BS EN 62321-1:2013

BSI Standards Publication

Determination of certain substances in electro-technical products

Part 1 Introduction and Overview

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National foreword

This British Standard is the UK implementation of EN 62321-1:2013. It is identical to IEC 62321-1:2013. Together with BS EN 62321-2:2013, BS EN 62321-3-1:2013, BS EN 62321-3-2:2013, BS EN 62321-4:2013, BS EN 62321-5:2013, BS EN 62321-6, BS EN 62321-7-1, BS EN 62321-7-2 and BS EN 62321-8 it supersedes BS EN 62321:2009, which will be withdrawn upon publication of all parts of the BS EN 62321 series.

The UK participation in its preparation was entrusted to Technical Committee GEL/111, Electrotechnical environment committee.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Determination of certain substances in electrotechnical products - Part 1: Introduction and overview

(IEC 62321-1:2013)

Détermination de certaines substances dans les produits électrotechniques - Partie 1: Introduction et présentation (CEI 62321-1:2013)

Verfahren zur Bestimmung von bestimmten Substanzen in Produkten der Elektrotechnik - Teil 1: Einleitung und Übersicht (IEC 62321-1:2013)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Foreword

The text of document 111/295/FDIS, future edition 1 of IEC 62321-1, prepared by IEC TC 111 "Environmental standardization for electrical and electronic products and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62321-1:2013.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2014-03-21
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2016-06-21

EN 62321-1:2013 is a partial replacement of EN 62321:2009, forming a structural revision and replacing Clauses 1 to 4.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 62321-1:2013 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60730-1:2010 NOTE Harmonised as EN 60730-1:2011 (modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
ISO/IEC 17025	-	General requirements for the competence of testing and calibration laboratories	EN ISO/IEC 17025	-
ISO 78-2	1999	Chemistry - Layouts for standards - Part 2: Methods of chemical analysis	-	-

CONTENTS

INTRODUCTION

The widespread use of electrotechnical products has drawn increased attention to their impact on the environment. In many countries this has resulted in the adoption of regulations affecting wastes, substances and energy use of electrotechnical products.

The use of certain substances (e.g. lead (Pb), cadmium (Cd) and polybrominated diphenyl ethers (PBDEs)) in electrotechnical products, is a source of concern in current and proposed regional legislation.

The purpose of the IEC 62321 series is therefore to provide test methods that will allow the electrotechnical industry to determine the levels of certain substances of concern in electrotechnical products on a consistent global basis.

The first edition of IEC 62321:2008 was a single 'stand-alone' standard that included an introduction, an overview of test methods, a mechanical sample preparation as well as various test method clauses.

The structure of the new multi-part IEC 62321 series comprises:

– Determination of certain substances in electrotechnical products – Part 1: Introduction and overview.
– Determination of certain substances in electrotechnical products – Part 2: Disassembly, disjointment and mechanical sample preparation.

The remaining parts specify screening and verification test methods for the determination of certain substances, each part representing a given substance.

WARNING – Persons using this International Standard should be familiar with normal laboratory practice. This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user to establish appropriate safety and health practices and to ensure compliance with any national regulatory conditions.

DETERMINATION OF CERTAIN SUBSTANCES IN ELECTROTECHNICAL PRODUCTS –

Part 1: Introduction and overview

1 Scope

This part of IEC 62321 refers to the sample as the object to be processed and measured. The nature of the sample and the manner in which it is acquired is defined by the entity carrying out the tests and not by this standard.

It is noted that the selection of the sample may affect the interpretation of the test results.

While this standard provides guidance on the disassembly procedure employed for obtaining a sample, it does not determine or specify:

- the level of the disassembly procedure required for obtaining a sample;
- the definition of a “unit” or “homogenous material” as the sample;
- conformity assessment procedures.

NOTE Further guidance on assessment procedures may be found in IEC/TR 62476 [2].

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 78-2:1999, *Chemistry – Layouts for standards – Part 2: Methods of chemical analysis*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

3.1.1
analyte
substance to be measured

3.1.2
electronics
material used in electrical or electronic equipment that is not metal or plastic (e.g. ceramic) or not uniform in composition throughout and cannot be practically disassembled to individual discrete materials

EXAMPLE Resistors, capacitors, diodes, integrated circuits, hybrids, application-specific integrated circuits, wound components, relays and their materials.

