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Major revisions of ISO 14644 Parts 1 and 2 are finally published in December 2015

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ISO standards are reviewed at five yearly intervals. In the case of ISO 14644 Parts 1 and 2, which were first published in 1999 and 2000, the reviews were initiated in 2005 in accordance with normal practice. A DIS (draft international standard) was produced for each of these Parts in 2010 and although voting was in favour of approving both standards, there were so many comments received with the voting that those responsible (WG1 of ISO TC209) decided that a second DIS enquiry and vote was required. This second DIS vote closed in November 2014 with a resounding positive vote to progress through the FDIS stage to final publication, which eventually took place in December 2015.

The changes from the original standards are comprehensively explained in the Introductions to the two standards, which are reproduced below. I have added a small number of comments with further explanations and these are in square brackets.

The UK edition of ISO 14644-2:2015, prefixed BS EN ISO, has an important additional Annex that recommends specific intervals for cleanroom tests. The rationale for this additional Annex is that testing intervals, which were considered to be a useful part of the original standard, have not been included in the 2015 revision. It was also an opportunity to review and revise the testing intervals and to include all tests relevant to cleanrooms, including those from ISO 14644-3. All this is explained in the UK National Foreword. The Annex is informative and not normative and might be considered useful guidance outside the UK. It is however only available from BSI in the UK edition, BS EN ISI 14544-2:2015.

Many years of work have gone into absorbing and reconciling the strongly held views of the experts with numerous meetings in different parts of the world. As Convenor of WG1 I would like to express my profound thanks to all the experts who contributed with their well-argued views and discussed those patiently in the meetings until we finally arrived at what we all believe are really useful revisions of these two standards that are at the heart of cleanroom technology.

Gordon Farquharson, December 2015

Extracts from the introductions to the standards

ISO 14644-1:2015
Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

Introduction
Cleanrooms and associated controlled environments provide for the control of contamination of air and, if appropriate, surfaces, to levels appropriate for accomplishing contamination-sensitive activities. Contamination control can be beneficial for protection of product or process integrity in applications in industries such as aerospace, microelectronics, pharmaceuticals, medical devices, healthcare and food.

This part of ISO 14644 specifies classes of air cleanliness in terms of the number of particles expressed as a concentration in air volume. It also specifies the standard method of testing to determine cleanliness class, including selection of sampling locations.

This edition is the result of a response to an ISO Systematic Review and includes changes in response to user and expert feedback validated by international enquiry. The title has been revised to "Classification of air cleanliness by particle concentration" to be consistent with other parts of ISO 14644. The nine ISO cleanliness classes are retained with minor revisions. Table 1 defines the particle concentration at various particle sizes for the nine integer classes. [This Table is normative and predominant and supersedes the formula that was normative in ISO 14644-1:2000]. Table E.1 defines the maximum particle concentration at various particle sizes for intermediate classes. The use of these tables ensures better definition of the appropriate particle-size ranges for the different classes. This part of ISO 14644 retains the macroparticle descriptor concept; however, consideration of nano-scale particles (formerly defined as ultrafine particles) will be addressed in a separate standard. [Table 1 differs from that in ISO 14644-1:2000 in that some of the single digit particle concentrations have been removed as testing for such low concentrations was considered to be impractical for reasons that are explained in the notes to the table].

The most significant change is the adoption of a more consistent statistical approach to the selection and the number of sampling locations; and the evaluation of the data collected. The statistical model is based on adaptation of the hypergeometric sampling model technique, where samples are drawn randomly without replacement from a finite population. The new approach allows each location to be treated independently with at least a 95 % level of confidence that at least 90 % of the cleanroom or clean zone areas will comply with the maximum particle concentration limit for the target class of air cleanliness. No assumptions are made regarding the distribution of the actual particle counts over the area of the cleanroom or clean zone; while in ISO 14644-1:1999 an underlying assumption was that the particle counts follow the same normal distribution across the room, this assumption has now been discarded to allow the sampling to be used in rooms where the particle counts vary in a more complex manner. In the process of revision it has been recognized that the 95 % UCL was neither appropriate nor was applied consistently in ISO 14644-1:1999. The minimum number of sampling locations required has been changed, compared with ISO 14644-1:1999. A reference table, Table A.1, is provided to define the minimum number of sampling locations required based on a practical adaptation of the sampling model technique. An assumption is made that the area immediately surrounding each sampling location has a homogeneous particle concentration. The cleanroom or clean zone area is divided up into a grid of sections of near equal area, whose number is equal to the number of sampling locations derived from Table A.1. A sampling location is placed within each grid section, so as to be representative of that grid section.

It is assumed for practical purposes that the locations are chosen representatively; a "representative" location (see A.4.2) means that features such as cleanroom or clean zone layout, equipment disposition and airflow systems should be considered when selecting sampling locations. Additional sampling locations may be added to the minimum number of sampling locations.

Finally, the annexes have been reordered to improve the logic of this part of ISO 14644 and portions of the content of certain annexes concerning testing and test instruments have been included from ISO 14644-3:2005.

The revised version of this part of ISO 14644 addresses the ≥ 5 µm particle limits for ISO Class 5 in the sterile products annexes of the EU, PIC/S and WHO GMPs by way of an adaptation of the macroparticle concept.

The revised version of this part of ISO 14644 now includes all matters related to classification of air cleanliness by particle concentration. The revised version of ISO 14644-2:2015 now deals exclusively with the monitoring of air cleanliness by particle concentration.

Cleanrooms may also be characterized by attributes in addition to the classification of air cleanliness by particle concentration. Other attributes, such as air cleanliness in terms of chemical concentration, may be monitored and the attribute's grade or level may be designated along with the classification of the ISO Class of cleanliness. These additional attributes do not suffice alone to classify a cleanroom or clean zone.

ISO 14644-2:2015
Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

Introduction
This revision of ISO 14644-2 emphasizes the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of a cleanroom or clean zone in accordance with ISO 14644-1:2015, 5.1. The monitoring activity provides a continuing flow of data over time, thereby providing a more detailed view of the performance of the installation.

Potential benefits gained from monitoring are

— faster response to adverse events and conditions,
— ability to develop trends from data over time,
— integration of data from multiple instruments,
— enhanced knowledge of installation and process, which allows for more effective risk assessment, and
— improved control of operational costs and product losses.

ISO 14644-2 specifies the requirements of a monitoring plan, based on risk assessment of the intended use. The data obtained provide evidence of cleanroom or clean zone performance related to air cleanliness by particle concentration.

In some circumstances, relevant regulatory agencies may impose supplementary policies, requirements or restrictions. In such situations, appropriate adaptations of the monitoring procedures may be required. After a monitoring plan is initially established and implemented, it may be necessary to revise the plan when significant changes are made to the installation or process requirements. It is also prudent to conduct periodic reviews of a monitoring plan based on data obtained and experience in use.

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