

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Live working – Conformity assessment applicable to tools, devices and equipment

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Travaux sous tension – Evaluation de la conformité applicable à l'outillage, au matériel et aux dispositifs

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CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions.....	6
4 General.....	8
5 Categories of tests.....	8
5.1 Overview.....	8
5.2 Routine tests.....	9
5.3 Sampling tests.....	9
5.4 Acceptance tests.....	9
6 Sampling procedure.....	9
Annex A (informative) Acceptance test.....	10
Annex B (informative) Recommendations for developing and applying equivalent alternative test methods.....	11
Annex C (informative) Classification of defects and tests to be allocated.....	12
Bibliography.....	14
Table C.1 – Classification of defects and associated requirements and tests.....	13

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IEC 61318:2007

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

This third edition cancels and replaces the first edition which was issued as a technical report in 1994 with its Corrigendum 1 (2000), and the second edition, withdrawn, which was issued as a standard in 2003. It includes the following significant technical changes from the previous edition:

- change of the purpose of the document from a support to standard writers to a standard for assessing the conformity by testing of products having completed the production phase;
- clarification of the definitions of critical, major and minor defects;
- specification of ISO 2859 for the manufacturers to define the appropriate sampling plans;
- review of the acceptance quality limit (AQL) to specify lower limits.

The text of this standard is based on the following documents:

FDIS	Report on voting
78/705/FDIS	78/713/RVD

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

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

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

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INTRODUCTION

This publication provides elements for product conformity assessment.

This standard is specified in each IEC product standard for live working for the purpose of assessing that products having completed the production phase meet the requirements of the relevant product standard.

It can be used as a basis for production certification.

TC 78 prepares product standards which include requirements and normative tests for design input (type tests).

Product conformity assessment elements related to the production phase (among them is the procedure to associate routine and sampling tests to the classification of defects) are included in the present standard.

This publication does not cover conformity of commercial shipments. Shipments can contain products coming from several production batches. Batches are here understood as related to production.

This publication is not a quality management systems standard.

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LIVE WORKING – CONFORMITY ASSESSMENT APPLICABLE TO TOOLS, DEVICES AND EQUIPMENT

1 Scope

This International Standard provides elements for product conformity assessment. Critical defects on tools, devices and equipment for live working are not acceptable. Major defects on 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.

This standard defines assessment methods for products having completed production phase to assure that they conform to the requirements of the corresponding product standard. It is to be used in conjunction with live working corresponding product standards.

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

- type tests;
- provisions and description for sampling and routine tests;
- the identification and classification of the corresponding defects resulting from a risk analysis.

2 Normative references

[IEC 61318:2007](#)

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The following referenced documents are indispensable for the application 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.

ISO 2859 (all parts), *Sampling procedures for inspection by attributes*

3 Terms and definitions

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

NOTE Some of the terms and definitions below have been modified in order to apply more exactly to live working product standards.

3.1

acceptance quality limit

AQL

maximum per cent defective (or the maximum number of defects per 100 items) for purposes of sampling inspections, that can be considered satisfactory as a process average

[ISO 2859-1, Definition 3.1.26, modified]

3.2

acceptance test

contractual test to prove to the customer that the item(s) meet(s) certain conditions of its specification

[IEV 151-16-23, modified]

3.3

conformity assessment

any activity concerned with determining directly or indirectly that relevant requirements are fulfilled

NOTE Examples of conformity-assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration, certification), registration, accreditation and approval as well as their combinations.

[ISO/IEC Guide 7, Definition 3.1]

3.4

critical defect

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

3.5

lot size

number of items in a lot to be evaluated for standard conformance

[ISO 2859-1, Definition 3.1.14, modified]

3.6

major defect

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

3.7

minor defect

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

3.8

responsible authority

concept used to maintain the neutrality of this document (primarily for specification purposes), irrespective of whether it is being invoked or applied by the first, second or third party

NOTE The responsible authority may be:

- a) the quality department within a supplier's organization (first party);
- b) the purchaser or procurement organization (second party);
- c) an independent verification or certification authority (third party);
- d) any of a), b) or c), differing according to function as described in a written agreement between two of the parties, for example a document between supplier and purchaser.

