

Certification Examination

CUCO

Certified USP 800 Compliance Officer



CANDIDATE
HANDBOOK

Recognition, Value, Expertise...

It is what certification is all about!

ABOUT CERTIFICATION

Competency-based certification allows pharmacists to demonstrate validated, practice-relevant knowledge in a defined specialty. Through CPS certification, candidates attest to professional accountability, lifelong learning, and safe, effective practice.

The Certification Commission for the Council on Pharmacy Standards (CC-CPS) is the independent body that designs, governs, and maintains CPS certification and recertification programs. CC-CPS operates at arm's length from CPS education and operations, with formal conflict-of-interest controls, documented firewalls, and term limits to preserve independence.

CC-CPS follows recognized best-practice frameworks, including ISO/IEC 17024, the Standards for Educational and Psychological Testing (AERA/APA/NCME), and guidance from ICE and NCCA.

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CRITERIA**All eligibility criteria must be met at the time of application****CURRENT LICENSURE**

Candidates must hold a Doctor of Pharmacy (Pharm.D.) or Bachelor of Science in Pharmacy (B.S. Pharm.) degree from a program accredited by the Accreditation Council for Pharmacy Education (ACPE). Graduates of programs outside of the U.S. must hold a degree deemed equivalent and/or possess a Foreign Pharmacy Graduate Examination Committee® (FPGEC) Certificate.

PRACTICE EXPERIENCE

Current/active unrestricted licensure as a pharmacist is required. An "unrestricted" license is not currently subject to any limitations, probation, or disciplinary action.

- **U.S. Licensed Pharmacists:** Must possess an active, unrestricted license to practice pharmacy in at least one U.S. state or territory.
- **International Pharmacists:** Must hold an active and unrestricted license in their country of practice. A certified English translation must be provided if the original license is not in English.

Candidates will need to upload their license or a printout of the verification that includes their name, license number, licensing state or country, and the date the license expires.

SPECIALTY QUALIFICATION

To ensure candidates have foundational knowledge in the specialty, one of the following two pathways must be met:

1. **Standard Pathway:** Completion of one year (12 months) of experience comprised of at least 2000 hours of practice time as a licensed pharmacist in one of the above exam specialties must be documented. **This is not an either/or requirement – both time and hours must be met.**
2. **Certificate Pathway:** The specialty experience requirement is met for candidates who hold an active certificate of completion from a nationally recognized provider in a related subject matter. This includes, but is not limited to, the completion of a relevant PGY residency, fellowship, certificate/training program, or a relevant graduate degree. Recognized providers include:
 - American Society of Health-System Pharmacists (ASHP)
 - American Pharmacists Association (APhA)
 - American College of Clinical Pharmacy (ACCP)
 - American Society of Consultant Pharmacists (ASCP)

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RESOURCES

CPS Exam Candidates

Use the [Study Guides & Preview Tests](#) page as the **official and most current source** for all exam materials.

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How to find your materials

1. Visit pharmacystandards.org/study-guides.
2. Search by certification name or acronym (e.g., CPOM).
3. Open the items under your credential:
 - **Outline** – Exam content outline & competencies
 - **Guide** – Candidate Guide with policies, sample items, and study tips
 - **Case Study** – Scenario-based practice
 - **Preview** – Short preview quiz
 - **Practice Exam** – Practice test with scoring



Before you register

- Read your Candidate Guide and Testing Guide (remote proctoring rules, ID requirements, system check, reschedule/cancel windows).
- Confirm your name on the account **matches your government ID**.
- Run the **system check** on the device and network you will use on test day.

Need help?

See FAQs or Contact Us from the Study Guides page.

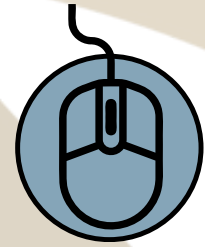
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Group Fee Payments

CPS will accept group payments for certification exams from institutions. Details are on the CPS website.

FEES

All fees are
non-refundable



\$395
TOTAL EXAM FEE

Application + Examination
Includes a **non-refundable**
\$50 application fee.

Examination Fees

- The total exam fee is \$395 (= \$50 Application + \$345 Examination).
- The \$50 application fee is non-refundable.
- If you are found ineligible, CPS refunds the \$345 examination portion automatically.
- After you schedule an appointment, reschedule/cancel windows and fees apply (see Administrative Policies, pp. 9–11).
- Payments are online only by Visa, Mastercard, or American Express (U.S. dollars).
- If paid by a third party (e.g., employer), any permitted refund is issued to that payer.
- Applications are not accepted by mail, phone, or fax.

