

TECHNICAL REPORT

Test method development – Guidelines for substance selection
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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL
ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

TEST METHOD DEVELOPMENT – GUIDELINES FOR SUBSTANCE SELECTION

FOREWORD

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IEC TR 62936, which is a Technical Report, has been prepared by IEC technical committee 111: Environmental standardization for electrical and electronic products and systems.

The text of this Technical Report is based on the following documents:

Enquiry draft	Report on voting
111/410A/DTR	111/441/RVC

Full information on the voting for the approval of this Technical Report 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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION

The large number of chemical substances currently regulated or under consideration for regulation necessitates the need for the development of reliable and acceptable test methods to be used as one approach for conformity assessment. For conformance demonstration, it is vital that interested parties agree that a particular test method is technically correct (i.e. provide reliable analytical results), is appropriate for the samples to be analysed, tested and vetted by technical experts, and is unbiased in its application. These criteria are generally fulfilled by test methods that are developed and published by a standards development organization (SDO) (e.g. IEC, ISO). Because of limited resources and the length of time needed to develop and validate these procedures, only a limited number of substances can be addressed at any given time for test method development.

This document provides a process for logically filtering, prioritizing and selecting candidate substances for development of test method standards. The objective of the filtering process is to partition the list of candidate substances into groups based on relative importance. Given that this document is intended for electrotechnical products, the candidate substances are largely drawn, but not exclusively, from the substance lists recorded in the IEC 62474 database [1]¹ on material declaration. The substances listed in the database are grouped into 3 categories with brief descriptions given below:

- IEC Criteria 1 – “currently regulated” or “explicitly included within an existing national law or regulation in an IEC member country”. The law or regulation is applicable to electrotechnical products and goes into force at a specific date.
- IEC Criteria 2 – “for assessment” or substance or substance group that meets criteria 1 with the exception that the law or regulation does not cite a specific effective date for the requirements.
- IEC Criteria 3 – “for information only” or does not meet requirement for either criteria 1 or 2. However, “there is a recognized industry-wide common market requirement for reporting this substance on substance group in electrotechnical products”.

NOTE Criterion/criteria is used in this document to denote a rule/principle for evaluating a substance against a set of requirements. The use of the term IEC criteria is specific to the regulatory status of a particular substance as defined in the IEC 62474 standard.

In addition to those substances that are under regulatory scrutiny, market requirements may also be of major consideration for the development of IEC test method standards. There are several very important influences that may dictate the ability of a product to enter or be introduced into the marketplace. Examples of market driven requirements may include EPEAT[®] (Electronic Product Environment Assessment Tool), Low Halogen initiative set by the electronics industry, Energy Star[®] ² for energy efficient products and others. Although there are no legal obligations that electrotechnical equipment meet the requirements set forth in these initiatives, failure to do so may put the supplier at a severe competitive disadvantage. In many cases, the supplier's product may be disqualified for purchasing consideration for failure to meet these requirements.

The filtering process is intended to screen out the majority of substances for consideration leaving only the “critical few” substances for further consideration. Due to the rapidly changing regulatory environment, the criteria used for filtering may or may not be the most appropriate for the substances under consideration. Thus, some judgement needs to be exercised in interpreting the resulting scores. The final selection process is intended to allow the consideration of additional requirements or criteria that are not captured in the initial filtering process. Subjective criteria (relative importance is not measureable) may also be introduced. No attempt has been made to try to define the criteria in the final selection process given the changing requirements in both the regulatory and market environments.

¹ Numbers in square brackets refer to the bibliography.

² EPEAT and Energy Star are registered trademarks. This information is given for the convenience of users of this document and does not constitute an endorsement by IEC of these registered trademarks.

TEST METHOD DEVELOPMENT – GUIDELINES FOR SUBSTANCE SELECTION

1 Scope

This document provides guidelines for the selection of substances for the development of test method standards. The substances and substance groups listed in the IEC 62474 database are the primary source of candidate substances. Other substances that are under regulatory roadmap and market requirements can also be considered for this filtering and selection process.

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

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

No terms and definitions are listed in this document.

