



# Technical Report

**ISO/TR 8417**

## **Risk management of particulate contamination for devices with intravascular access**

*Gestion des risques de contamination particulaire pour les  
dispositifs d'accès intravasculaire*

**First edition  
2024-10**

Reference number  
ISO/TR 8417:2024(en)

Full document details: ISO TR 08417-2024

© ISO 2024  **Documents**  
Document Sharing Hub



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

| Contents                                                                                               |                                                   | Page |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------|------|
| Foreword.....                                                                                          |                                                   | iv   |
| Introduction.....                                                                                      |                                                   | v    |
| 1                                                                                                      | Scope.....                                        | 1    |
| 2                                                                                                      | References.....                                   | 1    |
| 3                                                                                                      | Terms and definitions.....                        | 1    |
| 4                                                                                                      | Risk management on particulate contamination..... | 1    |
| 4.1                                                                                                    | Application of risk management.....               | 1    |
| 4.2                                                                                                    | Determination of particulate contamination.....   | 2    |
| Annex A (informative) Examples for hazards and risk control options related to particulate matter..... |                                                   | 3    |
| Annex B (informative) Rationales and history of the development of this document.....                  |                                                   | 7    |
| Bibliography.....                                                                                      |                                                   | 9    |

## 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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

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](http://www.iso.org/members.html).

## Introduction

Medical devices, that are part of the fluid path for delivery directly into circulating blood or are connected to those devices (such as administration or extension sets), include a risk of delivering particulate matter to the patient's body.

These particulates can be created or transferred to the devices during the production or application of those devices and can cause a variety of severe and fatal harms to patients (such as phlebitis, pulmonary emboli, pulmonary granulomas, immune system dysfunction, pulmonary dysfunction, infarction and death).

All parenteral products contain such particulate matter, as it is technically impossible to produce and use these devices without creating or transferring these particles to the devices. This is considered in technical standards and international pharmacopoeias that identify limits of particulate contamination, but these limits can only be considered as a definition of the maximum particle load that is based on current technical state of the art for various particle size ranges.

Several studies and publications imply, that no rationale for any tolerable number for the particulate contamination exists. The occurrence rates of related severe and fatal complications in patients that receive parenteral infusions is closely related to factors such as:

- route of administration;
- particle size and shape;
- number of particles injected;
- particle composition;
- patient population;
- exposure by multiple devices.

Additionally, the current specifications in standards and international pharmacopoeias are omitting the fact, that medical devices and drug containers are typically used in combinations with each other (e.g. container, infusion set, IV-catheter) and/or in parallel (e.g. several infusions running in parallel or in sequence) and/or repeatedly (e.g. several containers/infusion sets being used consecutively). With any of these, the total particulate load that patients receive is an addition of all those sources.

As the complexity of the number of influencing factors and their interrelations do not allow the derivation of any safe level of particulate contamination, the current specifications in standards and pharmacopeia can lead to an inappropriate assumption of safety by manufacturers, regulators, authorities, and clinical practitioners when these levels are met.

This document is intended to provide alternative perspectives on how to control risks related to particulate contaminations and to guide manufacturers, regulators, and authorities into a more comprehensive assessment of the measures related to reducing particulate contaminations.

The leading concept behind this alternative perspective is to apply the general methodology of risk management to identify, assess and control the risks that are related to particulate matter rather than defining an unsubstantiated level of assumed safety.