Note: If an applicant is determined ineligible, CPS refunds the \$345 examination portion. The \$50 application fee is non-refundable.

Other Non-refundable Payment Related Fees

Incomplete Application Fee



All incomplete applications are subject to a non-refundable \$30 reprocessing fee upon the submission of proper documentation. See page 9 for more information.

License Verification



If licensure information is requested requiring an additional submission, the candidate will have two weeks to provide the license with all the correct information and pay the non-refundable \$30 reprocessing fee. If this is not provided within the two weeks, the application will be marked ineligible. Ineligible applicants will receive a refund minus the \$50.00 non-refundable application fee. There are no refunds or withdrawals for applications using a bulk code.

Credit Card Chargeback



Assessed only if a credit-card dispute is resolved in CPS's favor. Future registrations may be blocked until balances are cleared.

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Computer exam candidates can change their scheduled testing date to a **\$50 non-refundable fee**.

Candidates may do this from within their CPS account.

Refer to CPS Testing Guide for details.

FEES

All fees are
non-refundable

Other Exam Related Fees

**Reschedule
(date/time) — \$50**



Allowed **≥ 48 hours** before your appointment via your CPS account. Changes inside 48 hours are not permitted; the **no-show** policy applies.

**Exam Change —
\$125**



Administrative change to switch to a different exam (before an appointment is scheduled). May require re-review of eligibility.

Withdrawal — \$165



Cancel your exam before scheduling or **≥ 7** days before your appointment to withdraw. CPS refunds the examination portion (\$345) minus \$165. Within 7 days, or after a no-show, the examination portion is forfeited. See Administrative Policies (pp. 9–11) for full timelines.

Retest — \$395



Retest candidates must pay the full application (\$50) and examination (\$345) fees and must observe a 45-day wait before reapplying.
See Retest Policy (p. 9).

Refunds

Ineligible Computer Testing Applicants will receive a refund of the \$345 examination portion (the **\$50 application fee is non-refundable**) minus any outstanding charges.

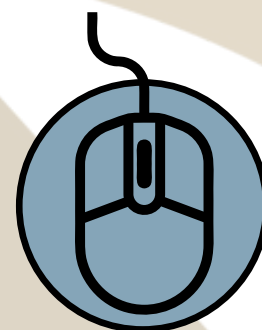
No refunds

will be issued for the following circumstances:

- Candidates who are not successful in achieving certification.
- No-shows or candidates who fail to test.
- Candidates who are unable to schedule within the eligibility period and do not withdraw per policy.
- Once an exam session has started.

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STEPS TO REGISTER

HOW TO REGISTER FOR A CPS EXAM
(REMOTE, COMPUTER-BASED)STEP
1**Confirm eligibility**

Review the **Eligibility Criteria** for your credential (link to section).

STEP
2**Submit your application**

Submit your application online at the CPS website **PharmacyStandards.org**. Applications can only be submitted online. You cannot submit an application by mail, telephone or fax. Payment must be made online by credit card. Individual or group payments can be made.

STEP
3**Prepare your documents**

To get prepared to complete the application - *see the application checklist on the next page*. It is a handy listing of all the information you will need to supply.

STEP
4**Email confirmation of your registration**

After completing and submitting the application, you will receive an email confirmation within 30 minutes. **This will be the ONLY confirmation notice you will receive for your application. If you do not receive it, please make sure the email in your profile is accurate and check your email folders.**

STEP
5**Application approval procedure**

The application will be reviewed to determine qualification to take the examination. This process can take up to two weeks, depending on the volume of applications received at the time of submission. If the application is incomplete, *see page 10* to learn how to resubmit the application and what fees will need to be paid.

STEP
6**Notification of eligibility to take the exam**

If approved, an Eligibility Letter will be emailed and posted in your CPS account with instructions to schedule your exam.

Before scheduling:

- Run the system check on the device/network you will use.
- If you need accommodations, submit your request before booking.
- Ensure your account name matches your government ID.

Eligibility period: You must schedule and test within your 365-day eligibility period (see your letter).

