

## PHARMACY TECHNICIAN

### Prepare Cytotoxic & Biological Agents



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## INTRODUCTION

1. This Qualification Training Package (QTP) was developed to enhance and standardize on-the-job training for 4P0X1 personnel. As a trainer, the QTPs provide teachable elements of task breakdowns. The teachable elements will assist in guiding the trainee towards **independent** task performance, **proficiency**, and serve as an **evaluation** tool for trainers/certifiers.
2. Review the volume(s) of the Career Development Course (s) (CDC) and identify which module(s) of the QTP is needed for the trainee's job position or upgrade skill-level training. The QTP training for each module should be accomplished in the order which most closely mirrors the area in which the trainee is working. Items in column 2 of the Pharmacy Job Qualification Standard (JQS)/Specialty Training Standard (STS) marked with a 5 or 7 are core tasks for the 4P career field. Additional proficiency training may be required for these tasks at the supervisor's discretion.
3. Ensure the trainee reviews the training references in each module prior to attempting any task or QTP evaluation. Review the performance checklist and training objective with the trainee. If the trainee has questions about the objective, clarify the desired outcome/results of performance, demonstration or completion of the task. Remember the objective of each QTP is to standardize training and allow sufficient time for the trainee to learn each task thoroughly in order to perform the task **independently**.
4. When the trainee has received sufficient training and is ready to be evaluated on the objective, follow the evaluation instructions. The performance checklist must be used as you evaluate each task objective. When the trainee successfully demonstrates and accomplishes the objective, document the task completion appropriately in the member's Air Force Training Record (AFTR).
5. The QTP task completion is to be annotated in the trainee's electronic training record. **NOTE:** The individual checklists and final evaluations are **not** filed in each member's user files.
6. If the trainee does not accomplish the objective, review the areas needing further instruction. Conduct feedback for each module with the trainee, and document appropriately in the member's Air Force Training Record. As the trainer, once you are satisfied the trainee is ready to perform the task; he/she will be re-evaluated until the objective is met.
7. If a task being trained requires third party certification by a task certifier/certifying official, the trainer ensures trainee is qualified to perform the task **independently**. The trainee will then be evaluated by certifier/certifying official. Tasks requiring certification are identified in column 2 of JQS with a number sign (#). The certifier/certifying official will ensure documentation in column 3E of the JQS. The certifier will ensure that a trainer's signature is documented prior to signing off on the task in AFTR.

8. Tasks associated with a QTP are identified in column 4D of the STS. The QTPs are a necessary tool for standardizing task qualifications for upgrade training or job position training. Such standardization benefits the JQS training concept throughout a member's career. These documents may also be used in assessing/certifying pharmacy technicians upon arrival at a new duty station.

9. Feedback is a vital and important part of improving our educational process for pharmacy technicians. Your first hand expertise is valued and feedback highly encouraged ensuring we have the most up-to-date information and training possible. Please direct all inquiries to: your immediate supervisor.

**SUBJECT AREA:** Inpatient Pharmacy

**TASK NAME(S):** Preparing Cytotoxic & Biological Agents

**CFETP/STS REFERENCE(S):** 6.2.2; 6.2.3; 6.2.4

**EQUIPMENT REQUIRED:**

1. Material Safety Data Sheets
2. Class II Biological Safety Cabinet
3. Class III Biological Safety Cabinet (if available)
4. Lint-free gown
5. 2 pair latex gloves
6. Safety glasses
7. Hair cover
8. Surgical mask
9. Shoe Cover (when needed)
10. Germicidal cleanser
11. Lint-free towels/gauze
12. Plastic sealable bag
13. Chemotherapy disposable bags/waste container
14. Chemotherapy warning labels
15. Prep mats
16. 70% alcohol solution/swabs
17. Detergent, hydrogen peroxide, or sodium hypochlorite (if available and approved)
18. Chemotherapy emergency personal spill kit (we need this in TRAVIS)
19. Chemotherapy contamination/spill kit
20. Syringes
21. Syringe caps
22. Needles
23. Parenteral solutions
24. Vials  
(chemo medication will not come in ampules due to the hazard of breaking the glass and potential harm it might cause the technician)
25. Filter needles/straws
26. Chemotherapy preparation mats
27. Closed-system drug transfer devices - Vial and Syringe adaptors (if available)
28. Secondary IV Set/Infusion Set/Low Sorbing Infusion Set (IV lines)
29. 0.2 Micron Low Protein Binding Filer/Filtered Extension Set (IV line filters)

**TRAINING REFERENCE(S):** Chemocheck™ Training and Certification Program, The OSHA Hazard Communication Standard

**REMARKS/NOTES:** In accordance with the OSHA Hazard Communication Standard everyone involved in the preparation, administration, and disposal of chemotherapeutic admixtures must be provided training on workplace risk and safe handling practices to include proper use of Material Safety Data Sheets. The trainee should be recertified on preparing chemotherapeutic admixtures annually.

