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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (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	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 5371

Containment high efficiency filtration unit (CHEFU) in ventilation system of biosafety facilities

ICS: 91.140.30

ISO/TC 142

Secretariat: **UNI**

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2024-07-18

Voting terminates on:
2024-10-10

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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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 142, *Cleaning equipment for air and other gases*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

In laboratories and facilities dealing with critical or hazardous biological materials, such as biosafety laboratories, vaccine manufacturing facilities and animal laboratory facilities, the removal of airborne bio-aerosols in the facilities that are released to the surrounding environment is always a major concern. In general, especially designed air cleaning devices, also called, Containment high efficiency filtration unit (CHEFU), are used for such purpose. Currently, there are two main types of CHEFU commercially available. One is CHEFU-OT which is installed at the room outlet of the exhaust system. The other is CHEFU-DT which is installed within the duct of the exhaust system. For CHEFU-OT, the required maintenance such as the decontamination and replacement of filters, are performed in the containment room, e.g., the high-level biosafety lab. For CHEFU-DT, all maintenance activities can be performed in the low-risk servicing area and special design for in-situ decontamination or containment filter replacement measures will be needed. This international standard provides suppliers and users basic performance requirements and test methods to validate the performance of the devices.

In addition, information is given in a number of annexes:

- [Annex A](#) describes the normative air tightness test method for CHEFU, the pressure decay method.
- [Annex B](#) gives an informative airtightness test method for CHEFU with cycling pressurised conditioning of the test device.
- [Annex C](#) describes the normative aerosol concentration uniformity test procedure.
- [Annex D](#) describes the information of the methodology verification procedure for the in situ decontamination of CHEFU.

Containment high efficiency filtration unit (CHEFU) in ventilation system of biosafety facilities

1 Scope

This document aims to provide basic performance requirements and corresponding test methods for containment high efficiency filtration units. This document is applicable to the devices used to remove harmful bio-aerosol in biosafety facilities and similar controlled environment. This document is not applicable to Filtration Unit for removing radioactive aerosol.

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 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10648-2:1994, *Containment enclosures — Part 2: Classification according to leak tightness and associated checking methods*

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 21501-1, *Determination of particle size distribution — Single particle light interaction methods — Part 1: Light scattering aerosol spectrometer*

ISO 21501-4, *Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces*

ISO 29463-1, *High Efficiency Filters and Filter Media for Removing Particles from Air — Part 1: Classification, performance, testing and marking*

ISO 29463-5, *High-efficiency filters and filter media for removing particles in air — Part 5: Test method for filter elements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 29463-1, ISO 29463-2, ISO 29463-3, 29463-4 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

containment high efficiency filtration unit

CHEFU

filtration unit used in specific biological risk environment to remove harmful bio-aerosol in the air