**DoseControl Dosimetry System Software Configuration Plan**

|  |
| --- |
| **Customer Name/Project:**  |
| **Dosimetry System Name:**  |
| **DoseControl Software version:**  |

PURPOSE

The *DoseControl Software Configuration Plan* is a template used to compile configuration information prior to software installation. This document can be referenced for the software configuration information in the DoseControl Dosimetry System IQOQ Protocol (GEX Doc# 100-280).

INSTRUCTIONS

Reference the DoseControl Software User Guide (GEX Doc #100-266) to complete the DoseControl software configuration. Write the configuration information in this document for easy reference and recordkeeping purposes.

**CONTENTS**

[1 SYSTEM CONFIGURATION 3](#_Toc150415873)

[2 USER MANAGEMENT 4](#_Toc150415874)

[3 INTEGRATION 7](#_Toc150415875)

[4 DOSIMETRY CONFIGURATION 7](#_Toc150415876)

[4.1 PATHWAYS 7](#_Toc150415877)

[4.2 DOSIMETER TYPES 8](#_Toc150415878)

[4.3 BATCHES 8](#_Toc150415879)

[4.4 READERS 8](#_Toc150415880)

[4.5 CALIBRATIONS (DOSIMETER BATCH) 9](#_Toc150415881)

[4.6 MISCELLANEOUS 10](#_Toc150415882)

[4.7 RE-READS 10](#_Toc150415883)

[4.8 PRODUCT SPECIFICATIONS MODULE (optional) 11](#_Toc150415884)

[4.9 PERFORMANCE VERIFICATION MODULE (optional – For Evolution reader) 12](#_Toc150415885)

[5 DOSIMETRY REPORT SETUP 13](#_Toc150415886)

[4.10 Report Types and header fields setup 13](#_Toc150415887)

# SYSTEM CONFIGURATION

This section involves the IT-related requirements necessary to set-up the DoseControl software.

DoseControl SYSTEM DETAILS

|  |  |
| --- | --- |
| DoseControl Software Version: |  |
| DoseControl Global Admin login: | *Username: admin*  |
| *Password: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* |

DATABASE LOCATION

|  |  |  |
| --- | --- | --- |
|  | Description | Location |
|[ ]  PC (MS SQL Express installation) |  |
|[ ]  MS SQL Server |  |

CONNECTION STRING

|  |
| --- |
| Write connection string here: |

|  |  |
| --- | --- |
| Data Source (the explicit SQL server) | *Server name* |
| Initial Catalog (the explicit name of the SQL database instance – what does the Client want the name to be for the GEX DoseControl database?) | *Name of database* |
| User ID (the SQL Server Authentication username) | *User Id* |
| Password (the SQL Server Authentication password) | *Password* |

# USER MANAGEMENT

1. **USER ACCESS:** Control of user access into the software (how users “sign-in” into DoseControl)
2. **USER ROLES**: Permissions to allow users access to distinct features within the DoseControl. You must chose all the roles each user is allowed.
* **System Admin** – allows access to the “Setup” screen for managing connections and storage locations, as well as user management.
* **Application Admin** – allows access to the “Settings” screen for configuring everything related to the dosimetry and measurement process.
* **Technician** – allows users to create reports and perform dosimetry measurements.
* **Additional permissions (for Users that are selected and trained in how to perform these activities):**
	+ - *Reread* – must be checked if using the reread role as part of reread policy
		- *Edit Thickness* – allows users to make edits to the thickness of dosimeter reading.
		- *Edit Dosimeter ID’s* – allows the user to have the ability to edit or delete dosimeters from a report.
1. **USER ACCESS**

|  |  |  |
| --- | --- | --- |
|  | Type | Description |
|[ ]  Basic | In Basic setup, there is no username and password requirement at login. This method will record the domain and username from Microsoft Windows as the user for the audit trail. Not 21 CFR part 11 compliant. |
|[ ]  DoseControl User Manager  | User Access control and user roles and permissions are managed by the System Administrator within the DoseControl application. The Sys Admin can setup users/passwords, assign roles, activate/inactivate users. |
|[ ]  LDAP (Active Directory) | Controls the login into DoseControl using the username that is currently logged into Microsoft Windows – whomever is logged into the PC is logged into DoseControl. LDAP group mapping assigns user roles/privileges within DoseControl. For 21CFR Part 11 compliance, must have “user lock-out” configured in Windows or DoseControl to lock user out of the software after period of inactivity. |
|[ ]  Explicit LDAP | User will be required to login to DoseControl software with Windows company network login and password. LDAP group mapping assigns user roles/privileges within DoseControl.  |

1. **USER ROLES**

Based on the User Manger type selection above, complete the corresponding User Access information.

