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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** |
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| **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 application.

1. Scope

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

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

1. Pre-requisites

| **No.** | | **Description** | **Pass/Fail**  **(P/F)** |
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|  | Gather software distribution: templates, DB script, user lists |  |
|  | Properly installed, licensed and configured Microsoft SQL Server 2008 |  |
|  | | Properly installed, licensed and configured Microsoft Office SharePoint Server 2010 Standard Edition |  |
|  | | Report Automation users configured in Active Directory |  |

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| **System Engineer Signature** | **Date** |

1. Installation Instructions

| **Step No.** | **4.1 SharePoint** | **Pass/Fail**  **(P/F)** |
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|  | On the top level SharePoint site, create Permission “Approve” to be used to set permissions on each library.   1. Go to Site Actions 2. Click Site Permissions 3. Select Permission Levels 4. Select Add Permission Level 5. Setup the Approve Permission as follows: 6. Capture and paste a screenshot of these settings into the Screenshot Information form RA-FRM-012 |  |
|  | Create the SharePoint groups in the following table (make sure all groups have the “Who can view the membership of the group” setting set to “Everyone"):   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **RA**  **Roles** | **Groups** | **Document Libraries** | | | **Lists** | | | **SharePoint** | **Studies** | **Report Templates** | **Protocols** | **Tasks** | **Billing Tasks** | | Study Director | SD | Approve | Approve | Contrib | Contrib | Contrib | | QA | QA\* | Contrib | Approve | Contrib | Contrib | None | | DPS | DPS\* | Contrib | None | None | Contrib | None | | DC | DC | None | Contrib | Contrib | None | None | | DE | DE | None | None | None | Contrib | None | | Billing | Billing | None | None | None | None | Contrib | | RAAdmin | RA\_Admin | Full | Full | Full | Full | Full |   \* The group name is a configurable setting in the Report Automation Ribbon application. |  |
|  | Add Active Directory User Accounts to SharePoint Groups   1. From Main Page go to Site Actions, Site Permissions 2. Select a Group Name to go into a specific Group 3. Select New, Add Users      1. Fill in the form. |  |
|  | Create the Studies document library. Navigate to the newly created Library, and to Library Settings > Versioning settings; make sure the below options are used:   * without content approval * with major and minor version * with only users who can edit items * without required check out   Capture and paste a screenshot of these settings into the Screenshot Information form RA-FRM-012 |  |
|  | Create the Protocol document library. Report Automation doesn’t include an approval workflow for Protocols. Navigate to the newly created Library, and to Library Settings > Versioning settings; make sure the below options are used:   * without content approval * with major and minor versions * with only users who can edit items * without required check out   Capture and paste a screenshot of these settings into the Screenshot Information form RA-FRM-012 |  |
|  | Create the Report Templates document library. Navigate to the newly created Library, and to Library Settings > Versioning settings; make sure the below options are used   * with content approval * with major and minor versions * with only users who can edit items * without required check out   Capture and paste a screenshot of these settings into the Screenshot Information form RA-FRM-012 |  |
|  | Create the Tasks task list. |  |
|  | Create the Billing Tasks task list. |  |
|  | Using the table in step 4.1.2, apply permissions to the respective document libraries and lists.  Providing Permissions for Studies Document Library   1. Go to Top Level of the site and select the Studies Document Library. 2. Once in the Studies Library click the Library menu selection 3. Select Library Permissions from the toolbar 4. Select Grant Permissions 5. Now add all the groups that have the Contribute Permission per the table in step 4.1.2, select the Contribute checkbox and click OK 6. Do the same for all the Groups with Approve Permission 7. Do the same for the RA\_Admin group, granting the group Full Permissions. 8. Capture and paste a screenshot of the Permissions page into the Screenshot Information form RA-FRM-012 |  |
|  | Providing Permissions for Report Templates Document Library   1. Go to Top Level of the site and select the Report Templates Document Library. 2. Once in the Report Templates Library click the Library menu selection 3. Select Library Permissions from the toolbar 4. Select Grant Permissions 5. Now add all the groups that have the Contribute Permission per the table in step 4.1.2, select the Contribute checkbox and click OK 6. Do the same for all the Groups with Approve Permission 7. Do the same for the RA\_Admin group, granting the group Full Permissions. 8. Capture and paste a screenshot of the Permissions page into the Screenshot Information form RA-FRM-012 |  |
|  | Providing Permissions for Protocols Document Library   1. Go to Top Level of the site and select the Protocols Document Library. 2. Once in the Protocols Library click the Library menu selection 3. Select Library Permissions from the toolbar 4. Select Grant Permissions 5. Now add all the groups that have the Contribute Permission per the table in step 4.1.2, select the Contribute checkbox and click OK 6. Do the same for all the Groups with Approve Permission 7. Do the same for the RA\_Admin group, granting the group Full Permissions. 8. Capture and paste a screenshot of the Permissions page into the Screenshot Information form RA-FRM-012 |  |
|  | Providing Permissions for Tasks List   1. Go to Top Level of the site and select the Tasks List. 2. Once in the Tasks List click the List menu selection 3. Select List Permissions from the toolbar 4. Select Grant Permissions 5. Now add all the groups that have the Contribute Permission per the table in step 4.1.2, select the Contribute checkbox and click OK 6. Do the same for all the Groups with Approve Permission 7. Do the same for the RA\_Admin group, granting the group Full Permissions. 8. Capture and paste a screenshot of the Permissions page into the Screenshot Information form RA-FRM-012 |  |
|  | Providing Permissions for Billing Tasks List   1. Go to Top Level of the site and select the Billing Tasks List. 2. Once in the Billing Tasks List click the List menu selection 3. Select List Permissions from the toolbar 4. Select Grant Permissions 5. Now add all the groups that have the Contribute Permission per the table in step 4.1.2, select the Contribute checkbox and click OK 6. Do the same for all the Groups with Approve Permission 7. Do the same for the RA\_Admin group, granting the group Full Permissions. 8. Capture and paste a screenshot of the Permissions page into the Screenshot Information form RA-FRM-012 |  |

