Technical Report

ISO/TR 23652

Nanotechnologies — Considerations for radioisotope labelling methods of nanomaterials for performance evaluation

Nanotechnologies — Considérations relatives aux méthodes de marquage radio-isotopique des nanomatériaux pour l'évaluation des performances

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Foreword

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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 document 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 229, *Nanotechnologies*.

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.

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Introduction

Prior to the clinical trials of nanomaterials intended for use in human medicine, their in vivo behaviour has been evaluated in animal experiments. Several quantitative methods for assessing the biodistribution of nanomaterials have been developed. Among these methods, the biodistribution of radioisotope-labelled nanomaterials provides quantitative information on their distribution throughout the entire body.

The use of radioisotope-labelled nanomaterials for biodistribution studies is a well-established method for understanding the pharmacokinetics or toxicokinetics of nanomaterials in vivo. These methods assume that the distribution pattern of nanomaterials and radioisotope-labelled nanomaterials will be similar or nearly identical in vivo.

Radioisotope labelling of nanomaterials can be accomplished using a wide variety of radionuclides and associated labelling methods. However, for nanomaterials used for medicinal purposes, there are only a few matching pairs of nanomaterial and radioisotope labelling method that ensure the in vivo integrity of the radioisotope-labelled nanomaterial. Failure to identify and apply matching pairs of nanomaterial and radioisotope labelling method in studies preceding the clinical trial phase can lead to experimental data on biodistribution in which the nanomaterial and radio-label separate during the experiment. This in turn can result in a large number of nanomaterials or nano-drugs failing in the clinical trial phase.

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Nanotechnologies — Considerations for radioisotope labelling methods of nanomaterials for performance evaluation

1 Scope

This document provides:

a) a review of radioisotope labelling methods that can be used for nanomaterials;

b) the advantages and disadvantages of each radioisotope labelling method;

c) information on the selection of a matched pair of nanomaterial and radioisotope labelling method to ensure the in vivo integrity of radioisotope-labelled nanomaterials[1] or the stability of their performance.

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 80004-1, *Nanotechnologies — Vocabulary — Part 1: Core vocabulary*

ISO/TS 80004-8, *Nanotechnologies — Vocabulary — Part 8: Nanomanufacturing processes*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 80004-1, ISO/TS 80004-8 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
nanoscale
length range approximately from 1 nm to 100 nm

[SOURCE: ISO 80004-1:2023, 3.1.1]

3.2
nanomaterial
material with any external dimension in the *nanoscale* (3.1) or having internal structure or surface structure in the nanoscale

[SOURCE: ISO 80004-1:2023, 3.1.4, modified — Notes have been removed.]

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