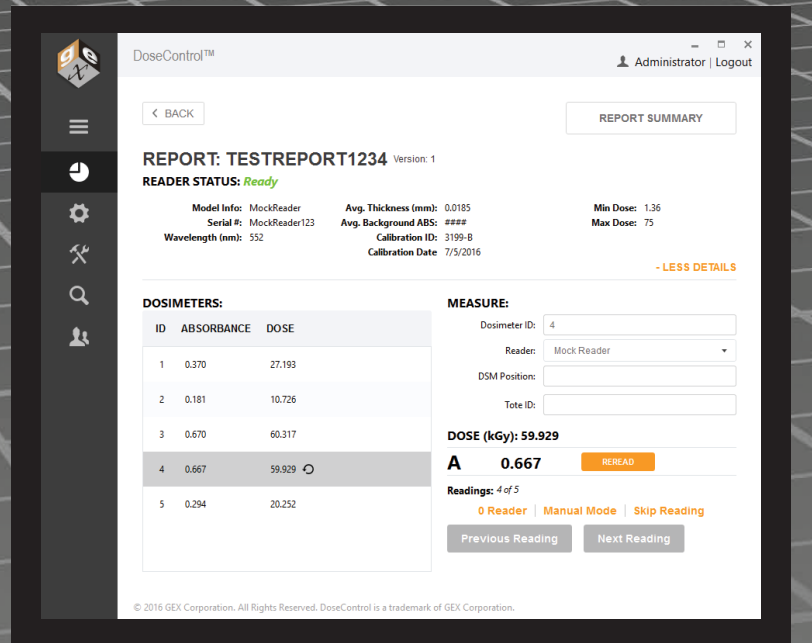


▷ DoseControl®

Powerful and flexible software to create and maintain 21 CFR compliant dosimetry records



- ▷ Controls dosimetry workflow
- ▷ Traceable audit trail
- ▷ Electronic record storage and retrieval
- ▷ Create and edit dosimetry reports with version control

For more information:

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DoseControl® is a 21CFR Part 11 conforming dosimetry software application that makes it simple to create and maintain dosimetry records and can provide step-by-step management of the dosimetry workflow. This powerful software integrates with a spectrophotometer to accurately record dosimeter measurements and related data, prepares electronic and paper reports, and provides a fully traceable and auditable electronic record of events. Designed with an intuitive user interface, DoseControl® manages many aspects of dosimetry such as tracking multiple dosimeter batches and calibrations, managing multiple irradiation pathways, and more. DoseControl® also handles several different types of dosimeters, such as B3, FWT and PMMA. Users can set up and configure the software application to meet their specific needs - the application administrator simply selects the preferred process workflow and configures data fields, sequences, and labels to customize the application.

Create and edit dosimetry reports

- 21CFR Part 11 compliant
- Create and edit dosimetry reports with version control
- Electronic record storage and retrieval
- Creates traceable audit trail - Captures specific user actions, and all dosimeter measurement data providing auditable records.
- Change control - changes to stored data such as calibration information or any other configuration settings are tracked.
- Captures and records all dosimeter measurements and associated data – dosimeter serial number, optical absorbance measurements, User ID, time of measurement, date, etc.
- Dosimeter re-measurement – two re-read user selection options:
 - Option 1 assumes all dosimeter re-measurements are equivalent and come from the same population. Re-read data is simply treated as a replacement value of the prior record value.
 - Option 2 forces multiple re-reads of each dosimeter being re-read. The software calculates the population mean and standard deviation values to determine a coefficient of variance (CV) value.

Security

- Data security policies retained by the user (e.g. database level data encryption).
- Role-based user management using either LDAP authentication or onboard user management.

Controls measurement workflow

- Integrates and controls spectrophotometer (Thermo Scientific™ GENESYS™ 30 and Evolution™ 220):
 - Verifies the instrument serial number
 - Sets and controls wavelength
 - Zeros/blanks the instrument
 - Sets and controls the spectral bandwidth (SBW) depending on dosimeter type
- Step-by-step control of measurement process, if desired.
- Manages re-reading dosimeters.
- Supports multiple dosimeter types: B3, FWT, PMMA (Harwell Red and Amber Perspex).
 - Internal integrated barcode reader for B3 DoseStix dosimeter available.
 - Internal integrated laser micrometer (thickness measurement) for Harwell Perspex dosimeters available.

