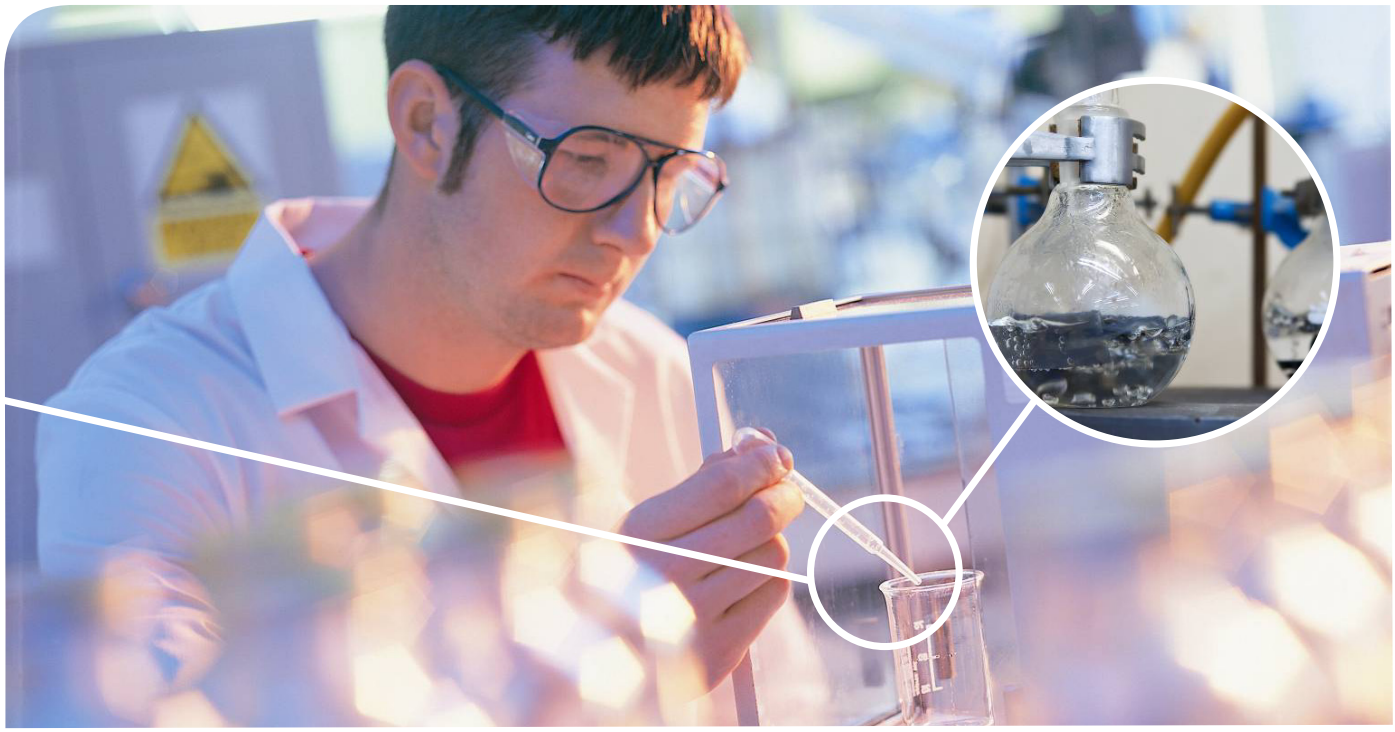
EN 61010-1, 3rd Edition

Quick Tips: Changes from 2nd to 3rd Edition

Intertek
Valued Quality. Delivered.



Intertek offers a full service solution to the challenges you face in the Healthcare industry. We provide industry-leading turnaround times to ensure compliance deadlines are met. Our global network of laboratories and expert engineers offer knowledge and proactive testing, certification and regulatory services to ensure that your laboratory equipment and healthcare applications get to market, faster.

EN 61010, 3rd Edition: The new standard was published in June 2010 and serves as a replacement for the 2nd Edition (published in 2001).Intertek is fully equipped to partner with you through your transition from the 2nd to the 3rd Edition – we help you navigate the standard revisions and applicable safety requirements.

Effective Compliance Deadline for Europe: Laboratory equipment that only requires certification to the general standard EN 61010-1 must demonstrate conformity to the 3rd edition by **October 1, 2013.**

Laboratory equipment requiring certification to a particular standard EN 61010-2-XXX must demonstrate conformity **within three years** of that particular standard's date of radification.

We focus on the most pressing breakthrough of all – your market entry.

- Intertek simplifies your transition from the 2nd to the 3rd edition
- Count on Intertek's speed and service to get your laboratory equipment into global markets

Intertek

Valued Quality. Delivered.

Clause 6 – Key Changes

Clause 6.5:

- New allowance for products with permanently-attached supply cords
- New test for transformers with a protective bonding screen

Clause 6.7:

- Requirements moved and sections renamed/redefined
- New requirements for layered PWBs, molded and potted parts, and thin-film insulation
- Table 4 now starts at <150 V; Distances are the same
- New clarification for secondary circuits' test voltages
- New requirements for the interior of void-free molded parts and multi-layer PWBs
- Working voltage measurements are required to determine the appropriate creepage and clearance values to be used

Clause 6.8:

- Test voltages are no longer based on clearance distances, thus interpolation is no longer needed
- Voltage tests on solid insulation are now 1 minute (used to be 5 seconds)
- New standard for impulse test is now EN 61180-1 (used to be EN 60060), and requires 5 impulses instead of 3

Clause 7 – Key Changes

Clause 7.2:

- Requirements for sharp edges were added

Clause 7.3:

- The requirements for moving parts now include review of risk assessment
- New requirements for 1) limiting forces and pressures and 2) gaps between moving parts

Clause 7.3.5:

- New requirement for load testing on parts supporting heavy loads

Clause 7.4:

- New requirement for support feet and castors

EN 61010, 3rd Edition Expanded Scope

The scope of the standard is expanded to cover the following types of equipment – regardless of where these products may be used.

- Electrical laboratory equipment
- Electrical industrial process-control equipment

Clause 8 – Key Changes

- Introduces risk assessment as a means of identifying the levels of energy the equipment must resist during mechanical stress testing
- Added the IK rating as a means to identify the degree of protection required for the enclosure referencing EN 62262

Clause 10 – Key Changes

- Surface temperature limits were modified to align with EN 563

Clause 11 – Key Changes

- Leakage and rupture at high pressure is checked by inspection – if a hazard could arise by test, then test values are lower
- Fluids now defined more clearly as including both liquids and gases
- Spillage test now includes aggressive substances (similar to the requirements for IVD equipment covered in EN 61010-2-101)

Clause 12 – Key Changes

- Radiation requirements have been modified to account for the distinction between intended emission and unintended emission

Clause 16 – Key Changes

- New requirements for reasonably foreseeable misuse and ergonomic aspects

Clause 17 – *NEW!*

- Added to deal with hazards and environments not covered by the standard, along with the new informative Annex J dealing with risk assessment
- Requires a review of the manufacturer's risk assessment file as part of the overall evaluation of the product

Intertek

545 E. Algonquin Road,
Suite F
Arlington Heights, IL
60005

1.800.WORLDLAB

www.intertek.com

For more information please visit www.intertek.com/medical, or contact us at icenter@intertek.com or +1 800 967 5352.

To find an office or laboratory in a particular country, please visit www.intertek.com/contact.