

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE

**Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances**

**Documentation technique pour l'évaluation des produits électriques et électroniques par rapport à la restriction des substances dangereuses**

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IEC 63000

Edition 1.0 2016-10

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b69dd54102cd/iec-63000-2016

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 01.040.01; 13.030.10; 31.020

ISBN 978-2-8322-3649-9

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**TECHNICAL DOCUMENTATION FOR THE ASSESSMENT  
OF ELECTRICAL AND ELECTRONIC PRODUCTS WITH RESPECT  
TO THE RESTRICTION OF HAZARDOUS SUBSTANCES**

## FOREWORD

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The text of this International Standard is based on the following documents:

CDV	Report on voting
111/413/CDV	111/434/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data related to the specific document. At this date, the document will be

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## INTRODUCTION

Certain substances contained in electrical and electronic products are restricted by legislation and/or customer specifications. Manufacturers of final products therefore need to be able to demonstrate that their products meet the applicable substance restrictions.

For those restrictions that apply at the component or material level, it is impractical for manufacturers of electrical and electronic products to undertake their own testing of all materials contained in the final assembled product. Instead, manufacturers work with their suppliers to manage compliance and compile technical documentation as evidence of compliance. This approach is well recognised by both industry and enforcement authorities.

The aim of this document is to specify the technical documentation that the manufacturer needs to compile in order to declare compliance with the applicable substance restrictions, under various substance regulations worldwide.

This document is based on European Standard EN 50581:2012, which supports Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

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# TECHNICAL DOCUMENTATION FOR THE ASSESSMENT OF ELECTRICAL AND ELECTRONIC PRODUCTS WITH RESPECT TO THE RESTRICTION OF HAZARDOUS SUBSTANCES

## 1 Scope

This document specifies the technical documentation that the manufacturer compiles in order to declare compliance with the applicable substance restrictions.

The documentation of the manufacturer's management system is outside the scope of this document.

## 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.

IEC 62321 (all parts), *Determination of certain substances in electrotechnical products*

IEC 62474:2012, *Material declaration for products of and for the electrotechnical industry*

## 3 Terms and definitions

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For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1

#### **restricted substance**

substance which is limited in its use in a product, sub-assembly, part or material

### 3.2

#### **manufacturer**

natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

### 3.3

#### **supplier**

organisation that provides the manufacturer with materials, parts and/or sub-assemblies

## 4 Technical documentation

### 4.1 Overview

The manufacturer shall compile technical documentation to demonstrate that electrical and electronic products comply with substance restrictions (see 4.2 and 4.3).



**4.2 Content of the technical documentation**

The technical documentation shall include at least the following elements:

- a general description of the product;

NOTE The description of the product together with its intended use is one of the factors that determines which exemptions (if any) apply.

- documents for materials, parts, and/or sub-assemblies (see 4.3);
- information showing the relationship between the technical documents identified in 4.3 and the corresponding materials, parts and/or sub-assemblies in the product;
- list of standards and/or other technical specifications that have been used to establish the technical documents identified in 4.3 , or to which such documents refer.

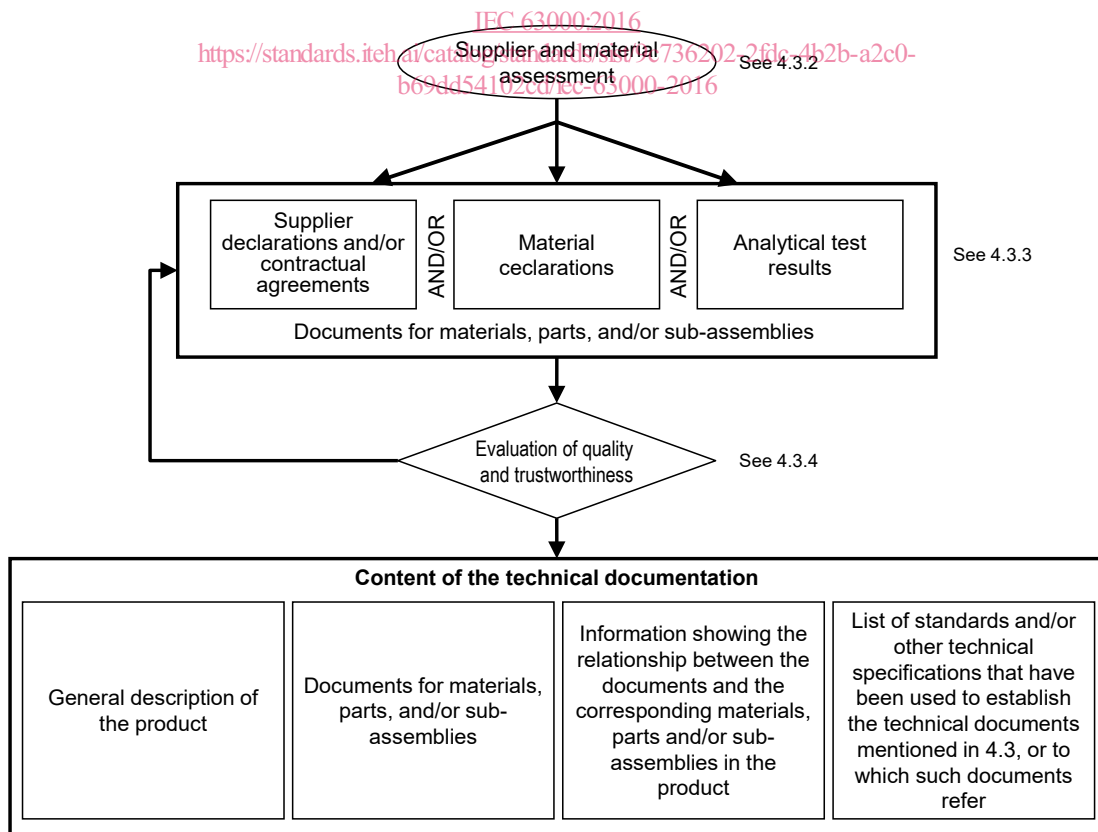
**4.3 Information on materials, parts, and/or sub-assemblies**

