

INDEX

A

accreditation organizations
 competence and, documenting and overseeing, 13, 57
 emergency power and, 37
 policies and procedures, 17
 risk assessment for storage of cardboard, 29, 39
 USP <795> incorporated in, 3, 7, 10

ACS. *see* American Chemical Society marking

Action Plan, 63–64

active pharmaceutical ingredients (APIs)
 aerosolization and, 33
 beyond-use dates and, 50, 51
 certificate of analysis and, 42
 compounding areas and, 39
 defined, 27
 engineering controls and, 32
 eye and respiratory risk when working with, 21, 24
 from FDA-registered supplier, 27
 Master Formulation Record and, 44
 personal protective equipment when working with, 21, 24, 26
 safety data sheets and, 42

administering medications, 9

aerosolization, 33

airborne particles, 18, 19–20, 25, 31, 39

air changes per hour (ACPH), 32, 35, 36

alcohol as sanitizing agent, 56, 57

alcohol-based hand gel, 23

algorithm, in compounding, 43

American Chemical Society (ACS) marking, 28

American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), 34, 40

animals, application of USP <795> to, 7, 27, 28, 51

anterooms, 35

antimicrobial effectiveness test, 50

antineoplastics, 4, 32–33

aqueous compounded nonsterile preparations, 50, 51

ASHP certificate program, 12, 13

ASHP Competence Assessment Tools for Health-System Pharmacies, 13

ASHP Guidelines on Handling Hazardous Drugs, 59

ASHP Pharmacy Competency Assessment Center, 13

ASHP Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies, 41

Assessment of Risk, 33, 36

ASTM standard D6978, 21, 23, 24

availability of USP <795>, 1

B

balance, in compounding area, 39

beard covers, 23, 24

beyond-use dates (BUDs), 6, 20, 49–52
 allowed by <795>, 49
 for animal nonsterile compounds, 51
 beginning of, 50
 category of compound and, 51
 in Compounding Record, 46
 default dates listed in <795>, 50
 designated person responsible for monitoring, 12
 expiration date distinguished from, 49
 in Master Formulation Record, 44, 47
 maximum, 50
 of opened jars of components, 51
 packaging and storage requirements, 49, 50, 52
 policies required and recommended in USP <795>, 20
 repackaging, 52
 of sterile water, 28
 USP monograph and, 49–50
 water activity and, 51

biological safety cabinet (BSC), 19, 63
 cleaning, 56
 engineering controls and, 31–34
 facility requirements for, 35, 38, 63
 respiratory and eye protection and, 26

Board Certified Sterile Compounding Pharmacist (BCSCP), 13

Board of Pharmacy Specialties (BPS), 13

buffer rooms, 35

bulk drug substances, 27, 29, 41. *See also* active pharmaceutical ingredients (APIs)