CPS is not responsible for lost or misdirected email. **Please make sure the email in your profile is accurate and check your account 5-7 days after you have registered** to ensure your application was complete and additional information is not needed. If you do not receive your examination eligibility letter within 2 weeks of your examination application submission confirmation, use the "Contact Us" link on **PharmacyStandards.org** and select "Application I already submitted" from the drop down menu, to inform CPS.

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APPLICATION CHECK LIST

Before filing your application look over the below checklist and gather the information needed to complete it.

☐**PERSONAL INFORMATION:**

You have complete contact details (name as it appears on your government ID, address, phone, email). Your CPS profile email is current and monitored.

☐**ELIGIBILITY:**

You reviewed the eligibility requirements and meet one pathway (Standard or Certificate/Training)

☐**LICENSURE:**

You have your pharmacist license or primary-source verification showing name, license number, jurisdiction, type, and expiration date ready to upload. If not in English, include a certified English translation. Non-US grads include FPGEC® Certification (as applicable). Your license name matches your government ID or you have legal name-change proof.

☐**EMPLOYMENT:**

You know your current employer contact info (address, phone, email) and have 5-year work history (titles, dates, specialty area, supervisor/contact). Include gaps/unemployment where applicable.

☐**SPECIALTY QUALIFICATION DOCUMENTS:**

You have documentation for your pathway:

- Standard: summary of qualifying duties and estimated 2,000 hours/12 months within the stated window (verifiable).
- Certificate/Training: certificate of completion (or PGY/residency/fellowship/degree) plus syllabus/competency summary.

☐**APPLICATION AGREEMENT:**

You will check the agreement box to e-sign the statements below. Applications cannot be submitted without consent.

I have read and agree to abide by CPS policies in the Candidate Guide and Testing Guide, including fees, reschedule/withdrawal timelines, and conduct rules. I understand and consent to remote proctoring, including room scan, screen share, and audio/video recording for security and audit. I certify the information provided is true and complete; I understand that false or misleading statements may result in denial, invalidation, or revocation. I understand my application is subject to audit and authorize CPS to contact employers, licensing boards, and education providers to verify information. I acknowledge the \$50 application fee is non-refundable and that other refunds are governed by the published policy.

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ADMINISTRATIVE POLICIES

Incomplete Application Processing

An application is **incomplete** if any of the following apply:

- Missing or incorrect information.
- Licensure proof missing required data (name, license number, jurisdiction, type, expiration date) or is not in English without a certified translation.
- Payment not authorized or reversed (declined card, return, or chargeback).
- Any issue that prevents CPS from determining eligibility.

Process:

Incomplete applications are returned with instructions to upload the missing items and pay a **non-refundable \$30 reprocessing fee**. All filing deadlines continue to apply. If the resubmission does not fully resolve deficiencies, the application is declared ineligible (the **\$50 application fee is not refundable**).

Retest Policy

Candidates who wish to retake a CPS exam must submit a **new application**, meet the then-current eligibility criteria, and pay the **full application (\$50) and examination (\$345) fees**. CPS does not limit lifetime attempts, but the maximum number of attempts in a calendar year is **three (3)**. Each retest uses a different form of the exam.

Mandatory waiting period

- A **45-day wait is required from the date/time of the last attempt before submitting a retest application or scheduling a new appointment**.
- The wait applies to all delivery modes of testing and all exam forms.
- Applications submitted before the 45-day mark are **not accepted**. If submitted in error, the **application fee remains non-refundable**.

Interruption / invalid attempt rules

- If an exam session experiences **candidate-side** failure (device, internet, environment, refusal of proctoring/ID), the attempt is **invalid** and a retest after 45 days is required; fees follow the **No-Refunds** policy.
- If CPS or the test vendor causes the outage, CPS will provide a no-cost reschedule of the same attempt (no 45-day wait) or, if the attempt cannot be restored, a retest after 45 days without additional fees beyond the original exam fee.

Result notice

- The 45-day date is shown on the candidate's **results/attempt notice** and in the CPS account.

All timelines and fees are governed by the most current online policy at pharmacystandards.org; online versions supersede print.

All policies and procedures are subject to change without notice

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ADMINISTRATIVE POLICIES

Changes & Withdrawals

Reschedule (date/time) — \$50 non-refundable

For the same exam, you may change your appointment ≥ 48 hours before the start time via your CPS account.

