The ISO contamination control standards

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Adapted by W. Whyte from a publication in European Journal of Parenteral Sciences 2003, Volume 8(2) pages 37-42, with their kind agreement

The elaboration of international standards for cleanroom technology is a joint effort of ISO, the International Organization for Standardization and CEN, the European Committee for Standardization. This paper gives a brief review of the objectives and guidance principles for work of ISO/TC 209, the Technical Committee responsible for the development of these standards, and then their present status of development will be assessed.

International cleanroom standards – why?

Until a decade ago, standardization and guidance work in cleanroom technology was handled almost exclusively by national bodies. This led ultimately to a grand total of more than 350 national standards and guidelines[1, 2]. For enterprises serving the world market via production facilities spanning the entire globe, this was a most inconvenient situation: for each site, a different set of rules had to be observed. This situation was no less unsatisfactory for the designers and builders of clean facilities: undesirable and counter-productive technical barriers to trade were to be overcome.

An international family of contamination control standards is now emerging, and ready to serve globally minded industries. The benefits they offer are indeed welcome: internationally agreed definitions, quality determinations such as air cleanliness classification, basic criteria for design, construction, start-up and operation of cleanrooms, for measurement procedures and many other topics. As an important side effect, they will also help to eliminate technical barriers to trade.

International standardisation – objectives and procedures

In the field of cleanroom technology, international harmonisation of standards is driven by two entities:

- on a European level by **CEN**, the **European Committee for Standardization**;
- on a totally global level by **ISO**, the **International Organization for Standardization**.

ISO, established in 1947, is a worldwide confederation of national standards bodies - one per nation - and it comprises at present 146 members[3], both technically developed nations and nations in development. Of these, 94 are full members enjoying voting rights, the remaining member bodies being correspondent and subscriber members. The scope of activities covers all kinds of technical standardization except electrical engineering and electronics. Its objective is to promote standardization on a world wide basis: it aims at facilitating international exchange of goods and services, and at developing co-operation in the spheres of intellectual, scientific, technological and economic activity. ISO is independent from the various political and economical blocks in existence throughout the world.

CEN, on the other hand, has been established in 1975 as a common organ of the **European Community** (now **European Union EU**) and the **European Free Trade Association EFTA**. Its objective is the elimination of technical barriers to trade between the CEN member nations through

harmonisation of the European technical standards. Its scope of work is identical with that of ISO. Presently, it embraces the 18 standardization bodies of the EU and EFTA nations plus those of the Czech Republic, Hungary, Malta and Slovakia. The other nations now applying for EU membership are expected, and indeed required, to join before long.

ISO and CEN have harmonised their standardization activities to the widest possible extent through the **Vienna Agreement on Technical Co-operation between ISO and CEN**. It entered into force in 1991 and establishes procedures for the mutual recognition of standards developed within one or the other of the two organisations.

What is the impact of this agreement on mutual recognition of standards? If ISO and CEN agree on the development of standards for a given technical field, the ISO and CEN approval procedures will be triggered in parallel. If through this procedure a standard is approved on ISO level, it will be published in the ISO collection of standards as **International Standard**. Each nation is then free to decide whether it wishes also to include it in its own national collection of standards. If the standard has also been approved during the parallel CEN voting, then **all CEN nations are bindingly obliged** to include this standard into their national standards collections as **European Standards**. Furthermore, all national standards conflicting with the European Standard thus adopted must be withdrawn, and no new national standards on the same subject may be elaborated henceforth.

International cleanroom standards: the first steps

The first step towards international harmonisation of standards in the field of contamination control technology took place in 1990: the establishment of the European Technical Committee **CEN/TC 243: Cleanroom Technology**. Its dynamic style and the speedy progress of work was recognised throughout the contamination control world, and soon paved the way for a proposal by the *United States of America* to upgrade these efforts to a truly international level. Thus, the International Technical Committee **ISO/TC 209: Cleanrooms and associated controlled environments** was launched in 1993 - a mere three years after CEN/TC 243 had been created. Without much delay, a common approach to cleanroom technology standardization was agreed between ISO and CEN. As a consequence, the CEN activities were fully integrated into the ISO effort, so that the parallel approval procedures as established by the *Vienna Agreement* apply. This gives tremendous weight to the standards thus approved, as the inclusion into 20 national collections of standards is guaranteed right from the beginning. No better point of departure for broad international recognition can be imagined.