C

cabinets, 19, 38, 56

capsules, opening of, 9, 33, 42

cardboard boxes, 29–30, 38–39

ceilings
 cleaning, 57
 facility requirements for, 35, 38

Centers for Disease Control and Prevention (CDC), 22–23

certificate of analysis (CoA), 42

certification of hoods, 19, 34, 39

certification reports, 40, 63

Certified Compounded Sterile Preparation Technician™ (CSPT™), 13

- The Chapter <800> Answer Book*, 4, 18, 21, 22, 29, 31, 32, 33, 35, 36, 37. See also USP <800> *Hazardous Drugs—Handling in Healthcare Settings*
- cleaning, 5, 13, 19, 20, 35, 55–56, 60
- cleaning agents and solutions, 20, 55, 56, 60
- closed system drug-transfer device (CSTD), 32
- closed system processing devices, 5, 20, 32, 39
- committee, as designated person, 11
- community pharmacies, 8, 32–33
- competence, documenting, 12, 13–14, 19, 34, 57, 60
- Competence Assessment Tools for Health-System Pharmacies*, 13
- complaint receipt, 20, 64
- complaints, patient, 61
- compliance with USP <795>, 3, 4, 7–8, 10
- components of CNSPs, 6, 27–30
 - active pharmaceutical ingredients, 27
 - expiration date, 28
 - marking, 27, 28
 - policies required and recommended in USP <795>, 19
 - quality of, 27
 - receiving and storing, 29–30
 - selection, handling, and storage, 6
 - water as, 28
- Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, 10, 27, 41
- compounded nonsterile preparations (CNSPs)
 - designated person for supervising, 11–13
 - dispensing of, 53–54
 - facility design for, 35–38
 - general information on, 41–43
 - for long-term care facility, 8
 - packaging (see packaging)
 - quality assurance and quality control of, 6, 20, 27, 61
 - receiving and storing components, 29–30
 - storage (see storage)
 - training for compounding, 13, 14
 - transporting (see transporting)
- compounder
 - designated person compared to, 11
 - key competencies of, 13
 - responsibilities of, 5, 13
 - training for, 13, 14
- compounding
 - activities considered as, 8–9
 - administering medications distinguished from, 9
 - algorithm in, 43
 - for animal patients, 7, 27, 28, 51
 - beyond-use dates, 49–52
 - categories of, 5
 - controls, 6
 - documentation, 6
 - general information for, 41–43
 - general principles of, 5
 - Master Formulation Records (MFRs), 44–45
 - policies required and recommended in USP <795>, 19–20
 - from powders, garb required for, 21, 24
 - process, 5
 - space for, 19, 35, 39
- compounding with active pharmaceutical ingredient, 39
 - engineering controls, 31–34
 - facility requirements, 35, 38
- compounding areas, 39–40
 - cardboard in, 29–30, 38–39
 - cleaning, 56, 57
 - facility design, 19, 35–38
 - personal protective equipment in, 22, 23, 25
 - policies required and recommended in USP <795>, 18, 19
 - spills in, 56, 57, 59–60
- compounding aseptic containment isolator (CACI), 32
- compounding equipment, 5, 13, 34, 56. See also disposable equipment; personal protective equipment (PPE)
- compounding facilities, 5, 35–40
- compounding areas, 39–40
 - design of, 35–38
 - storage areas, 38–39
- compounding kit, 42
- compounding personnel, 13. See also personnel; pharmacist
- compounding records (CRs), 5, 20, 45–46, 48
- compounding supervisor, 11. See also designated person
 - compounding aseptic containment isolator, 32
- containment devices, 32
- containment ventilated enclosure, 19, 31–35, 38, 39, 56, 63
- containment segregated compounding areas (C-SCAs), 35
- containment ventilated enclosure (CVE), 19, 63
 - cleaning, 56
- contamination
 - cleaning to protect against, 56, 57
 - in compounding area, 19
 - containment and work practices to protect against, 4, 33, 39
 - disposable mops to protect against, 56
 - hair covers to protect against, 24
 - microbial, from cardboard, 38–39
 - personnel responsibilities for minimizing, 19
 - sanitizing to protect against, 55
 - sinks and, 37
- contents of sections of USP <795>, 5–6
- Controlled Environment Testing Association (CETA), 34, 40
- conventionally-manufactured products, 29, 33
- counters, 19, 37, 38
- counting tray, disposable, 34
- curtains, to define compounding area, 36

