

Certification Examination

CSCP

Certified Sterile Compounding Pharmacist



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.

TABLE OF CONTENTS

Eligibility Criteria	3
Resources for Exam Candidates	4
Fees	5-6
Steps to Register for Computer Testing	7
Application Checklist	8
Administrative Policies	9 - 11
General Policies	12 - 14
Exam Content Outline	15
About CPS	20

CANDIDATE
HANDBOOK ELIGIBILITY
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)

CANDIDATE HANDBOOK

RESOURCES

CPS Exam Candidates

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

Use the Study Guides & Preview Tests page as the official and most current source for all exam materials.

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.

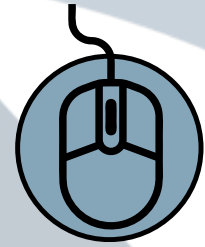
CANDIDATE HANDBOOK

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.

CANDIDATE
HANDBOOK

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).

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.

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

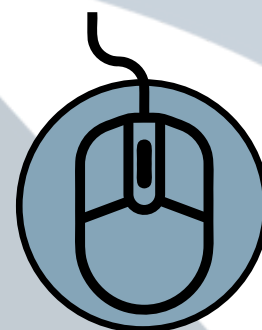
will be issued for the following circumstances:

- 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.

CANDIDATE
HANDBOOK

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.

CANDIDATE
HANDBOOK

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.

CANDIDATE
HANDBOOK

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

CANDIDATE HANDBOOK

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.

CANDIDATE
HANDBOOK

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

CANDIDATE
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

CANDIDATE
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

CANDIDATE
HANDBOOK

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

CANDIDATE
HANDBOOK

EXAM CONTENT OUTLINE

How to Study

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.

Domain 1: Foundations, Standards, and Regulations (15%)**Task 1: Apply the principles of USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations.**

Define the scope of USP <797> and its applicability to different practice settings.

Differentiate between CSP Categories 1, 2, and 3 based on compounding conditions and BUD limits.

Identify the roles and responsibilities of the designated person(s) overseeing the compounding program.

Explain the importance of a risk-based approach to sterile compounding policies and procedures.

Interpret the relationship between USP <797>, <795>, and <800>.

Task 2: Apply principles of pharmaceutical microbiology to prevent contamination.

Identify common sources of microbial contamination in the cleanroom environment (e.g., personnel, air, surfaces).

Describe the characteristics of microorganisms relevant to sterile compounding (e.g., bacteria, fungi, endotoxins).

Explain the mechanisms of action and appropriate uses of various disinfecting and sterilizing agents.

Apply first-air principles during aseptic manipulations to prevent contamination.

Analyze microbial growth kinetics and its implications for beyond-use dating.

Task 3: Interpret and apply other relevant standards and regulations.

Apply principles from USP <71> Sterility Tests and USP <85> Bacterial Endotoxins Test.

Recognize the applicability of FDA cGMP (21 CFR Parts 210/211) for 503B outsourcing facilities.

Incorporate principles from USP <1163> Quality Assurance in Pharmaceutical Compounding into the QMS.

Adhere to applicable state board of pharmacy, FDA, and DEA regulations for sterile compounding.

Incorporate guidance from organizations like ASHP and ISMP into sterile compounding practices.

Task 4: Manage medication safety principles within the sterile compounding process.

Develop procedures to prevent common medication errors in compounding (e.g., wrong drug, wrong concentration).

Implement strategies to mitigate risks associated with high-alert medications.

Analyze look-alike/sound-alike (LASA) risks within the compounding pharmacy.

Utilize failure mode and effects analysis (FMEA) to proactively identify process risks.

Establish a non-punitive reporting system for compounding errors and near misses.

Domain 2: The Sterile Compounding Environment (25%)**Task 1: Evaluate the design and classification of the sterile compounding facility.**

Differentiate between the ante-room, buffer room, and primary engineering control (PEC) areas.

**CANDIDATE
HANDBOOK**

EXAM CONTENT OUTLINE

Verify that cleanroom suites meet the required ISO classifications (e.g., ISO 7 buffer room, ISO 5 PEC).

Assess the placement of equipment and fixtures to ensure proper airflow and cleanability.

Ensure proper pressure differentials and airflow between adjacent classified areas.

Evaluate the design of segregated compounding areas (SCAs) and their limitations.

Task 2: Manage Primary and Secondary Engineering Controls (PECs and SECs).

Differentiate between various PECs (e.g., laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators).

Ensure all PECs and SECs are certified according to CETA standards at least every 6 months and when moved.

Review and maintain certification reports for all engineering controls.

Develop procedures for the proper daily use and cleaning of PECs.

Manage the response to any out-of-specification results from engineering control certification.

Task 3: Develop and oversee a cleaning and disinfection program.

Develop evidence-based standard operating procedures (SOPs) for cleaning and disinfecting all classified areas.

Select appropriate agents for cleaning, disinfection, and sporicidal treatment based on their properties and dwell times.

Establish and verify the frequency of cleaning for all surfaces (daily, monthly).

Ensure proper cleaning techniques, materials (e.g., low-lint wipes), and solution application.

Train and validate the competency of all personnel responsible for cleaning.

Task 4: Oversee the environmental monitoring program.

Develop a comprehensive environmental monitoring plan based on risk assessment.

Manage the collection of viable air and surface samples according to the required frequency.

Establish alert and action levels for microbial contamination.

Investigate any out-of-specification results, identify the root cause, and implement corrective actions.

Analyze environmental monitoring data over time to identify trends and proactively address potential issues.

