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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Live working – Methods for assessment of defects and verification of performance applicable to tools, devices and equipment

Travaux sous tension – Méthodes d'évaluation des défauts et vérification des performances applicables aux outils, dispositifs et équipement

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CONTENTS

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LIVE WORKING – METHODS FOR ASSESSMENT OF DEFECTS AND VERIFICATION OF PERFORMANCE APPLICABLE TO TOOLS, DEVICES AND EQUIPMENT

FOREWORD

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International Standard IEC 61318 has been prepared by IEC technical committee 78: Live working.

This fourth edition cancels and replaces the third edition published in 2007. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) change of the purpose of the document from a prescriptive testing standard to a standard assisting the project team in the conformance to respective product standard;
b) introduction of conformance test, record of process, quality control documentation, adapted to the standard product;
c) change of prescribed sampling procedure to adapted *sampling tests* to the product standard;

d) suppression of the term “conformity assessment”;

e) Introduction of the term “verification method” replacing “conformity assessment application”.

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

FDIS	Report on voting
78/1339/FDIS	78/1353/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, the following characters are used:

– requirements: roman characters;

– terms defined in Clause 3: *italics*.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under 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.

INTRODUCTION

This document is applied by each IEC Live Working product standard for the purpose of assessing whether or not each product meets the requirements of the relevant product standard.

LIVE WORKING – METHODS FOR ASSESSMENT OF DEFECTS AND VERIFICATION OF PERFORMANCE APPLICABLE TO TOOLS, DEVICES AND EQUIPMENT

1 Scope

This document defines methods to assess defects and to verify that products after the manufacturer process meet the requirements of the corresponding product standard.

The principles of assessment of defects for live working products are detailed in this document to assist product standard developers in prescribing the best means to achieve suitable quality of every finished tool, device and piece of equipment.

The following elements are not covered by the present document, but are included in each product standard:

– *type tests*;
– provisions and description for *routine, sampling* and *acceptance tests*;
– identification and classification of defects;
– *risk analysis.*

This document does not cover conformity assessment of commercial shipments or certifications.

2 Normative references

There are no normative referenced documents.

3 Terms and definitions

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
acceptance test
contractual test to prove to the customer that the item meets certain conditions of its specification

[SOURCE: IEC 60050-151:2001, 151-16-23, modified – The main term "hand-over test" has been deleted.]

3.2
critical defect
any defect where judgement and experience indicate that it is likely to result in hazardous or unsafe conditions for individuals using or depending on the product

3.3
harm
physical injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO IEC Guide 51:2014, 3.1, modified – Addition of "physical".]

3.4
hazard
potential source of *harm*

Note 1 to entry: The term *hazard* can be qualified in order to define its origin or the nature of the expected *harm* (e.g. electric shock *hazard*, electric arc *hazard*, crushing *hazard*, cutting *hazard*, toxic *hazard*, fire *hazard*, drowning *hazard*).

[SOURCE ISO IEC Guide 51:2014, 3.2, modified – Addition of Note 1 to entry.]

3.5
major defect
defect of product, other than critical, that is likely to result in failure, or to reduce significantly the functionality of the product

3.6
minor defect
defect of product that is not likely to reduce significantly the functionality of the product

3.7
non-conformance
non-fulfilment of a requirement

[SOURCE: ISO 16426:2002, 3.15]

3.8
risk
combination of the probability of occurrence of *harm* and the severity of that *harm*

[SOURCE: ISO IEC Guide 51:2014, 3.9, modified – The note 1 to entry was deleted.]

3.9
risk analysis
systematic use of available information to identify *hazards* and to estimate the *risk*

[SOURCE: ISO IEC Guide 51:2014, 3.10]

3.10
routine test
test made on each individual item during or after manufacture

[SOURCE: IEC 60050-151:2001, 151-16-17, modified – the term “conformity” was deleted]

3.11
sampling plan
combination of sample size(s) to be used and associated lot acceptability criteria

[SOURCE: ISO 2859-1:1999, 3.1.17, modified – Deletion of the notes.]

3.12
sampling test
test on a sample

[SOURCE: IEC 60050-151:2001, 151-16-20]

3.13
type test
test made on one or more items representative of the production

[SOURCE: IEC 60050-151:2001, 151-16-16, modified – the term “conformity”]

3.14
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The term “verified” is used to designate the corresponding status.

Note 2 to entry: Design *verification* is the application of tests and evaluation to assess that the design meets the specified requirements.

[SOURCE: ISO 9000:2015, 3.8.12, modified – The Notes to entry have been modified.]