D

D6978 (ASTM standard), 21, 23, 24
 decontamination, 55
 designated area, 36
 designated person, 11–13, 18, 63
 activities responsible for, 12
 certification for, 12, 13
 cleaning monitored by, 56
 compounder distinguished from, 11
 Master Formulation Record and, 12, 45
 policies required and recommended in USP <795>, 18
 policies reviewed by, 17
 quality assurance monitored by, 27, 61
 training for, 12, 18
 design of compounding facilities, 19, 35–38
 dilution of cleaning solutions, 55
 disinfection, 55
 dispensing, 53–54
 disposable equipment, 34
 mop heads, 56
 personal protective equipment, 22, 23, 24, 59
 in spill kit, 59, 60
 disposal
 of hazardous drugs, 18, 29
 of used garb, 18
 waste segregation and, 20, 60
 distributors, 14
 documentation, 6, 19–20
 certification of hoods and rooms, 39
 certification reports, 40
 of cleaning, 56
 of competency, 12, 13–14, 19, 34, 57, 60
 Compounding Record, 5, 6, 20, 45–46, 48
 equipment records, 19
 hazard communication plan, 14, 15
 of repackaging, 3, 9, 41, 52
 Safety Data Sheets, 14–15, 19, 42
 of spills, 20
 See also Master Formulation Records (MFRs)
 doffing and donning of PPE, 21
 dosage forms, 7
 of antineoplastics, 32–33
 aqueous, 51
 beyond-use dates and, 49
 on compounded nonsterile preparation label, 53
 in Compounding Record, 45, 48
 in Master Formulation Record, 44, 47
 safety data sheets and, 15, 42
 solid, 51
 spill kit and, 59
 water activity in, 51
 drapes, to define compounding area, 36

E

emergency power, 37
 enforcement of USP <795>, 10
 engineering controls, 31–34
 Environmental Services, 57
 equipment, 5, 13, 34, 56. See also disposable equipment; personal protective equipment (PPE)
 equipment records, 19
 expiration dates, 28, 45, 48, 49, 51. See also beyond-use dates (BUDs)
 eyeglasses, prescription, 25
 eye protection, 24–25, 26
 eyewash, 19

F

facility design, 19, 35–38
 Federal Food, Drug & Cosmetic Act (FD&C Act), 10, 27, 41
 503A bulk list, 10, 27, 41
 fixtures, 19, 35, 38
 floors
 cleaning, 57
 facility requirements for, 35, 38
 Food and Drug Administration (FDA)
 active pharmaceutical ingredients and, 27, 42, 51
 approved drug products, 41, 42
 certificate of analysis and, 42
 Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act, 10, 27, 41
 on compounding, 41, 42
 guidance documents on repackaging, 3, 9, 41, 52
 registered suppliers, 27, 51
 fume hood, 33

G

gap analysis, 63
 garb, 18, 21–26
 general information, 21–22
 gloves, 18, 21, 23
 hand hygiene, 22–23
 other articles of, 23–26
 personal protective equipment distinguished from, 21
 policies required and recommended in USP <795>, 18
 for receiving and storing components, 29
 reusable, 22
 storage of, 37
 surgical masks, 25–26
 See also personal protective equipment (PPE)
General Chapters, 1
General Notices, 1
 general principles of USP <795>, 3–4

glossary, 6
 gloves, 18, 21, 23
 ASTM standard D6978, 21, 23, 24
 chemotherapy, 21, 24
 disposable, 23
 in spill kit, 59, 60
 sterile, 23
 washing, 23
 goggles, 22, 23, 24–25, 59
 gowns, 21, 22, 23, 24, 60
 graduates, 34, 56

H

hair covers, 21, 23, 24, 26
 half tablets, 9
 hand hygiene, 13, 18, 22–23
 Hazard Communication Plan, 14–15
 Hazard Communication: *Small Entity Compliance Guide for Employers That Use Hazardous Chemicals*, 15
 Hazard Communication Standards, OSHA, 14–15, 29, 42
 hazardous drugs (HDs)
 engineering controls for, 32–33
 facility requirements for, 35–36, 37
 garb required for, 21, 22, 24
 Hazard Communication Plan, 14–15
 hazardous chemicals distinguished from, 14
 NIOSH list of, 4, 9, 14, 24, 25, 32–33, 42
 powder containment hood for, 37
 receiving and storing, 29
 transporting, 20
 in USP <795>, 4, 7
 in USP <800>, 3–4, 7, 8, 32–33, 37
 head covers, 23, 24
 health-system policies, 7, 17
 high-efficiency particulate air (HEPA) filter, 33, 34
 hormone powders, 32
 hospital pharmacies, 8, 14
 human resources, 11–15
 compounding personnel, 13
 designated person, 11–13
 documenting competence, 13–14
 hazard communication plan, 14–15
 humidifier, 38
 humidity requirements, 37–38
 hygiene. *See* personal hygiene