## **OBJECTIVE:**

1. Given a provider's order and the necessary equipment, safely prepare and transport chemotherapeutic admixtures and dispose of hazardous waste.

**EVALUATION INSTRUCTIONS:** In evaluating the trainee's knowledge and technique, trainer should use non-hazardous medication solutions such as Fluorescein that will fluoresce under UV light. OSHA recommends knowledge and competence of trainee be evaluated after the first training session and annually thereafter.

1. After the trainee has received instructions, allow sufficient practice on each part of the task.
2. Use the performance checklist to ensure all steps of the task are accomplished without assistance and without error.
3. Document task competency upon completion of the evaluation in the trainee's AFTR record. Initial evaluation should be documented in the CFETP. All recurring evaluations should be documented on AF Form 1098.

## **STEPS IN TASK PERFORMANCE:**

### **1. Risk Of Exposure To Chemotherapeutic Medications**

Many medications used in the preparation of chemotherapeutic admixtures are cytotoxic (work by eliminating existing cancer cells but can also harm and kill healthy cells), mutagenic (cause changes in the reproductive (DNA) material of the cell resulting in miscarriage, and birth defects, therefore should not be handled if pregnant) or carcinogenic (cancer causing). Some are also vesicants and irritants, causing skin rash, blistering, or discoloration. They must be handled differently from less hazardous medications in order to reduce the risk of inadvertent exposure to staff and patients through inhalation, absorption, ingestion, and accidental injection.

Risk of exposure from **inhalation** is greatest when drug particles enter the environment through aerosolization while being injected into a vial or parenteral solution, or when air from a drug-filled syringe is expelled. This risk can be reduced by using the technique of maintaining negative pressure during injection and the use of a Biological Safety Cabinet or a respirator.

Risk of exposure from **absorption** may occur when the skin comes in contact with the medication through aerosolization, spraying, spills or touching a contaminated surface. It is important to immediately wash the contaminated area to prevent prolonged exposure. Additionally, (should not have ampules for chemotherapeutic medications) uncapped needles can also lead to exposure. Use of proper technique in inserting and withdrawing needles and capping and uncapping syringes (to reduce potential injury, mishap, and spills, Travis AFB has implemented the use of Vial and Syringe Adaptors). Also, do not

wear soft contact lenses when preparing chemotherapeutic medications (chemotherapeutic medications should not be prepared outside the BSC). These lenses are permeable and may absorb medication particles or dust which can be absorbed into the body.

Risk of exposure from **ingestion** may occur when medication particles or droplets enter the body orally by way of food, beverages, etc. Never take any items that may be ingested into areas where chemotherapy medications are stored or prepared. Hand washing is a must before and after any handling of cytotoxic agents to help prevent and reduce the risk of exposure from ingestion and absorption.

Risk of exposure from **injection** can occur if a contaminated needle or broken glass from an ampule, broken vial or medication container accidentally punctures the skin. To prevent this, it is imperative to keep the needle capped when not in use or use of the closed-system drug transfer devices - vial and syringe adaptors (if available). Punctures can occur when capping and uncapping the needle and when opening ampules. Be sure to always proceed slowly and cautiously during these procedures and even in handling of vials and medication containers.

## **2. Reducing Risk Of Exposure To Chemotherapeutic Medications**

OSHA guidelines for the safe handling of hazardous medications require the use of a Class II Biological Safety Cabinet (sometimes referred to as a vertical flow hood) and/or Class III Biological Safety Cabinet (sometimes referred to as the Laminar Flow Glovebox/Isolator).

The Class II Biological Safety Cabinet or the vertical flow hood equipment provides a Class 100 clean-air workstation while providing some protection to the preparer and the work area from exposure to the product being prepared. It also has a glass barrier that pulls down on the front for added protection.

The Class III Biological Safety Cabinet or the Laminar Flow Glovebox/Isolator (LFGI) equipment uses a High Efficiency Particulate Air (HEPA) filters to provide the highest level of operator and product protection. By definition, a Class III BSC is a totally enclosed ventilated cabinet of leak-tight construction. The cabinet is maintained under negative air pressure and the supply air is drawn in through HEPA filters. The exhaust HEPA filter handles all air exiting the LFGI and all purged air that is purged inside the HEPA Purge airlock. All filters are rated to remove particulates and aerosols 0.3 micron in size with a minimum efficiency of 99.99%.