- Must remain within your 365-day eligibility period.
- Limit: 1 reschedule per registration (additional changes require a withdrawal + new registration).
- No changes allowed < 48 hours before the appointment or on exam day.
- See Fees for no-show rules.

Exam or Eligibility-Window Change — \$125 non-refundable

Use this to switch to a different CPS exam or to adjust your eligibility period (no appointment scheduled yet).

- Re-establish eligibility for the new exam; CPS may request additional documentation.
- Any approved change uses the original 365-day period (no reset).
- Request must be submitted ≥ 30 days before the end of your eligibility period.
- Limit: 1 exam/window change per registration.
- No refunds of original fees or the change fee.

Rescheduling (same exam): \$50 | Exam change: \$125

All candidates requesting a change

MUST:

- Submit the change request within one calendar year from the first date of their original assigned eligibility period.
- Cancel their exam date (if they have one scheduled), before submitting a change. Scheduled exams may also be canceled using the "Schedule" link in your account.
- Use the CPS website online Change Request Form.
- Submit a non-refundable fee of \$125 with the Change Request Form.

Not permitted

- Changes on exam day or after the appointment start time.
- Switching exams after check-in begins.
- Only CPS pharmacy credentials may be selected.

To change examination category:

- Eligibility must be re-established for the new exam category, and additional documentation and fees may be required.
- The time to consider eligibility for the new category will count toward the original assigned computer testing window.
- **Examinees must take the exam for which they have been determined eligible. No changes will be permitted on examination day.** If a candidate knowingly or unknowingly takes an examination other than they were found eligible to take, the examination will not be scored. No refunds will be allowed, and all fee policies will apply if the candidate reapplies for an examination.
- Candidates must submit their request at least 30 days prior to the end of their 365-day eligibility period.

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ADMINISTRATIVE POLICIES

Withdrawal Policy - Computer Testing

- Only the applicant/candidate may request a withdrawal.
- When you may withdraw:
 - Before scheduling an appointment, or
 - ≥ 7 days before your scheduled appointment time (withdrawal cancels the appointment).
- Refund: CPS refunds the examination portion (\$345) minus a \$165 withdrawal fee $\rightarrow$ \$180. The \$50 application fee is not refundable. Any outstanding charges are deducted from the refund.
- Requests < 7 days before the appointment or after a no-show are not eligible for any refund.

Withdrawal Policy - Bulk Purchase Voucher

Withdrawals are not allowed after eligibility is determined. Refunds are governed by the bulk purchase agreement; CPS does not issue refunds for redeemed codes. (Institutions manage reassignment within their terms.)

Substitution Policy

Candidate substitutions are not allowed. The name on the registration must match the government ID presented on test day. Name changes require legal documentation before scheduling.

Score Cancellation

CPS may cancel scores and/or invalidate an attempt for irregularities (e.g., identity mismatch, prohibited items, coaching, tampering, exam content disclosure, policy violations) with or without proof of intent. Fees are not refunded. CPS may impose waiting periods or bar future testing per policy.

Auditing Applications

Applications are subject to audit. Candidates must provide requested documentation (e.g., licensure, employment verification, training certificates) within 14 days. Failure to respond or verify may result in denial or revocation. By submitting an application, you authorize CPS to contact employers, licensing boards, and education providers for verification.

All policies and procedures are subject to change without notice

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HANDBOOK**Test Disclosure**

CPS does not release live test questions, answer keys, or full forms. Using, sharing, soliciting, or possessing exam content—before or after testing—is a security violation and may result in score invalidation, revocation, and suspension of testing privileges.

GENERAL POLICIES

How Exams are Scored

CPS exams are **criterion-referenced**: your outcome is compared to a predefined performance standard, **not** to other candidates. The passing standard is set through periodic **standard-setting studies** (e.g., Angoff/Bookmark) conducted with subject-matter experts and approved by the CPS Board.

CPS uses **item response theory (IRT)** and **test equating** to place different forms of the exam on a common scale. Because some forms may be slightly harder or easier, equating ensures fairness—candidates meeting the standard on any form receive the **same pass/fail decision**.

Score reports provide:

- Your **overall result** (Pass/Fail).
- **Content-area diagnostics** to guide study. These diagnostics are **not percent correct** and are **not comparable** across candidates or attempts. Labels indicate performance **relative to the standard** (e.g., **Below Target / Near Target / At Target / Above Target**).

