

ISO Process and Standards Under Development

S.C. Nichols
7 November 2006

ISO Principles

“ISO standards are developed according to the following principles:

- **Consensus**
The views of all interests are taken into account: manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organizations.
- **Industry-wide**
Global solutions to satisfy industries and customers worldwide.
- **Voluntary**
International standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place.”
(From <http://www.iso.org>)

“Enforcement” and application of ISO standards depends on national laws and regulations in each country.

ISO Members

“A member body of ISO is the national body "most representative of standardization in its country". Only one such body for each country is accepted for membership of ISO. Member bodies are entitled to participate and exercise full voting rights on any technical committee and policy committee of ISO.”

To get actively involved in the ISO process, you should approach and become a member of your country's national standard-setting organization, e.g.

- Canada: Standards Council of Canada (CSS)
- Germany: Deutsches Institut für Normung (DIN)
- Great Britain: British Standards Institution (BSI)
- USA: American National Standards Institute (ANSI)
- etc.

(From <http://www.iso.org>)

ISO Process

International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a six step process:

- Stage 1: Proposal stage (new work item proposed to ISO)
- Stage 2: Preparatory stage (working draft is prepared by a group of experts)
- Stage 3: Committee stage (draft is commented on and approved by TC)
- Stage 4: Enquiry stage (voting and comments by ISO members – national standards agencies)
- Stage 5: Approval stage (yes/no voting by ISO members)
- Stage 6: Publication stage (of the Official ISO Standard)

(based on: <http://www.iso.org/iso/en/stdsdevelopment/whowhenhow/proc/proc.html>)

B----- 3 years ----- à

STAGE 0 PWI	STAGE 1 NP	STAGE 2 WD	STAGE 3 CD	STAGE 4 DIS	STAGE 5 FDIS	STAGE 6 ISO
Preliminary Work	New work Item / Draft Docs	Working Draft	Committee Draft	Draft Intl. Standard	Final Draft Intl. Standard	Publication

Requirements for Globally Relevant Standards

- Respond to global regulatory and market needs
- Have no adverse effects on fair competition
- Gain the commitment and participation of all interested parties
 - Manufacturers
 - Users
 - Test houses and notified bodies
 - Regulators
 - Developed and developing countries
- Do not stifle innovation and technological development
- Should be performance based as opposed to design prescriptive
 - Horizontal as opposed to vertical approach
 - Fewer revisions
 - Fewer commercial conflicts

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Relevant ISO Standards Under Development

1. Aerosol drug delivery devices — Requirements and test methods

Being developed by Technical Committee 84
“Devices for Administration of Medicinal Products and
Intravascular Catheters”
Working Group 5 “Pulmonary Delivery Devices”

2. Anaesthetic and respiratory equipment - Respiratory therapy devices - Part 1: Nebulizer systems

Being developed by Technical Committee 121
“Anaesthetic and respiratory equipment”
Subcommittee 2 “Tracheal tubes and other equipment”

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ADDD Standard (ISO CD 20072)

- Scope: MDIs, DPIs, nasal sprays, etc. (i.e., everything except nebulizers)
 - "This international standard applies to performance and testing requirements for hand-held single-use and multiple-use aerosol drug delivery devices (ADDD) intended to deliver metered or pre-metered aerosolized medicinal product to or by means of the human respiratory system."
- Out of scope: nebulizers
 - "Continuous or semi-continuous aerosolization devices covered in EN 13544-1, aerosolization devices which do not emit API, general purpose aerosolization devices (for use with ventilators, nebulizers and atomizers)."
- Objective: Design Verification of Aerosol Drug Delivery Devices (ADDD)
 - "The objective of the standard is to verify that the design of the ADDD consistently meets the manufacturer's device requirements and performance profile for delivery to or by means of the respiratory tract as determined by a risk assessment"
- Focus: Inhaler as a device (not drug product)
- Philosophy: Manufacturer conducts Risk Assessment and develops a Performance Profile, which would be tested against this standard
- Likely to be finalized as ISO standard in 2007-2008

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ADDD Standard (cont'd)