Scope and guidance principles for work

The ISO cleanroom standards are intended to cover all relevant aspects of contamination and biocontamination control technology. For their development, the following general guidance principles have been agreed:

- The series of standards to be developed shall address only subjects of general applicability to all cleanroom usage areas.
- Application-specific standardisation remains outside the brief of ISO/TC 209.
- The standards to be prepared should be target oriented and establish objectives to be met.
- As much freedom as possible should be granted regarding the path leading to the goal.
- The standards should promote and encourage progress, rather than impeding it.
- The standards should contribute to the elimination of technical barriers to trade, and promote understanding between nations.
- The standards should neither favour nor prejudice individual nations.

Target orientation ensures maximum freedom regarding the path how the target is reached, providing an automatic incentive for technical progress.

Table 1: The working groups of ISO/TC 209 and their allotment of convenorship

Secretariat: IEST/USA (on behalf of ANSI) **Chairman:** Richard A. Matthews		
Working Group	**Short title**	**Convenorship**
WG 1	**Air cleanliness classification**	**BSI / United Kingdom**
WG 2	**Biocontamination control**	**BSI / United Kingdom**
WG 3	**Metrology and test methods**	**JISC / Japan**
WG 4	**Design, construction and start-up**	**DIN / Germany**
WG 5	**Operations**	**ANSI / USA**
WG 6	**Terms and definitions**	**SNV / Switzerland**
WG 7	**Clean air hoods, glove boxes, isolators, minienvironments**	**ANSI / USA**
WG 8	**Molecular contamination**	**BSI / United Kingdom**
WG 9*	**Surface cleanliness**	**SNV / Switzerland**

* **in formation**

The individual standards are elaborated by internationally composed Working Groups (**Table 1**; the national standardization bodies entrusted with convenorship are identified in brackets). Each nation, as a rule, is represented by a single, highly competent professional. In their personal composition, the Working Groups should combine the expertise of designers, constructors and users. Membership should comprise not only the highly developed, but also the emerging nations: their role in cleanroom technology is constantly increasing. A broad base in competence and experience – gained under most differing circumstances – forms the background for the technical deliberations and ensures a high quality level of the determinations arrived at. This quality level is further enhanced by the requirement of consensus decisions on Working Group level. This serves to eliminate vague and prejudiced determinations from the drafts and this is a most important factor for ensuring future acceptance of the standard by the world's community of professionals. Also furthering acceptance is, of course, the democratically transparent approval procedure established for the ISO and CEN standardization effort.

The present status of international cleanroom standardisation

Table 2 summarises the present state of development of the international cleanroom standards.

Table 2: ISO/TC 209: Cleanrooms and associated controlled environments: Standards in development

Document-No.	**Short Title**	**Status 04.03**
ISO 14644-1	**Air cleanliness classification**	**Std. 05.99**
ISO 14644-2	**Specification for testing cleanrooms to prove continued compliance with ISO 14644-1**	**Std. 09.00**
ISO 14644-3	**Metrology and test methods**	**DIS 09.02**
ISO 14644-4	**Design, construction and start-up**	**Std. 04.01**
ISO 14644-5	**Operations**	**DIS 07.01**
ISO 14644-6	**Terms and definitions**	**CD 06.01**

ISO 14644-7	**Clean air hoods, glove boxes, isolators, minienvironments**	**DIS 02.01**
ISO 14644-8	**Classification of molecular contamination**	**CD 12.02**
ISO 14698-1	**Biocontamination control: General principles and measurement of biocontamination of air, surfaces, liquids and textiles**	**FDIS 04.03**
ISO 14698-2	**Biocontamination control: Evaluation and interpretation of biocontamination data**	**FDIS 04.03**
ISO 14698-3	**Biocontamination control: Measuring the efficiency of cleaning and disinfection processes for inert surfaces**	**DIS 02.99**

The standardization effort is split into two families of standards:

- the **ISO 14644 series** covering general contamination control topics;
- the **ISO 14698 series** on biocontamination control issues.

