BS EN ISO 14644-13:2017

BSI Standards Publication

Cleanrooms and associated controlled environments

Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications (ISO 14644-13:2017)

Documents
Document Sharing Hub

Full document details: BS EN ISO 14644-13:2017

National foreword

This British Standard is the UK implementation of EN ISO 14644-13:2017.

The UK participation in its preparation was entrusted to Technical Committee LBI/30, Cleanroom technology.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2017
Published by BSI Standards Limited 2017

ISBN 978 0 580 82492 0

ICS 13.040.35

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2017.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS EN ISO 14644-13:2017

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14644-13

August 2017

ICS 13.040.35

English Version

Cleanrooms and associated controlled environments - Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications (ISO 14644-13:2017)

Salles propres et environnements maîtrisés apparentés - Partie 13: Nettoyage des surfaces afin d'obtenir des niveaux de propreté par rapport aux classifications particulaire et chimique (ISO 14644-13:2017)

Reinräume und zugehörige Reinraumbereiche - Teil 13: Reinigung von Oberflächen zur Erreichung definierter Reinheitsgrade hinsichtlich Partikel- und Chemikalienklassifikationen (ISO 14644-13:2017)

This European Standard was approved by CEN on 26 May 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

© 2017 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 14644-13:2017 E

Documents
Document Sharing Hub

Full document details: BS EN ISO 14644-13:2017

European foreword

This document (EN ISO 14644-13:2017) has been prepared by Technical Committee ISO/TC 209 "Cleanrooms and associated controlled environments" in collaboration with Technical Committee CEN/TC 243 "Cleanroom technology" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2018 and conflicting national standards shall be withdrawn at the latest by February 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14644-13:2017 has been approved by CEN as EN ISO 14644-13:2017 without any modification.

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 209, *Cleanrooms and associated controlled environments*.

A list of all parts in the ISO 14644 series can be found on the ISO website.

© ISO 2017 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

Introduction

The term surface refers to the interface between two phases. For the purpose of this document, the surface is a solid. A “clean surface” is where one or more of the contamination categories (particles, chemical) are under control due to cleaning/decontamination. The degree of cleanliness is specified in the corresponding surface cleanliness classifications (see ISO 14644-9 and ISO 14644-10). Different cleaning methods are necessary depending on the degree of cleanliness (cleanliness class) required. This document gives guidance on the selection of cleaning methods to achieve specified cleanliness levels. For the selection procedure, the aspects of surface description, cleanliness specifications, types of contamination, cleaning techniques, material compatibility, and assessment methodology are taken into consideration. Most of the methods are suitable for removal of more than one contamination category at the same time; therefore, a common standard for the selection of a cleaning method for both particles, as well as chemical contamination, is needed.

© ISO 2017 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

Cleanrooms and associated controlled environments —

Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications

1 Scope

This document gives guidelines for cleaning to a specified degree on cleanroom surfaces, surfaces of equipment in a cleanroom and surfaces of materials in a cleanroom. Under consideration are all surfaces (external or internal) that are of interest. It provides guidance on the assessment of cleaning methods for achieving the required surface cleanliness by particle concentration (SCP) and surface cleanliness by chemical concentration (SCC) classes and which techniques should be considered to achieve these specified levels.

The appropriateness of cleaning techniques will make reference to the cleanliness classes and associated test methods found in ISO 14644-9 and ISO 14644-10.

The following matters of general guidance will be provided:

— expected surface cleanliness levels;

— suitability of cleaning methods;

— compatibility of surfaces with the cleaning technique;

— assessment of cleaning appropriateness.

The following will be excluded from this document:

— classification of cleaning methods;

— product produced within a cleanroom;

— specific surface-related cleaning methods;

— detailed description of cleaning mechanisms, methods and procedures of various cleaning methods;

— detailed material characteristics;

— description of damage mechanisms by cleaning processes and time-dependent effects;

— references to interactive bonding forces between contaminants and surfaces or generation processes that are usually time-dependent and process-dependent;

— other characteristics of particles such as electrostatic charge, ionic charges, etc.;

— chemical reactions between molecular contaminants and surfaces;

— microbiological aspects of surface cleanliness;

— radioactive aspects of contamination;

— health and safety considerations;

— environmental aspects such as waste disposal, emissions, etc.;

© ISO 2017 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

— selection and use of statistical methods.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14644-8, *Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)*