**4.3.1 Tasks to be undertaken by the manufacturer**

The manufacturer shall undertake the following four tasks:

- determine the information needed (see 4.3.2);
- collect the information (see 4.3.3);
- evaluate the information with regard to its quality and trustworthiness and decide whether to include it in the technical documentation (see 4.3.4);
- ensure that the technical documentation remains valid (see 4.3.5).

Figure 1 shows the process to create the technical documentation:



**Figure 1 – Schematic representation of process to create the technical documentation**

#### 4.3.2 Determine the information needed

The types of technical documents (see 4.3.3) that are required for materials, parts and/or sub-assemblies shall be based on the manufacturer's assessment of:

- a) the probability of restricted substances being present, in materials, parts or sub-assemblies, and
- b) the trustworthiness of the supplier.

Materials that are added during the production process (such as solder, paint, adhesives) shall also be considered as part of the assessment.

When undertaking the assessment of the probability of restricted substances being present (see item a) the manufacturer may apply technical judgement, as some substances are unlikely to be contained in certain materials (e.g. organic substances in metals). Such technical judgement should be based on technical information available via the electrical/electronic industry, or a literature investigation of the materials/parts used in electrical/electronic products. Additional information that may be used when undertaking the assessment includes material types typically used in the part or sub-assembly, and the historical likelihood of restricted substances being present in each material type.

When undertaking the trustworthiness assessment of the supplier (see item b) the manufacturer may apply:

- historical experience with the supplier organization;
- results of previous supplier inspections or audits.

NOTE The assessment and its associated procedures can form part of a quality management system or equivalent.

#### 4.3.3 Collecting information

As a result of the manufacturer's assessment, the following documents on materials, parts, and/or sub-assemblies shall be collected:

- a) Supplier declarations and/or contractual agreements, such as:
  - Supplier declarations, confirming that the restricted substance content of the specified material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied;
  - Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.
  - Such declarations or agreements shall cover a specific material, part and/or sub-assembly, or a specific range of materials, parts and/or sub-assemblies.

and/or

- b) Material declarations:
  - Material declarations providing information on specific substance content and identifying any exemptions that have been applied.
  - The material declaration content should meet the requirements specified in IEC 62474:2012, 4.2.3 for the applicable substances.

NOTE The use of standards for such declarations helps ensure consistent and cost-effective flow of information throughout the supply chain.

and/or

- c) Analytical test results:
  - Analytical test results using the methods described or referenced in the IEC 62321 series.

#### 4.3.4 Evaluation of information

The manufacturer shall establish procedures that shall be used to evaluate the documents described in 4.3.3 in order to determine their quality and trustworthiness.

NOTE 1 IEC TR 62476 provides a framework for the use of internationally accepted standards, tools and practices to evaluate electrical and electronic products with respect to restricted substances.

The manufacturer shall evaluate, in accordance with these procedures, the source and content of each document received in order to determine whether or not the material, part, or sub-assembly meets the specified substance restrictions.

NOTE 2 Aspects such as the origin of the document, contact information, responsibility of the named person or signatory, and date can be considered when evaluating the source and content.

This evaluation will enable the manufacturer to decide whether the documents provide sufficient evidence of compliance to justify their inclusion in the technical documentation.

If a particular document is:

- considered to be of sufficient quality and trustworthiness, then it shall be included in the technical documentation;
- not considered to be of sufficient quality or trustworthiness, then the manufacturer shall determine what further actions are necessary – possible actions include requesting additional information from the supplier or undertaking his own substance analysis.

#### 4.3.5 Review of the technical documentation

The manufacturer shall:

- perform a periodic review of the documents contained in the technical documentation to ensure that they are still valid;
- ensure that the technical documentation reflects any changes to materials, parts or sub-assemblies in accordance with 4.3.3.

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