

How MediaLab Can Help You Meet ISO 15189 Requirements for Document Control

ISO 15189 is a comprehensive standard that touches on all areas of the laboratory. Section 4.3 presents standards relating specifically to document control.

ISO requirements are paraphrased from the original ISO 15189 document. For exact requirements, please consult <http://www.iso.org>.

ISO 15189 4.3 Standard	MediaLab's Capability	Subscriber's Steps to Address
All documents are to be reviewed and approved by authorized personnel before use.	Enforces that documents follow applicable approval processes, including the lab director's signature, before they are marked as "approved" and made available to employees.	Select lab director (under "Permissions" tab). Set up approval processes (under "Permissions" tab).
All documents must carry identifying information, including: title, unique identifier on each page, version date or version number, page count, authority for issue.	On-screen and printed documents display the name, version number, effective date and page count on every page. On-screen and printed documents also display the applicable lab director approval and date.	Automatic
Current approved documents are tracked on a document register or master index.	Provides an automatically updating index, including information on current version number, last approval, last review, and next review due date.	View index at any time (under "Reports" tab)
Hand-edits are identified and approved appropriately	Hand-edits are not allowed in Document Control. Edits to documents are tracked	n/a

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	as new major or minor revisions that must follow applicable approval processes before they are made available.	
Changes to documents are identified.	Edits to documents create new versions of documents that can be compared to older versions. Note fields and "Track Changes" capability present changes to employees.	Automatic
Documents are readable.	Displays and prints legible copies of Word, Excel, PowerPoint, PDF, HTML, and image files. User formatting is preserved. Edits, stamps, signatures, headers, and footers do not interfere with legibility of documents.	Automatic
Documents are reviewed on a periodic basis to make sure they are still applicable and correct.	Notifies designated employees 90 days before biennial or annual review date. Sends regular reminders until task is completed. Designated employees sign off that they have reviewed of each document.	Select annual or biennial review period (under "Permissions" tab). Perform periodic review when task appears on To-Do list.
Obsolete documents are retired and marked as such.	Marks retired documents and older versions of current documents with appropriate warnings.	Retire documents as needed.

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	Restricts access to authorized administrative users.	
Obsolete documents are retained for archival purposes.	Retains retired documents and older versions of current documents indefinitely. Documents can be viewed at any time by authorized administrative users.	View retired documents (under "View Documents & Manuals" tab).