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:
www.gexcorp.com
sales@gexcorp.com
+1 303 400.9640
DOSECONTROL® MAKES OPERATIONS EFFICIENT AND AUDITS EASY

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, data, 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 (ThermoFisher Scientific Genesys 20 and Evolution 200):
  – 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 Rod 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

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.

REPORT SUMMARY SCREEN
- Displays report information and measurements
- Record and version comments for the report
- Print report, create .xls file, or sync with database
EXAMPLE SCREEN SHOTS: DOSIMETRY SYSTEM SETUP

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:**

**AUDIT LOG SCREEN**
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

For more information:
www.gexcorp.com
sales@gexcorp.com
+1 303 400.9640