*Note:* Users must be placed in one or more of the three sub-groups (Sys Admin, App Admin, Technician) based on the desired user access privileges for that employee. For example, if you want an employee to be able to administer the DoseControl software and also read dosimeters, this person needs to be in the *Application Admin* sub-group to administer the dosimetry aspects in the software and in the *Technician* sub-group to measure dosimeters (i.e., checking multiple user roles for a single user).

DOSECONTROL USER MANAGER SETUP

|  |  |
| --- | --- |
|  | User Role |
| Username | **Display Name** | **Password** | **SysAdmin** | **AppAdmin** | **Tech** |
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]
|  |  |  |[ ] [ ] [ ]

|  |  |
| --- | --- |
|  | Permissions |
| Username(assigned above) | **ReRead** | **EditThickness** | **EditDosimeterIDs** |
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]
|  |[ ] [ ] [ ]

LDAP/EXPLICT LDAP USER MANAGER SETUP

***Sign-in Manager Type – choose one:***

|  |  |
| --- | --- |
| Type | Connection String – AD address |
| LDAP user manager |  |
| Explicit LDAP user manager |  |

***Group Mapping Assignments:***

|  |  |
| --- | --- |
| Role | LDAP Group Mapping |
| System Administrator |  |
| Application Administrator |  |
| Technician |  |

|  |  |
| --- | --- |
| Permissions | LDAP Group Mapping |
| Reread |  |
| EditThickness |  |
| EditDosimeterIds |  |

# INTEGRATION

Enterprise license provides the ability to integrate DoseControl with other electronic systems/enterprise software.

CLIENT REPORT SERVICE

|  |  |
| --- | --- |
|  | Type (select one) |
|[ ]  No integration |
|[ ]  GEX Client Repository (DoseControl will be integrated with another system) |

INTEGRATION CONNECTION STRING

|  |
| --- |
| Write connection string here: |

DOSIMETRY CONFIGURATION

Reference: DoseControl Software User Guide (GEX Doc #100-266), Section 6 Configure Dosimetry Process Parameters

## PATHWAYS

A “pathway” is the client’s facility, irradiator, or pathway within a given irradiator. Add rows the table below as needed.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Pathway ID | Desc. (same as PathwayID) | Ref ID (same) | External ID (same) | Prod Report1 | Default? | Active? | DSM Locked?2 |
|  |  |  |  | No |[ ] [ ] [ ]
|  |  |  |  | No |[ ] [ ] [ ]
|  |  |  |  | No |[ ] [ ] [ ]

1Produces Report should always be unchecked (not active). For Enterprise license integrations ONLY.

2DSM Locked should be always be unchecked (not active) unless GEX instructs you otherwise. For Enterprise license integrations ONLY.

## DOSIMETER TYPES

DoseControl can manage multiple types (kinds) of dosimeters, such as B3, FWT, PMMA. Add rows the table below as needed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Dosimeter ID (name) | Manufacturer | Spectral bandwidth | Comment | Uses Micrometer?1 | Edit Thickness?2 |
|  |  |  |  |[ ] [ ]
|  |  |  |  |[ ] [ ]

1For PMMA/Harwell Perspex dosimeter types that have a laser micrometer installed inside the Thermo Evolution (GEX product).