The Biological Safety Cabinet should be certified according to specification of the National Sanitation Foundation Standard 49 and Class 100 specifications of Federal Standard 209C before use.

Decontaminate weekly or immediately after a spill to remove the chemical contamination. The hood should be decontaminated per manufacturer's recommendation. Most hoods are decontaminated by wiping down the interior of the hood with a moisten gauze or towel of detergent, alcohol, hydrogen peroxide, or sodium hypochlorite. All waste should be discarded in sealable plastic bags and placed in a plastic chemotherapy waste container for disposal.

In addition to a Biological Safety Cabinet, properly utilized protective clothing and other equipment can minimize the risk of exposure to hazardous medications. Healthcare workers preparing chemotherapeutic admixtures should wear powder free disposable gloves of 8 gauge and 18 gauge in thickness, lint free disposable gowns with a closed front, long sleeves, tight-fitting elastic or knit cuffs, hair cover, surgical mask, and shoe covers (if needed for clean room). The 18 gauge outer gloves should have already been tested and verified for use with chemotherapy drugs. The inner gloves (second gloves) should be at least 8 gauges in thickness. The inner gloves (second gloves) do not require have been tested and verified for use with chemotherapy drugs. Gloves should also be changed in between each medication, every 30 minutes, or if a puncture occurs (which ever comes first) to prevent contamination. Proper technique and supplies designed to aid in safe preparation should also be used. The build-up of positive pressure in medication vials and syringes must be avoided at all times to reduce aerosolization. Syringes with Luer-lock should be used in order to reduce the potential for accidental leaks or separation of the fittings. Venting devices with hydrophobic filters when used properly can provide an added safety. Closed-system drug transfer devices combined with safe handling practices add an even great level of protection.

### **3. Preparing the Work Area**

3.1. Review Material Safety Data Sheet (MSDS) for medication being prepared

3.2. Double check calculations

3.3. Assemble the supplies needed to make the admixture (sealable bag, 70% alcohol solution, gauze, towels, syringes, needles, filter needles, vials, etc.)

3.4. Don protective clothing

- Shoe Covers
  
- Put on the hair cover tucking all hair inside the cap
  
- Put on surgical masks

Don respirator and safety goggles (if not using a Class II Biological Safety Cabinet)

- Using proper technique, wash hands with a germicidal cleanser for at least 60 seconds. (Start at the top of the hands and work your way down to elbow. It is also very important to clean under the nails and in between

the fingers to ensure proper cleaning. When rinsing, do so from the tip of the fingers to the elbow, do not let the water run off of your fingertips)

- Put on the gown (must be worn with sleeves down)
- Put on the first pair of gloves and tuck them under the cuffs of the gown
- Put on the outer gloves, pulling them securely over the gown cuffs to prevent skin exposure. Wash gloves with germicidal cleanser if not sterile. Replace gown if it gets wet.)
- Pull the gown sleeve into place

3.5. If using Class II BSC, clean work area with 70% alcohol solution or other approved cleaning solution and lint free gauze or towels (wipe from top to bottom, and back to front). If using Class III BSC, clean all cytotoxic agent vials with alcohol for any possible cytotoxic residue before placing the items in the purge box of the LFGI. Also, clean the work area with 70% alcohol solution or other approved cleaning solution with lint free gauze or towels (wipe from back to front). Discarded waste in sealable plastic bag

3.6. Place preparation mat in the hood

3.7. Place plastic bag against a side wall

3.8. Place all supplies on preparation mat

3.9. Once all supplies are in the hood, swab the stoppers on vials and ports of injections. Discard gauze in the plastic bag in the hood.

#### **4. Preparing the Chemotherapeutic Admixture**

4.1. Prime intravenous (IV) infusion lines and/or filters with the correct base IV solution

4.2. Attach the “primed” IV infusion line and filter (if applicable) to the base solution bag

4.3. Reconstitute medication

4.4. Withdraw liquid from vial. Be sure to use the negative pressure technique when withdrawing from the vials. Do not fill the syringe more than 75% of the syringe to prevent the stopper from coming out from the bottom of the syringe and risk of exposure/contamination.