[ISO 2859-1, Definition 3.1.12, modified]

3.9

risk

combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51, Definition 3.2]

3.10

risk analysis

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

[ISO/IEC Guide 51, Definition 3.10]

3.11

routine test

test performed on each item during or after production to ascertain whether it complies with certain criteria

[IEV 151-16-17, modified]

3.12

sample size

number of items in the sample

[ISO 2859-1, Definition 3.1.16]

3.13

sampling plan

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

[ISO 2859-1, Definition 3.1.17]

3.14

sampling test

test on a sample

[IEV 151-16-20]

3.15

type test

test performed on one or more items representative of the production, made to show that the design of the product meets certain requirements

[IEV 151-16-16, modified]

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4 General

The conformity assessment of every finished tool, device and equipment having completed the production phase can be achieved by the application of the provisions of this standard.

Alternative test methods based on quality and safety assessment (see Annex B) are acceptable if they warrant the same level of conformity and safety and are validated by a “responsible authority”.

NOTE Where appropriate, the product standards should include alternative test methods when the methods specified at the type test level are found less or not practicable at the production level. Nevertheless, it could happen that a test method provided in the product standard is not found adequate by a manufacturer. In such case, the present standard permits to replace this test by another equivalent alternative test.

These alternative test methods shall be justified, described, maintained and recorded.

NOTE To justify an alternative test method the manufacturer will have to provide objective evidence that it warrants the same level of conformity and safety.

In any cases test results shall be recorded and kept by the manufacturer in accordance with national or regional regulations but not less than five years.

5 Categories of tests

5.1 Overview

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

- type tests (not covered by this standard),
- routine tests (see 5.2),
- sampling tests (see 5.3),
- acceptance tests (see 5.4 and Annex A).

This standard is intended to be used for managing routine and sampling tests in the purpose of conformity assessment during the production phase.

This standard provides an informative annex related to acceptance tests.

NOTE Other tests may be included in the conformity assessment documentation – for example, tests recommended for use during production to monitor the production process, but they are not covered by this standard.

5.2 Routine tests

Routine tests shall be performed to avoid critical defect.

An annex within each product standard identifies critical defects and associated tests (see a typical example in Annex C). To be in accordance with the present standard, these tests or alternative test methods as specified in Clause 4 shall be used as routine tests.

5.3 Sampling tests

Sampling tests shall be performed to avoid major and minor defects.

An annex within each product standard identifies major and minor defects and associated tests (see a typical example in Annex C). To be in accordance with the present standard, these tests or alternative test methods as specified in Clause 4 shall be used as sampling tests.

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Sampling procedures and the validation of test results shall be in conformance with Clause 6.

5.4 Acceptance tests

Annex A provides guidance on the use of acceptance tests at customer's request within the frame of a commercial contract.

6 Sampling procedure

The sampling procedure is based on the availability of non-destructive sampling tests. When the tests proposed within the product standard are destructive, the manufacturer could propose if possible alternative non-destructive test methods according to Clause 4.

The manufacturer shall define a sampling plan, using the rules of ISO 2859. According to the nature of the product and the lot size, the manufacturer will select the more appropriate sampling parameters while respecting the following:

- major defects : $AQL \leq 2,5$;
- minor defects : $AQL \leq 4$.

Annex A
(informative)

Acceptance test

An acceptance test is a contractual test to prove to the customer that the item(s) or product in question meet(s) the customer's specification.

If the customer requests additional tests or increase of the stringency of the sampling procedure this should be acceptable after agreement between the customer and the supplier.

In that case the customer should include this within his own specification.

The disposition of tested products should be considered. If a test is destructive the product should be re-built, if possible, or destroyed to insure that worker safety is not jeopardized from the later use of a damaged product.

If the test is non-destructive and the products are not damaged, they could be (or not) included in the customer order as a normal part of the order.

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