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Nanotechnologies — Considerations for in vitro studies of airborne nano-objects and their aggregates and agglomerates (NOAA)

Nanotechnologies — Considérations pour les études in vitro des nano-objets en suspension dans l'air et de leurs agrégats et agglomérats (NOAA)



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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.

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

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Introduction

Inhalation is one of the prominent routes by which humans can come in contact with natural, unintended and engineered nano-objects and their aggregates and agglomerates (NOAA). Due to the physiological, biochemical and anatomical differences between humans and animals, as well as the considerable time, cost and animal numbers required to conduct in vivo toxicity tests, there is much interest in developing in vitro strategies for risk assessment that are based on human cells and mechanisms of toxicity. To enable comparability of the results of in vitro assay and in vivo effects observed after inhalation of NOAA, certain parameters should be considered, including:

- a) the choice of cell types;
- b) characterization of the NOAA throughout the assay, including life-cycle transformations;
- c) the choice of nano-object concentration relevant to human exposures;
- d) generation of NOAA form that mimics human exposures;
- e) the use of relevant dispersants;
- f) the use of appropriate mode of exposure (submerged or air liquid interface) and exposure duration^[1].

This document includes descriptions of the aforementioned parameters with regard to using in vitro-based strategies for assessing specific aspects related to the inhalation toxicity of NOAA. For example, for inhalation studies, it is critical to choose the proper equipment for generation, exposure to, and characterization of the nano-objects. This document includes information about available in vitro aerosol exposure chambers and biological models that have been used to assess the inhalation toxicity of NOAA. This document does not include details regarding the techniques for aerosol generation or characterization of specific nanomaterials (NMs), their life cycle transformations or in vivo testing. An overview of the aerosol generation of NMs and in vivo testing is given in ISO/TR 19601^[2].