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| **System Engineer Signature** | **Date** |

| **Step No.** | **4.2 Post SharePoint setup** | **Pass/Fail**  **(P/F)** |
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|  | Upload template “12-ISO-Agar-Diffusion-G” to the Report Templates Document Library and complete the approval workflow using the DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-Agar-Diffusion-G-A” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-Ames-N” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-Ames-N-A” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-Kligman-N” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-Kligman-N-A” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-MEM-Elution-G” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload template “12-ISO-MEM-Elution-G-A” to the Report Templates Document Library and complete the approval workflow using a Toxikon\_DC account, by checking the checkbox next to it and selecting “Publish” on the tool bar. |  |
|  | Upload the 4 protocol templates to the Protocols Document Library. This requires no document approval so they can all be uploaded at once into the Protocols Library. There should be 1 for each report:   * 12-ISO-Agar-Diffusion-G * 12-ISO-Ames-N * 12-ISO-Kligman-N * 12-ISO-MEM-Elution-G |  |

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| **System Engineer Signature** | **Date** |

| **Step No.** | **4.3 SQL Server** | **Pass/Fail**  **(P/F)** |
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|  | Using SQL Server Management Studio create the Toxikon\_ra database using the provided scripts (in Database directory with install files):   * BuildDB.sql * FillEmpty.sql * FillOrdinal.sql * FillProtocols.sql * FillUsers.sql |  |
|  | Grant the AD RAUsers group appropriate permissions on the Toxikon\_ra database (db\_datareader and db\_datawriter). |  |
|  | Verify the database contains:   * Data for static tables such as tblOrdinal * Protocol records for the four protocols * One RAAdmin user with the username Toxikon\_RAAdmin |  |
|  | (Optional Step)  If data is needed for testing, run the DB script that will fill tables with test data:   * FillTestData.sql |  |
|  | Using SQL Server Management Studio change the value of the txtUserName field to match the AD username of a user who will be a member of the RAAdmin role. |  |

