

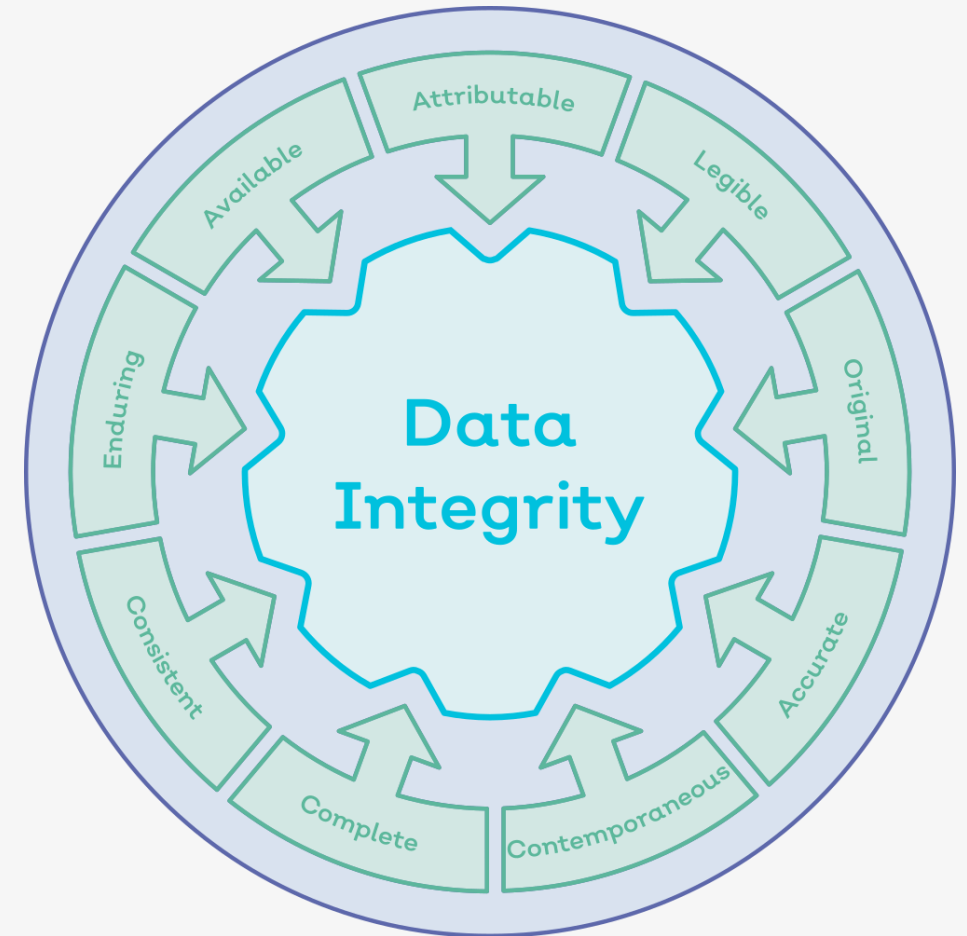
Data integrity with Document Manager

Applying the 9 principles

Qualsys summer user group 2019

What is data integrity?

- Scope: from initial data generation and recording through processing, use, retention, archiving, retrieval and destruction
- Applies to paper and electronic data and records, within the scope of a quality management system




Benefits of good data governance

- Better decision-making
- Transparency into processes (Standard Operating Procedures/Policies)
- Reduce operating costs
- Improved strategic planning
- Reduced risk of data loss and corruption
- Confidence in your document control

Your Quality Management System (QMS) provides more than a regulatory requirement checkbox and data integrity is key to best practice.

