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**Biotechnology — Minimum  
requirements for optical signal  
measurements in photometric  
methods for biological samples**

*Biotechnologie — Exigences minimales relatives aux mesures  
de signaux optiques dans les méthodes photométriques pour les  
échantillons biologiques*



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ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document defines terms and provides general guidance for accurate measurement of optical signals used for analysis of biological samples in photometric methods. These photometric methods can use optical signal measurements, including bioluminescence, chemiluminescence, fluorescence or absorption measurement, that can be applied in the fields of biotechnology, life science and medicine. A measured optical signal value is applied for evaluating biological parameters qualitatively or quantitatively, including cellular and metabolic activities, and gene expressions. Photometric methods are used in applications such as toxicity testing, environmental risk assessment, biomanufacturing, drug development, regenerative medicine and biobanking.

There are significant needs for both manufacturers and users for high quality optical signal measurement in photometric methods in industry to increase confidence in the repeatability, intermediate precision and reproducibility for analysis of biological samples. While repeatability of the photometric method is already sufficient for qualitative characterization of biological samples, quantitative characterization requires more accurate intermediate precision and reproducibility of optical signal measurement. It requires proper optical signal measurements, and it also requires assessment of deviations from the ideal proportionality of the optical signal and the output of the photometric method. Requirements for proper optical signal measurement are an important component of the description of specific applications of photometric methods.

This document provides a general framework to support proper measurement of an optical signal in a photometric method. It focuses on the utilization of optical references and relevant technical issues for optical signal measurement in photometric methods, including procedures for verification of instruments, continual performance monitoring of instruments and photometric method validation. Optical references can be used to verify instruments to increase confidence in the repeatability, intermediate precision, and reproducibility of optical signal measurement. For example, an optical signal emitted from biological samples can be compared on a common measurement scale within a laboratory, between manufacturer and manufacturer, manufacturer and user, or user and user.



# Biotechnology — Minimum requirements for optical signal measurements in photometric methods for biological samples

## 1 Scope

This document specifies minimum requirements to support accurate measurement of optical signals in photometric methods used for qualitative or quantitative characterization of biological samples.

This document is applicable to optical signals that are generated, for example, by bioluminescence, chemiluminescence and fluorescence, and optical signals that are detected as changes of light due to absorption.

This document addresses the verification of optical signal measurement instruments used in photometric methods for measurement of biological samples including considerations for the use of optical references.

This document does not provide sector- or application-specific performance criteria for the workflow of measuring biological samples. When applicable, users can also consult existing sector- or application-specific standards, or both.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### **accuracy**

closeness of agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: The concept “measurement accuracy” is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term “measurement accuracy” should not be used for measurement trueness and the term “measurement precision” should not be used for “measurement accuracy”, which, however, is related to both these concepts.

Note 3 to entry: “Measurement accuracy” is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

Note 4 to entry: ISO 5725-1:1994 uses a different definition for “accuracy”.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified — “measurement accuracy” and “accuracy of measurement” deleted as terms. Note 4 to entry added.]