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| **System Engineer Signature** | **Date** |

| **Step No.** | **4.4 Data Entry Web Forms** | **Pass/Fail**  **(P/F)** |
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|  | On SharePoint server, unzip/unrar the InstallRAForms.rar that is supplied with the software package |  |
|  | Run the setup.exe as an Administrator, Click Next then enter the settings:   * Site – “Sharepoint – 80” * Virtual directory – “ToxikonDE” * Application Pool – Same as Site   Click Next and start the install process |  |
|  | Open IIS and drill down to the site (Sharepoint – 80) where ToxikonDE was installed. Remove the ToxikonDE Application that was created by the installer |  |
|  | Now expand \_layouts, right click on ToxikonDE and Convert to application |  |
|  | Open C:\Windows\assembly, confirm RAForms is here (the dll was added correctly) |  |
|  | Add the database ConnectString to the web.config file found at C:\Inetpubs\wwwroot\wss\VirtualDirectories\<site>.  In the ConnectionStrings section of the file, the setting is:  <add name="ToxikonConnectionString" connectionString="Data Source=TOXDB;Database=Toxikon\_ra;Integrated Security=SSPI;User ID=raadmin;Password=<Password>" providerName="System.Data.SqlClient"/> |  |
|  | Add RAForms to the list of safe controls in the web.config file found at C:\Inetpubs\wwwroot\wss\VirtualDirectories\<site>.  In the Settings section of the file, the setting is:  <SafeControl Assembly="RAForms,Version=1.0.0.0, Culture=neutral,PublickeyToken=6c87ecf3329e4b47" Namespace="RAForms" TypeName="\*" Safe="True" /> |  |
|  | Add the tag below to the tagMapping section of the web.config file found at  C:\Inetpubs\wwwroot\wss\VirtualDirectories\<site>  <remove tagType="System.Web.UI.WebControls.SqlDataSource, System.Web, Version=2.0.0.0, Culture=neutral, PublicKeyToken=b03f5f7f11d50a3a" /> |  |
|  | Confirm that the new application uses the same application pool as its parent. |  |
|  | Restart IIS. |  |

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| **System Engineer Signature** | **Date** |

| **Step No.** | **4.5 Final Setup Tasks – Add users to RAAdmin** | **Pass/Fail**  **(P/F)** |
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|  | Connect to the site using the Toxikon username configured for the RAAdmin user (step 4.3.2 of SQL Server installation). |  |
|  | Open the users form (Site URL + \_layouts + <foldername from step 4.1.1 of web forms initial install (ToxikonDE)> + /users.aspx). |  |
|  | Click the New button and add the **Toxikon\_RAAdmin** test user where:  Username = <admin username>  User Role = RAAdmin  Full Name = <admin name>  Email = <admin e-mail>  Phone = <admin number>  Capture and paste a screenshot of the user settings into the Screenshot Information form RA-FRM-012 |  |

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

1. Build/Install Worksheet Information

Instructions: Complete this build/install worksheet during the installation of Report Automation server side portion on server <Server ID> to record relevant information for the qualification and support of the software.

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| 5.1 Server Build Worksheet | |
| **Worksheet Completed By** |  |
| **Builder/Installer Name** |  |

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| 5.2 Owner/Point of Contact (POC) Information | | | |
| **Company Name** | Toxikon | | |
| **POC Name** | Sanjay Desai | **POC Number** | 781-275-3330 |

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| 5.3 System Information | | | |
|  | **Requirements** | **As Built** | **Pass/Fail (P/F)** |
| **Server Name** |  |  |  |
| **Windows Server Version (2003, 2008, Etc.)** |  |  |  |
| **SharePoint Edition (Standard / Enterprise)** | 2010 Standard |  |  |
| **AD Username of an RAAdmin** |  |  |  |
| **Other Components to be Installed:** |  | | |

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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. | | |
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| **Technical Representative Signature** | | | **Date** |
|  | | |  |
| **Quality Assurance Representative Signature** | | | **Date** |
| **Overall Status (Pass/Fail)** | |  | |