

Usually this involves obtaining authority and instructions from the local DEA field office as specified in 21 CFR 1307.21. Such registrants also have the option of returning controlled substances to the manufacturer or to a reverse distributor.

Appropriateness of Security and Other Requirements That Apply to Manufacturers

Commenters recommended creating a separate category for reverse distributors, as a subcategory of distributors, who would be subject to the existing registration and other requirements for distributors. Commenters stated that reverse distributors should, therefore, not be subject to the security, inventory, recordkeeping, and reporting requirements of the proposed rule that apply to manufacturers.

DEA's Response

Since DEA has decided to create a completely separate category for reverse distributors, persons who fall under this category will be required to comply with the same security, reporting, and other requirements that apply to distributors rather than the requirements that apply to manufacturers.

Proposed Security Requirements: Monitoring Systems

DEA received one comment on the language in proposed 21 CFR 1301.71(b)(14) which requires the applicant or registrant to document the adequacy of its system for monitoring the receipt, manufacture, distribution, and disposal of controlled substances. The commenter stated that all of the "waste to energy" facilities that it operates have demonstrated that the implementation of supervised monitoring of the receipt and disposal process, by the disposer, has proven effective and that it would be physically impossible for them to construct the vaults or other security barriers that the regulations require for storage at manufacturer's locations (under 21 CFR 1301.72). Instead, this commenter recommended that disposers be required to develop a set of Standard Operating Procedures, to be approved by DEA, for the receipt and disposal of controlled substances.

DEA Response

With respect to the issue of physical security, it should be noted that the commenter does not take possession of the controlled substances that are to be destroyed. Instead, the commenter maintains incineration facilities at

which DEA registrants carry out witnessed destruction of their controlled substances. As a result, the commenter is not subject to DEA's requirements and does not have to establish or maintain physical security as required under 21 CFR 1301.72 of the regulations.

Proposed Security Requirements: Compliance With Other Laws

One commenter commented on proposed 21 CFR 1301.71(b)(15), which would require DEA to consider the applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste, as they would apply to applicants and registrants. The commenter stated that this requirement would be inappropriate because it would exceed DEA's statutory authority. While DEA inspectors should be concerned with compliance with DEA statutes and regulations during audits, the inspectors should not be empowered to look for violations of other Federal, State, and local laws governing the management of waste. Enforcement of those laws should be left to the other Federal agencies and individual jurisdictions. Therefore, the commenter requested DEA clarification on this issue.

DEA Response

With respect to this comment, the items listed in 21 CFR 1301.71(b)(1) through new (b)(15) are factors that the Administrator may consider in evaluating whether the security controls provided by a DEA registrant are adequate to guard against theft and diversion of controlled substances and appropriate to the registrant's business. Not all of the factors may be relevant for evaluation of a particular registrant's operation. DEA is adding a new factor regarding the applicability of other Federal, State, or local laws, not as an enforcement issue for those specific laws, but only as guidance to the registrant that DEA may consider how the registrant is complying with such laws in making an evaluation of the adequacy of the registrant's security system. DEA has the statutory authority under 21 U.S.C. 823 to consider an applicant's compliance with applicable State and local laws before granting a registration.

Proposed Inventory Requirements

A commenter that provides disposal facilities at which registrants may conduct witnessed destructions recommended that additional language be added to the end of proposed 21 CFR 1304.20 (current 21 CFR 1304.11) to

require that the information required under 21 CFR 1304.15(a), (c), and (d) be provided by the manufacturer or its agent when tendering the substances for disposal.

DEA Response

The commenter's suggested change is not necessary because in witnessed destructions the registrant conducting the destruction must accurately document the controlled substances being destroyed on DEA Form 41. Further, a disposal facility of the type operated by the commenter does not take possession of the controlled substances being destroyed and, thus, is not subject to the registration, inventory, and recordkeeping requirements under the law.

Proposed Recordkeeping Requirements

Several commenters made recommendations to change the language of proposed 21 CFR 1304.30(a) (current 21 CFR 1304.22) to make the specific requirements clear.

A commenter also expressed concern about proposed paragraph (b) and stated that the disposer should not be expected to recount and itemize the individual dosage units and containers for each substance being delivered for disposal. This would put their employees at possible risk for exposure to these substances, increase opportunities for diversion, and significantly slow down the disposal operation. Instead, the commenter recommended that sufficient controls be placed on the manufacturer and its representatives prior to disposal so that the disposer can focus on rapid and effective disposal procedures.

DEA Response

The comments primarily address problems that could have arisen if the reverse distribution function was included under manufacturing, as proposed. These concerns are mostly addressed by treating reverse distribution as a separate category of registration. The concerns expressed by disposers are, as previously discussed, not relevant as long as legal control of the controlled substances remains with a person who is registered with DEA.

Recordkeeping requirements for reverse distributors are set forth in new paragraph (e) of 21 CFR 1304.22. These requirements are tailored to the reverse distributor role and address recordkeeping for controlled substances in both bulk and finished form. These requirements are consistent with existing practice.