



A technician preparing to run microbial genomes on the Roche 454 sequencing platform at the Advanced Technology Research Facility (ATRF), Frederick National Laboratory for Cancer Research, National Cancer Institute.

Advanced methods for assessment of risks of false decisions in analytical chemistry (testing) laboratories—basic concepts and associated terms

There are three main documents by ISO and IEC for risk management: ISO 31000:2018 “Risk management—Guidelines”, IEC 31010:2019 “Risk management—Risk assessment techniques”, and ISO 31073:2022 “Risk management—Vocabulary”. These documents provide a common approach (based on the risk assessment) for the management of any type of risk and are not industry- or sector- specific. They can be customized to any organization, and are applicable to any activity, including decision-making. However, the authors of the documents (ISO/TC 262) emphasize that in practice the concepts and terminology need to be adapted to the field or discipline of application, to avoid misinterpretation, misrepresentation, or misuse.

During the past decade several IUPAC projects have been dedicated to risk assessment in an analytical laboratory:

1. A position paper of the IUPAC project team (project 2014-027-1-500) on the risks of false decisions originated by human errors (2013), <https://doi.org/10.1007/s00769-012-0934-y>, has reached about 16000 readers (ResearchGate, 25 July 2024). The IUPAC/CITAC Guide on assessment of the risks caused by human errors (2016), <https://doi.org/10.1515/ci-2016-0520>, was implemented recently even in such unexpected fields as medicine (2023), <https://doi.org/10.21037/jlpm-23-7>, and military equipment testing (2024),

<https://doi.org/10.37701/dndivsovt.20.2024.15>.

2. The topic of risks of false decisions in conformity assessment due to measurement uncertainty was initially addressed in the IUPAC/CITAC Guide on assessment of the risks of out-of-specification test results of a single component content (2012), <https://doi.org/10.1351/PAC-REP-11-10-04>. It was further developed in the IUPAC/CITAC Guide for multicomponent objects, when test results may be correlated (2020), <https://doi.org/10.1515/pac-2019-0906>; and in the IUPAC/CITAC Guide for multicomponent objects under a mass balance constraint (2023), <https://doi.org/10.1515/pac-2022-0801>.

In the current project a harmonization of basic concepts and associated terms applied in advanced methods for assessment of the risks is offered. This harmonization will contribute to quality assurance wherever measurements and tests are made in analytical chemistry (testing) laboratories, in industry, trade, environmental analysis, or another field. The project will also contribute to the IUPAC Mission “providing a common language for chemistry”.

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IUPAC HELM Glycans Extension

HELM (Hierarchical Editing Language for Macromolecules) is a machine-readable linear notation for representing biopolymers, including peptides,