

제18차 ISO/TC209 Meeting 참석결과 보고

안강호 | 한양대학교 기계공학과
교수

1. 회의 장소 : 중국 북경
2. 회의 날짜 : 2006년 9월 8 - 9일
3. 참석국 : 한국, 미국, 일본, 영국, 독일, 프랑스,
중국, 브라질, 스웨덴, 러시아, 스위스
4. 회의(출장) 일정
2006. 9. 7(목) : 인천 국제공항 출발
2006. 9. 8(금) : ISO/TC209 총회 참석
2006. 9. 8(금) : 인천공항 도착

5. 주요 회의내용 및 의결사항

■ ISO/TC209 총회

1. Welcome 인사 : ISO/TC209 새 의장(David E. Brande, Director, NNE US Inc., 7868 US Hwy 70 West, Clayton, NC 27520, USA : dvib@nne.dk ; www.nne.biz) 인사
2. Roll call of Delegates
3. Adoption of the agenda [첨부1]
4. Appointment of the drafting committee
5. Report of the seventeenth meeting of ISO/TC209(September 2005, Moscow, Russian Federation)
 - 5 resolutions
 - Swiss : #3 resolution에 대한 이견제의: rejected by Secretariat
 - 전원 일치로 Moscow minutes 채택

6. Report of the Secretariat : report by B. Mielke[첨부2]

현재 표준화 진행 상황

- ISO14644-1 : 표준임. 5년이 경과하여 revise 하는 중.
- ISO14644-2 : 표준임. 5년이 경과하여 revise 하는 중.
- ISO14644-3 : 2005년 12월에 표준으로 채택됨.
- ISO14644-4 : 표준임. 현재 체계적으로 review 중임. 2006년9월7일에 투표완료.
- ISO14644-5 : 표준임.
- ISO14644-6 : 2006년 8월31일에 ISO 본부에 FDIS투표를 위해 제출
- ISO14644-7 : 표준임
- ISO14644-8 : 표준임, 2006년 8월 15일에 발효.
- ISO/WD 14644-9 : draft를 New Work Item 과 함께 현재 작업중임
- ISO14698-1 : 표준임
- ISO14698-2 : 표준임

7. Review and progress reports of working groups

- 7.1 WG1 :
 - 2005년 7월부터 작업시작. 2008년 10월에 완료 예정

- 2006년 6월 Stockholm의 Swedish Standard 에서 WG1 회의
- 2006년 9월 북경에서 WG1회의
- 지금까지 회의 결과
- * Classification Table 1의 0.3, 0.5, 1.0 μ m에서 2, 4, 8개의 입자로 표시되어 있는데 현장에서 사용시 문제가 있어 이에 대한 정의를 없애거나, 10과 같은 2자리수로 표시하기를 원함.
- 14644-1의 Informative annex A의 1 particle/ m^3 = ISO3.5, 20particle/ m^3 = ISO4.8과 같은 소수점 class에 대한 문제
- * Sample location 수에 대한 변경
- * B.5.2의 T-test사용보다는 sample 수를 늘려 T-test사용을 안 할 수 있도록 검토
- * Annex F Sequential sampling, Fig. F. 1의 사용이 어려워 예제 삽입예정
- 14644-2
 - Testing and Monitoring의 문제 => improve the explanation
 - Table of test frequencies
 - Real-time Monitoring System
 - Specify the essential requirements of such systems that should be considered
 - Annex B, Risk Assessment
 - Remove this Annex -> Aspects of Risk Assessment to be in main text
- WG1 Timeline
 - Oct. 2008 ~ Jan. 2009 : Target Publication
 - CD by Sept. 2006-10-05
 - DIS by Mar. 2007
 - FDIS by Jan. 2008
 - WG1에서 가장 어려운 것 : Data 분석, 샘플 location 수, 통계처리 문제
 - WG2 : Dr. White ISO14698 revision Proposal 을 내고, UK가 간사국이 됨. 포르투갈, 미국, 일본, 프랑스, 스웨덴, 독일, 중국(?) 이 참여예정 [첨부3]
 - WG3 : No meeting since last year's general meeting
 - WG4 : No meeting. No vote results yet.
 - WG5 : Nothing is taking place.
 - WG6 : Particle에 대한 정의가 2가지인데 이를 하나로 함.
 - Nanoparticle에 대한 정의가 모호함. TC229와 같이 검토
 - 번역에 대한 문제 : 예) frequently
 - WG8 : Surface contamination control (SCC) 로 개명
 - 4th meeting: Nov. 21, 2006
 - CD on early 2007
 - WG9 : Clean Surfaces : Swiss - convener (Werner Straub)
 - Measurement methods
 - Cleaning methods
 - Other informative elements
 - 2documents (Surface particle classification including test method, Surface cleaning)
 - WG8 and WG9 will work together

<첨부 1>

**International Organization for Standardization/Technical
Committee 209 (ISO/TC209)
Cleanrooms and Associated Controlled Environments**