3.1.3
field replaceable unit
part, component or subassembly that is easily removed (mechanically disjointed) using ordinary tools

Note 1 to entry: "Easily removed" means using ordinary tools to perform such functions as screwing or disconnecting, and only without irreversibly destroying the unit.

[SOURCE: IEC Guide 114:2005, definition 3.7] [3]

3.1.4
matrix
substance or mixture and its form or state in which analyte is embedded or to which analyte is attached

3.1.5
performance-based measurement system
set of processes wherein the data needs, mandates or limitations of a program or project are specified, serving as criteria for selecting appropriate methods to meet those needs in a cost-effective manner

Note 1 to entry: The criteria may be published in regulations, technical guidance documents, permits, work plans or enforcement orders.

3.1.6
precision
closeness of agreement between independent test results obtained under stipulated conditions

3.1.7
reference material
material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties

3.1.8
repeatability
precision under repeatability conditions

[SOURCE: ISO 5725-1:1994, definition 3.13] [4]

3.1.9
reproducibility
precision under reproducibility conditions

[SOURCE: ISO 5725-1:1994, definition 3.17]

3.1.10
screening
analytical procedure to determine the presence or absence of substances in the representative part or section of a product, relative to the value or values chosen as the criterion for presence, absence or further testing

Note 1 to entry: If the screening method produces values that are not conclusive, then additional analysis or other follow-up actions may be necessary to make a final presence/absence decision.

3.2 Abbreviations

AAS	Atomic Absorption Spectrometry
C-IC	Combustion – Ion chromatography
CV-AAS	Cold Vapour Atomic Absorption Spectrometry
CV-AFS	Cold Vapour Atomic Fluorescence Spectroscopy
EPA	Environmental Protection Agency
FRU	Field replaceable unit
GC-MS	Gas chromatography – mass spectrometry
GLP	Good laboratory practice
HPLC-UV	High-performance liquid chromatography – ultraviolet
IC	Ion Chromatography
IAMS	Ion attached mass spectrometry
ICP-MS	Inductively coupled plasma mass spectrometry
ICP-OES	Inductively coupled plasma optical emission spectrometry
IS	Internal standard
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of detection
LOQ	Limit of quantification
MDL	Method detection limit
PBB	Polybrominated biphenyl
PBDE	Polybrominated diphenyl ether
PBMS	Performance-based measurement system
PWB	Printed wiring board
QC	Quality control
UV-VIS	Ultraviolet–visible Spectroscopy
XRF	X-ray fluorescence

4 Test methods – Overview

4.1 Field of application

The contents of the test methods to determine the levels of certain substances are grouped in two important steps:

a) analytical test methods;

b) laboratory implementation.

Analytical test methods were developed and validated to ensure their suitability to the task. The structure of each of the test methods are generally aligned in accordance with ISO 78-2 where applicable, i.e.:

– Foreword
– Introduction
– Title
– Warnings
– Scope
– Normative references
– Definitions

– Principle
– Reactions
– Reagents and materials
– Apparatus
– Sampling
– Procedure
– Calculation
– Precision
– Quality assurance and control protocols
– Special cases
– Test report
– Annexes
– Bibliography

Laboratory implementation is not covered in this standard, as laboratories are able to implement test methods described using test methods and standards addressed in other sources. The implementation step includes suitable quality assurance measures and a validation protocol that documents the performance of the analytical method using the instruments in the laboratory. Quality assurance systems such as good laboratory practice (GLP) and/or accreditation to similar international or national systems (e.g. ISO 17025) are strongly encouraged.

4.2 Sample

This standard refers to the sample as the object to be processed and measured according to the test methods to determine the levels of certain substances. A sample can either be a polymer, a metal or electronics.

The entity carrying out the test methods shall define the sample and how to produce it with respect to applicable normative documents.

NOTE The entity can either be the organization commissioning the work or the organization carrying out the work. In practice, the requestor and the analyst will agree on the sample to be taken.

The entity may decide to prepare a sample from homogenous material. For this kind of sample, the test methods applicable to metals or polymers are especially suitable.

The entity may also decide to prepare a sample from an electronic component, an electronic assembly or a FRU. For this kind of sample, the test methods applicable to electronics are especially suitable.

4.3 Test methods – Flow chart

Figure 1 gives a flow chart of the test methods to determine the levels of certain substances in electrotechnical products.