The passing standard may be reviewed periodically to reflect current practice and blueprint updates.

Retention of Computer Answer Strings

CPS retains computer answer strings and operational testing data for a minimum of 3 years and may retain longer for quality assurance and legal/regulatory purposes. Identity verification media (e.g., audio/video from remote proctoring) are retained per the CPS Privacy & Data Retention Policy.

All policies and procedures are subject to change without notice

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HANDBOOK**Designation
Authorization**

Certification is a non-transferable, revocable, limited, non-exclusive license to use the certification designation, subject to compliance with the policies and procedures, as may be revised from time to time.

Any use or display of CPS certification marks and/or logos without the prior written permission of the CPS is prohibited. Any candidate or certificant who manufacturers, modifies, reproduces, distributes or uses a fraudulent or otherwise unauthorized CPS certificate, CPS designation or other credential may be subject to disciplinary action, including denial or revocation of eligibility or certification. Any individual who engages in such behavior also may be subject to legal action.

GENERAL POLICIES

ADA and Nondiscrimination Policies

CPS does not discriminate on the basis of **age, sex, pregnancy, race, color, religion, national origin, ethnicity, disability, marital status, sexual orientation, gender identity or expression, military/veteran status, or genetic information.**

Testing accommodations. CPS provides **reasonable accommodations** consistent with the Americans with Disabilities Act (ADA) for qualified candidates. Requests must be **submitted with the application and before scheduling** an appointment, using the CPS Accommodation Request Form (see **pharmacystandards.org/accommodations**). Documentation must be **current** and signed by a qualified clinician describing the functional limitations and recommended accommodations. CPS will acknowledge requests within **5 business days** and issue a determination within **15 business days** of receiving complete documentation. Information is **confidential** and used only for accommodation determinations. Denials may be **appealed** per the Appeals Procedure below.

Appeals Procedure

Candidates may appeal eligibility determinations, accommodation decisions, exam administration irregularities, or policy applications. Appeals must be **submitted in writing within 60 days** of the decision or event and should include relevant facts and supporting documents. CPS will acknowledge receipt within **5 business days** and render a written decision within **30 days** (or notify if additional time is required). Appeals are reviewed by the **CPS Policy Review Committee**, independent of the original decision maker, and may be escalated to the **Board of Directors**. CPS does **not** release exam content or answer keys; score verification involves **administrative/technical re-scoring only**.

Revocation

Certification may be denied, suspended, or revoked for: falsification or misrepresentation; **exam security violations** (cheating, proxy testing, item disclosure); misuse of CPS names, logos, or marks; failure to meet or maintain eligibility/recertification requirements; **loss or restriction of the license to practice pharmacy**; nonpayment of required fees; or other material policy violations.

Prior to action, CPS will provide **written notice** of the allegations and an opportunity to **respond**. A written decision (which may include sanctions and eligibility to reapply after a specified period) will be issued and may be **appealed** under this policy.

All policies and procedures are subject to change without notice

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For further details, visit the CPS website PharmacyStandards.org and download the recertification catalog for a full description of the recertification process. Click on **Renew your Certification** on the home page.

GENERAL POLICIES

Renew Your Certification

CPS requires **recertification every three (3) years** to verify ongoing competence in each credential's core knowledge areas.

Recertification Steps

Earn the required credit using either:

1. Continuing Education (CE) that fits your topics, or
2. Approved professional activities (e.g., teaching, publications, precepting, quality-improvement/projects, committee work).
3. Finish within 3 years, upload documentation, and keep records for audit.

Lapse & Reinstatement

If requirements are **not met by the deadline**, the credential **expires**. Expired credentials may be regained only through **re-examination**, subject to the then-current eligibility criteria. CE completed **after** expiration cannot be applied retroactively.

Audits & Recordkeeping

CPS randomly audits recertification applications. If selected, you must provide CE certificates and short activity descriptions within the requested timeframe. Maintain CE documentation **throughout the cycle and until approval**.

Verification of Your Credential

CPS provides **third-party verification** of active credentials on request.

- **When available:** After official results post to your CPS account and your digital certificate is issued.
- **What is verified:** Credential name and ID (if applicable), **status** (active/expired), **original certification date**, and **current expiration date**.
- **How to request:** From the CPS website (see pharmacystandards.org/verification), select **Request a Verification**, enter the recipient's email, and submit payment.
- **Fee & delivery:** **\$30 per request**. Verifications are sent by email to the designated party.
- **Notes:** CPS cannot verify until certification is achieved. Ensure your name and profile information are accurate before submitting a request.