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>

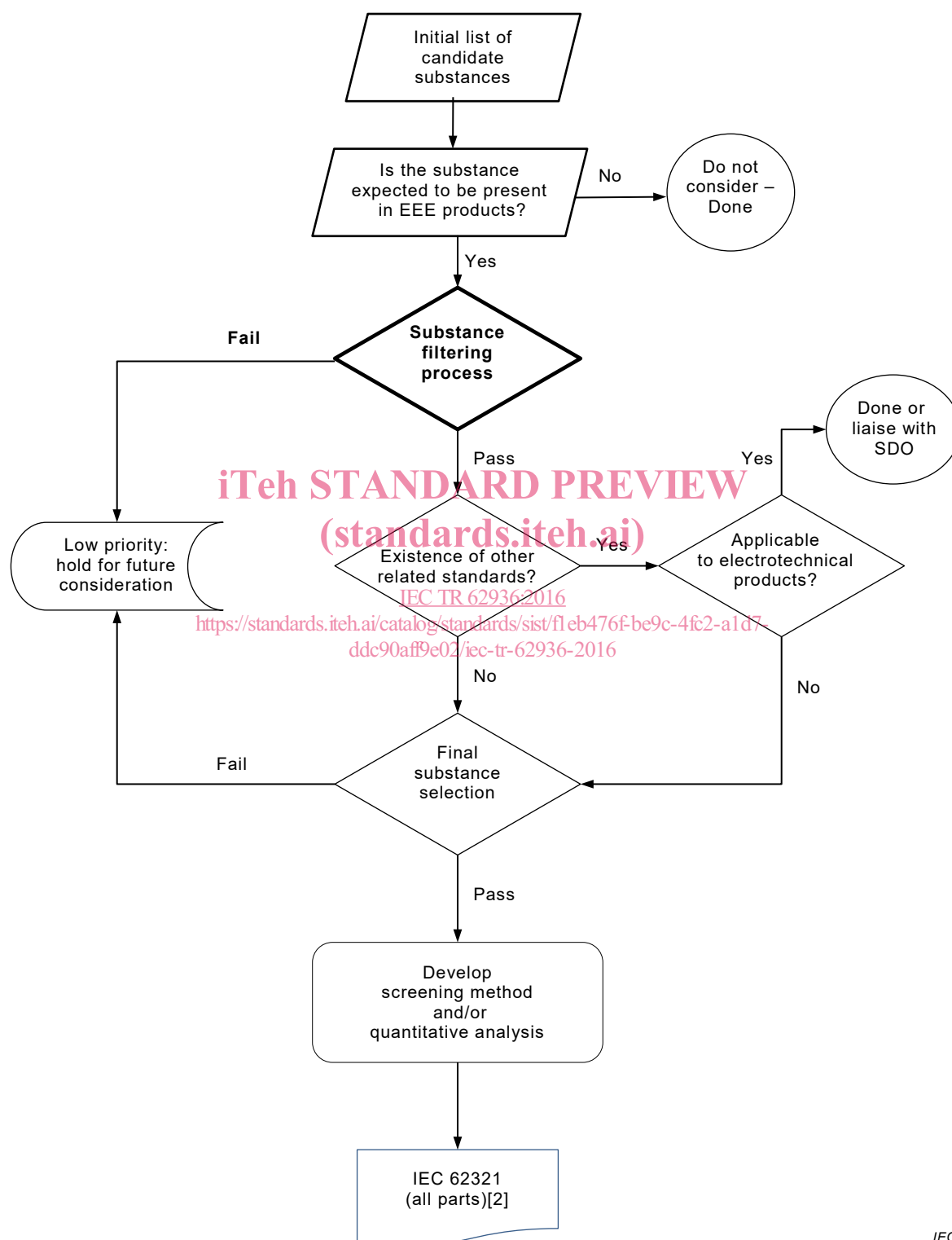
3.2 Abbreviated terms

CMR	carcinogenic, mutagenic or toxic to reproduction
CoRAP	community rolling action plan
EEE	electrical and electronic equipment
REACH	registration, evaluation, authorization and restriction of chemicals
RoHS	restriction of hazardous substances
SDO	standards development organization
SIN	substitute it now
SVHC	substances of very high concern

4 Process flow

Substances that are contained in the IEC 62474 database have undergone technical scrutiny to determine applicability to electrotechnical products. This vetting process provides an effective first screen to narrow down the potential number of substances that may be considered for test method development within IEC. Specifically, these substances have been evaluated by technical experts to be used in electrical and electronic equipment (EEE) products. This type of assessment will need to be performed for substances that are not

contained in the IEC 62474 database. A conceptual flow for the general substance selection decision making process is given in Figure 1.