The colum*n 'Status 04.03'* in *Table 2* identifies the actual state of approval of each work item on the 12th February 2003, the approval procedure being subdivided into three stages:

- an informal circulation as **Committee Draft CD**, with the objective of inviting technical comments from the nations actively involved in the ISO/TC 209 work;
- a first formal circulation as **Draft International Standard DIS** for the parallel **ISO** and **CEN enquiry**, inviting technical and editorial comments and requesting a generic statement on the merits of the draft by means of a preliminary vote;
- and finally the second formal circulation as **Final Draft International Standard FDIS**, for the parallel **ISO** and **CEN voting** leading – if successful – to approval and subsequent publication in the ISO and CEN collections of standards.

As is evident, three documents have already achieved the status of formally approved International and European Standards, and others are to follow soon.

In addition to the work items listed in *Table 2*, work is soon to commence on an international standard devoted to the important issue of *surface cleanliness*, and an ad-hoc task force has recently been established by ISO/TC 209 for assessing whether the subject of *cleanroom garments* also merits the elaboration of an international standard.

The impact of the ISO standards on contamination control practice

What is the impact of the new ISO family of cleanroom technology standards upon industry? From DIS status onwards, these standards:

- are publicly and freely available and can be purchased through the national standardisation bodies and their outlets;
- can be used as reference documents and as base documents for projects and for customer/supplier agreements;
- are considered to represent the state-of-the-art in any legal dispute.

Therefore, from DIS status onwards, these international standards merit priority over national standards and over guidelines and recommended practices elaborated by professional societies. With 9 international cleanroom standards now in the DIS stage and beyond, a comprehensive collection of guidance documents is already available to serve industry.

Air cleanliness classification according to ISO 14644-1

It had been common practice throughout industry to classify cleanrooms according to **U.S. Federal Standard 209 E**[4]. This standard has, however, been officially withdrawn, on 29 November 2001, by the *General Services Administration* of the U.S. Government. Its nominated replacements are **ISO 14644-1**[5] for air cleanliness classification and **ISO 14644-2**[7] for proving continued compliance of a cleanroom with ISO 14644-1. This event definitely marks the breakthrough of the ISO air cleanliness classification scheme.

The air cleanliness classification scheme according to ISO 14644-1 is distinguished by a mathematically coherent approach and based upon a formula:

$C_n = 10^N (0{,}1/D)^{2{,}08}$

where

C_n = maximum number concentration of particles per m^3 with diameter ≥ the considered particle diameter, rounded to a maximum of 3 digits;

N = ISO classification number;

D = considered particle diameter;

0,1 = the reference diameter, a constant with the dimension μm.

Table 3 shows the ISO class limits in tabular form.

Table 3: Air cleanliness class limits according to ISO 14644-1 in tabular form

ISO classification number	Maximum concentration limits (particles/m^3 of air) for particles of the considered sizes shown below					
N	≥ 0,1 μm	≥ 0,2 μm	≥ 0,3 μm	≥ 0,5 μm	≥ 1 μm	≥ 5 μm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

With the selection of **0,1 μm** as the **reference particle diameter** for air cleanliness classification purposes a very straightforward denomination scheme results - thus overcoming elegantly the principal drawback of the metric air cleanliness classes according to the now defunct U.S. Federal Standard 209E. Simple, single-digit class denominations now correspond with the traditional classes of said standard: ISO 5, for example, replaces class 100 (U.S. metric class M 3.5), and ISO 8 substitutes class 100 000 (U.S. metric class M 6.5).

The range of particle diameters for air cleanliness classification extends from 0,1 to 5 μm. Thus, it is focussed upon the detection capabilities of the **discrete-particle counter** which has been

identified as the **reference test method** for demonstrating compliance with ISO 14644-1. These tests shall be conducted with calibrated instruments.

The **exponent 2,08** of the correlation between particle concentration and particle diameter ensures the best possible coincidence with the particle concentrations according to U.S. Federal Standard 209E at that standard's reference particle diameter of 0,5 µm. Thus, a harmonious connection to previous generations of standards is assured, and reclassification of existing cleanrooms according to the ISO determinations is very straightforward.

Class limits must be met with the rigours of the 95 % upper confidence limit.

The remaining parts of the ISO 14644 series - an overview

The following compilation is intended as a highly concentrated insight into the contents of the remaining standards of the ISO 14644 series on general cleanroom technology.

ISO 14644-2[6] establishes the minimum requirements for reclassification and requalification work as well as the minimum time intervals between subsequent reclassifications. Periodical reclassifications are recommended in intervals of 6 months for areas classified ISO Class 5 or better, and 12 months for all other classified areas. The interval between reclassifications can be extended in case of continuous performance monitoring of the installation.