ISO 14644-9, *Cleanrooms and associated controlled environments — Part 9: Classification of surface cleanliness by particle concentration*

ISO 14644-10, *Cleanrooms and associated controlled environments — Part 10: Classification of surface cleanliness by chemical concentration*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14644-9, ISO 14644-10 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
cleanliness
<of a solid surface>condition of a solid surface where the amount of *contamination* (3.4) (particle, chemical) is controlled to a specific level

3.2
cleaning appropriateness
relation between the required *cleanliness* (3.1) and the accomplished cleanliness under controlled conditions

Note 1 to entry: In some languages, the term cleaning efficacy is used to indicate cleaning appropriateness.

Note 2 to entry: In case of real operational conditions or monitoring, the term cleaning effectiveness is used.

3.3
cleaning efficiency
fraction of specific contaminants removed from a surface by a cleaning process

Note 1 to entry: The fraction is determined by the accomplished surface cleanliness in respect to the initial surface cleanliness.

3.4
contamination
unwanted matter in an undesirable location

3.5
particle
minute piece of matter with defined physical boundaries

[SOURCE: ISO 14644-1:2015, 3.2.1]

© ISO 2017 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

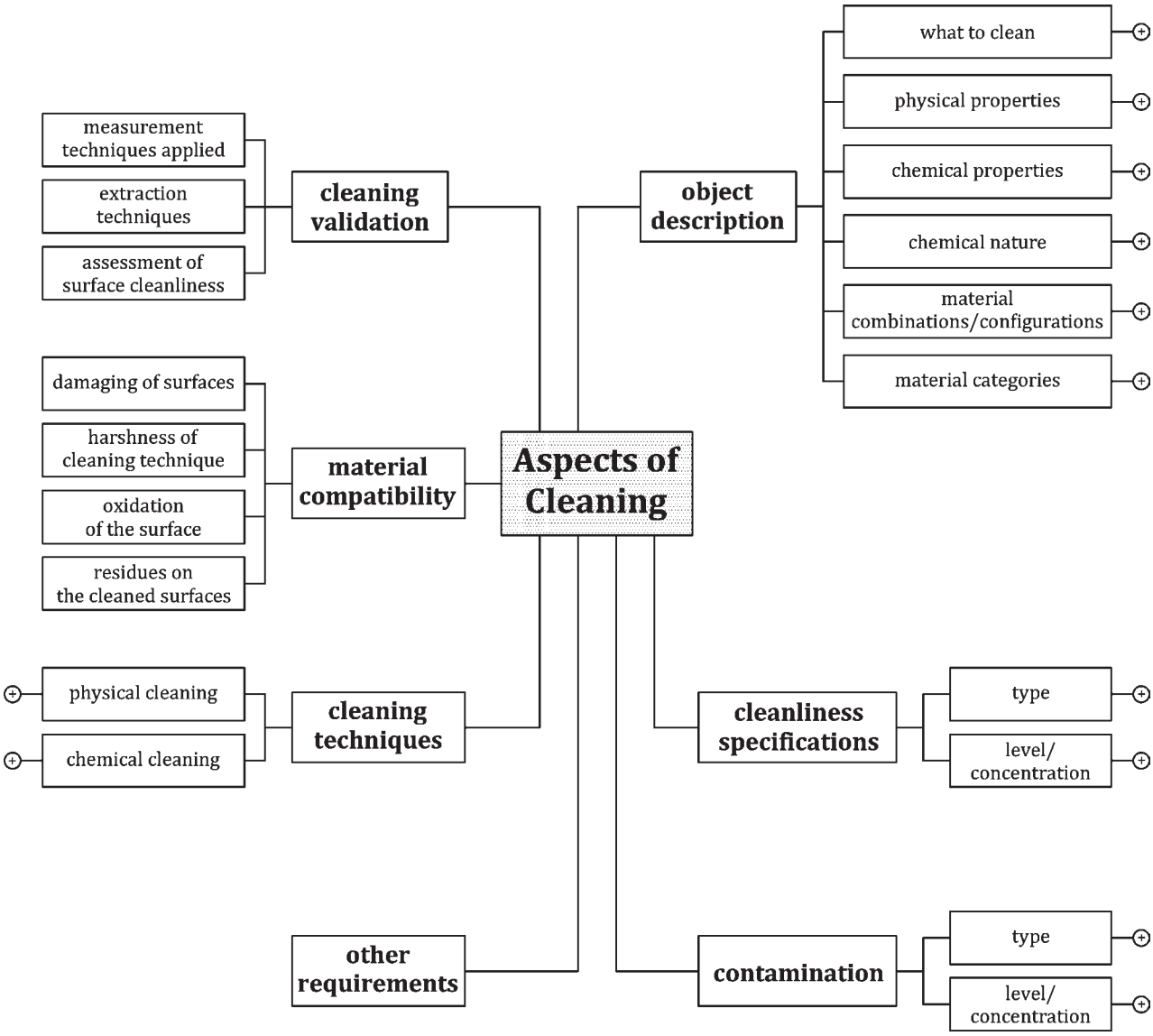
3.6
particle contamination
particles (3.5) having the potential to affect the process, the product, the personnel or the facilities