A: Attributable

The user that performed the task must be identifiable within the system



ID

Title

First Name

Surname


Logon Name

Password

Version

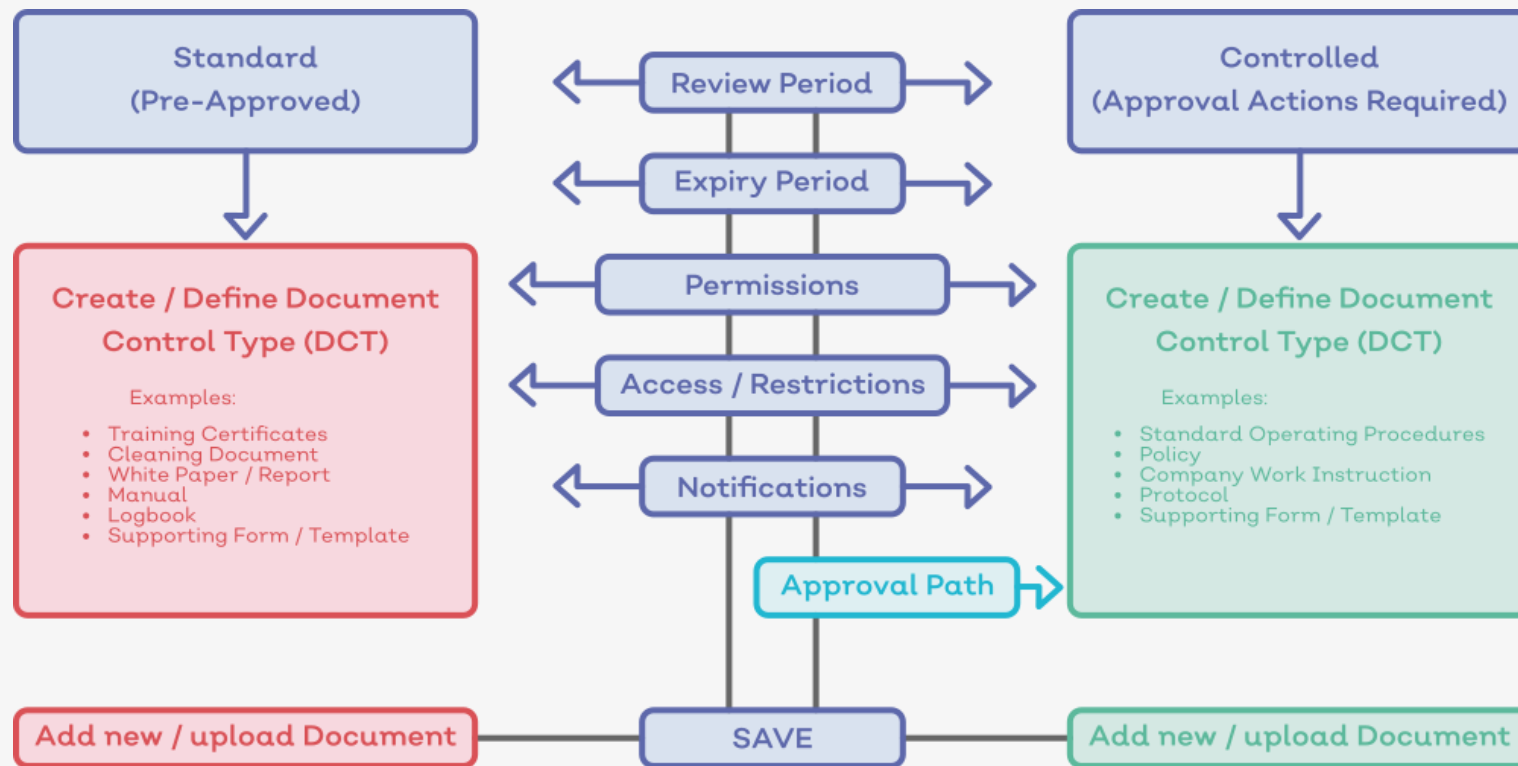
Issue Date

Owner User Group



L: Legible

Data is readable, understandable, and allows a clear picture of the sequencing of steps/events in the electronic record



C: Contemporaneous, complete

Contemporaneous

System makes a record of an activity at the time it takes place

Complete

All recorded data features an audit trail to show nothing has been deleted or lost

