AxIS Z 21 CFR Part 11 Statement

Section		Summary	AxIS Z Features
11.10 Controls for Closed Systems			
11.10(a)	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	System Validation	AxIS Z software is validated by Axion BioSystems to ensure accurate, reliable, and consistent intended performance of the Maestro system. IQ/OQ procedures ensure proper function of the Maestro system. Electronic records are created with a checksum to discern altered records. System validation is further supported by a built-in impedance signal test, fit-for-purpose validation protocol based on ISO 20391-2, and the internal quality management system of Axion BioSystems.
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. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such	Electronic Records	The system owner/operator is solely responsible for record storage. AxIS Z software stores the results and all relevant analysis parameters in a human-readable format. A report containing the analysis layout and results can be exported to

	review and copying of the electronic records.		Excel in XLSX format or for LIMS import in CSV format. Accuracy and completeness are ensured by digital signatures and checksums in enclosing zip files.
11.10(c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Electronic Records	The system owner/operator is solely responsible for record storage. AxIS Z keeps all data which are relevant for operation inside the Maestro system indefinitely. Accuracy and completeness of human readable records are ensured by digital signatures and checksums.
11.10(d)	Limiting system access to authorized individuals.	Access	AxIS Z runs on PCs with the Windows 10 operating system and integrates with Microsoft's Active Directory server to define AxIS Z administrative users. The owner/operator is responsible for limiting user access, administrative status, and log-in on these PCs.
11.10(e)	Use of secure, computer-generated, time-stamped audit trails to 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. Such 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.	Audit Trails	A system-wide, time-stamped audit trail tracks instrument status and changes, such as calibration, firmware updates, and alerts. An experiment-specific, time-stamped audit trail tracks user actions, such as environmental changes, plate map changes and data import/export. Audit trails can be exported at any time. Records cannot be overwritten or obscured. Accuracy and completeness are secured by digital signatures and checksums at export.
11.10(f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate	Operational System Checks	AxIS Z will only connect to an authentic Maestro system. The system uses a barcode scanner to ensure an authentic plate is loaded, initiate environmental controls, and automatically record data. Any required user actions are prompted and sequenced by the system. All system and user actions are tracked in the audit trail, including deviations or alerts.

11.10(g)	Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	Authority Checks	AxIS Z runs on PCs with the Windows 10 operating system. AxIS Z integrates with Microsoft's Active Directory server to define AxIS Z administrative users. AxIS Z is accessible by any logged-in Windows user, but certain actions are limited to administrators. Data records cannot be overwritten or obscured, and all changes, such as plate map entries, are tracked per user in the audit trail. The owner/operator is responsible for ensuring that each Windows user account can be traced to a real individual and limiting user access and administrative status.
11.10(h)	Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	Device Checks	AxIS Z connects only to licensed Maestro systems which are developed by Axion BioSystems. Each datum is checked for validity before storage on the Maestro. Data from the Maestro can only be imported by AxIS Z, and checksums are used to ensure that data has not been altered before allowing import. Finally, a File Verification feature employs checksums to verify that records were created by Axion BioSystems and have not been altered.
11.10(i)	Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	Training and Accountability	All Axion BioSystems personnel are trained according to their roles. Axion BioSystems provides AxIS Z software and Maestro user training. The owner/operator is responsible for training on their SOPs in regard to electronic records and electronic signatures. Axion BioSystems supports the use of these SOPs in relation to AxIS Z.
11.10(j)	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.		The owner/operator is solely responsible.
11.10(k)	Use of appropriate controls over systems documentation including: (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. (2) Revision and change control	System Document Control	AxIS Z is delivered with user documentation which can be accessed directly in the software. User documentation (release notes, user guide, installation guides, etc.) is controlled by Axion BioSystems, including version control information. Context-sensitive help is provided

	procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.		within the software. Once delivered, further control and distribution of documentation is the responsibility of the owner/operator.

11.30 Controls for Open Systems

11.30	Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.		Not Applicable. The Maestro operates as a closed system.

11.50, 11.70, 11.100, 11.200, 11.300

These sections regulate the use of electronic signatures. AxIS Z does not implement electronic signatures. However, digital signatures are used to ensure data integrity and security.