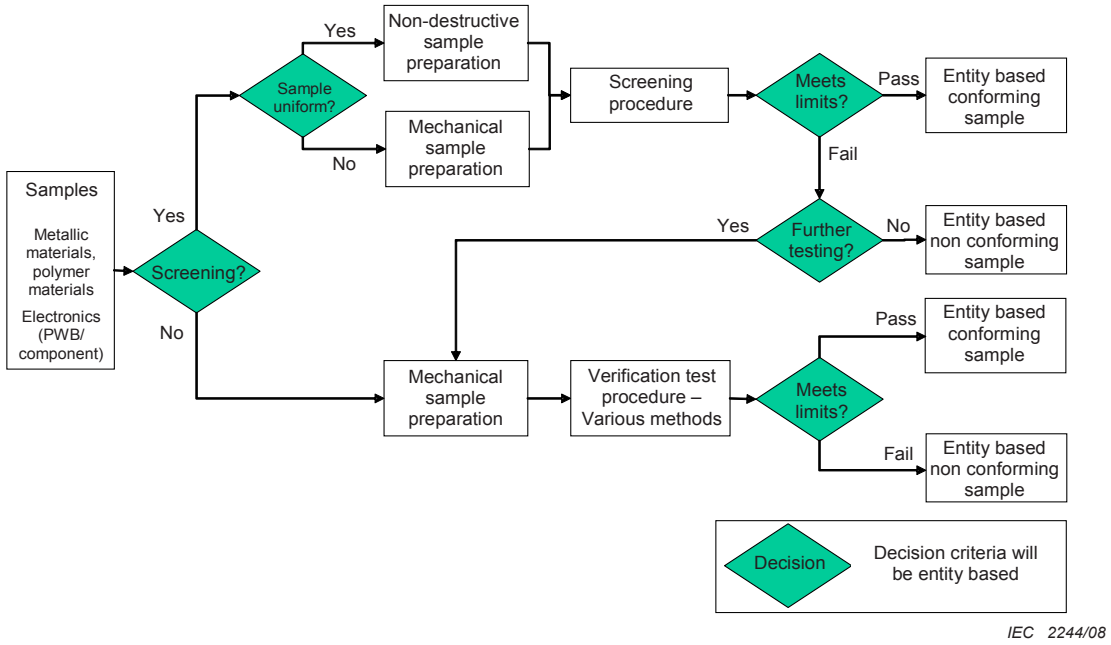

Figure 1 – Flow chart of the test methods

After obtaining the sample, a decision is taken as to whether the screening procedure or the verification procedure using a variety of test methods will be used.

The use of the term “screening” for the evaluation of certain substances (e.g. lead, cadmium, hexavalent chromium, etc.) in electrical and electronic equipment is widely used in reference to analytical testing methods. Screening methods provide the analyst a convenient approach to evaluate for the presence or quantity of certain substance(s) in samples. Screening may employ qualitative or semi-quantitative methods. In some cases, a quantitative method may be used for screening purposes if the actual targeted substance(s) are difficult to analyse directly (e.g. hexavalent Cr).

Depending on the screening results however, additional analysis methods may need to be employed to definitively verify the presence or quantity of certain substances. These definitive analysis methods are referred to as verification methods.

While X-ray fluorescence spectrometry (XRF) is the tool most commonly associated with the screening approach, it is not limited to this analytical measurement technique. Users of this family of standards will understand that multiple measurement techniques can be employed for the purpose of “screening”.

Screening for hexavalent chromium (Cr VI) for example, can be accomplished by a total chromium measurement using a non-destructive XRF analysis method. Similarly, total chromium analysis could be performed by a destructive analysis using an inductively coupled plasma measurement method. Either measurement can be effectively employed to evaluate for the presence or quantity of hexavalent chromium since the concentration of the hexavalent species can be no greater than the total chromium concentration value.

Likewise, a total bromine measurement using a non-destructive XRF analysis method or C-IC method can be used in the same fashion. Either measurement can be effectively employed to evaluate for the presence or quantity (PBBs) or (PBDEs) in a sample when relating the total bromine content to the composition of these compounds.

In both examples however, the detection of elevated total element levels requires additional verification method analysis (e.g. UV-VIS or GC-MS techniques) to confirm the potential presence or quantity of hexavalent chromium (Cr +IV) or PBB/PBDE compound species.

It can therefore be seen that the prudent analyst can effectively employ different screening procedures to achieve the same result.

