

**CBER Standards Recognition Program for Regenerative Medicine Therapies  
Standards Recognition Summary (SRS)**

**Recognition Number:** 48

**Date of Recognition:** 12/9/2025

**SDO Name/Designation:** ISO 24421

**Year of Publication:** 2023

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

**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.

**Extent of Recognition:** Complete Recognition

**Rational for Recognition:** The standard is applicable to regenerative medicines and does not conflict with FDA regulations and policy.

**Standards Development Organization:** [www.iso.org](http://www.iso.org)

*Please note that this standard may also be recognized under the Center for Devices and Radiological Health's (CDRH) Recognized Consensus Standards Database for Medical Device, found here: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> .*