I

importers, 14
International Journal of Pharmaceutical Compounding, 44
 investigational agents, 8
 ISO classifications, 36

L

labeling, 20, 53–54
 beyond-use dates, 49, 51
 of compounding kit, 42
label distinguished from *labeling*, 53
 in Master Formulation Record, 44, 47
 for reconstitution and storage, 42
 required use of personal protective equipment, 31
 of sterile water, 28
 long-term care (LTC) facilities, 8
 lot number, 45–46, 53

M

mail-order pharmacies, 8
 manufacturers
 cleaning information provided by, 55
 compliance with USP <795>, 8
 on Compounding Record, 45, 48
 cycle time identified by, 39
 equipment information provided by, 13, 34
 expiration dates established by, 28, 49, 51
 FDA-approved drugs deemed hazardous by, 42
 Safety Data Sheets provided by, 14–15, 42
 storage requirements provided by, 29, 35, 38
 masks, 23, 25–26
 Master Formulation Records (MFRs), 5, 20, 44–45
 in Compounding Record, 45, 48
 designated person and, 12, 45
 dispensing and, 53
 example of, 47
 repackaging and, 9
 Material Safety Data Sheets (MSDSs), 14–15, 42
 medications, administering, 9
 microbial growth, 50, 51
 mixers, 34
 molds, 34
 monographs, 1, 6, 27, 28, 41, 44, 49–50
 mops, reusable, 56
 mortars and pestles
 cleaning, 56
 disposable, 34

N

N95 respirators, 25–26
 National Formulary (NF), 27, 28, 41, 49
 National Institute for Occupational Safety and Health (NIOSH)
 certified N95 respirators, 25
 List of Antineoplastics and Other Hazardous Drugs, 4, 9, 14, 24, 25, 32–33, 42
 Respirator Trusted-Source Information, 21, 24, 25

nonsterile preparations. *see* compounded nonsterile preparations (CNSPs); USP <795> *Pharmaceutical Compounding-Nonsterile Preparations*
 nursing homes, 8

O

Occupational Safety and Health Administration (OSHA), 14–15, 29, 42
 ointment slab, 39
 ointment tiles, 34
 old policies, 17
 opened jars, beyond-use date of, 51

P

packaging, 6, 20
 beyond-use dates and, 49, 50, 52
 engineering controls and, 32–33
 of mailed or shipped CNSPs, 54
 prepackaging, 8–9, 41
 repackaging, 3, 4, 8–9, 41, 52
 Safety Data Sheets and, 15, 42, 59
 stability and, 52
 paper towels, 23
 particles
 aerosolization of, 33
 airborne, 18, 19–20, 25, 31, 39
 patient counseling, 22
 peer-reviewed sources, 8, 28, 44, 49
 personal hygiene, 5, 21–26
 general information, 21–22
 gloves, 23
 hand hygiene, 13, 18, 22–23
 See also garb
 personal protective equipment (PPE), 21–22
 disposable, 22, 23, 24, 59
 donning and doffing, 21
 garb distinguished from, 21
 general information, 21–22
 gloves (*see* gloves)
 labeling compound with required use of, 31
 masks, 23, 25–26
 policies and procedures for wearing, 24, 29
 for spills, 22, 59, 60
 See also garb
 personnel
 receiving, 29
 responsibilities, 19
 training, 5, 12, 18, 63
 pharmaceutical manufacturers, 8
 pharmacist
 certification, 13
 competency documented by, 14
 compounding, 41
 designated person as, 11, 13

