# SOLABS QM 10:  Document Periodic Review Cycles

## Introduction:

This document covers how to manage Periodic Reviews for documents that may require one.   Default values for Periodic Review requirements can be set for Document Types.

## Setting Periodic Review Cycle Defaults for Document Types

When creating a new Document Type, there are fields to identify whether or not a Periodic Review Cycle is required and the timeframes for that cycle.

To create and revise Document Types you must have the **SOLABS Document Administrator** role assignment.

To see all of the settings for Document Types, refer to **SOLABS QM 10: Guide for Document Administrators** on the SOLABS Knowledge Base.  This document will cover just the settings for **Periodic Review Cycles**.

The fields for defining the Periodic Review settings are included in the **Standard Attributes** section under **Effective Date**.   If you would like to define a Period Review Cycle, select Effective Date.  This will bring up the selections for setting the **Periodic Review Cycle**.



The **Default Periodic Review Cycle (months)** can be selected  from a single-item selection list. If you require other settings in this section but do not need a Periodic Review Cycle, simply select the option of **N/A**.

You can also select a **Planned Review task default duration (months)** setting.  In a future version of SOLABS QM 10, this setting will trigger email Notifications to the Document Owner, Author and/or Document Coordinator that many months ahead of the Periodic Review due date so that the review activities can be initiated.  If N/A is selected for the Default Periodic Review Cycle, the Planned Review task duration will automatically default to N/A.

## Modifying Default Periodic Review Cycle Settings on a Document

When a Document Type is selected on the Authoring page, all the defaults for that Document Type are brought in automatically but many, including the Periodic Review Cycle settings can be edited if needed. The values can be changed as needed. Simply removing the checkmarks will change the settings to N/A.



When the document becomes Approved & Effective, the **Next Review Date** field will be populated.



Although the **Next Review Date** field is grayed out, it can be changed or removed on an Approved & Effective document using the **Modify Metadata Only** option on the Document Actions menu. Users need at least Modify permissions in order to see this option. This will enable the Periodic Review Cycle fields for editing. When those changes are Submitted and Confirmed (a Reason for Change will be required), the Next Review Date field will reflect the revised date, or N/A if that was selected.



You will be required to enter a **Reason for Change** when submitting and confirming the change to the Periodic Review Cycle fields. This will be captured in the **Audit Trail** so including the justification for this change will be available as proof that the document was reviewed and the update to the Next Review Date was intentionally revised. When using this option documents could keep the same effective for long periods of time, even though they will be periodically reviewed, so ensure your internal SOPs allow for this and state that such updates are captured as part of the Audit Trail.

## What if the Periodic Review results in a decision that no updates are necessary?

Moving out the Next Review Date, as described above, can be handy if the Document Owner reviews the content as part of the Periodic Review and determines that no updates are required. In this case the document revision and effective date will remain the same but another review will trigger again at the later date. As mentioned above, be sure your internal SOPs allow for this option and include the fact that such updates, and the related justification, are captured as part of the document Audit Trail.

Note that since the document revision does not change in this case, any Training Activities set for Recurrence based on Document Revision will not be retriggered.

If the Document Owner indicates that no updates are required but would still like training to be retriggered so that people can refresh on the content of the document, the best option would be to process the document for revision. In this case the Reason for Change field could include a statement such as "Reviewed as required per Document Periodic Review requirements; no updates necessary at this time." If there is a related Training Activity set for Recurrence based on Document Review, this will retrigger training. If not, the training can be manually created for the new revision.

If no updates are required but the Document Owner would like to reset the default Periodic Review Cycle without retriggering training (since there are no changes), the document should be processed for revision using the **Cosmetic Change** option during authoring. This will result in no training requirements for that particular version of the document.



The Reason for Change can still include a statement such as "Reviewed as required per Document Periodic Review requirements. No changes needed so no retraining is required." This will be captured as part of the document Audit Trail.

## Monitoring for Next Review Dates

As mentioned on the last page, a future release of SOLABS QM 10 will trigger email Notification based upon the **Planned Review task default duration (months)** setting for a document.

Document owners, authors and Document Coordinators can also use various **Views** to monitor documents coming due for Periodic Review. All of these views will list any documents due for Periodic Review within the next 6 months. These views are available from the left-hand menus when in the DOCUMENT section of SOLABS QM 10.

SOLABS QM 10 **Reports** can also be used to monitor for Next Review Dates. The following reports include the Next Review Date metadata so can be filtered based on that information:

Excel Datasets:

 Ds Document Metadata TRN_Trial124

SSRS Document Listing Reports:

 Detailed Report

 Printable Summary

 Summary With Doc Control Process Data

 Summary With Last Modifier Data



**My Documents**
Top 30 (last 90 days)
Read (last 30 days)
Effective (last 90 days)
I acted on (last 90 days)
I am the author or owner
I am the author or owner - by next review date
**Document Coordinator**
In process - my
In authoring - my
In review - my
In approval - my
To retire - my
In retire - my
Due for review - my
In process - all
To retire - all
In retire - all
Approved, not effective - all
Awaiting retire date - all
Superseded and retired - all
Due for review - all
Back from review
Rejected during approval

## Processing Document Revisions for Periodic Reviews

If Document Coordinators see a document coming due for Periodic Review, they can initiate a revision to the document that includes just a Review Cycle, with the Document Owner as the one Reviewer. A dedicated Document Workflow Template would facilitate this.

The Reason for Change field can then be used by the Document Coordinator to communicate the upcoming Periodic Review, request that they review the attached document and then use the **Provide Feedback** option of **Reviewed, see comments**. The Document Coordinator can even provide a list of feedback comments to choose from, such as:

- I have reviewed this document and it requires changes. Changes can be identified in the Comments field or by attaching a revised document.
- I have reviewed this document and it requires no changes. Please keep this revision Effective but move the Next Review Date to ____.
- I have reviewed this document and it requires no changes. Please process for revision so that training is retriggered. State as Reason for Change that it was "Reviewed as required per Document Periodic Review requirements; no updates necessary at this time."
- I have reviewed this document and it requires no changes. Please process for revision to reset the Periodic Review Cycle period but use the Cosmetic Change option so that training is not retriggered.

## Using the Document Control Process to Manage Periodic Reviews

The Document Control Process also be used to help Document Coordinators manage the Periodic Reviews for documents they see approaching the Next Review Date.

The Document Coordinator can initiate a Document Control Process when a document is nearing its Next Review Date.



At **Step 1, Change Request for Creation, Revision or Retire of Document** they can select **Type of Change** = **REVISION**.

They can use the **Description of Change** and **Purpose of Change** fields to state that the document is coming due for Periodic Review and provide similar instructions as those included in the previous section.

The **Target Completion Date** field can be used to enter the Next Review Date.



If the Document Type is set to require approval by the Owner-Manager, that field will be enabled for the Document Coordinator to choose the Document Owner. When Step 1 is submitted and confirmed, the Document Control Process will then move to **Step 2, Owner-Manager Approval**. This will notify the Document Owner that the document is due for review and will allow them to provide appropriate feedback.

If the Document Type is not set to require approval by the Owner-Manager, that field will be greyed out.  In this case, when Step 1 is submitted and confirmed, the Document Control Process will instead proceed **to Step 3, Document Coordinator Processing.**   At this point the Document Coordinator can initiate a Revision to the document and start a Review Cycle that includes only the Document Owner, as described on Page 4 under **Processing Document Revisions for Periodic Reviews**.   Again, this will provide a means to notify the Document Owner that the document is due for review and allow them to provide appropriate feedback.