The screening procedure may be carried out either by directly measuring the sample (non-destructive sample preparation) or by destroying the sample to make it uniform (mechanical sample preparation). This decision shall be made by judging the uniformity of the sample. A screening of representative samples of many uniform materials (such as polymers, alloys, glass) may be carried out non-destructively, while for other more complex samples (such as a FRU), mechanical sample preparation may be an appropriate solution. Mechanical sample preparation is the same for both the screening and the verification test procedure.

Verification test procedures are often employed to confirm the presence or quantity of certain substances of concern after a screening procedure has been performed (e.g. to determine if the source of “screened” bromine is from a bromine compound of concern). Alternatively, verification test procedures can be performed independent of a screening procedure.

Verification procedures are typically performed after mechanical and chemical sample preparation using a variety of test methods tailored to the substances of concern and the sample, which can be a polymer, a metal or electronics.

Tables 1 and 2 give an overview of typical screening/verification test methods, which are described in detail in the individual substance test method parts of this standard.

Table 1 – Overview of typical screening and verification testing procedure elements – Preparation

Procedure	Sample preparation	Polymers	Metals	Electronics (PWBs/components)
Sample Preparation	Non destructive	No preparation	No preparation	No preparation
	Mechanical sample preparation	Grinding or milling	Grinding or milling	Grinding or milling
	Chemical sample preparation	• Aqueous/alkaline extraction • Acid digestion • Dry ashing • Organic solvent extraction • Combustion/ extraction • Thermal gold-amalgamation	Acid digestion	• Aqueous/alkaline extraction • Acid digestion • Organic solvent/ extraction • Combustion/extract ion

Table 2 – Overview of typical screening and verification testing procedure elements – Substance type

Procedure	Substance type	Polymers	Metals	Electronics (PWBs/components)
Analytical measurement	Organic compounds (e.g. PBDEs)	• GC-MS • IAMS • HPLC-UV	NA	• GC-MS • IAMS • HPLC-UV
	Elemental bromine	• XRF • IC	NA	• XRF • IC
	Ionic species (e.g. Cr +VI	Colorimetry/UV-VIS	Colorimetry/UV-VIS	Colorimetry
	Elemental (metals) analysis (e.g. Pb, Cd)	XRF, AAS, CV-AAS, CV-AFS, ICP-OES and ICP-MS		

After the verification procedure has been carried out, it shall be decided whether the sample meets the limits based on the entity's criteria for certain substances.

4.4 Quality assurance and control

Where applicable, the quality assurance and control clauses of the individual test method standards shall include control sample requirements regarding testing frequency and acceptance criteria. These clauses shall also include method specific quality control concerns regarding the determination of limits of detection (LOD) and limits of quantification (LOQ). Where applicable, the LOD and LOQ section shall be consistent with the descriptions in 4.7. Examples of other method-specific quality control concerns include requirements regarding method blanks, calibration check standards, spike or surrogate samples, internal standard responses and the like.

4.5 Blank solution

Where applicable, the precision clause of the individual test method standards shall include repeatability and reproducibility statements (see Annex B of ISO 78-2:1999) supported by statistical data derived from interlaboratory study or the equivalent.

4.6 Adjustment to the matrix

Test methods for certain substances that are present at relatively low levels amongst other chemical elements or compounds at relatively high concentrations, or those that represent the major constituent of the sample, are very often material or matrix dependent. Therefore, the test methods shall be adjusted to the materials to be tested, either by introducing the appropriate blanks and matrix-adjusted calibration samples, or by a preparation step that separates the analyte from the adherent materials or the main matrix. The main material types (or matrices) in electronic equipment are polymers (mostly technical polymers containing additives and sometimes having coated surfaces), metals or alloys (they may also be coated) and electronics. Matrix adjustment may be difficult for electronic products.

4.7 Limits of detection (LOD) and limits of quantification (LOQ)

In its simplest form, a limit of detection (LOD) or method detection limit (MDL) is typically described as the lowest amount or concentration of analyte in a test sample that can be reliably differentiated from zero for a given measurement system.

Instrument detection limits represent an instrument's ability to differentiate low concentrations of analytes from "zero" in a blank or standard solution, and are commonly used by manufacturers to demonstrate the measurement capability of a system (e.g. atomic absorption

spectrometer). Whilst instrument detection limits are useful, they are often considerably lower than a limit of detection representing a complete analytical measurement process.