Domain 3: Personnel Training, Competency, and Aseptic Technique (30%)

Task 1: Design and manage a comprehensive personnel training program.

Develop a didactic training curriculum covering all aspects of sterile compounding theory and practice.

Ensure training includes principles of microbiology, aseptic technique, and cleanroom conduct.

Provide education on medication safety, calculations, and proper documentation.

Incorporate training on the proper use of all equipment used in the compounding process.

Maintain complete documentation of all initial and ongoing training activities for each employee.

Task 2: Manage hand hygiene and garbing procedures.

Develop and enforce strict SOPs for hand hygiene and garbing based on USP <797> requirements.

Ensure proper sequence for donning and doffing all personal protective equipment (PPE).

Select appropriate garb (e.g., sterile gloves, gowns) based on the compounding activity.

Train personnel on the importance of garbing as a critical contamination control measure.

Regularly observe and provide feedback on garbing practices.

CANDIDATE
HANDBOOK

EXAM CONTENT OUTLINE

Task 3: Validate personnel competency in garbing and hand hygiene.

Conduct initial and recurring competency validation for hand hygiene and garbing.

Perform gloved fingertip and thumb sampling (GFTS) after garbing to assess aseptic technique.

Establish passing criteria for GFTS based on USP <797> action levels.

Investigate and remediate any GFTS failures through retraining and re-evaluation.

Document all competency validation activities for regulatory review.

Task 4: Validate personnel competency in aseptic manipulation (Media-Fill Testing).

Design media-fill tests that simulate the most complex and challenging compounding procedures performed.

Oversee the aseptic conduct of media-fill tests for all compounding personnel.

Ensure proper incubation and examination of completed media-fill units for any signs of microbial growth.

Investigate the root cause of any media-fill test failure and implement corrective actions.

Conduct and document successful media-fill testing initially and at required intervals for all staff.

Domain 4: Formulation, Preparation, and Release of CSPs (20%)**Task 1: Review and verify orders for Compounded Sterile Preparations (CSPs).**

Assess the clinical appropriateness of the prescribed formulation for the patient.

Verify the accuracy and completeness of the medication order.

Perform all necessary pharmaceutical calculations (e.g., dose, volume, infusion rate).

Consult Master Formulation Records and Compounding Records for preparation instructions.

Ensure all required information is documented before compounding begins.

Task 2: Determine appropriate Beyond-Use Dates (BUDs) for CSPs.

Assign BUDs based on the CSP Category and storage conditions as defined in USP <797>.

Utilize peer-reviewed literature and stability data to assign BUDs that ensure chemical and physical stability.

Differentiate between sterility-based BUDs and stability-based BUDs.

Develop policies for assigning BUDs to different types of preparations (e.g., single-dose, multi-dose).

Understand the requirements and testing needed to extend BUDs beyond default limits.

Task 3: Oversee the aseptic preparation and final verification of CSPs.

Ensure proper aseptic technique is used throughout the entire compounding process.

Manage the introduction and disinfection of components into the PEC.

Implement and manage technologies to enhance safety (e.g., IV workflow systems, barcode scanning, gravimetrics, image capture, robotics).

Develop procedures for visual inspection of CSPs against a lighted background for particulate matter and defects.

Oversee the final verification of the CSP, including checking ingredients, volumes, and final product integrity.

Task 4: Manage the proper labeling, storage, and transport of CSPs.

Ensure all CSP labels contain the required information in a clear and standardized format.

Verify that storage conditions (e.g., refrigeration, protection from light) are met after compounding.

Develop procedures to maintain the integrity and sterility of CSPs during transport.

Use temperature-controlled packaging and monitoring when necessary.

**CANDIDATE
HANDBOOK**

EXAM CONTENT OUTLINE

Provide clear instructions for patients or caregivers on proper handling and storage at home.

Domain 5: Quality Management Systems and Documentation (10%)

Task 1: Establish and maintain a formal Quality Management System (QMS).

Develop a written quality assurance and quality control plan for the compounding facility.

Ensure all policies and procedures (SOPs) are well-documented, approved, and reviewed regularly.

Utilize data analytics and dashboards to monitor quality trends (e.g., environmental monitoring, deviations, personnel competency).

Manage a change control program to evaluate and approve any changes to processes or facilities.

Conduct routine audits of the QMS to ensure ongoing compliance and effectiveness.

Task 2: Manage deviations, complaints, and adverse events.

Develop a system for documenting, investigating, and resolving any deviations from SOPs.

Perform a thorough root cause analysis (RCA) for any significant event or out-of-specification result.

Implement a formal process for handling product complaints and reports of adverse drug events.

Establish and test a recall procedure for any potentially non-sterile or defective CSPs.

Analyze event data to identify trends and implement preventative actions.

Task 3: Oversee the component and release testing program.

Establish procedures for qualifying vendors and verifying the quality of all components and supplies.

Manage the process for sterility and endotoxin testing for CSPs requiring it.

Interpret the results of release testing and take appropriate action.

Ensure that no CSP requiring release testing is dispensed before satisfactory results are received.

Maintain complete documentation of all component verification and release testing activities.

Task 4: Maintain comprehensive documentation and records.

Ensure Master Formulation Records and Compounding Records are accurate, complete, and properly maintained.

Maintain all records related to personnel training, competency, and qualifications.

Keep organized records of facility certification, environmental monitoring, and equipment maintenance.

Ensure all documentation is readily retrievable for review by regulatory and accrediting bodies.

Adhere to all record-keeping requirements for controlled substances used in compounding.

**CANDIDATE
HANDBOOK**

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.