Flexible and powerful

Configure the software application to suit your needs:

- Default reports available for dosimeter measurements and/or create custom reports
- Manage multiple dosimeter batches.
- Manage multiple batch calibrations.
- Manage one or many irradiation pathways.
- Configure report field names.
- Supports localization - system architecture will support additional languages in the future

Custom integration with enterprise software

- Our Enterprise Level license of DoseControl allows you access to share data with your enterprise software (SAP, SQL, Oracle).

EXAMPLE SCREEN SHOTS: REPORTS

HOME SCREEN:

- Create new reports
- Search for and select existing reports
- Search by Report ID or dosimeter ID

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SEARCH REPORTS

Include all versions

REPORT ID	VERSION	STATUS	DATE	TIME	LAST EDITED BY
TestReport1234	1	Incomplete	06/07/2016	08:42 PM	Administrator
MikeTest111	2	Incomplete	06/07/2016	08:40 PM	Administrator
MikeTest105	1	Complete	06/07/2016	08:36 PM	Administrator
MikeTest108	1	Complete	06/07/2016	08:36 PM	Administrator
MikeTest107	1	Complete	06/07/2016	08:07 PM	Administrator
MikeTest112	1	Incomplete	06/07/2016	10:04 AM	Administrator

MEASUREMENT SCREEN

- Indicates measurement reader status
- Executes dosimeter measurements
- Records all readings, re-readings, user actions
- Displays configured dosimetry system information such as calibration ID, Reader ID.

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[< BACK](#) **Report name** **REPORT: TESTREPORT1234** Version: 1 **REPORT SUMMARY**

READER STATUS: Ready **Calibration info**

Model Info: MockReader
Serial #: MockReader123
Wavelength (nm): 552 **Intrument info**

Avg. Thickness (mm): 0.0185
Avg. Background ABS: ###
Calibration ID: 3199-B
Calibration Date: 7/5/2016

Min Dose: 1.36
Max Dose: 75 **- LESS DETAILS**

DOSIMETERS:

ID	ABSORBANCE	DOSE
1	0.370	27.193
2	0.181	10.726
3	0.670	60.317
4	0.667	59.929 <input type="button" value="REREAD"/>

MEASURE:

Dosimeter ID:
 Reader:
 DSM Position:
 Tote ID:

DOSE (kGy): 59.929
A 0.667

Readings: 4 of 5

Measurement list **Measurement action**

REPORT SUMMARY SCREEN

- Displays report information and measurements
- Record and version comments for the report
- Print report, create .xls file, or sync with database

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[< BACK](#) **REPORT: TestReport1234** Version: 1

RESULTS:

Overall Minimum Dose (kGy): 10.726 **Minimum Dose Spec (kGy):** 1.360
Overall Maximum Dose (kGy): 60.317 **Maximum Dose Spec(kGy):** 75.000

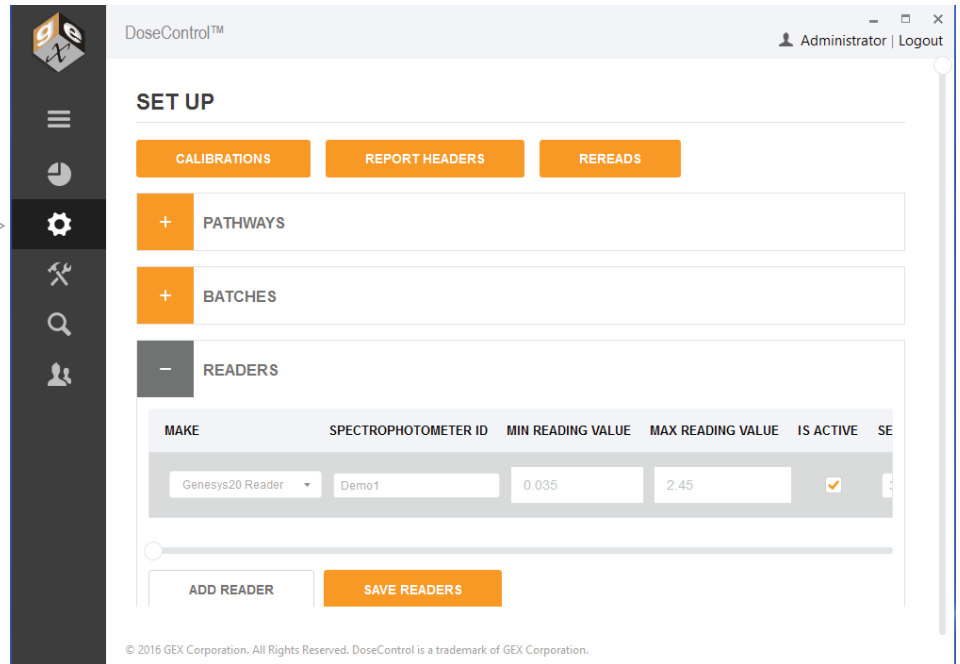
REPORT INFORMATION

READINGS

COMMENTS

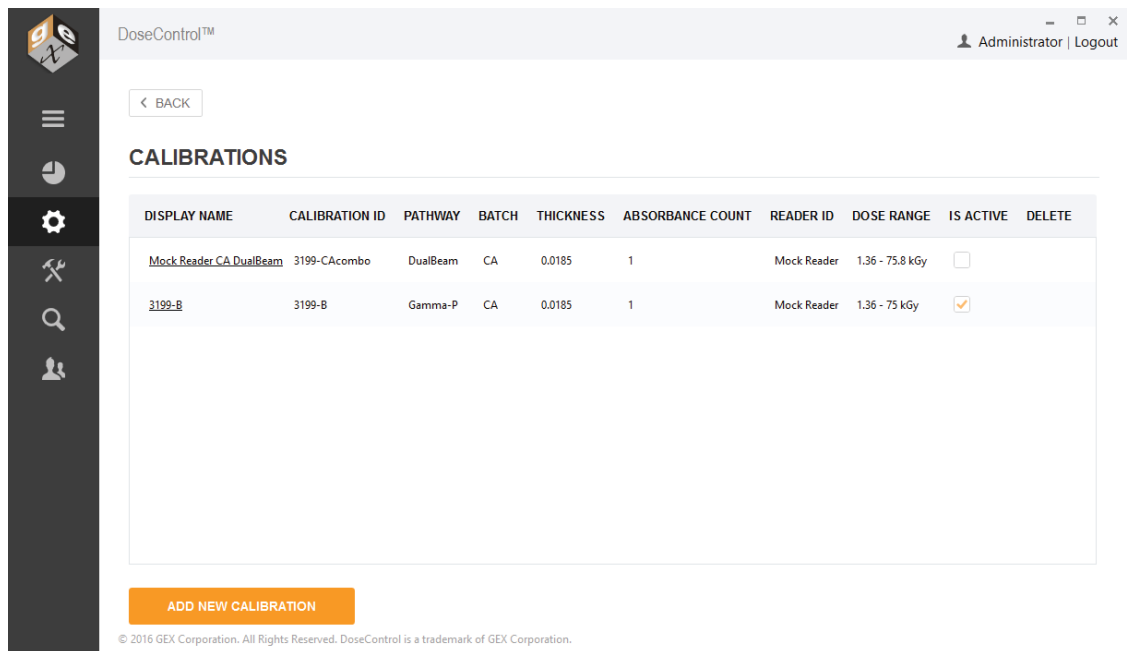
SETUP OPTIONS SCREEN

- Create new and define calibration information
- Add and define irradiation pathways
- Add and define dosimeter batches
- Add and define dosimeter measurement instruments
- Define report headers
- Configure and define reasons for dosimeter re-reads



SETUP CALIBRATIONS SCREEN:

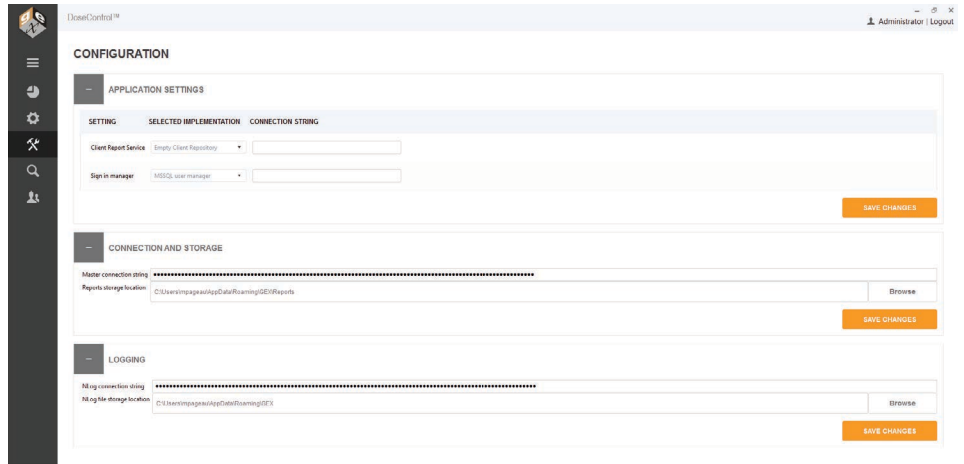
- Add and manage dosimetry system calibrations.



