**Qualis LIMS (ReactJS) 1.0**

**Installation Qualification**

This information is believed to be complete and accurate as of publication, and is subject to change without notice.

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**1. Purpose**

The objective of this protocol is to verify the installation of the Qualis LIMS program and to   
 verify that it performs its intended function in a consistent and reproducible manner. Specific   
 test objectives and acceptance criteria are defined.

**1.1. Installation Qualification**

The Installation Qualification consists of tests to ensure that the components of the Qualis   
 LIMS program have been properly installed. Specific test objectives and acceptance criteria   
 are defined..

**2. Scope**

This protocol specifies the Installation Qualification tests that are to be applied to the Qualis LIMS program, which will be used in a cGMP/cGLP environment, for the purpose of verifying proper installation. The Qualis LIMS is installed to manage Laboratory workflows and data generated in process over the LAN to a database. Within the scope of this protocol are the activities and tasks that must be performed throughout the qualification process.  
Changes made to the software and/or computer systems after validation is completed must be conducted under the appropriate system change control procedure. Parts of the protocol may be used for reconfirmation or revalidation, if necessary.

**3. Validation Methodology**

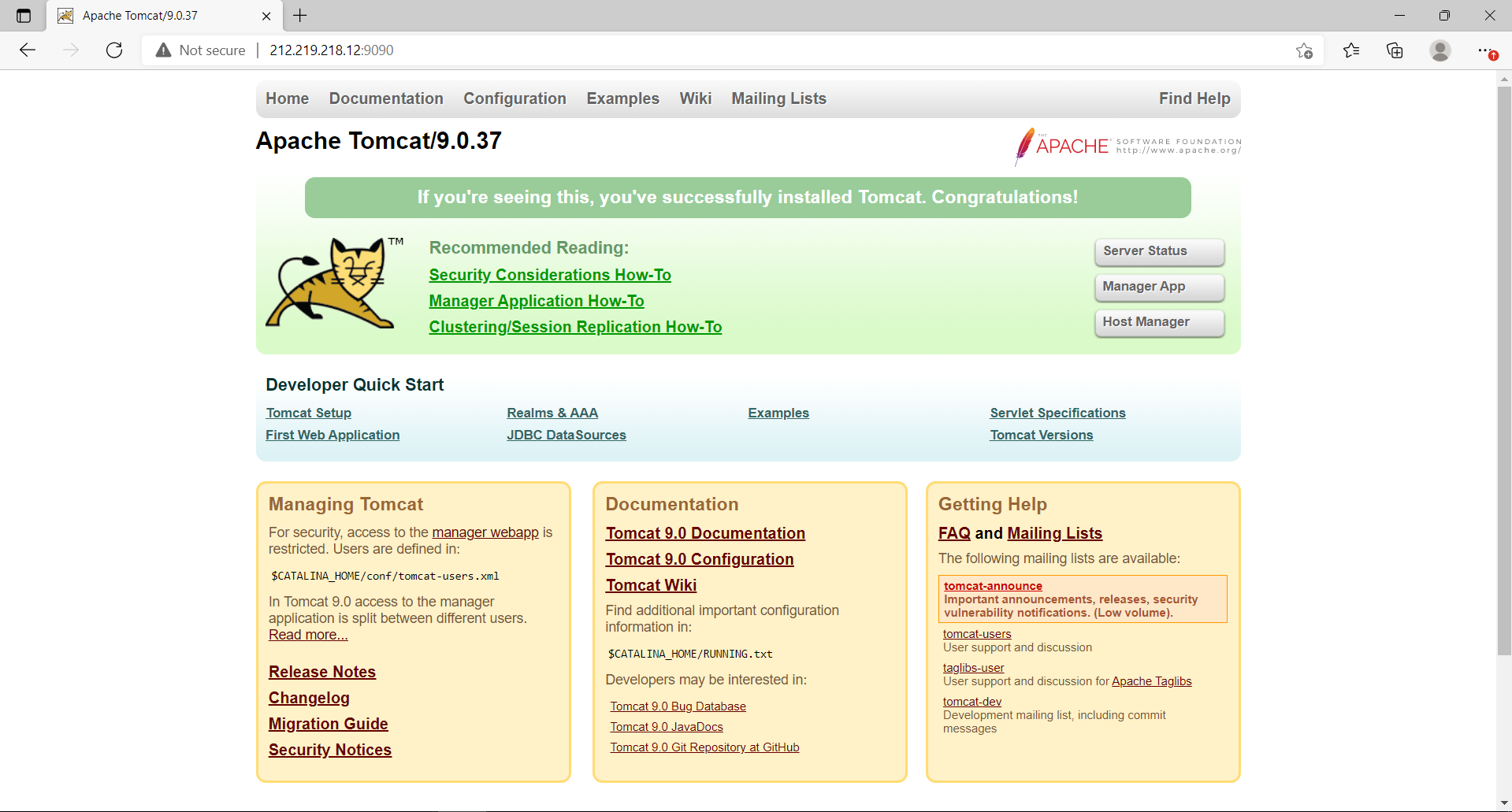
Tests within this protocol have been designed to verify that all-important elements of the Qualis LIMS program installation adhere to the requirements set forth by the manufacturer, when successfully completed. For each installation test in this protocol, a cover sheet is provided to define the test objective, procedure, and acceptance criteria. Following each cover sheet are the data sheets. These data sheets outline the information that must be verified and/or documented, as well as provide space for recording additional information. The information recorded on the test data sheets combined with referenced supporting test documentation provides a method whereby adherence to the test acceptance criteria can be verified.  
  
