Ph 102.01 "Active pharmaceutical ingredient (API)" means any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Conventionally manufactured drug product is not an API but is typically manufactured from an API.

Ph 102.02 "Adulterated drug" means any drug:

(1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe to be administered to humans or other animals;

(2) That has been manufactured, composed, prepared, stored, or dispensed in such a manner that may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to humans or other animals; or

(3) That can be defined as an adulterated drug under RSA 146:4 or federal law.

Ph 102.03 "Aseptic technique" means a set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient, which is accomplished through practices that maintain the microbe count at an irreducible minimum.

Ph 102.?? "Compounded nonsterile preparation (CNSP)" means …

Ph 102.?? "Compounded sterile preparation (CSP)" means **a preparation** intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering of a drug or bulk drug substance.

Commented [GRH1]: bd will provide std definition

Commented [GRH2R1]: USP defines a process; Ph rules define a thing

Ph 102.?? "Drug diversion" means the illegal distribution of prescription drugs or the transfer of any legally-prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

Ph 102.?? "Hazardous drugs" means any drug on the current National Institute for Occupational Safety and Health's (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, Table 1 or other drugs determined to be hazardous by the permit holder based on at least one of the following criteria:

(1) Carcinogenicity, teratogenicity, or developmental toxicity;

(2) Reproductive toxicity in humans;

(3) Organ toxicity at low dose in humans or animals; or

(4) Genotoxicity or new drugs that mimic existing hazardous drugs in structure or toxicity.

Ph 102.?? "ISO class" means a classification of air cleanliness in terms of concentration of airborne particles in cleanrooms and clean zones established by the International Organization for Standards (ISO).

?? Ph 102.?? "Labeling" means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

Ph 102.?? "Laminar airflow system (LAFS)" means an air handling system that provides an ISO Class 5 or better environment for sterile compounding, by providing a unidirectional HEPA-filtered airflow designed to prevent contamination of a sterile compounding environment.

Ph 102.?? "Laminar airflow workbench (LAFW)" means a primary engineering control (PEC) that is a type of laminar airflow system that provides an ISO Class 5 or better environment for sterile compounding, by providing a unidirectional HEPA-filtered airflow.

Ph 102.?? "Misbranded drug" means a drug:

(1) Whose label misrepresents the contents or is misleading;

(2) Dispensed by prescription with a label that does not comply with applicable requirements in RSA 318 or RSA 318-B; or

(3) That is misbranded as provided in RSA 146 or applicable federal law.

Ph 102.?? "Preparation" as a noun means a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug in order to be dispensed. will be part of new info provided

Ph 102.?? "Purified water" means source water as defined in Ph 102.?? that has been treated to remove impurities using unit operations such as deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable procedures. <bd. Says info will be provided>

Ph 102.?? "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally-occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

Ph 102.?? "Spill kit" means a container of supplies, warning signage, and related materials used to contain the spill of a drug.

Ph 102.?? "Source water", for purposes of the definition of "purified water", means drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA) or comparable agencies of the European Union, Japan, or the World Health Organization (WHO).

Ph 102.?? "Sterility" means the absence of viable microorganisms.

Ph 102.?? "Unit-dose" means a single-unit container that is designed to hold a quantity of drug product intended for administration as a single dose and labeled with the identity, quantity, and strength, name of the manufacturer, lot number, and expiration date of the drug product.

Commented [GRH3]: How can a "workbench" be a "primary control"?

Commented [GRH4]: "Preparation" is also used as a verb in the existing rules.

Commented [GRH5]: ?? Is this ("in order to be dispensed") what is meant?

Commented [GRH6]: The spill of "a drug" only? What about reagents, etc.?