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| Installation Qualification (IQ) Test Script |

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| **Pre-approval** | The signatures below attest to the signer’s agreement that the testing presented in this document is a sound approach for that signer’s area of influence and expertise. It indicates their approval of this IQ Test Script for execution. | |
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| **Technical Representative Signature** | | **Date** |
|  | |  |
| **Quality Assurance Representative Signature** | | **Date** |

1. Purpose

This purpose of the Installation Qualification (IQ) document is to provide the instructions for the installation and the verification of the installation of the Report Automation client application.

1. Scope

The installation of the client side portion of the Report Automation application is in scope for this document.

The installation of the server side software is not in scope for this document.

1. Pre-requisites

| **No.** | **Description** | **Pass/Fail**  **(P/F)** |
| --- | --- | --- |
|  | RA-IQ-002 has been executed successfully. |  |
|  | Active Directory User ID is available. Note User ID.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The new user must be assigned to the following role(s):  RAAdmin  Study Director  QAU  DPS  DC  DE |  |
|  | MS Outlook 2010 is installed. |  |
|  | Adobe Reader 8.0+ is installed. |  |
|  | VSTO Runtime (Provided with Software package) is installed. |  |
|  | SQL Server Client (Provided with Software package) is installed. |  |
|  | Create a directory on the C:\ drive called “Toxikon”, create “Temp” inside of “Toxikon”, create “Compare” inside of “Temp”. Copy the following files from the CD to “C:\Toxikon”   * draft.pdf * pdftk.exe |  |

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| **Performed By** | |
|  |  |
| **System Engineer Signature** | **Date** |

1. Install Client Component

| **Step No.** | **4.1 Installation of RA Ribbon and Other RA Components** | **Pass/Fail**  **(P/F)** |
| --- | --- | --- |
|  | Run the setup.exe that is in the Toxikon RA Ribbon Installer directory |  |
|  | Locate and confirm the “Toxikon Report Automation.dll.config.deploy” settings:   | **Setting** | **Purpose** | **Value** | | --- | --- | --- | | SPSiteURL | SharePoint site URL | http://ra.toxikon.com | | DBConnectionString | Database connection information | Provider=<valid connection string> (must match SQL client) | | SPStudiesFolder | Top level folder name for studies | Studies | | SPProtocolsFolder | Top level folder name for protocols | Protocols | | SPReportTemplatesFolder | Top level folder name for report template | Report Templates | | LocalFolder | Folder on local workstation | C:\Toxikon\ (note trailing backslash) | | LocalTempFolder | Folder on local workstation for temporary files | C:\Toxikon\Temp\ (note trailing backslash) | | CustomDictionaryPath | Path to custom dictionary | C:\Toxikon\Toxikon.dic | | ReportPassword | Password used to protect reports | D0cM@nager | | QAGroupName | SharePoint group name for QA | QA | | DPSGroupName | SharePoint group name for DPS | DPS | | SendEmailWhenAssignTask | Whether or not to send email when assigning task | True | | Domain | Domain name | TOXIKON | |  |
|  | If the user for this client install is a Data Control (DC) user,  run the setup.exe located in the Template Tool Installer directory. |  |
|  | If the user for this client install is a RA Admin user,  run the setup.exe that is located in the RA Admin Installer directory. |  |
|  | Add Study Director Image to Database  Start up the RAAdmin utility and log in as an RAAdmin and add signature images for the users with Study Director role |  |
|  | Add QA User Image to Database  Start up the RAAdmin utility and log in as an RAAdmin and add signature images for the users with QA role |  |

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| **Installer** | The execution of this IQ was performed by: | |
|  | |  |
| **System Engineer Signature** | | **Date** |
| **Number of Attachments** | |  |

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| **Post-approval** | The executed IQ Test Script and associated evidence have been reviewed and approved by the following persons, who attest to the completeness of the effort relative to their areas of expertise and influence. | | |
|  | | |  |
| **Technical Representative Signature** | | | **Date** |
|  | | |  |
| **Quality Assurance Representative Signature** | | | **Date** |
| **Overall Status (Pass/Fail)** | |  | |