C: Contemporaneous, complete

Date Modified

Last Retrieved



Rob Needham updated **Document** record with ID 10078 - Policy Template, setting the **Last Retrieved Date** field to **21 May 2018 21:10** and changing the **Read Count** field from **0** to **1**

21 May 2018 21:10:22

Liam Pollard updated **Document** record with ID 10078 - Policy Template, setting the **ID** field to **10078** and changing the **Status** field from **10 - Link to Structure** to **5 - Live**

5 February 2018 16:44:43

Liam Pollard linked **Document Organisational Area** record **13 - Services**

5 February 2018 16:44:43

Liam Pollard linked **Document Topic** record **8 - Planning**

5 February 2018 16:44:43

Liam Pollard created a new **Document** record with ID 10078 - Policy Template and set the following 15 fields:

- **Approval Path** field to **0**
- **Batch** field to **333 - Alliance Medical Supporting Docs**
- **Change Manager** field to **Guest Account**
- **Checked Out** field to **0**
- **Document Control Type** field to **106 - Product Implementation - Customer**
- **Issuer** field to **Guest Account**
- **Original Filename** field to **Policy Template.doc**
- **Owner** field to **Liam Pollard**
- **Owner Group** field to **0**
- **Read Count** field to **0**
- **RFC** field to **0**
- **Status** field to **10 - Link to Structure**
- **Title** field to **Policy Template**
- **Version** field to **1.0**
- **Version Date** field to **05 Feb 2018 16:45**

5 February 2018 16:44:43

O: Original

The original captured data (record) must be retained

Metadata

Default	Sequence	Active	Mandatory
Uncontrolled Copy: <input type="text"/>	0	<input checked="" type="checkbox"/>	<input type="checkbox"/> ✗
Regulatory Impact: <input type="radio"/> Yes <input checked="" type="radio"/> No	1	<input checked="" type="checkbox"/>	<input type="checkbox"/> ✗
Training Impact: <input type="text"/>	2	<input checked="" type="checkbox"/>	<input type="checkbox"/> ✗

Owner:

Uncontrolled Copy:

Regulatory Impact: Yes No

Training Impact:

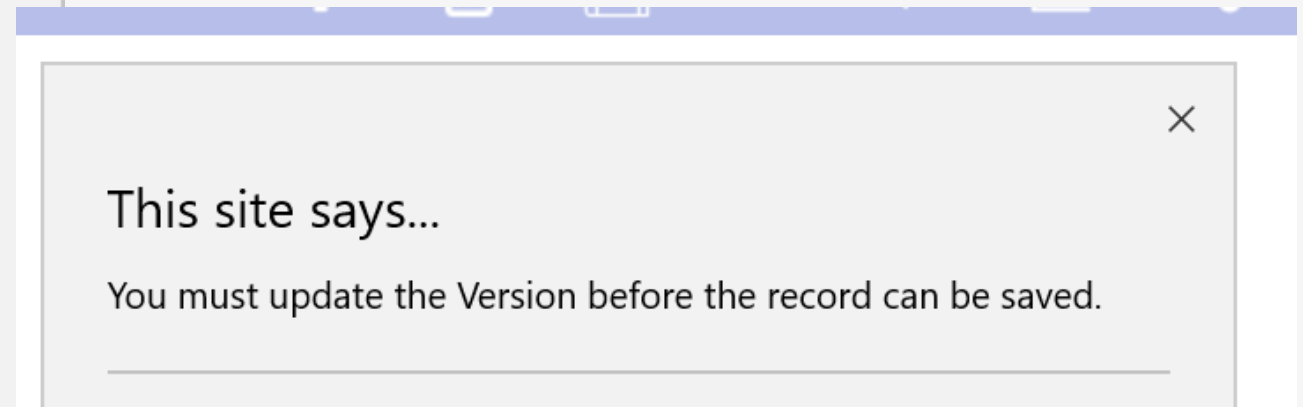
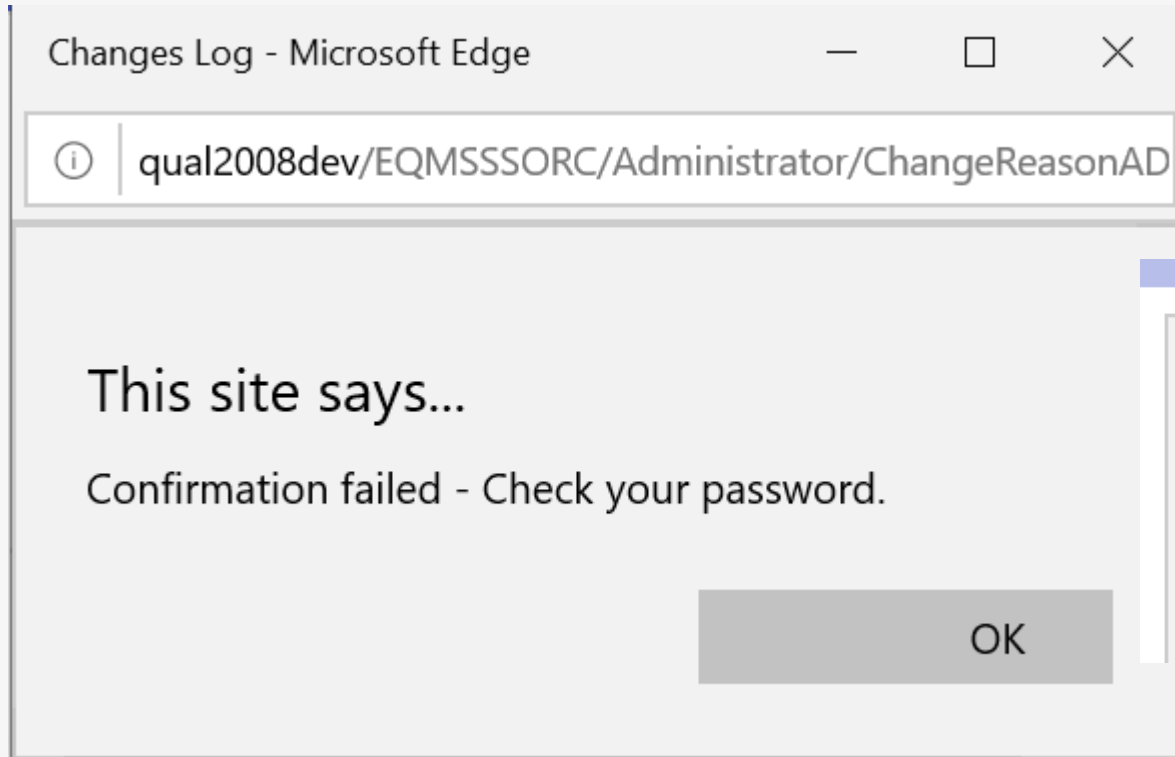
Owner: User Group

Metadata: %Uncontrolled Copy:M1928%

Date: %:Date: M025%

A: Accurate


When recording data electronically, the system must have built-in accuracy checks and verification controls



C: Consistent

Consistency with records requires change/version management and traceability matrices

Details For Live Document 2623



Changes Log - Microsoft Edge

qual2008dev/EQMSSSORC/Administrator/ChangeReasonAD

Enter an ID and reason for the Change

Reason

Password

OK Cancel

Changes Log Version:




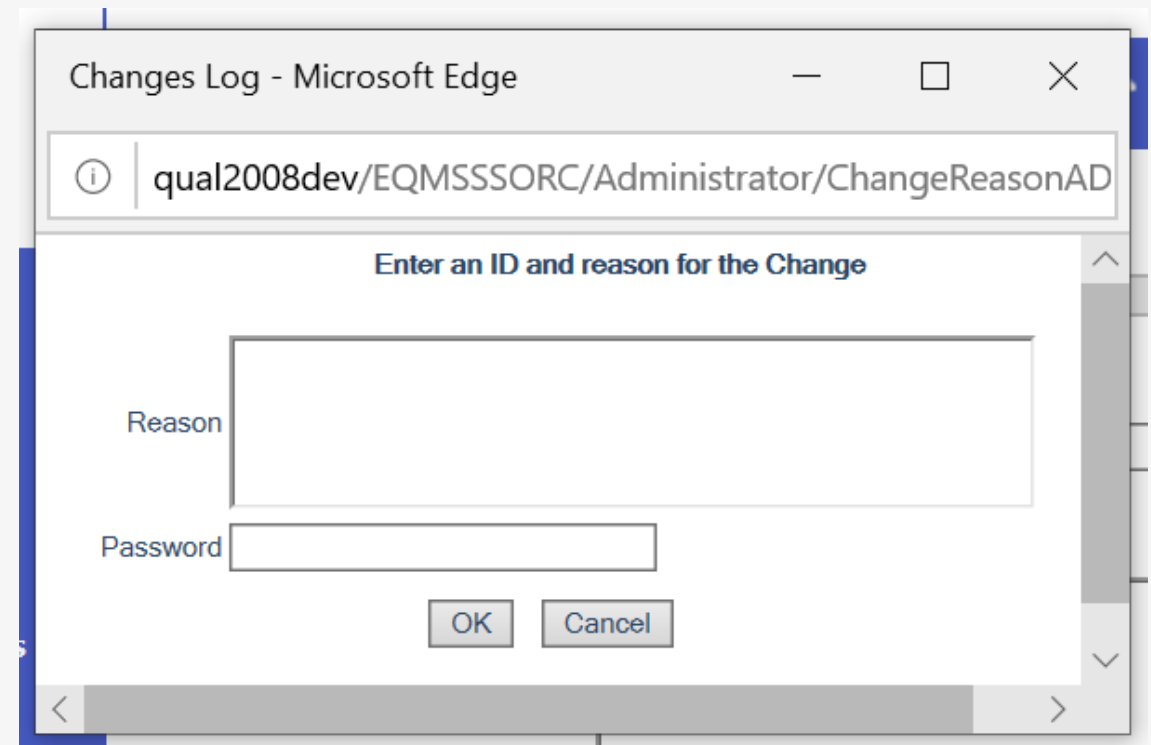
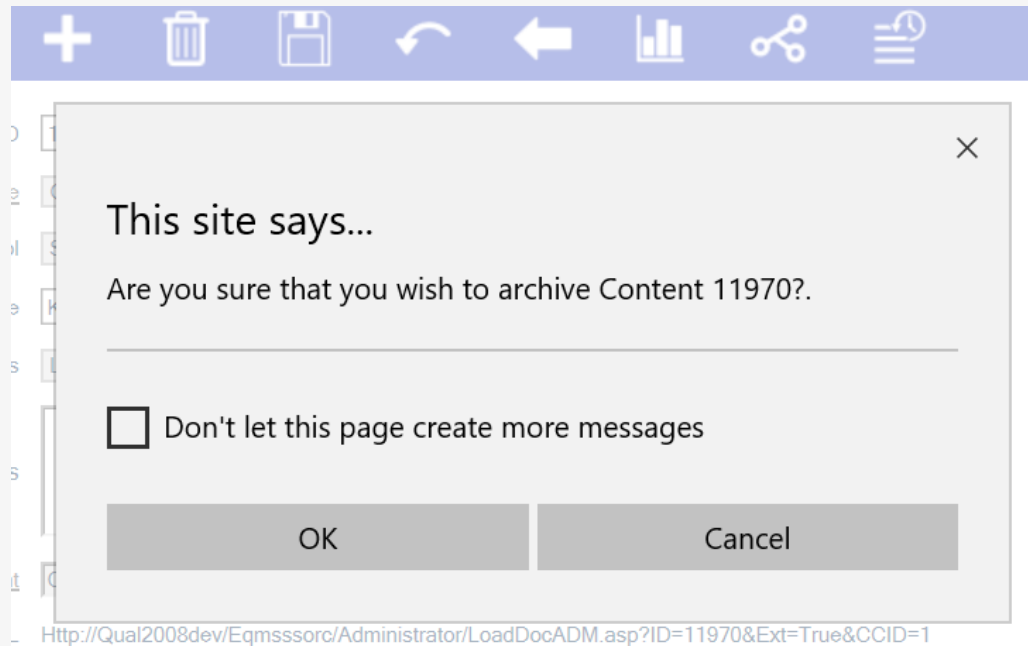
Log ID	Comments	Changed By	Date Changed	Version	
1872	Training certificate text updated	Kaye Eames	08 Jul 2019	2.0	
1874	Rebranded document	Kaye Eames	08 Jul 2019	3.0	
1876	Updated module type and certificate text	Kaye Eames	08 Jul 2019	4.0	