Any deviation from the specified acceptance criteria/expected results must be recorded on a deviation report.

**4. Acronyms**

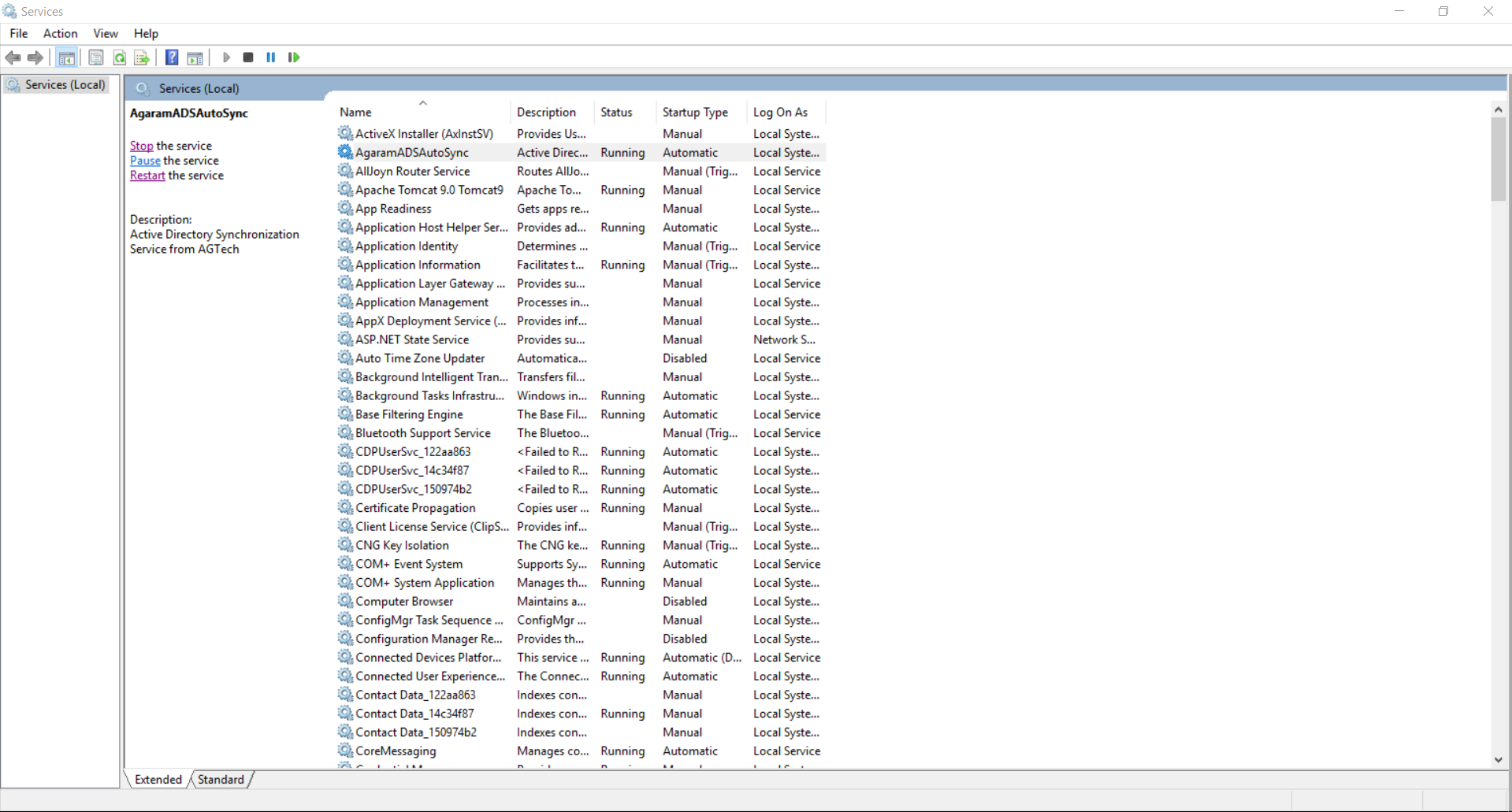
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| **Acronym/Initials** | **Meaning** |
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**8. Qualification Support Environment screen shots**