All policies and procedures are subject to change without notice

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CPS does not provide review courses or study materials for the examination. CPS views the examinations as an evaluative process. Eligibility criteria have been established to identify minimum levels of preparation for the examinations. CPS believes your practice experience is your best preparation. Candidates can review detailed test outlines and suggested resources in the Candidate Guides.

EXAM CONTENT OUTLINE

Domain 1: Program Management and Regulatory Oversight (25%)

Task 1: Fulfill the responsibilities of the designated person for the hazardous drug (HD) safety program.

Analyze and apply the responsibilities of the designated person(s) as defined in USP <800>.

Oversee the development, implementation, and maintenance of all HD-related standard operating procedures (SOPs).

Ensure compliance with all applicable federal and state laws, regulations, and standards (e.g., OSHA, EPA, NIOSH, Boards of Pharmacy).

Manage interdisciplinary collaboration between pharmacy, nursing, environmental services, and facilities.

Monitor the effectiveness of the overall HD safety program and implement continuous improvements.

Task 2: Manage the entity's HD list and Assessments of Risk (AoR).

Implement a systematic process to create, maintain, and review the entity-specific HD list at least every 12 months.

Lead a multidisciplinary team to conduct and document compliant Assessments of Risk for eligible NIOSH Table 1 dosage forms.

Evaluate and approve alternative containment strategies and work practices identified through the AoR process.

Assess the risks of new drugs as they enter the market to determine if they should be added to the HD list.

Ensure all AoR documentation is complete, accessible, and reviewed annually.

Task 3: Integrate USP <800> with related compounding and safety standards.

Differentiate the specific requirements of USP <795>, <797>, and <825> as they apply to HDs.

Design workflows that incorporate the overlapping requirements for non-sterile, sterile, and radiopharmaceutical HDs.

Develop integrated training programs that cover all applicable USP chapters for staff handling HDs.

Ensure facility design and engineering controls meet the combined requirements of all relevant standards.

Create a unified quality assurance program that addresses the unique risks of different HD compounding activities.

Task 4: Manage compliance with state and accrediting body regulations.

Interpret and apply state-specific Board of Pharmacy interpretations of USP <800> and related chapters.

Coordinate with accrediting bodies (e.g., The Joint Commission, ACHC, URAC) to prepare for and manage USP <800> compliance surveys.

Serve as the primary subject matter expert during regulatory inspections of the HD program.

Develop and implement formal corrective action plans (CAPAs) in response to any identified deficiencies.

Maintain a state of continuous readiness for unannounced inspections or audits.

Domain 2: Facility, Engineering Controls, and Environmental Monitoring (20%)

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EXAM CONTENT OUTLINE

Task 1: Assess the design and lifecycle management of engineering controls.

Evaluate the design of Containment Primary and Secondary Engineering Controls (C-PECs and C-SECs) against USP <800> requirements.

Verify proper ventilation, pressure differentials, and air exchange rates for all HD handling and storage areas.

Manage the semiannual certification and recertification of all C-PECs and C-SECs.

Oversee facility lifecycle events, including the renovation, certification, or decommissioning of HD rooms and C-PECs.

Ensure all certification documentation is complete and corrective actions for failures are documented and resolved.

Task 2: Develop and monitor facility cleaning, decontamination, and disinfection SOPs.

Select appropriate deactivating, decontaminating, cleaning, and disinfecting agents based on HD characteristics and surface compatibility.

Design detailed, step-by-step SOPs for the routine and terminal cleaning of all HD handling areas and equipment.

Implement a training and competency program for personnel responsible for cleaning and decontamination.

Evaluate the effectiveness of cleaning protocols through visual inspection and environmental sampling data.

Maintain comprehensive logs of all cleaning and decontamination activities.

Task 3: Implement and manage an environmental surface sampling program.

Design a routine environmental wipe sampling program that defines locations and frequency based on risk.

Interpret wipe sampling results against established action levels and lead root cause analysis for any excursions.

Develop and implement a formal Corrective and Preventative Action (CAPA) plan in response to out-of-spec results.

Use sampling data to evaluate the effectiveness of cleaning procedures, work practices, and containment strategies.