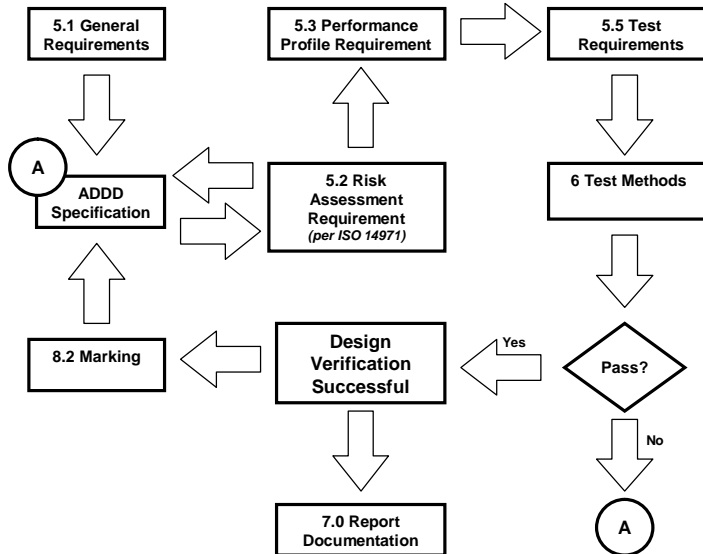
- A risk assessment is conducted by the manufacturer,
- From which a performance profile is created.
 - The performance profile shall include at least the determination of emitted mass and appropriate size distribution .
- The design shall be verified across an appropriate range of operational and environmental conditions.
- A table is provided in the standard, as a menu for the device developer to select appropriate tests.
- Detailed test methods are NOT provided.
- The standard recognizes the wide variety of portable inhalers on the market and under development

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Flow Process for ADDD Standard (ISO CD 20072)



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ADDD Standard (ISO CD 20072): Table of Contents

<u>DRAFT: Table of Contents</u>	
-1-	-2-
1. Scope	7. Test Report
2. Normative References	8. Information supplied by Manufacturer
3. Terms and Definitions	<ul style="list-style-type: none"> • General • Marking • Instructions for Use
4. Symbols and Abbreviated Terms	Informative Annexes
5. Requirements:	Bibliography
<ul style="list-style-type: none"> • General Requirements • Risk Analysis Requirement • Performance Profile Requirement • Test Requirements 	
6. Test Methods	

Ref N49: Sept 2003

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TC121/SC2 Nebulizer Standard, (ISO CD 27427)

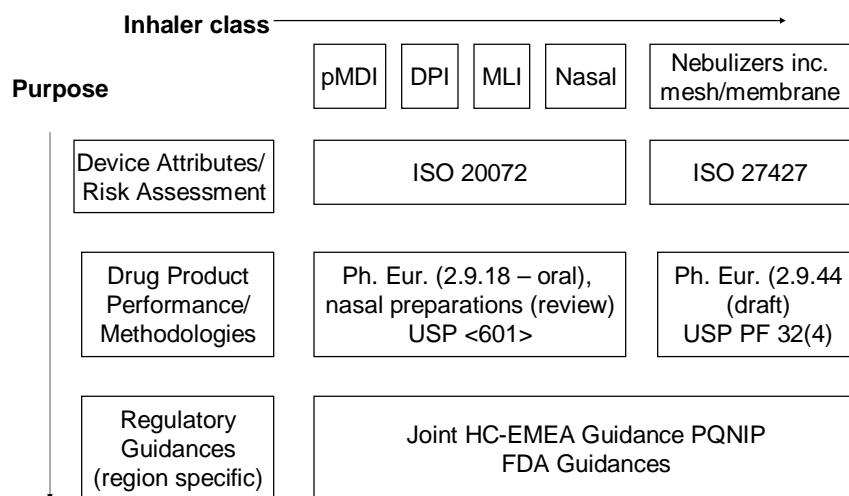
- 'Anaesthetic and respiratory equipment - Respiratory therapy devices - Part 1: Nebulizer systems
- Developed out of CEN Standard 13544:2001 – nebulizers.
- Subcommittee discussed this twice, a draft will be sent to national bodies for comment later this year.

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Hierarchy of Regulatory and Other Standards



Based on a slide courtesy of Jolyon Mitchell, member of TC84/WG5 and TC 121/SC2

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Questions?

- Further details to be discussed in today's Breakout Session
- Track D (4:00-4:45 PM and 4:45-5:30 PM; Tuesday, 11/7/2006)
 - "Progress Report and Q&A on ISO Standards for MDI/DPI and Nebulizers
 - Moderators:
 - *Ann A. Graham, Branch Chief, Anesthesiology & Respiratory Devices Branch, US Food and Drug Administration*
 - *Hal Yeager, Sr. Regulatory Advisor, Global Product Safety, Eli Lilly & Company*
 - *S.C. Nichols, New Technology Coordination Manager, sanofi-aventis*
- **Please review slides in the Conference Binder before attending the breakout session, and come prepared to ask interesting and relevant questions.**