3.7
particle size
diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the *particle* (3.5) being measured

4 General methodology

4.1 Overview

Multiple aspects need to be considered for cleaning. Figure 1 provides an overview of the factors that contribute to the suitability of cleaning methods to achieve a defined level of surface cleanliness. For more details, see Annex A.



Key

\+ more details in Figure A.1

Figure 1 — Overview of cleaning aspects (non-exhaustive)

© ISO 2017 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

4.2 Methodology

Appropriateness of a cleaning technique for an application depends on many factors. For complex objects, it is advised to follow the sequence described in this clause and in the decision tree (see Figure 2). By using this procedure, it can be assured that all important issues are covered. For simple objects or surfaces, deviations from the sequence are allowable, as long as the critical information is documented.

The approach starts with describing the object that has to be cleaned. The description should cover, among others, composition of materials, chemical characteristics, surface finish and shape factors like geometrical complexity and size (step 1). In the second step, the objective of the cleaning procedure is to be specified in terms of the desired cleanliness of the object. To have a starting point, the initial contamination level should be assessed (step 3) and other requirements shall be listed (step 4). Based on type of contaminants and the required removal efficiency, a cleaning technique or a combination of techniques can be selected (step 5). The cleaning methodology shall be checked against the materials from the first step in order to avoid material compatibility issues (step 6). At the last step, a validation method shall be carried out (step 7). The validation shall at least comprise methods for determination of the cleaning performance and material compatibility. The performance of the cleaning shall be checked against the specification.

© ISO 2017 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

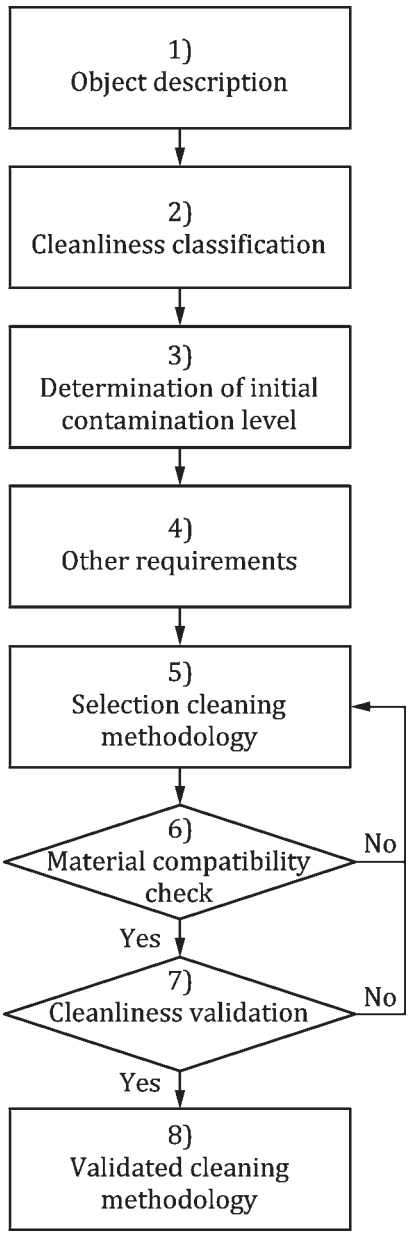


Figure 2 — Decision tree

© ISO 2017 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

5 Object description

In the object description, the following aspects shall be considered.

Physical properties of the object:

— physical dimensions;

— form/shape/complexity of the object;

— critical surfaces.

