfilling the requirements of interested parties.
- 96 The quality of an organization's products and services is determined by not only the ability to satisfy a
- 97 particular customer but also the intended and unintended impact on other interested parties.
- 98 The quality of products and services include not only their intended function, but also their perceived value
- 99 and benefit to the customer.

#### 100 2.2.2 Quality management system

- 101 Quality management systems manage the interacting processes, sub-systems, procedures, and resources
- 102 required to:
- provide value to all relevant interested parties, and
- realize the outputs, outcomes, or results of the whole organization
- Anticipating the impact of outcomes is essential in managing performance.
- 106 Quality management systems provide a means of managing the cost of quality. Awareness of these costs
- enables organizations to take action in order to optimise utilization of resources.