4 General

Principle methods for assessment and *verification* for live working products are detailed in this document to assist product standard developers in prescribing the best means to demonstrate that every finished tool, device and piece of equipment meet the standard requirements.

Non-conformance to product standards may results in defects. Product defects are categorized into three levels; *critical, major* and *minor defects* as defined in Clause 3.

Assessment and *verification* involve tests, records of processes, *sampling plans* and quality control documentation. The required records are determined through *risk analysis*, classification of defects and corresponding methods of preventing these defects.

Assessment and *verification* records shall be kept by the manufacturer for at least five years and in accordance with national or regional regulations.

5 Determination of defect type

In the application of this document, every significant defect shall be determined and then classified according to type.

In order to determine the type of defects applicable to each product, it is necessary to understand the intended functionality. The properties required in the finish product relate to the application of the product. Where these properties are deficient, the resulting lack of functionality will have an impact which shall be evaluated.

Critical defects on tools, devices and equipment for live working are not acceptable. *Major defects* of tools, devices and equipment for live working are likely to result in failure or in a significant reduction of functionality, while *minor defects* do not reduce significantly the functionality.

The evaluation of impact due to functional or other defects involves a *risk analysis*. The ISO/IEC Guide 51 provides a framework for performing *risk analysis*.

6 Defects assessment methods

6.1 General

The main methods used in product manufacturing to prevent defects and ensure that standard requirements are met are testing, process documentation and quality assessment. A guide to developing general test methods (such as alternative test methods) is provided in Annex A.

6.2 Testing

6.2.1 General

Four categories of tests are included within live working product standards:

– *type test;*
– *routine test;*
– *sampling test;*
– *acceptance test.*

6.2.2 Type test

*Type test*s are performed on a relatively small number of items which are to be typical of all products. Tests performed on these few are to determine basic design and functional capabilities to their mechanical or electrical limits. Significant damage to the test object is probable.

*Type test*s often involve rigorous laboratory tests requiring specialized equipment. Products manufactured to the same specifications and using the same materials are expected to perform and have the same characteristics as those used in *type test*s.

While *type test*s provide design *verification*, they are not usually suitable to be performed continuously on production units. To verify some or all of the significant characteristics and functionality, it may be useful to develop other practicable test methods which could be applied to a wider number of items.

6.2.3 Routine test

*Routine test*s demonstrate performance and functionality according to specified levels and are conducted on each manufactured product. While verifying a level of conformance to standard requirements, these tests should not degrade or negatively impact the product.

Whenever the standard developer determines *routine tests* to be necessary those *routine test*s should be used to determine *critical defect*s.

6.2.4 Sampling test

*Sampling test*s are performed on either component parts of a product or finished items. These involve only a prescribed amount or number of items and may involve testing of performance to any level including destruction. *Sampling plan* parameters are determined statistically and shall be followed precisely to yield meaningful results. ISO 2859-1:1999 provides rules to follow in regard to determine *sampling plan*s for these tests. The adequate acceptable quality level (AQL) is determined according the *risk analysis*.

6.2.5 Acceptance test

An *acceptance test* is a contractual test to prove to the customer that the product meets the customer's specification. These tests are performed on a predetermined number of items in the complete batch of ordered units and are of varying severity.

*Acceptance test*s may be destructive or potentially damage the product. In this case, the disposition of the tested products should be considered. The product should be re-built or destroyed to ensure that worker safety is not jeopardized from use of a damaged product.

6.3 Process documentation

Process documentation is a means of ensuring that all products are manufactured in a traceable and consistent fashion. In this way, each item produced most exactly replicates those used in type testing. Where production processes and materials are verified, function and performance characteristics may be inferred in the finished product.

7 Verification methods

7.1 General

Verification methods involve the systematic means of identifying and preventing possible product defects and ensuring that manufactured products meet the requirements of the associated product standard.

Following a *risk analysis*, information pertaining to verification method including a rationale of the *defects* (*critical, major and minor*) shall be provided in normative annexes of each product standard. This information is best presented in tables where each defect is identified and classified along with the required tests and relevant subclauses. An example presentation of defects assessment information requirements for IEC 61481-2:2014 is presented in Annex B.

7.2 Identification and classification of defects

The classification of possible defects shall be based on a *risk analysis*, considering:

– the severity of the *harm*;
– and the probability of occurrence of the *harm*.

7.3 Requirements and tests

Each live working product standard provides appropriate means for ensuring that all significant features of the product are measurable and verifiable. These include tests, documentation, processes and other requirements detailed in each product standard.

For each defect identified, an explanation or appropriate clause or subclause of the product standard shall be identified as shown in Table B.1 and Table B.2.