Document all sampling activities, results, investigations, and corrective actions in an auditable format.

Task 4: Evaluate the use of technology and automation in HD handling.

Assess the role of supplemental engineering controls, such as Closed System Transfer Devices (CSTDs), in minimizing exposure.

Evaluate the impact of automation and robotics on the safety and efficiency of HD compounding and dispensing.

Ensure that any technology used for HD handling is integrated into the facility's overall safety program.

Develop procedures for the cleaning and decontamination of automated compounding devices.

Verify that the use of CSTDs does not compromise the sterility of the final preparation.

Domain 3: Safe Handling Practices and Personnel Management (20%)**Task 1: Implement a personnel training and competency assessment program.**

Design a comprehensive training curriculum for all personnel who handle HDs, covering risks, SOPs, and emergency procedures.

Implement a robust competency assessment program, including didactic, observational, and practical components, at least annually.

Verify specialized competencies for personnel engaged in sterile versus nonsterile HD compounding.

Maintain complete and auditable records of all personnel training and competency assessments.

Ensure all personnel of reproductive capability acknowledge in writing that they understand the risks of HD handling.

Task 2: Manage policies for Personal Protective Equipment (PPE) and safe handling across the HD lifecycle.

Evaluate and select appropriate PPE that meets the standards specified in USP <800> for each handling activity.

Develop and enforce SOPs for all stages of the HD lifecycle: receipt, storage, compounding, administration, and disposal.

Ensure proper procedures for donning, doffing, and disposing of PPE to prevent self-contamination.

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EXAM CONTENT OUTLINE

Audit work practices to ensure consistent adherence to safe handling policies.

Manage the supply chain for PPE to prevent shortages of critical items.

Task 3: Implement and oversee a medical surveillance program.

Establish a comprehensive medical surveillance program in collaboration with occupational health professionals.

Ensure that baseline and periodic health assessments are conducted and documented for all at-risk personnel.

Analyze aggregate data from the surveillance program for exposure trend analysis to guide preventative actions.

Maintain the confidentiality of individual employee health information while using data to improve program safety.

Develop policies that support staff who may need to be reassigned to non-HD handling duties for medical reasons.

Task 4: Establish and manage an exposure incident reporting system.

Develop a clear and accessible SOP for reporting and managing acute personnel exposure incidents.

Lead a confidential investigation into the root cause of any reported exposure event.

Ensure affected personnel receive immediate post-exposure care and follow-up in accordance with occupational health protocols.

Implement and document corrective actions to prevent the recurrence of similar incidents.

Integrate the exposure incident reporting system with the organization's OSHA logs and HR processes.

Domain 4: Quality Assurance, Auditing, and Emergency Response (15%)

Task 1: Manage a comprehensive quality assurance (QA) and continuous improvement program.

Establish a written QA program with key quality metrics to track and trend over time.

Lead investigations into any quality failures or process deviations using CQI principles.

Conduct annual internal audits of the entire HD safety program to identify gaps and vulnerabilities.

Develop and track CAPAs to address any findings from internal or external audits.

Integrate HD safety audits into the organization's broader patient safety and medication safety programs.

Task 2: Develop and manage the emergency response and business continuity program for HDs.

Develop comprehensive SOPs for the management of HD spills and acute personnel exposures.

Ensure that appropriately stocked spill kits and emergency equipment are readily accessible.

Lead investigations into the root causes of spills and exposures to implement preventative measures.

Develop and maintain contingency plans for C-PEC/C-SEC downtime to ensure business continuity.

Document all emergency events, responses, and follow-up actions in a detailed and auditable manner.

Task 3: Conduct mock drills and simulation training to validate emergency response readiness.

Design and schedule regular mock spill and exposure drills for all personnel who handle HDs.

Evaluate staff response during drills against established emergency procedures to identify performance gaps.

Conduct debriefing sessions after drills to identify areas for improvement in training and response protocols.

Use findings from simulation training to refine emergency SOPs and equipment placement.

Document all drill activities, participant performance, and action items for improvement.

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EXAM CONTENT OUTLINE

Domain 5: Hazardous Drug Waste Management and Environmental Safety (10%)

Task 1: Design and manage a compliant HD waste segregation and disposal program.

Establish clear procedures for segregating trace and bulk HD waste at the point of generation.

