

components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable (mechanical failure, accidents, fire, etc.), that all controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the registered location.

(2) With regard to the requirement of paragraph (e)(1) of this section, that upon completion of the operation of the mobile NTP on a given day, the conveyance must be immediately returned to the registered location, and all controlled substances must be removed from the conveyance and secured within the registered location, an NTP may apply for an exception to this requirement as provided in this paragraph. The application for such an exception must be submitted in accordance with § 1307.03 of this chapter and must include the proposed alternate return period, enhanced security measures, and any other factors the applicant wishes the Administrator to consider. The Administrator may grant such an exception in his discretion and will evaluate each application on a case-by-case basis in determining whether the applicant has demonstrated exceptional circumstances that warrant the exception. In making this determination, the Administrator will consider the applicant's security and recordkeeping as well as any other factors he deems relevant to determining whether effective controls against diversion will be maintained.

[36 FR 18730, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1301.72, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: *Provided*, That he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

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