

FDA 21 CFR Part 11 | Subpart B - Electronic Records | Section 11.10 Controls for Closed Systems | §11.100 General Requirements

Sec. Ref.	Section Description	Explanation
11.10 (a)	Validation of systems to ensure accuracy, reliability, consistent intended performance. Validation of the system to discern invalid or altered records.	GEX has validated the DoseControl dosimetry system meets the expected performance requirements.
11.10(b)	The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.	DoseControl can generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying. - The system puts all electronic data in the connected application database. - The system can output dosimetry data in the form of reports in secure PDF and Excel format at any time throughout the life of the system. - The PDF and/or Excel file output from the system can be saved electronically on the user's PC or network, or printed. - The system can output dosimetry data to the system's export tables. The end-user must integrate a system with these export tables to collect the data, and the end-user is responsible for generating copies of the data in both human readable and electronic format.
11.10(c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	The system protects all records and data permanently throughout the lifetime of the software, until the end-user decides to delete the software and application database. Dosimetry data, reports and related records and configuration data cannot be overwritten or deleted by any user at any time. If a modification is made to a configured item, the original value is never overwritten and cannot be deleted by any user.
11.10(d)	System access limited to authorized individuals	The software includes user authentication and user access permission functionality that could be configured to limit system access and control the user activity within the software.

Sec. Ref.	Section Description	Explanation
11.10(e)	Audit trail shall be used that: - Are secure, computer-generated, and time-stamped - Independently record the date and time of operator entries and actions that create, modify, or delete electronic records. - Record changes shall not obscure previously recorded information. Audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	This can be demonstrated through the functionality of the software itself. DoseControl software contains this audit trail functionality. - The audit trail is always active and cannot be inactivated. - The audit trail cannot be modified. - The Audit trail is accessible at any time by an authorized user; this user can view and filter the Audit Trail at will. The Audit trail, and filtered records of the audit trail, can be printed in secure PDF format. - The Audit trail is retained permanently for the life of the software or until the user decides to delete the application database.
11.10(f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	This can be demonstrated through the functionality of the software itself. The software controls the attached active spectrophotometer, and has functionality to control the zeroing of the device, and status of the spectrophotometer device. The software enforces the use of only active configured items (items can be active/inactive). The software enforces the workflow of dosimeter measurement activities, and has a sequence of steps for each measurement that is controlled by the software. The software enforces a workflow to guide the user through the connected sequence of events for the performance verification test of the Evolution spectrophotometer within the PV Module.
11.10(g)	Use of authority checks to ensure that only authorized individuals can: - Use the system access the operation or computer system input or output device, - Electronically sign a record - Alter a record, - Perform the operation at hand.	This can be demonstrated through the functionality of the software itself. User authentication and access permissions with the software provide this functionality. DoseControl does <u>not</u> have electronic signature functionality.
11.10(h)	If appropriate, does the system use device checks to determine the validity of the source of data input or operational instruction (e.g., system console, specific physical location)?	This can be demonstrated through the functionality of the software itself. Prior to allowing the measurement workflow to proceed, the software checks: - The attached spectrophotometer (Reader) is configured, active, verifies the serial number and calibration due date - The correct dosimeter batch Calibration is configured, active, verifies the calibration ID, calibration use date, calibration due date. - The correct dosimeter Batch ID, irradiation Pathway ID, Dosimeter Type is configured and active, as associated with the attached active spectrophotometer and dosimeter batch Calibration ID. The software checks the identity of the attached Evolution spectrophotometer reader prior to executing a performance verification test in the PV Module feature of the software.

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11.10(i)	Determination that the following persons have the education, training and experience to perform their assigned tasks: • Developers of the system • Maintainers of the system • Users of the system	Software release information from GEX could satisfy this requirement: DoseControl is designed and validated by GEX to be compliant with Compliant with ISO 11137, ISO/ASTM 51275, 51261, 51649, 52628 consensus standards for the intended use of measuring dosimeters and generating dosimetry reports for commercial/industrial radiation processing applications. GEX validation documentation is available for audit at GEX offices in Palm City, FL U.S.A. or electronic copies may be purchased. Current product specification and usage documents are available in the document library, and maintained in accordance with GEX QMS policies. GEX DoseControl user manual provides information regarding system maintenance. GEX can provide maintenance contracts services; or trained staff and SOPs could support this requirement. End-user training SOPs and training records should be maintained.
11.10(j)	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures.	N/A. DoseControl does not have electronic signature functionality.
11.10(k)	Use of appropriate controls over systems documentation, including:	
11.10(k) [1]	Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance Adequate controls over the access to documentation such as directions for modifying security features	Customer SOPs could satisfy this requirement Customer SOPs could satisfy this requirement
11.10(k) [2]	Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	Customer SOPs could satisfy this requirement. GEX is ISO 9001 certified and maintains revision control of published documentation.