 garb and, donning and doffing, 22
 re-licensure of, 12
 Pharmacy Technician Certification Board (PTCB), 13
 physician offices, 8, 11
 policies required and recommended in USP <795>, 18–20
 policy development, 63
 positive pressure, 33, 36
 powder containment hood, 32, 34, 37, 39, 56. *See also* containment ventilated enclosure (CVE)
 powders, 18, 21, 24, 26, 27, 32, 33, 39. *See also* active pharmaceutical ingredients (APIs)
 powered air purifying respirators (PAPRs), 25
 prepackaging, 8–9, 41
 prescription eyeglasses, 25
 primary engineering control (PEC), 19, 31, 32, 37
 printers, 40

Q

quality assurance/quality control (QA/QC), 6, 20, 27, 61
 quality of component, 27

R

radiopharmaceuticals, 4
 raw materials, 21, 24, 27. *See also* active pharmaceutical ingredients (APIs)
 receiving and storing components, 29–30
 receiving personnel, 29
 recipes for compounds, 44
 reconstituting, 8, 9, 42
 refrigerators, 40
 release inspections, 20
 religious head covers, 24
 repackaging, 3, 4, 8–9, 41, 52
 reports
 certification, 40, 63
 of testing and sampling performed, 18
 respirators, 23, 25–26
 respiratory protection, 21, 25–26, 59
 review of policies, 17
 risk assessment, 29, 39

S

Safety Data Sheets (SDSs), 14–15, 19, 29, 31, 32, 42, 59
 sanitizing, 5, 13, 20, 30, 35, 55–56, 57
 secondary engineering control (SEC), 31, 32
shall or *must* statements, 3, 63
 shelving, 5, 19, 35, 38, 40
 shipping. *see* transporting
 shipping containers, 20, 29, 38–39, 53
 shoe covers, 21, 23, 24, 26, 59, 60
should statements, 3, 63

sinks
 cleaning, 56
 facility design and, 19, 35, 37, 38
 sleeve covers, 23
 solid dosage forms, 51
 solutions, cleaning, 20, 55, 56, 60
 sources of compounds, 44
 space for compounding, 19, 35, 39
 spatulas, 34
 spill kit, 20, 59–60
 spills, 59–60
 in compounding area, 56, 57, 59–60
 garb worn when cleaning up, 22, 59, 60
 policies required and recommended in USP <795>, 20
 response team, 20, 60
 stability
 beyond-use date and, 49, 50, 52
 container used for package and, 52
 water activity and, 51
 standard operating procedures (SOPs), 6, 12, 17
 sterile compounding
 areas, 19, 23, 25, 35, 36
 certification for, 12, 13
 disinfection required for, 55
 personal protective equipment for, 22, 23, 25
 sterile preparations, 1, 8
 Sterile Water for Irrigation, 28
 storage, 5, 18, 19, 29–30
 areas, 38–39
 beyond-use dates and, 49, 50, 52
 of cardboard, 29–30, 38–39
 on floor, 39
 garb, 37
 labeling for, 42
 requirements
 in Compounding Record, 46
 in Master Formulation Record, 44, 47
 temperature, 28, 35, 37–38, 49, 53
Strength and Stability Testing for Compounded Preparations, 50
 surfaces
 cleaning, 55–56, 57
 contamination of, 33, 57
 engineering controls and, 33
 facility requirements for, 35, 38
 finishes of, 38
 surgical masks, 25–26

