Question 13.19

Topic: Validation of Stored Data during DAHS Downtime

Question: Data Acquisition and Handling Systems (DAHS) are often made up of multiple components such as a Programmable Logic Controller (PLC), which does limited data processing and short term data storage, and a PC, which does more complete data processing and long term data storage.

Because of this, it may be possible to collect and store raw data during a DAHS downtime and complete the processing of that data when the complete DAHS is running again. For example, this might occur during the installation of upgraded software or when a PC crashes. May we collect and store raw data in a component such as a PLC during a DAHS downtime and then complete processing of the data when the complete DAHS system is operating again? If so, would our data be considered valid if the reason for the DAHS downtime is a change to the DAHS that requires recertification?

Answer: Yes, to both questions. It is acceptable to store raw data during a period when the complete DAHS is not available (e.g., during installation and DAHS verification testing for a new software version or when the DAHS PC crashes) and later complete processing of that data in the DAHS and report that data as valid during the entire time that the DAHS was unavailable---provided that the raw data (including any necessary quality assurance data) are:

(1) Quality-assured based on all other applicable criteria (e.g., daily calibration has been passed);

(2) Stored electronically in a component (e.g., PLC, data logger) that is identified in the data pathway diagram (in the monitoring plan) of a certified system; and

(3) Captured, stored, and transferred electronically.

If the software is being upgraded, but the data storage component is not affected, data may be collected and stored in the storage component while the missing data and formula verification tests are run on the software. As long as those tests are passed, the data collected and stored in the storage component may be processed by the newly certified DAHS component and may be considered valid. Please note, however, that if the storage component (e.g., PLC, data logger) is also being modified or replaced, data may not be stored on the new or modified component until after the required recertification or diagnostic tests (as applicable) are completed.

References: § 75.10(a)

History: First published in March 1996, Update #8; revised in 2013 Manual