PACKAGING 17

(See Sections 11 and 12 in <800>.)

<800> allows the entity to perform an Assessment of Risk to evaluate exempting specific dosage forms of HDs from the containment strategies and/or work practices. Antineoplastics that require only counting or packaging, non-antineoplastic agents, and reproductive hazards may be considered for the entity's Assessment of Risk if alternative containment strategies and/or work practices are identified and implemented.

17.1 Is unit dosing of antineoplastics considered compounding, and does it have to be performed in a controlled environment?

Pre-packaging of antineoplastics isn't compounding, but it *is* covered under <800> since it is handling a hazardous drug (HD). If you include this in your Assessment of Risk, you may exempt dosage forms of antineoplastics that require only counting or packaging. Oral tablets could be considered for this. However, if you have the appropriate facilities for compounding HDs, why not use them to protect personnel during pre-packaging, too?

This is a two-step issue:

(1) The pharmacy staff would have a higher level of risk, since they need to directly handle the HDs. (2) Once they are packaged, the risk of handling the finished dosage form is reduced. Consider using your containment device (containment ventilated enclosure [CVE], biological safety cabinet [BSC], or compounding aseptic containment isolator [CACI]) as the location where your oral antineoplastics are packaged. If using a BSC or CACI in your negative pressure sterile compounding area, you would need to use the same restrictions as you would for nonsterile compounding: do this only while no sterile compounding is occurring, and decontaminate, clean, and disinfect the surfaces following completion of the pre-packaging. In any case, consider restricting specific counting trays and spatulas for HDs you package, and include specific instructions in your procedures for decontamination and cleaning the equipment.

17.2 Is it OK to use a packaging machine to unit dose HDs?

Solid oral antineoplastics must not be placed in packaging or counting devices because that process could create powders, which would contaminate the system. Use a manual unit-dose system for oral antineoplastic agents, and consider using your containment device (CVE, BSC, or CACI) in which to do the packaging. For non-antineoplastic and reproductive hazards in solid oral formulations, you can address alternative containment strategies in your Assessment of Risk. For example, you might dedicate specific equipment for this, decide to use a manual system, or perform the pre-packaging in your containment device.

17.3 Which oral dosage forms of HDs don't require counting in negative rooms?

This depends on your Assessment of Risk. If you determine alternative containment strategies, you could exempt solid oral dosage forms of non-antineoplastics and/or reproductive hazards from this requirement.

17.4 Even though <800> allows antineoplastics in final forms that require only counting or packaging, why wouldn't I use a powder hood or BSC to pre-package them?

If you have the proper facility, use your powder hood or BSC to limit risk to personnel who are pre-packaging or counting antineoplastics.

17.5 What precautions are needed for crushing tablets or opening capsules of HDs?

This is manipulation of a HD. Pharmacy should be packaging these dosage forms, so nursing or other staff do not have to manipulate the drug in an area without the controls of a negative primary engineering control (PEC) or negative room. Additionally, providing ready-to-use dosage forms is expected by the Centers for Medicare & Medicaid Services (CMS) and accreditation organizations.

17.6 Our obstetric department uses misoprostol in 25-mcg tablets. They are available only in 100-mcg tablets. How can we best comply with their needs?

Misoprostol is on Table 3 (reproductive hazards) in the National Institute for Occupational Safety and Health (NIOSH) list of HDs.[5] All containment strategies in <800> are required unless you consider this in your Assessment of Risk.

If you include it in your Assessment of Risk, you could consider some of these approaches:

- Define restrictions concerning who may package the 25-mcg doses, based on the reason misoprostol is on the list.
- Dedicate a specific tablet splitter only for misoprostol use.
- Develop a method to place the quarter-tablets in a consistent packaging system (e.g., a manual unit-dose bubble).
- Label the bag with whatever caution is required by your Assessment of Risk.
- Place the doses in a lidded container in the automated dispensing cabinet (ADC) with a warning on the lid.

17.7 Do patient-specific doses of antineoplastic oral solution HDs need to be drawn up in a negative pressure room? How about non-antineoplastic HD oral solutions?

This is manipulation of a HD, so containment strategies are necessary. <800> permits use of the BSC or CACI in your sterile negative pressure compounding room for occasional nonsterile use, as long as the stipulations listed in <800> are followed. If you do this routinely, you need to have the proper equipment for nonsterile HD compounding/repackaging.