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Nanotechnologies — Aerosol generation for air exposure studies of nano-objects and their aggregates and agglomerates (NOAA)

Nanotechnologies — Génération d'aérosols pour réaliser des études d'exposition à l'air des nano-objets et de leurs aggrégats et agglomérats (NOAA)

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Foreword

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This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

Introduction

Inhalation is a primary route of exposure to aerosolized nano-objects and their aggregates and agglomerates (NOAA). The NOAAs include nano-objects with one, two or three external dimensions in the nanoscale from approximately 1 nm to 100 nm, which might be spheres, fibres, tubes and others as primary structures. NOAAs can consist of individual primary structures in the nanoscale and aggregated or agglomerated structures, including those sizes larger than 100 nm. To evaluate the inhalation toxicity of NOAA, it is important to consider certain parameters that make the toxicity testing relevant to human exposure. The three critical aspects to consider when designing and conducting nanomaterial inhalation toxicity study are

a) uniform and reproducible nano-object aerosol generation that is relevant to realistic exposures,

b) thorough characterization of nanomaterials throughout the duration of testing including starting and generated materials, and

c) use of occupational exposure limits (OEL) and reference concentrations (RfC) (as derived from existing studies and/or real-time exposure monitoring data) for dosimetry.

Therefore, to conduct *in vitro* and *in vivo* NOAA, it is important to choose an appropriate NOAA aerosol generator and use online and off-line techniques for nano-object characterization.

Aerosol generation techniques are well established and have been used in laboratory studies, inhalation therapy and industry for many years. A number of aerosol generation techniques are routinely used for other materials that can be adapted for nano-object inhalation toxicity studies. In principle, aerosol generation involves application of some form of energy to the material to reduce its size or to form small particles that are dispersed in a gas stream.

This document provides the status of nano-object aerosol generators. This document further discusses the advantages and limitations of the respective nano-object generators, which can aid in choosing the appropriate generator when conducting the nano-object inhalation toxicity study. No matter what generation system is used for toxicity study, the generated atmospheres should be thoroughly characterized in order to allow for comparison to occupational exposure atmospheres so that a valid risk assessment/occupational exposure limit (OEL) can be developed. Therefore, this document will also provide nano-object aerosol size information generated from respective generators along with the proper nano-object characterization methods. This document complements the work of the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterial (WPMN) and other related framework documents. Recommendations and guidelines to assist investigators in making appropriate choices of an aerosol generator for their target NOAAs to be tested are presented in this document.