2 DO NOT check Edit Thickness box for B3 dosimeter type.

## BATCHES

Add specific dosimeter batches. Add rows the table below as needed.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Batch ID (2-didget alpha numeric) | External ID (same) | Dosimeter Type | Thickness | Description |
|  |  |  |  |  |
|  |  |  |  |  |

## READERS

Readers are the spectrophotometers being used in system. Add addition table for each spectrophotometer.

|  |  |  |  |
| --- | --- | --- | --- |
| Reader ID |  | Client Machine Name1 |  |
| Model Info |  | **Zero (min)** |  |
| Min read value | 0.001 | **COM Port Number** |  |
| Max read value |  | **Baud rate** | 115200 |
| Serial number |  | **Req. barcode scanner2** |[ ]
| Description |  | **Req Laser Mic3** |[ ]
| Make |  |  |  |

1 PC name

2 Integrated barcode scanner installed inside reader (GEX product). Does not refer to an external handheld scanner.

3 Laser micrometer (GEX product) installed inside spectrophotometer. For PMMA/Harwell Perspex only.

## CALIBRATIONS (DOSIMETER BATCH)

Provided by calibration laboratory. Calibration functions define the mathematical relationship between the dosimeter response and dose for each instrument. Add additional table for each calibration to be configured. For first time DoseControl dosimetry system installation and qualification, you can use a temporary test Calibration; after dosimetry system IQOQ you need to complete a calibration for the dosimetry system.

|  |  |  |  |
| --- | --- | --- | --- |
| Display name |  | CoEff A |  |
| Calibration ID |  | **CoEff B** |  |
| External ID (same) |  | **CoEff C** |  |
| Pathway |  | **CoEff D** |  |
| Batch |  | **CoEff E** |  |
| Initial Avg Abs. |  | **Wavelength2** |  |
| Reader ID |  | **Corr. Factor3** | 1 |
| Abs count1 |  | **Autogen dosimeter IDs?** |[ ]
| Dose Units |  |  |
| Dose range min |  |  |
| Dose range max |  |  |

1 Number of dosimeters per pouch. Usually a “1”

2 Dosimeter measurement wavelength

3 Correction Factor. ALWAYS enter a “1” unless GEX instructs otherwise.

## MISCELLANEOUS

|  |  |  |
| --- | --- | --- |
| Setting | Option | Description |
|[ ]  **Manual Mode** | Allows entry of absorbance values on the Measure screen. Flagged as ‘manual’ entry in audit trail.  |
|[ ]  **Zero ‘0’ Reader** | Adds button on the measure screen and allows the technician who is reading dosimeters option to zero the instrument. |
| [ ] (\_\_\_\_\_\_\_\_\_ minutes) | **User Lock-out** | Allows the Admin to configure the system to lock the user out of the software after a period of inactivity (in minutes).  |
|[ ]  **Report search by pathway** | Allows user to modify the view on the Home screen to display/sort Reports List by pathway. |

## RE-READS

You do not need to configure a reread process. The default allows unlimited number of rereads.

Reason Configuration:

|  |  |  |  |
| --- | --- | --- | --- |
| Reason No. | Defined reason for re-read: | Simple | Statistical |
| 1 |  |[ ] [ ]
| 2 |  |[ ] [ ]
| 3 |  |[ ] [ ]

**For each Reason (above), configure the Simple or Statistical information:**

Simple Configuration:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| No. | Limit number of re-reads? | If yes, number of re-reads allowed | Diff User Req? | RoleReq? | CommentReq? |
| 1 |[ ]   |[ ] [ ] [ ]
| 2 |[ ]   |[ ] [ ] [ ]
| 3 |[ ]   |[ ] [ ] [ ]

Statistical Configuration:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Include original measurement? | Limit number of re-reads? | If yes, number of re-reads allowed\* | C.V. | DiffUser Req? | RoleReq? | CommentReq? |
|  |[ ] [ ]   |  |[ ] [ ] [ ]
|  |[ ] [ ]   |  |[ ] [ ] [ ]
|  |[ ] [ ]   |  |[ ] [ ] [ ]

\* A Statistical reread session is comprised of 3 rereads, which is analyzed for a single result. Set the allow limit number as factor of 3 (3, 6, 9, 12, etc.), where 3 equals one session.