T

tablets, 3–4, 8–9, 26, 33, 42, 51
 temperature requirements, 19
 for nonsterile compounding area, 37–38
 for shipping CNSPs, 54
 for storage, 28, 29, 35, 37–38, 49, 51, 53, 64
 for transporting, 20, 54
 3-year expiry, 28

training, 5, 12, 63
 for cleaning compounding area, 57
 for compounding CNSPs, 13
 for designated person, 12, 18
 for documenting competency, 14
 frequency of, 14
 for quality assessment/quality control program, 20
 for receiving personnel, 29
 transporting
 hazardous drugs, 20
 key competencies in, 13
 packaging requirements for, 54
 policies required and recommended in USP <795>, 20
 shipping containers, 29, 38–39, 53
 temperature monitors in, 20, 54
 28-day beyond-use date, 28

U

unit-dose package, 9, 33, 41, 52
 USP <41> *Balances*, 39
 USP <51> *Antimicrobial effectiveness testing*, 50
 USP <659> *Packaging and Storage Requirements*, 50
 USP <795> *Pharmaceutical Compounding—Nonsterile Preparations*
 Action Plan for, 63–64
 animals and, 7, 27, 28, 51
 as an official standard, 1
 application of, 7–8
 availability of, 1
 beyond-use dates, 6, 20, 49–52
 cleaning and sanitation, 5, 13, 19, 20, 35, 55–56, 60
 compliance with, 3, 4, 7–8, 10
 components, 6, 27–30
 compounding (see compounding)
 contents of sections of, 5–6
 design of compounding facilities, 19, 35–38
 dispensing, 53–54
 enforcement of, 10
 engineering controls and equipment, 31–34
 as federal standard, 7
 garb and hand hygiene, 18, 21–26
 general principles of, 3–4
 as a guideline vs. a requirement, 1
 hazardous drugs addressed in, 4
 human resources, 11–15
 Immediate Use and, 9
 most recent official version, 7
 policies and procedures, 18–20
 quality assurance and quality control, 6, 20, 27, 61
 radiopharmaceuticals addressed in, 4
 receiving and storing components, 29–30
 as a regulation, 1, 7
 revisions to, 1, 3, 11, 9, 51
 scope of, 7–10
shall or must and should in text of, distinction
 between, 3, 63

- as a standard, 1, 7
 - where to start with information from, 63
 - USP <797> *Pharmaceutical Compounding—Sterile Preparations*, 1, 3, 10
 - ACPH requirements, 36
 - compliance with, 7, 8
 - disinfection in, 55
 - engineering controls and, 31–34
 - hood certification, 34, 39
 - Immediate Use and, 9
 - ISO classifications, 36
 - segregated compounding area in, 35, 38
 - temperature requirements, 37–38
 - USP <800> *Hazardous Drugs—Handling in Healthcare Settings*, 1, 3–4, 7, 8
 - ACHP requirements, 36
 - compounding, 8–9, 39
 - containment, 3–4
 - decontamination and, 55
 - engineering controls and, 31–34
 - facility design and, 36
 - hazardous chemical vs. hazardous drug, 14
 - prepackaging, 8–9
 - USP <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*, 1, 4
 - USP <1075> *Good Compounding Practices*, 1
 - USP <1112> *Application of Water Activity Determination for Nonsterile Pharmaceutical Products*, 51
 - USP <1163> *Quality Assurance in Pharmaceutical Compounding*, 61
 - USP <1168> *Compounding for Phase 1 Investigational Studies*, 8
 - USP <1176> *Prescription Balances and Volumetric Apparatus Used in Compounding*, 39
 - USP <1178> *Good Repackaging Practice*, 3, 9, 41, 52
 - USP <1231> *Water for Pharmaceutical Purposes*, 28
 - USP <1251> *Weighing on an Analytical Balance*, 39
 - USP *Compounding Compendium*, 1, 44, 49
 - USP markings, 27
 - USP monographs, 1, 6, 27, 28, 41, 44, 47, 49–50
-
- V**
- ventilation control, 31, 32
 - veterinary clinics, 11
-
- W**
- walls
 - cleaning, 57
 - facility requirements for, 35, 38
 - waste segregation and disposal, 20, 60
 - water activity (aw), 51
 - water as component, 28, 51
 - written policies, 17