**AGENDA
8-9 September 2006**

1. Opening of the meeting (1000 hours Friday, 8 September 2006, Beijing, China)
 - 1.1 Welcome from the Chinese Delegation
2. Introductions of those present
 - 2.1 Roll call of delegates
3. Adoption of the agenda
4. Appointment of the drafting committee
5. Report of the seventeenth meeting of ISO/TC209(September 2005, Moscow, Russian Federation)
6. Report of the Secretariat
7. Review and progress reports of working groups
 - 7.1 WG 1-Airborne particulate cleanliness classes, Convenor:UK
 - 7.2 WG 2-Biocontamination, Convenor:UK
 - 7.3 WG 3-Metrology and test methods, Convenor: Japan
 - 7.4 WG 4-Design and construction, Convenor: Germany
 - 7.5 WG 5-Cleanroom operations, Convenor: USA
 - 7.6 WG 6-Terms, definitions, and units, Convenor: Switzerland
 - 7.7 WG 7-Enhanced cleaning devices, Convenor: USA
 - 7.8 WG 8-Molecular contamination, Convenor: UK
 - 7.9 WG 9-Clean surfaces, Convenor: Switzerland
8. Relationships between ISO/TC209 and other groups/organizations(liaisons)
 - 8.1 CENTC 243
 - 8.2 ISO/TCs (TC 229, TC 198, and TC 142)
 - 8.3 ICCCS
 - 8.4 CEN/TCs
9. Any other business
10. Requirements concerning a subsequent meeting
11. Approval of resolutions
12. Closure of meeting(1500 Saturday, 9 September 2006)

<첨부 2>

ISO Technical Committee 209

Secretary's Report - 8 September 2006

Current documents status

ISO 14644-1 : Standard. To be revised. WG 1 is working on a revision for this Part of the standard. WG 1 will give their report on the status at this meeting.

ISO 14644-2 : Standard. To be revised. WG 1 is working on a revision for this Part of the standard. WG 1 will give their report on the status at this meeting.

ISO 14644-3 : Standard. Published 15 December 2005.

ISO 14644-4 : Standard. Undergoing Systematic Review, vote closed 7 September 2006.

ISO 14644-5 : Standard.

ISO/FDIS 14644-6 : Submitted on 31 August 2006 By the Secretariat to ISO for FDIS vote.

ISO 14644-7 : Standard.

ISO 14644-8 : Standard. Published on 15 August 2006.

ISO/WD 14644-9 : WG 9 will report on their status on the document at this meeting. They are continuing to work on a draft to submit along with the New Work Item submission.

ISO 14698-1 : Standard.

ISO 14698-2 : Standard.

Submitted By : Rebert L. Mielke
Secretary, ISO/TC 209

<첨부 3>

Proposals for the Revision of ISO 14698

The standard

ISO 14698 consists of two parts under the general title 'Cleanrooms and Associated Controlled Environments-Biocontamination Control' :

Part 1 : General principles and methods. This gives information on how to establish a risk management system, methods for measuring micro-organisms in the cleanroom, and validation methods for air samplers and washing clothing.

Part 2 : Evaluation and interpretation of biocontamination data. This gives information on how to deal with the results obtained from measuring micro-organisms in a cleanroom.

The background to the writing of the standard

At the start of the writing of these standards the French held the Secretariat. It was then transferred to the UK. Despite the years spent in writing, the standards are considered by many never to have been fully completed. The UK considered that the cleanroom industry would have a problem understanding and implementing the standard, and therefore would not use it. This has proved to be correct.

The problem with the content of the standard

The problem with the content of the ISO 14698 standards is considered to be as follows :

ISO 14698-1 : This standard should describe a risk system for use in a cleanroom. However, what it actually gives is a brief summary of the principles of the HACCP system(in less than a page), and devotes most of the remainder of the standard to inadequately describing methods for sampling the surface, air and liquids in cleanrooms, and giving validation methods for checking the efficiency of washing clothing, and air samplers (but not surfaces or liquid sampling methods).

ISO 14698-2 : This standard should describe how to deal with the results obtained from microbial sampling. However, it gives little information on how to statistically analyse results.

The proposed revision of the standard

It is suggested that the standard be revised along the following lines :

ISO 14698-1 : It is suggested that this standard should be further divided into two parts:

Part 1 should be written to describe risk management and risk assessment methods that can be used in biocleanrooms. The present ISO 14698-1 is based on the HACCP system, which was written for use with the food industry but is inadequate for use in pharmaceutical and other bio-cleanrooms. Risk systems have evolved considerably since this edition of the standard was first considered and more appropriate systems are now available e.g. Parenteral Society Monograph No. 14 on Risk Management Control. These should be used as the basis of the standard.

Part 2 : This should give standard methods for sampling the cleanroom environment i.e. the air, surface and liquids. It will probably be necessary to give choice of methods. Methods should also be given to validate the sampling methods i.e. establish their efficiency and so avoid inefficient methods being used that allow inadequate cleanrooms to appear to achieve the correct standard. Consideration should be given to whether the method for validating the washing of clothing should be included in this standard.

ISO 14698-2 : the writing should be clarified and include more advice on available statistical methods that can be used to analyse the sampling results.

It is considered that if these, or similar, revisions are made to these standards they will become more acceptable, useful, and will therefore be used by the cleanroom industry. The revision of this standard would occur in 2008. It is suggested that because of the urgent need to improve these standards, preliminary moves should be made so that an early start can be made on the revision of these standards.