Ensure all waste containers are properly labeled, stored in a secure area, and meet regulatory specifications.

Apply federal EPA Resource Conservation and Recovery Act (RCRA) compliance standards to the management of bulk HD waste.

Develop protocols for managing different types of HD waste, including sharps, PPE, and expired drug products.

Train all personnel on proper waste segregation to minimize cost and ensure compliance.

Task 2: Oversee hazardous waste vendor relationships and ensure regulatory compliance.

Evaluate and select a licensed and reputable hazardous waste vendor for the transport and disposal of HD waste.

Manage contracts and service level agreements with the waste vendor.

Ensure all hazardous waste manifest documentation is accurately completed and maintained according to regulations.

Audit the waste vendor's practices to ensure they are compliant with all federal and state regulations.

Maintain a complete and auditable file of all waste disposal documentation.

Task 3: Apply sewer disposal restrictions and environmental safety protocols.

Implement a strict policy prohibiting the disposal of raw HDs and contaminated body fluids down drains or sewers.

Identify specific HDs that are subject to sewer bans under federal or local regulations.

Educate clinical staff on proper handling and disposal of patient waste contaminated with HDs.

Assess the environmental impact of the facility's HD handling and disposal practices.

Develop procedures to minimize the environmental footprint of the HD program.

Domain 6: Leadership, Ethics, and Compliance Culture (10%)

Task 1: Advocate for and cultivate a culture of safety and compliance.

Champion the importance of HD safety to executive leadership to secure necessary resources and support.

Communicate cost-safety trade-offs and return on investment for USP <800> resource allocation to leadership.

Foster a non-punitive reporting environment where staff feel empowered to report near misses and safety concerns.

Promote interdisciplinary ownership of the HD safety program across pharmacy, nursing, and environmental services.

Serve as a visible role model for safe work practices and ethical behavior.

Task 2: Manage change and overcome resistance to USP <800> implementation.

Develop a strategic plan for implementing new policies, procedures, or facilities related to USP <800>.

Identify potential barriers to change and develop strategies to address staff concerns.

Communicate the rationale for compliance requirements, linking them directly to staff and patient safety.

Engage frontline staff in the design and implementation of new workflows to increase buy-in.

Celebrate milestones and successes to maintain momentum during long-term implementation projects.

Task 3: Model and communicate ethical obligations related to staff and patient safety.

Articulate the ethical imperative to protect healthcare workers from occupational exposure to HDs.

Ensure that all staff, including those of reproductive capability, are fully informed of the risks.

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EXAM CONTENT OUTLINE

Model ethical decision-making when balancing staff safety against operational demands or financial constraints.

Advocate for patient safety by ensuring that HDs are handled in a manner that prevents contamination of final preparations.

Establish a clear process for addressing ethical concerns raised by staff regarding HD handling.

CANDIDATE
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ABOUT CPS

The Council on Pharmacy Standards (CPS) develops and administers professional certification programs for pharmacists. CPS awards credentials to qualified candidates who meet eligibility requirements and successfully pass the appropriate examination. Our programs validate advanced competence in contemporary practice areas, helping candidates demonstrate specialized expertise and employers verify it.

CPS certifications span pharmacy law and compliance, sterile and non-sterile compounding, immunization and public health, point-of-care testing, medication safety and quality, controlled substances stewardship, pharmacogenomics, telepharmacy, veterinary compounding, specialty pharmacy, and pharmacy informatics.

CPS PHILOSOPHY OF CERTIFICATION

Certification is a voluntary, rigorous evaluation that allows pharmacists to demonstrate advanced knowledge and be recognized for the expertise they possess. CPS certification and subspecialty examinations are designed to assess specialty knowledge and its application in contemporary pharmacy practice.

CPS credentials do not confer licensing authority or independent practice rights. Licensure and the ability to practice are governed by state boards of pharmacy and other applicable regulators. While some employers or jurisdictions may reference certification within their qualifications, CPS does not set licensure policy and cannot require recognition of its credentials. Practice and educational standards inform CPS examinations; however, the development of such standards rests with professional organizations, regulators, and the education community.

CPS encourages candidates to verify how certification relates to state licensure requirements, institutional policies, the standards of relevant professional organizations, and local employer expectations. For specific guidance, candidates should consult state boards of pharmacy, colleges and schools of pharmacy, professional associations, and prospective or current employers.