

Risk-Based QC Sampling

Overview

When a document is sent to QC, eTMF determines the destination based on the document's risk level and associated QC percentage. Based on the outcome, the document will either be sent to QC or will be finalized. The Business Administrator sets these percentages in the **Risk-Based QC Sampling Levels** tab of the **System Configuration** window.

The percentages determine the following destinations:

- If the QC percentage is 100, the document will be sent to QC.
- If the QC percentage is 0, the document will be finalized.
- If the QC percentage is between 1 and 99, the system will generate a random number and compare it to the specified QC percentage. If the number is less than or equal to the QC percentage, the document will be sent to QC. If the number is greater than the QC percentage, the document will be finalized.

The risk level of a document is determined by its associated document type in the master list on a 1 – 10 scale. If the risk level is blank for a document type, the system assumes a QC percentage of 100, meaning the document will always be sent to QC.

Configure Risk-Based QC Sampling

1. As the Businesses Administrator click the **More** menu in the global header and select **Administration**.
2. In the **Systems Configuration** window, select the **Risk Based QC Sampling Levels** tab.
3. Change the QC% for risk levels as needed.

Note: Setting the level to 0% will result in all documents at

that risk level bypassing QC. Setting the level to 100% will result in all documents at the risk level being sent to QC unless bypassed by a Privileged Contributor.

4. Click the **Actions** dropdown, then select **Save**.