CHAPTER OVERVIEW

Section 7: Exposure Standards and Guidelines

Learning Objectives

After completing this lesson, you will be able to:

- Explain the difference between exposure standards and guidelines.
- Identify approaches to regulating consumer products and drug safety.
- Describe standards and guidelines for environmental and occupational exposure.

In this section...

Topics include:

What We've Covered

This section made the following main points:

- **Standards** are legally acceptable exposure levels or controls set by Congressional or Executive mandate.
- **Guidelines** are recommended maximum exposure levels and are voluntary and not legally enforceable.
- Consumer products
  - The U.S. Consumer Product Safety Commission (CPSC) protects the public from unreasonable risks of harm connected with consumer products.
  - The CPSC establishes consumer exposure standards for hazardous substances and articles.
  - The CPSC requires warning labels on containers of household products that are toxic, corrosive, irritating, or sensitizing.
- Drugs
  - FDA approval is required before pharmaceuticals can be marketed.
  - Animal studies and human clinical trials are required to determine toxic dose levels.
  - The New Drug Application (NDA) contains guidance for drug usage and warnings regarding side effects and interactions.
  - Information about a drug's harmful side effects must be provided through labeling and package inserts, publication in the Physicians' Desk Reference (PDR), and direct-to-consumer marketing.
- Food additives
  - The FDA is responsible for approving food additives.
  - **Direct additives** are intentionally added to foods for functional purposes and include processing aids, flavors, appearance agents, and nutritional supplements.
  - **Indirect additives** are not intentionally added to foods and are not natural constituents of foods, but become constituents during production, processing, packaging, and storage.
  - FDA scientists must review new direct food additives before they can be used in foods.
  - Generally Recognized as Safe (GRAS) additives are generally accepted as safe for an intended use and can be introduced into the food supply without prior FDA approval.
- Environment
  - The EPA establishes exposure standards for pesticides, water pollutants, air pollutants, and hazardous wastes.
  - Pesticides must be registered with EPA after undergoing extensive analyses.
  - The EPA prepares health advisories (HAs) as voluntary exposure guidelines for drinking water contamination.

- Ambient water quality criteria help control pollution sources at the point of release into the environment.
- National Ambient Air Quality Standards (NAAQS) protect public health and welfare from air pollution.
- Hazardous wastes are regulated under the Resource Conservation and Recovery Act (RCRA) and Superfund.
- RCRA regulates hazardous and non-hazardous solid waste.

- Occupational Safety
  - The Occupational Safety and Health Administration (OSHA) establishes legal standards for worker exposure in the United States.
  - Permissible Exposure Limits (PELs) list air concentration limits for chemicals, but not skin absorption or sensitization.
  - Short Term Exposure Limit (STELs) PELs are concentration limits of substances in the air that workers may be exposed to for 15 minutes without adverse effects.
  - Ceiling limits are concentration limits for airborne substances that must not be exceeded.
  - Immediately dangerous to life or health (IDLH) designates an airborne exposure or atmosphere that could lead to death or immediate or delayed permanent adverse health effects.
  - Control banding (CB) determines a control measure based on a band of hazards, such as skin irritation or carcinogenic potential, and exposures.
