

# ASSESSMENT OF RISK

# 6

## 6.1 What are my options to handle HDs?

<800> details the containment strategies and work practices that are required. For antineoplastics (other than those that require only counting or packaging), you must use all the containment strategies and work practices listed in <800>. For antineoplastics that require only counting or packaging, non-antineoplastics, or reproductive hazardous agents, you have two options: (1) treat them with all the containment strategies and work practices listed in <800> or (2) perform an Assessment of Risk to develop and use alternative containment strategies and/or work practices.

## 6.2 What is a practical way to approach identifying the HDs I use that might be candidates for an Assessment of Risk?

*Here's one approach:*

- Print out the National Institute of Occupational Safety and Health (NIOSH) list of hazardous drugs (HDs).
- Identify the drugs and dosage forms that you handle in your organization.
- Sort them into five lists:
  1. Active pharmaceutical ingredient (API) of any drug on the NIOSH list of HDs.
  2. Antineoplastic drugs and dosage forms that must be manipulated.
  3. Antineoplastic drugs and dosage forms that require only counting or packaging.
  4. Non-antineoplastic drugs and dosage forms.
  5. Reproductive HDs and dosage forms.

API of any of the drugs on the NIOSH list of HDs must be handled with all the elements listed in <800>. Antineoplastics that must be manipulated must be handled with all the elements listed in <800>. You can then assess the agents on your other categories that might be acceptable to handle with other containment strategies or work practices. Consider the risks to personnel. For example, methotrexate tablets may require only packaging, but it would be best to do that in the negative pressure engineering controls you already have. It would be more of a risk to pharmacy personnel who are packaging it than to the nurse who is provided a ready-to-administer unit-dose package.

## 6.3 Do I have to include all medications on the NIOSH list?

You need to review the NIOSH list of HDs and identify the drugs and dosage forms you handle. You probably do not use all the drugs on the list; those you don't handle do not need to be on your list.

#### **6.4 Our hospital decided not to include phenytoin and warfarin on our HD list. Is this OK?**

No. You need to include them on your list. All of the agents listed on the NIOSH list of HDs<sup>5</sup> need to be included on your list. You may entity-exempt some of the agents from all of the requirements of <800>, but you must identify the alternative containment strategies and/or work practices that you use to protect employees.

#### **6.5 What needs to be included in the Assessment of Risk?**

You need to consider the type of HD (antineoplastic, non-antineoplastic, or reproductive hazard), the dosage forms of each of those drugs that you handle, the risk of exposure to personnel, the packaging of the drug, and what manipulations you have to perform to get it to a finished dosage form.

#### **6.6 Can I do an Assessment of Risk for an entire class of drugs (e.g., hormones) instead of each individual drug?**

No. <800> requires the Assessment of Risk to be specific to the drug and to a particular dosage form. You may find that certain subsets of drugs and dosage forms will use the same alternative containment strategy or work practice, but your entity's list must be specific to the drug and dosage form.

#### **6.7 Is there a template I can use to list each drug and dosage form to determine if it's acceptable to be included in our Assessment of Risk?**

<800> does not require a specific form. A spreadsheet with the drug, dosage form, and <800> requirements could be developed. See **Exhibit 6-1** for an Assessment of Risk template that could be used to assess each drug and dosage form used.

#### **6.8 Can non-antineoplastics and reproductive hazards be handled differently than antineoplastics?**

Yes, if you perform an Assessment of Risk to identify and implement alternative containment strategies and work practices.

#### **6.9 Should all MABs be treated as hazardous?**

Not all monoclonal antibodies (MABs) are on the NIOSH list of HDs. You must treat the ones that are on the list as hazardous. You also may add other agents to your list.

#### **6.10 Why is an Assessment of Risk allowed by <800> if all the drugs on the NIOSH list are hazardous?**

An Assessment of Risk is allowed because not all dosage forms may have the same level of risk. Working with powders or crushing tablets is more of a risk of exposure than handling a manufacturer's unit-dose tablet. Mixing intravenous (IV) solutions is more of a risk than purchasing pre-mixed solutions from a manufacturer or U.S. Food and Drug Administration (FDA)-registered outsourcing facility. <800> applies to all healthcare facilities where HDs are handled including health-system pharmacies, community pharmacies, physician offices, and other locations. Not all entities manipulate HDs to the same degree.