Complete analytical method detection limits are most appropriately determined experimentally by performing replicate, independent measurements on low-level or fortified sample matrices (e.g. plastic) carried out through the entire test procedure, including sample digestion or extraction. A minimum of six replicates and analyte concentrations of 3 to 5 times the estimated method detection limit have been suggested as suitable for this analysis. The complete method detection limit for an entire test procedure is determined by multiplying the standard deviation of the replicates by an appropriate factor. IUPAC recommends a factor of 3 for a minimum of six replicates, whilst EPA utilizes a one-sided confidence interval with the multiplier equal to Student's *t* value chosen for the number of replicates and the level of confidence (e.g. t = 3,36 for six replicates for 99 % confidence).

NOTE An illustrative calculation example is given in Annex A.

The limit of quantification (LOQ) or estimated quantitation limit for a given measurement system is typically described as the lowest concentration that can be reliably determined within specified or acceptable limits of precision during routine laboratory operating conditions. The acceptable precision limit is often defined as 10 % relative standard deviation or simply expressed as a fixed multiple (2 to 10) of the method detection limit.

4.8 Test report

The work carried out by the testing laboratory shall be covered by a report that accurately, clearly and unambiguously presents the test results and other relevant information. Each test report shall include at least the following information:

a) name, address and location of any laboratory involved in the analysis and name of the operator;

b) date of receipt of sample and date(s) of performance of test(s);

c) unique identification of report (such as a serial number) and of each page and total number of pages of the report;

d) description and identification of the sample, including a description of any product disassembly performed to acquire the test sample;

e) a reference to this standard, the method used or performance-based equivalent (including digestion method(s) and equipment);

f) the limit of detection (LOD) or limit of quantification (LOQ);

g) the results of the test expressed as milligram/kilogram (mg/kg) in samples tested;

h) any details not specified in this standard which are optional, and any other factors that may have affected the results. Any deviation, by agreement or otherwise, from the test procedure specified here.

The results of all quality control (QC) tests (e.g. results from method blanks, matrix spikes, etc.) and a list of reference materials used and their origin shall be available upon request.

Corrections or additions to a test report after issue shall be made only in a further document suitably marked, e.g. "Amendment/Addendum to test report serial number XXX" (or as otherwise identified), and shall meet the relevant requirements of 4.2 to 4.6).

4.9 Alternative test methods

Alternative test methods, digestion methods or analytical techniques may be utilized once the performance effectiveness has been validated according to PBMS criteria, referenced in the quality control clauses of the test methods. Any deviation from the described test methods shall be evaluated and documented in the test report.

Annex A
(informative)

Limit of detection (LOD) or method detection limit (MDL) – Example of calculation

A sample containing an amount (~9,5 mg/kg) of cadmium approximately 3 to 5 times the estimated method detection limit (~2 mg/kg) underwent nine (9) separate digestions and quantitative measurements. The results are shown in Table A.1.

Table A.1 – Experimental results

Replicate (digestion) number	Measured cadmium content mg/kg
1	9,49
2	10,20
3	9,79
4	9,44
5	9,42
6	9,80
7	9,94
8	8,89
9	10,20

The limit of detection (LOD) or method detection limit (MDL) was determined using the appropriate student's t-value (t-statistic) and formula shown in Table A.2 and Formula (A.1).

Table A.2 – Students t-values (t-statistic)

No. of samples	t-statistic (n-1, α = 0,99)
3	6,96
4	4,54
5	3,75
6	3,36
7	3,14
8	3,00
9	2,90
10	2,82

$$\text{LOD or MDL} = t\text{-statistic} \times \text{standard deviation } (s_{n-1}) \quad \text{(A.1)}$$

The limit of quantification (LOQ) or estimated quantitation limit is expressed as a fixed multiple (5) of the limit of detection (LOD) or method detection limit (MDL) as shown in Table A.3.

Table A.3 – Calculation results

Mean	9,69 mg/kg
t-statistic (n-1, α = 0,99)	2,90
Standard deviation (s_{n-1})	0,42 mg/kg
LOD or MDL	1,22 mg/kg
LOQ @ 5x MDL	6,09 mg/kg

Based on the results of the calculations, it is appropriate to quote the estimated LOD as 1,2 mg/kg and the estimated LOQ as 6.0 mg/kg.

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[1] IEC/TR 62476:2010, *Guidance for evaluation of products with respect to substance-use restrictions in electrical and electronic products*

[2] IEC Guide 114:2005, *Environmentally conscious design – Integrating environmental aspects into design and development of electrotechnical products*
(withdrawn)

[3] ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

Additional non-cited references

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