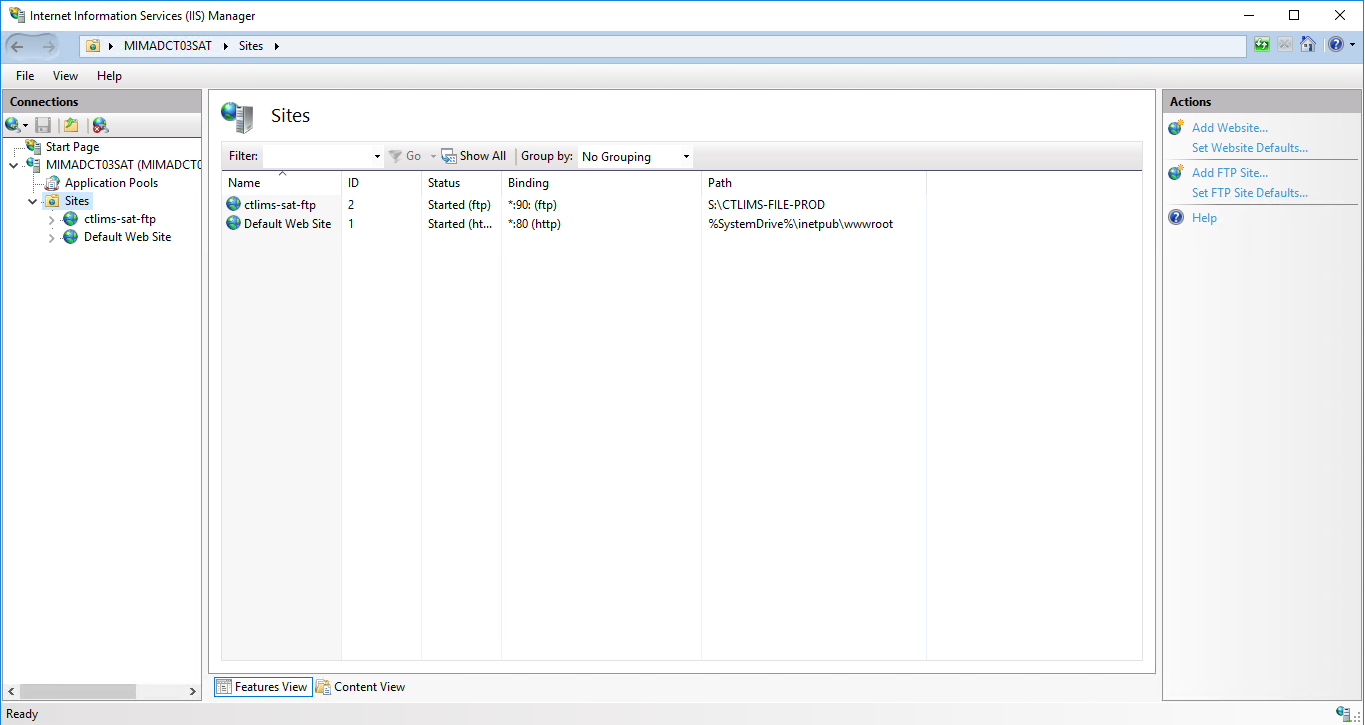
**Tomcat**



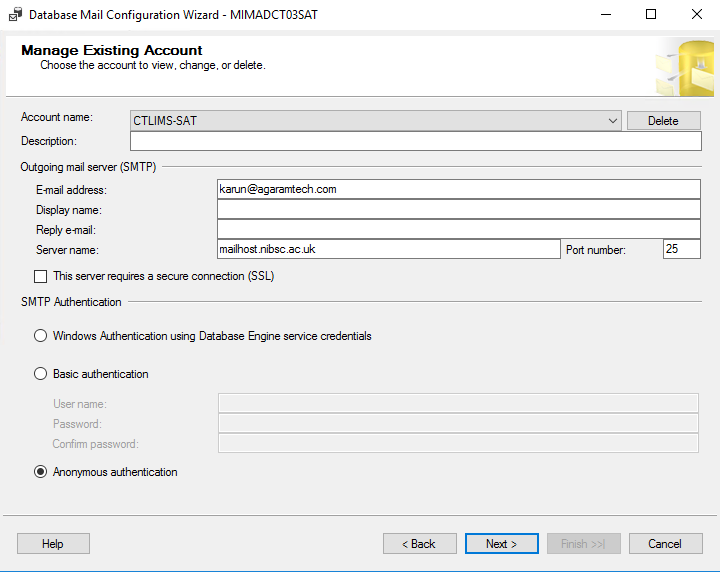
**ADS Services**



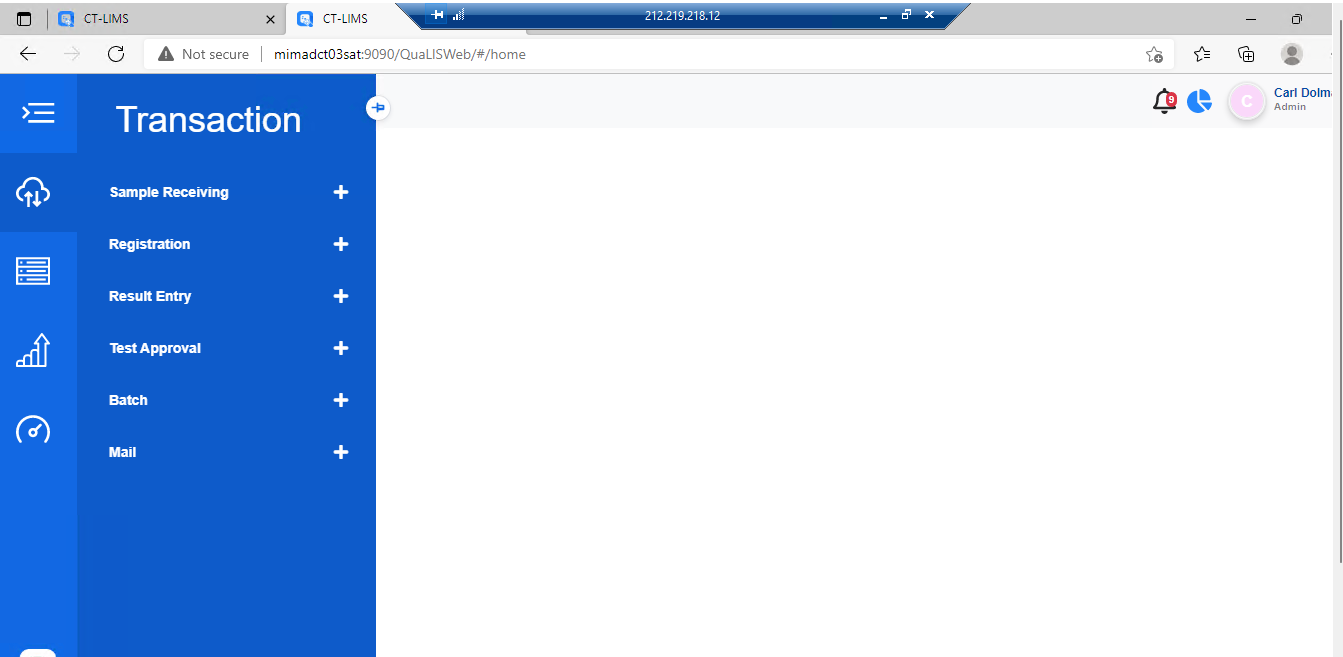
**IIS**



**Email**



**Application**



**9. Deficiency and Change Request Log**

In the following Deficiency Log, record the deviation numbers for any created deviation reports. Include a brief description of the issue. When the deviation is resolved and approved, write the date resolved.

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| **Deficiency number** | **Brief description** | **Date resolved** |
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**10. Document Approval**

The Operational Qualification document has been reviewed and approved.

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| --- | --- |
| Prepared by |  |
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| Name:   Printed Name: | Date:   LIMS Site Admin NIBSC |