A general description of the object shall be given. Size, shape, complexity and identification of the critical surfaces set many boundary conditions for a cleaning method.

Surface(s):

— material composition of the object surface(s);

— complexity;

— materials/critical materials (sensitive to cleaning agents);

— thin/atomic surface layers (e.g. protective layers);

— other physical properties (e.g. electrostatic).

The composition of the object could be simple (one or more similar material(s)) or a system consisting of a range of different materials (e.g. metal/plastic/glass composition). Each individual material should be taken into account when choosing a cleaning method. Some combinations of materials can be very difficult to clean as one cleaning method may be suitable for one material but not the other. The selection of the cleaning method shall be the best compromise between minimal damage of the materials at maximum cleaning efficiency.

Chemical properties of the surface(s):

— chemical composition;

— state of the surface (hydrophobic, hydrophilic, lypophobic, lipophilic, etc.);

— energetic state of the surface (zeta potential).

Physical and chemical properties of a surface have a large influence on the choice of a cleaning method. Choice of a method shall take into account all involved materials/chemical composition of the surface(s) and the combination of materials undergoing cleaning.

The activity of the surface is determined by the chemical configuration of the final atomic layer. This is an important parameter in determining the choice of method. These layers may be hydrophilic (water wettable-lipophobic) or hydrophobic (water repellent but oil-wettable-lipophilic). The cleaning method used can influence the surface activity. The surface activity also influences the electrostatic properties of a material — a hydrophilic surface will have fewer tendencies to electrically charge.

Morphology:

Cleaning is influenced by the morphological aspects of a surface such as shape, size, structure, surface roughness or porosity. Morphological aspects may further complicate cleaning due to the accessibility of the surfaces to be cleaned and to the retention of cleaning agents and materials used for cleaning.

Object specific requirements:

— intended use of the object;

© ISO 2017 – All rights reserved
Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017

— environmental conditions, both pre- and post-cleaning;

— critical surfaces — surfaces with either high importance in the application or sensitive to cleaning.

6 Cleanliness specifications

The rationale of determining appropriateness of the cleaning method should include the contaminants of concern, as well as acceptable levels of contamination for the application.

The required cleanliness shall be specified in terms of particle concentration according to ISO 14644-9 and/or in terms of the concentration of a specific group of chemicals according to ISO 14644-10.

The specification of the targeted cleanliness class can be determined in various ways:

— cleanliness class required by customer;

— common cleanliness class required for similar objects;

— by performing an analysis on the impact of contamination of the surface in the (future) function of a product or process where the cleaned surface will be used;

— by performing tests or simulations with various cleanliness classes of the considered surface and/or;

— by performing an analysis of the contamination that caused failure or quality loss.

7 Determination of initial contamination level

7.1 General

To select the cleaning procedure for achieving a required surface cleanliness level, the initial surface cleanliness shall be established. The initial surface cleanliness by chemical and/or particle concentration shall be determined for the surfaces of interest. This can be determined qualitatively or quantitatively.

Qualitative evaluation is a non-numerical assessment (e.g. a visual inspection).

Where the quantitative surface cleanliness is determined, it can be related to the efficiency of the cleaning procedure in respect to the required surface cleanliness by particle concentration and/or chemical concentration. The quantified contamination (particle and/or chemical) shall be related to the area of the representative surface. This evaluation allows determination of the initial cleanliness class.

7.2 Determination of initial contamination level with respect to particle concentration

The initial surface cleanliness by particle concentration shall be determined for the different surfaces. Depending on the required cleanliness class, a qualitative assessment of the initial cleanliness level may be sufficient. For quantitative assessment, the number and size of particles shall be characterized by a measurement method as described in Clause 12. The surface cleanliness classification as outlined in ISO 14644-9 shall be applied.

The quantified particle concentration shall be related to the area of the representative surface. This evaluation allows determination of the initial cleanliness class.

7.3 Determination of initial contamination level with respect to chemical concentration

The initial surface cleanliness by chemical concentration shall be determined for the different surfaces. Depending on the specific application, a qualitative assessment (e.g. water break test) of the initial cleanliness level might be sufficient. For quantitative assessment of the mass and nature of the chemical contaminants, a measurement technique according to Clause 12 and ISO 14644-10 shall be applicable.

© ISO 2017 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS EN ISO 14644-13:2017