Data Integrity Compliance of JEOL NMR

JEOL NMR systems have had all FDA 21 CFR Part 11 support functions available in the standard Delta software since version 4.3 was released in 2004. All newer versions of the software have maintained and added to this functionality.
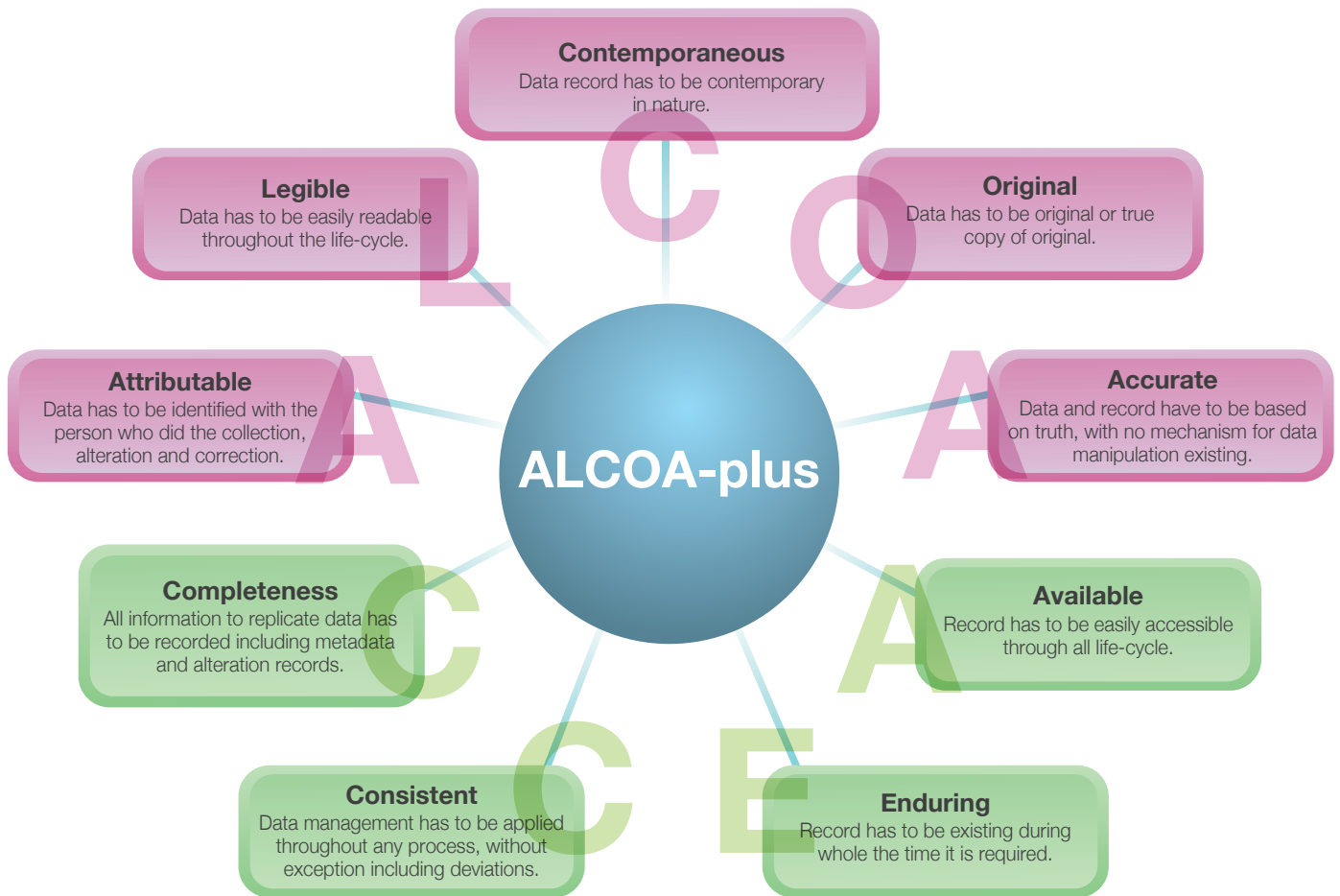
An essence of GMP management is regularization and documentation, and thus the software is required to provide 4 basic functions as detailed below.

Security

■ A system for allowing unique user accounts to be created for each user or manager of the system with appropriate permissions or restrictions as necessary.

Electronic Record

■ An electronic record according to the guidelines on each regulator has to be automatically recorded during the use of the instrument including measurement and processing of data.

Data Protection

■ Data and all records have to be kept in a browsable condition through the whole life cycle of data.

Electronic Signature

■ A function to put electronic signature into each data according to guidelines on each regulator has to be implemented.

In a JNM-ECZ series NMR system, a built-in spectrometer control computer in the spectrometer and an operation PC are completely independent of each other. This system architecture allows for very secure operation of data management. An NMR data (JDF format) file generated by an JNM-ECZ series spectrometer includes not only the traditional NMR data but also all kinds of metadata, e.g. measurement parameters, data processing parameters, audit trails, and electronic signature(s) in single file. It is not necessary to connect multiple files, making data management more straightforward.

ALCOA-plus principles support

Modern data integrity guidance requires 5 principles (ALCOA) as well as 4 additional principles (CCEA, also known as ALCOA-plus) to be followed by the system.

Contemporaneous
Data record has to be contemporary in nature.

Legible
Data has to be easily readable throughout the life-cycle.

Original
Data has to be original or true copy of original.

Attributable
Data has to be identified with the person who did the collection, alteration and correction.

Accurate
Data and record have to be based on truth, with no mechanism for data manipulation existing.

ALCOA-plus

Completeness
All information to replicate data has to be recorded including metadata and alteration records.

Available
Record has to be easily accessible through all life-cycle.

Consistent
Data management has to be applied throughout any process, without exception including deviations.

Enduring
Record has to be existing during whole the time it is required.

ALCOA	Attributable	Delta software automatically records when/who/where/what have been done during all data collection and all data processing steps.
	Legible	Delta software equips File Information Viewer to browse records and metadata.
	Contemporaneous	Delta software records data collection and data processing with time stamps at the same time of operation.
	Original	Delta software does not allow alteration of data without records nor any correction of records.
	Accurate	Delta software automatically records time stamp, user name, computer name, IP address and operational details, and thus there is no way to tamper with the data or falsify information.
CCEA	Completeness	NMR data file of Delta software, which is binary data, includes all metadata including pulse program, measurement parameters, data processing details, and etc.
	Consistent	Delta software records all data collection including interrupted experiment, and also records all data processing details including reprocessing.
	Enduring	Remote Maintenance Tool, which is provided with Delta software, equips a function to back up all data regularly.
	Available	Delta software is forwards compatible in principle, and compatibility of the file information browsing feature is always kept.