

of this chapter, including any linked data.

(10) For orders, 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 digital certificate must meet the following requirements:

(1) The cryptographic module must be FIPS 140–2 validated.

(2) The digital signature system and hash function must be compliant with FIPS 186–2 and FIPS 180–1.

(3) The system must determine that an order has not been altered during transmission. The system must invalidate any order that has been altered.

(4) The system must decrypt the digital signature using the sender's public key. The system must invalidate any order that cannot be decrypted.

(5) The system must check the certificate revocation list automatically and invalidate any order with a certificate listed on the certificate revocation list.

(6) The system must check the validity of the certificate and the Certification Authority certificate and

invalidate any order that fails these validity checks.

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

(8) The system must check the substances ordered against the schedules that the signer is allowed to order and invalidate any order that includes substances the signer is not allowed to order.

(9) The system must ensure that an invalid finding cannot be bypassed or ignored and the order filled.

(10) The system must archive the order and include the digital certificate attached to the order in the record of each order.

(11) If a registrant sends daily reports on orders to DEA, the system must create a report that includes, for each order, all the data fields listed under § 1305.28(a) of this chapter.

(d) For systems used to process orders, the system developer or vendor must have an initial independent third-party audit of the system and an additional independent third-party audit whenever the signing or verifying functionality is changed to determine whether it correctly performs the functions listed under paragraphs (b)

and (c) of this section. The system developer must retain the most recent audit results and retain the results of any other audits of the software completed within the previous two years.

§ 1311.65 Recordkeeping.

(a) A supplier or purchaser must maintain records of electronic orders and any linked records for two years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records by Schedule and controlled substance name.

(b) Electronic records must be easily readable or easily rendered in a readable format. They must be made available to the Administration upon request.

(c) Certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

Dated: June 19, 2003.

William B. Simpkins,

Acting Administrator.

[FR Doc. 03–16082 Filed 6–26–03; 8:45 am]

BILLING CODE 4410–09–P