EXAMPLE SCREEN SHOT: OTHER MAIN MENU BAR ITEMS

SETTINGS:

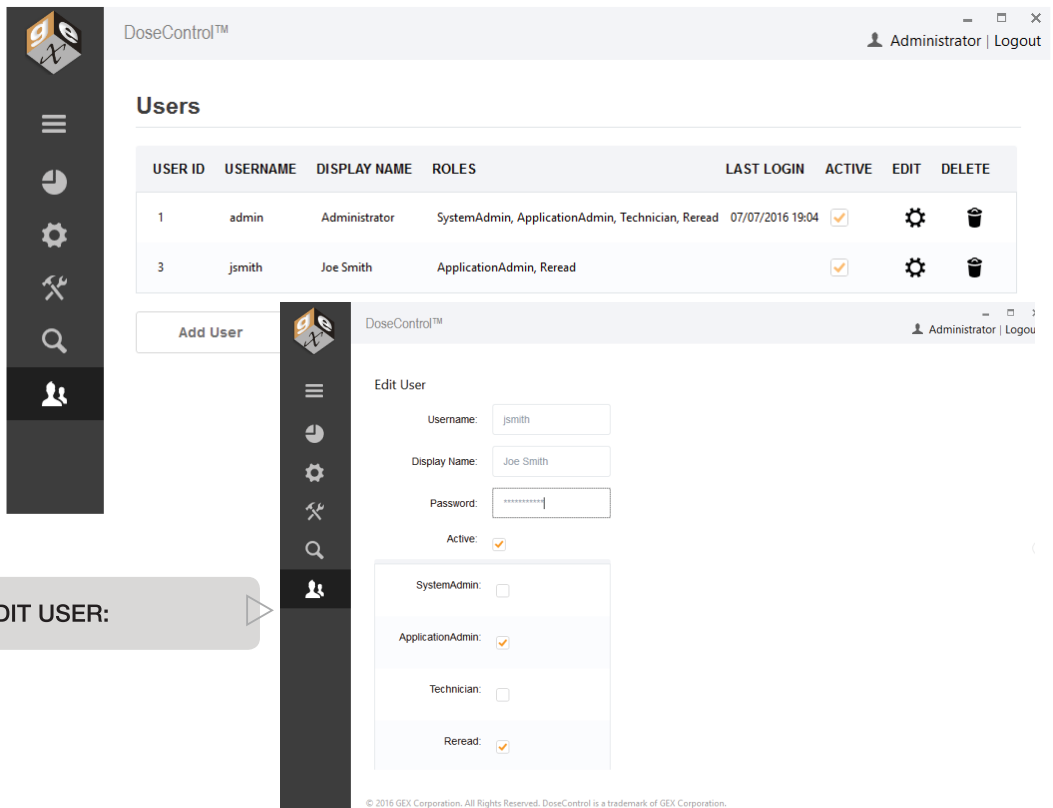
- Define application connection strings to enterprise software
- Choose type of sign-in manager
- Default file storage pathway
- Default application log pathway



USER MANAGEMENT:

- Add users
- Edit roles

EDIT USER:



▷ DoseControl® Licenses

SITE LICENSE OPTIONS

DoseControl® software is offered with three different levels of site license options:

- BASIC - Single, standalone dosimetry system on a PC
- PREMIER - Multiple dosimetry workstations with local area network (LAN) integrated database
- ENTERPRISE - Multiple dosimetry station with LAN database and ability to integrate with enterprise software system(s).

About GEX...

WHO WE ARE

Since 1991, GEX is a single source provider of a complete range of dosimetry products and services for the radiation processing industry. We serve the complete spectrum of gamma, e-beam, and x-ray radiation process applications, such as medical device sterilization, surface decontamination, the curing of inks and coatings, and food irradiation.

WHAT WE DO

We offer everything you will need for a successful dosimetry program:

- Dosimetry Systems
- Dosimeters
- Dosimetry Software
- Accessories
- Procedures
- Dosimeter Batch Calibration Services
- Customer Support
- Expert Experience and Knowledge

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