5 Process flow steps

5.1 Chemical substance list

Substances under consideration for test method development are found in the IEC 62474 materials declaration database and other readily available sources. The IEC 62474 database is generally the initial source of information since it provides a vetted and frequently updated list of substances that is under scrutiny by either having regulatory obligations associated with them or potentially will be in the future. Given the large number of substances either being regulated or under consideration for regulation, this database provides an effective screening of substances present in electrotechnical products. The IEC 62474 validation team is responsible for maintenance of the materials declaration database.

5.2 Substance filtering process

Given the large number of substances that are potential candidates for test method development, a systematic approach is needed for reducing the number of candidates for consideration before final selection. This can be accomplished by employing a filtering process. The basis of the filtering process is to apply a set of criteria that defines the timeliness and impact for test method development for a particular substance. Important categories for the filtering criteria include:

- presence of substance in the final product;
- regulatory or market requirements;
- regional impact;
- regulatory impact;
- intentional addition of substance;
- strategic or future impact;
- test method development.

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Table 1 details the criteria and associated weighting factors to be used in the filtering process. Note that the criteria pertaining to “regulatory or market requirements” and “regulatory impact” are assigned scores based on the information used by the IEC 62474 validation team for assessing which substances are added to the database. For substances not listed in the database a similar assessment will need to be performed. The list of criteria and its relative weighting will be revised annually since the regulatory environment is dynamic. The weighting factors used are adopted from the Quality Function Deployment/Six Sigma methodology [3], [4]. Although the output from this process is a scoring for the substances under consideration, its intention is only to identify those substances where test method development would be most impactful or provide the most value to the electrotechnical industry. Technical Committee (TC) 111 will be tasked to determine, based on the scored list, which substances will be included in the final selection process.

Table 1 – Substance filtering criteria

Criterion	Weighting factor	Comments
Substance presence		
Is substance expected to be present in the final EEE product?	Yes/No	If a substance fails this criterion it will be eliminated as a candidate for the process.
Regulatory or market requirements		
Substance is currently under regulation – Criteria 1 or market requirements or other forces make it mandatory to self-regulate substance. Impact to business is high.	9	For substances that are regulated but not necessarily restricted.
Substance will be under regulation – Criteria 2 or market requirements or other forces make it highly advantageous to self-regulate substance. Impact to business is moderate.	3	No timeframe defined but substance on watch list; substance will be added to a designated list.
Substance has no timeline for regulation to be in force – Criteria 3 or market or other forces make it desirable but not necessary to regulate. Impact to business is low.	1	Also includes substances that have been phased out but may still be in products in use. Substance may not be regulated but could represent a disposal hazard.
Regional impact		
Global	9	Multi-country or region: 2 or more.
Regional	3	Country or region specific.
Local	1	Within a country.
No impact	0	Substance impact is undefined or very low.
Regulatory impact		
Criterion 1: Substance is restricted	9	Threshold limit is established
Criterion 2: Substance is not restricted but requires reporting or other regulatory obligation	3	Threshold limit is established
Criterion 3: Substance does not have any regulatory obligations.	1	No restrictions
Intentional addition of substance		
Is the intentionally added substance expected to be present in the final product above threshold?	3 or 1	Substance of interest would be expected to be present in final product at levels above threshold. Yes = 3 No = 1
Strategic considerations		
Substance is currently IEC 62474 criteria 2 or 3 but has the following attributes: <ul style="list-style-type: none"> – Industry accepted test method standard not available and not currently under development. – Widely used in EEE. – Substance is anticipated to be important for new or emerging markets e.g. wearable electronics. – Need to recover high value substances e.g. precious metals. – High degree of confidence that substance will be regulated within 3 to 5 years. 	9,3,1	Early identification of substances that is important to the electrotechnical industry but not currently regulated. These substances may be considered high risk for future regulatory or market driven requirements. NOTE If the substance is not criteria 2 or 3, it will be assigned a 1. 9 = meets ≥ 4 criteria 3 = meets 2 or 3 of criteria 1 = meets 0 or 1 criterion
Test method development		
TM1: Is there a viable approach for testing the substance of interest?	3 or 1	Criterion that helps to define probability of success for development Yes = 3 No = 1