ISO/DIS 14644-3[7] provides most welcome guidance for the acceptance and qualification tests of physical parameters as well as for the corresponding measuring activities related to process monitoring. It covers a total of 14 measurement tasks (**Table 4**) such as particle counting, air velocity measurements, filter integrity tests, flow visualisation and the measurement of recovery times. In addition, the minimum performance requirement for the test instruments are specified systematically.

Table 4: Measuring parameters covered by ISO/DIS 14644-3

Annex no.	Measuring parameter
B. 1	Airborne particle count for classification and test measurement of cleanrooms and separative devices
B. 2	Airborne particle count for ultrafine particles
B. 3	Airborne particle count for macroparticles
B. 4	Airflow test
B. 5	Air pressure difference test
B. 6	Installed filter system leakage test
B. 7	Airflow visualisation
B. 8	Airflow direction test
B. 9	Temperature test
B. 10	Humidity test
B. 11	Electrostatic and ion generator test
B. 12	Particle deposition test
B. 13	Recovery test
B. 14	Containment leak test

ISO 14644-4[8] offers, for example, very comprehensive guidance for approval and qualification of cleanrooms. Another highlight of ISO 14644-4 is a systematic compilation of all the determinations having to be agreed between customer and supplier during design and development of a cleanroom system. It is condensed into a comprehensive checklist covering 12 subject areas with a grand total of 151 items! If the design activities are cross-checked with its help, it is almost impossible that something of importance has been overseen!

ISO/DIS 14644-5[9] addresses the operational aspects of cleanrooms with a focus on the principal hazards: cleanroom clothing, personnel, stationary equipment, materials as well as portable and mobile equipment, and cleanroom cleaning. A specific Annex is devoted to each of these risk areas; education and training is identified as a key factor in controlling the hazards capable of prejudicing cleanroom operation.

ISO/CD 14644-6[10] is devoted to terms and definitions. In this document, all terms and definition used in the other standards prepared under the auspices of ISO/TC 209 will be compiled. For this reason, this standard can only be finalised when work on all these other standards has been terminated. This fact causes no problems for the readability of these other standards: presently, each of them contains a compilation of the definitions relevant for it.

ISO/DIS 14644-7[11] addresses the generic and application-neutral requirements on clean air hoods, gloveboxes, isolators and mini-environments. Guidance is limited to issues not covered in ISO/DIS 14644-3 and ISO 14644-4, for example isolator-specific measurement tasks such as integrity testing of containments and glove-sleeve systems. This draft is presently being readied for the formal FDIS vote.

ISO/CD 14644-8[12] addresses molecular contamination, i.e. the contamination risks caused by airborne molecules - an area of utmost relevance in microelectronics and aerospace, but so far of less impact for the pharmaceutical industry. This standard will focus on classification as well as on measurement and analysis issues. Four classes of compounds are distinguished: acids, bases, organics and inorganics; and five contaminant categories: biotoxics, condensables, corrosives, dopants and oxidants.

The biocontamination control standards reviewed

Under this heading, a brief summary of the contents of the ISO 14698 series of biocontamination control standards is compiled.

ISO/DIS 14698-1.2[13] is devoted to the general principles of the measurement of biocontamination. It provides guidance on the measurement of airborne biocontamination as well as of the biocontamination of surfaces, textiles and liquids. It also covers the validation of air sampling and of laundering processes. In addition, the subject of personnel training is briefly addressed. As initial acceptance of this draft was lukewarm, it had to be submitted twice to the DIS enquiry procedure. It has since passed the second enquiry successfully and has recently been circulated for the formal FDIS vote.

ISO/DIS 14698-2[14] on evaluation and interpretation of biocontamination data has also recently been submitted to the formal FDIS vote.

ISO/DIS 14698-3[15] on the measurement of the efficiency of processes of cleaning and/or disinfection of inert surfaces bearing biocontaminated wet soiling or biofilms limits itself to the description of a single assessment procedure. This highly specialised document was deemed by ISO/TC 209 to be of limited interest only to the contamination control community as a whole. It will therefore not proceed into FDIS voting. Instead, it will be published, as soon as ISO 14698-1 and -2 have been formally approved, as an ISO Technical Report.

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NOTE: All EN ISO and ISO standards referred to above are available from S2C2