Diagram description: A central toolbar with four icons (save, undo, history, search) is connected by blue arrows to a 'Changes Log' dialog box on the left and a 'Changes Log' table on the right. The arrow from the save icon points to the 'Reason' field in the dialog. The arrow from the history icon points to the 'Version' column in the table.

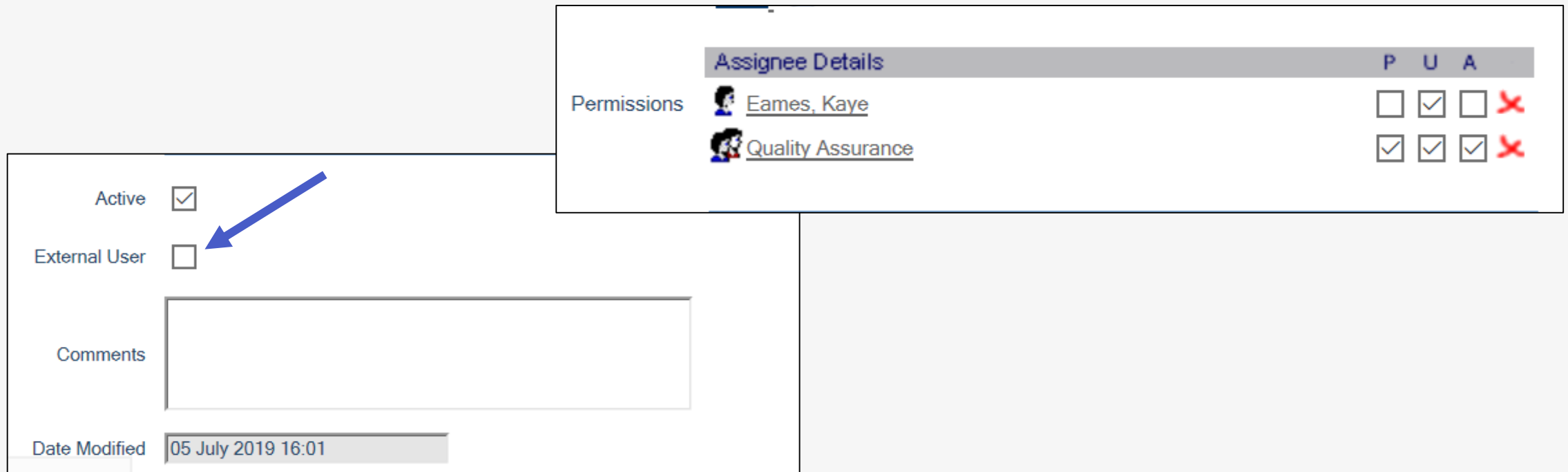
E: Enduring

Ensuring records and information exist and are readable during the entire period in which they might be needed, including long after recording... in some cases, decades!



A: Available

Records must be accessible in a readable format to all applicable personnel responsible for their review or other operational processes. These must also be available for review/inspection to external users if relevant.





Active

External User

Comments

Date Modified 05 July 2019 16:01

Assignee Details		P	U	A	
Permissions	 <u>Eames, Kaye</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	 <u>Quality Assurance</u>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Thanks for listening

Aizlewood's Mill,
Nursery Street,
Sheffield
S3 8GG

 +44 114 282 3338

 info@qualsys.co.uk