

Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 425.400 Computerized Drug Processing; Input/Output Checking (CPG 7132a.07)

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BACKGROUND:

Section 211.68 (automatic, mechanical, and electronic equipment) of the Current Good Manufacturing Practice Regulations requires, in part, that input to and output from the computer or related system of formulas or other records or data be checked for accuracy. This requirement has generated questions as to the need for and extent of checking a computer's input and output.

The agency received several petitions to delete or modify the requirement on the grounds that a validated computer system need not have its input/output routinely checked. The request to delete or modify the requirement was denied because our experience has shown that input/output error can occur, even in validated systems. Printouts, for example, can contain errors as a result of faulty input, programming, or equipment malfunction. More significantly, there is the human element which can induce errors. At worst, input/output errors can result in serious production errors and distribution of adulterated or misbranded products. Several recalls have, in fact, been conducted because of insufficient input/output checks.

Despite the general need for input/output checks, not all input and output need be checked. The regulation is, in fact, deliberately silent on the required frequency and extent of data checking to afford firms the necessary flexibility. Also, the use of efficient input edits, for example, could mitigate the need for more detailed manual data checks.

POLICY:

Input/Output checks of data for computer systems, as required by 21 CFR 211.68, are necessary to assure the quality of a drug product processed using such systems. The extent and frequency of input/output checking will be assessed on an individual basis, and should be determined based upon the complexity of the computer system and built in controls.

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