§ 1311.55 Requirements for systems used to process digitally signed orders.

(a) A CSOS certificate holder and recipient of an electronic order may use any system to write, track, or maintain orders provided that the system has been enabled to process digitally signed documents and that it meets the requirements of paragraph (b) or (c) of this section.

(b) A system used to digitally sign Schedule I or II orders must meet the following requirements:

(1) The cryptographic module must be FIPS 140-2, Level 1 validated, as incorporated by reference in §1311.08.

(2) The digital signature system and hash function must be compliant with FIPS 186-2 and FIPS 180-2, as incorporated by reference in §1311.08.

(3) The private key must be stored on a FIPS 140-2 Level 1 validated cryptographic module using a FIPS-approved encryption algorithm, as incorporated by reference in §1311.08.

(4) The system must use either a user identification and password combination or biometric authentication to access the private key. Activation data must not be displayed as they are entered.

(5) The system must set a 10-minute inactivity time period after which the certificate holder must reauthenticate the password to access the private key.

(6) For software implementations, when the signing module is deactivated, the system must clear the plaintext private key from the system memory to prevent the unauthorized access to, or use of, the private key.

(7) The system must be able to digitally sign and transmit an order.

(8) The system must have a time system that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The system must archive the digitally signed orders and any other records required in part 1305 of this chapter, including any linked data.

(10) The system must create an order that includes all data fields listed under §1305.21(b) of this chapter.

(c) A system used to receive, verify, and create linked records for orders signed with a CSOS digital certificate must meet the following requirements: