

HUMAN RESOURCES

7

(See Sections 4, 8, 9, and 18 in USP <800>.)

7.1 MEDICAL SURVEILLANCE

7.1-1 What does *medical surveillance* mean?

Entities that handle hazardous drugs (HDs) should incorporate the standards in the Chapter into their occupational safety plan. Medical surveillance evaluates the protection provided by engineering controls, work practices, and personal protective equipment (PPE) as well as worker education concerning the materials exposed to during employment. The purpose is to minimize adverse health effects in personnel exposed to HDs. Medical surveillance programs include assessment and documentation of symptoms, physical findings, and laboratory studies to determine if there is deviation from expected norms. The National Institute of Occupational Safety and Health (NIOSH) document on *Medical Surveillance for Health Care Workers Exposed to Hazardous Drugs*¹⁰ provides an overview.

7.1-2 What department determines how this will work?

This is an employee health issue, so there needs to be a system-wide policy concerning all healthcare personnel who may be exposed to HDs.

7.1-3 What types of medical surveillance will be required?

There is no requirement for medical surveillance; it is a recommendation. Of course, if your organization has specific policies, you are required to follow them. NIOSH has a document on medical surveillance available at <http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf>, and the Oncology Nursing Society (ONS) has excellent information in their publication *Safe Handling of Hazardous Drugs*.¹¹

7.1-4 Should all employees have to sign lists acknowledging risk/NIOSH drug list?

Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs. This has been a requirement in <797> since 2008 and is required by <800>.

7.1-5 Should pregnant or breast-feeding pharmacy technicians and pharmacists, or any employees trying to conceive, be removed from work duties of preparing chemo?

This is an issue of employee health policies. NIOSH has published recommendations that may be helpful to review. See <https://www.cdc.gov/niosh/docket/review/docket279/pdfs/alternativedutycibrevised12012014.pdf>.

7.1-6 Should nurses who are pregnant or wish to become pregnant avoid taking care of patients who are on HDs due to administration and drug elimination in bodily fluids?

That is an issue your Employee Health and Risk Management leaders must determine. The NIOSH document on medical surveillance¹⁰ and the ONS publication *Safe Handling of Hazardous Drugs*¹¹ are excellent resources.

7.2 DESIGNATED PERSON

All entities must designate a specific individual who is responsible for overseeing activities handling HDs. This cannot be eliminated even if using the Assessment of Risk approach.

7.2-1 Who is the *designated person* mentioned in <800>?

Each entity—any site where HDs are handled—must have an individual who oversees the responsibilities of handling HDs. This person is responsible for developing and implementing policies and procedures; overseeing compliance with <800> and any other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the facilities used for storing and compounding HDs.

7.2-2 Can the *designated person* be a committee instead of an individual?

There needs to be a particular person identified. That person can lead a committee if that approach is chosen by the entity.

7.2-3 Does the *designated person* need to be a pharmacist?

No. It can be anyone qualified to perform all the required functions. Healthcare systems will most likely have a pharmacist in this position, but many entities (e.g., physician offices, veterinary clinics) may not have a pharmacist available for this function.

7.2-4 Does the *designated person* need to be a manager?

No. It is up to the entity to assign the specific person to oversee this.

7.2-5 Is the *designated person* responsible for compliance with USP <800>?

Yes, that is a key function of the designated person.

7.2-6 Does oversight of handling HDs have to be the *designated person's* sole job responsibility?

No. It is up to the entity to assign job functions.