## PRODUCT SPECIFICATIONS MODULE (optional)

Add additional table for each Specification. Is the Product Specification Module installed (Y/N)? \_\_\_\_\_\_\_\_\_

SPECIFICATION

Add Catalog Number(s) to the Specification ID as needed

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Specification ID |  | Catalog Number(s): | Catalog Number(s): | Catalog Number(s): | Catalog Number(s): |
| Ref to Min Ratio |  |  |  |  |  |
| Ref to Max Ratio |  |  |  |  |  |
| Min Dose Spec. |  |  |  |  |  |
| Max Dose Spec |  |  |  |  |  |

## PERFORMANCE VERIFICATION MODULE (optional – For Evolution reader)

Add P.V. Method configuration tables as needed. Performance Verification Module part of system setup (Y/N)? \_\_\_\_\_\_\_\_\_

P.V. METHOD:

|  |  |  |  |
| --- | --- | --- | --- |
| PV Method ID |  | Photometric Standard ID |  |
| Description |  | **Photometric Standard Description** |  |
| PV Freq (hrs) |  | **Photometric Standard Nominal Absorbance (A)** |  |
| Reference Standard Kit Serial Number |  | **Testing wavelength (nm)** |  |
| Kit description |  | **Photometric Standard Certified Absorbance (A)** |  |
| Kit manufacturer |  | **Uncertainty (A)** |  |
| Kit Model Number |  |  |
| Kit Calibration Certificate Number |  |

P.V. METHOD BRACKET WAVELENGTH OF USE:

|  |  |  |  |
| --- | --- | --- | --- |
| PV Method ID |  | Photometric Standard ID |  |
| Description |  | **Photometric Standard Description** |  |
| PV Freq (hrs) |  | **Photometric Standard Nominal Absorbance (A)** |  |
| Reference Standard Kit Serial Number |  | **1 -Testing wavelength (nm)** |  |
| Kit description |  | **1 - Photometric Standard Certified Absorbance (A)** |  |
| Kit manufacturer |  | **2 -Testing wavelength (nm)** |  |
| Kit Model Number |  | **2 - Photometric Standard Certified Absorbance (A)** |  |
| Kit Calibration Certificate Number |  | **Uncertainty (A)** |  |

# 5 DOSIMETRY REPORT SETUP

## Report Types and header fields setup

Report Types are configured in the software. Add addition Reports as needed.

For each Report Type, you can add report header Field Names that are specific to your dosimetry process. Add field name rows the tables below as needed.

**Report No: 1**

**Report Name:**

**Exporter Type** (What is the “Exporter Type” for this report - custom PDF, Std 1 Pack PDF, GEX Default 2 Pack, Ref Dose 1 Pack, Ref Dose 2 Pack):

**Report output formats (Excel, PDF, custom PDF)? :**

**Does this report use the Product Specification module (Y/N)?** :

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq. | Field name | Field Type | Label (Screen) | Req? | Edit?\*(Always yes) | Add’l validation (optional) | Special Value (optional) |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |

\*Report header fields should be editable, unless otherwise instructed by GEX.

**Report No: 2**

**Report Name:**

**Exporter Type** (What is the “Exporter Type” for this report - custom PDF, Std 1 Pack PDF, GEX Default 2 Pack, Ref Dose 1 Pack, Ref Dose 2 Pack):

**Report output formats (Excel, PDF, custom PDF)? :**

**Does this report use the Product Specification module (Y/N)?** :

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq. | Field name | Field Type | Label (Screen) | Req? | Edit?\*(Always yes) | Add’l validation (optional) | Special Value (optional) |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |

**Report No: 3**

**Report Name:**

**Exporter Type** (What is the “Exporter Type” for this report - custom PDF, Std 1 Pack PDF, GEX Default 2 Pack, Ref Dose 1 Pack, Ref Dose 2 Pack):

**Report output formats (Excel, PDF. custom PDF)? :**

**Does this report use the Product Specification module (Y/N)?** :

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq. | Field name | Field Type | Label (Screen) | Req? | Edit?\*(Always yes) | Add’l validation (optional) | Special Value (optional) |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |

**Report No: 4**

**Report Name:**

**Exporter Type** (What is the “Exporter Type” for this report - custom PDF, Std 1 Pack PDF, GEX Default 2 Pack, Ref Dose 1 Pack, Ref Dose 2 Pack):

**Report output formats (Excel, PDF. custom PDF)? :**

**Does this report use the Product Specification module (Y/N)?** :

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Seq. | Field name | Field Type | Label (Screen) | Req? | Edit?\*(Always yes) | Add’l validation (optional) | Special Value (optional) |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |
|  |  |  |  |[ ] [x]   |  |