- 4.5. Have pharmacist check the “primed” IV infusion lines and filters (if applicable) to ensure that the lines have no air bubbles trapped inside the IV infusion lines
- 4.6. Have pharmacist check the solution bag and its expiration of the bag with the pharmacy patient label to ensure that it is the correct base solution that the medication will be injected into
- 4.7. Have pharmacist check the drug and diluent (if applicable), expiration date of the drug, and quantity of drug in the syringe with the pharmacy patient label to assure accuracy
- 4.8. Check the bag and line is locked and closed.
- 4.9. Inject the medication solution into the bag/bottle (use the negative pressure technique)
- 4.10. Seal IV bag/bottle

## 5. **Preparing the Medication for Delivery**

- 5.1. Have pharmacist check the admixture to assure that it is correct
- 5.2. Label the admixture with the IV label containing patient’s information and the Chemo Warning Label. Warning label must be clearly visible on the outside of the bag and should read as follow:

<p style="text-align: center;"><b>CAUTION:</b> CHEMOTHERAPY HANDLE WITH GLOVES DISPOSE OF PROPERLY</p>
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- 5.3. Have pharmacist check pharmacy label and finished product for accuracy
- 5.4. Place properly labeled medication in a plastic chemo bag (first bag) labeled with the pharmacy patient label and bag the bag again (double bag) in a plastic chemo bag with the pharmacy patient label. Ensure bag/bottle is capped and sealed before transport. Hand-carry to ward or clinic or let the nurse/doctor know the product is ready for pick-up per local procedures. Ensure anyone transporting the products takes a Chemotherapy Spill Kit and is briefed on safe handling and risks of exposure.

## 6. **Cleaning the Work Area**

- 6.1. Place items to be discarded into sealable plastic bag
- 6.2. **Disinfect** Biological Safety Cabinet by wiping down with 70% alcohol and/or other approved cleaning detergent/solution. Allow alcohol/solution to dry on surface. Do

not rinse or towel dry. The use of alcohol for disinfecting the BSC or LFGI will not deactivate any hazardous drugs and may even result in the spread of contamination rather than any actual cleaning. Most MSDSs for many hazardous drugs recommend sodium hypochlorite solutions as an appropriate deactivating agent.

6.3. Dispose of all gauze and toweling in sealable bag and place in chemotherapy waste container for disposal along with needles, syringes, vials, and other waste

6.4. Remove protective clothing:

- First, remove the outer pair of gloves by placing your gloved fingers on the outside of the glove cuff. Remove one glove halfway by scooping the cuff over the palm of the hand. Never touch the inner glove or the skin with the outside of the gloved fingers. Once the top glove is over the palm it can be removed easily without touching the contaminated fingertips to any clean area. Remove the outer glove from the other hand and dispose of both in a plastic sealable bag.
- Remove and dispose of the gown, glasses, mask, hair cover, shoe covers, and inner gloves.

6.5. Dispose of all contaminated clothing and disposable equipment in a plastic sealable bag and place in the chemotherapy waste container

6.6. Wash hands thoroughly

## 7. **Cleaning a Spill Inside the Biological Safety Cabinet**

7.1. Don protective clothing

7.2. Contain the spill with gauze (liquid spill) or water wet toweling (powder spill)

7.3. Remove gloves, dispose of them properly and don two fresh pair

7.4. Carefully remove all sharp fragments and glass pieces with adequate amount of lint free gauze or towel and place them in the chemotherapy waste disposal container

7.5. Absorb the spill with gauze and dispose of it in a sealable bag

7.6. **Decontaminate** Biological Safety Cabinet by washing surface with the appropriate cleaning solution, including the area underneath the work tray, walls and shield with detergent. Place gauze in a sealable bag.

7.7. Rinse the surface, walls and shield with gauze saturated with distilled water

7.8. Repeat washing and rinsing three times. Place gauze in a sealable bag

- 7.9. Dry the surface, walls and shield with fresh gauze
- 7.10. Dispose of gauze in a sealable bag
- 7.11. Remove the outer pair of gloves and dispose of them in a sealable bag
- 7.12. Seal the bag and dispose of it in a chemotherapy waste disposal container
- 7.13. Remove protective clothing and place in a chemotherapy waste disposal container
- 7.14. Wash hands thoroughly

## **8. Cleaning a Spill outside the Biological Safety Cabinet**

- 8.1. Obtain a chemotherapy medication spill kit. Do not leave the area if there is a spill, call for help if needed. Only trained workers with appropriate PPR and respirators should attempt to manage a hazardous drug spill.
- 8.2. Place warning sign at spill site
- 8.3. Don protective clothing, gloves, gown, hair cover, outer utility gloves, chemical safety glasses, shoe covers, and respirator
- 8.4. Remove glass particles and other debris using spill kit scoop. Place in the disposal waste bag or appropriate sharps container
- 8.5. Absorb liquid spills with absorb pads or powder and dispose of them in the first waste disposal bag
- 8.6. Absorb powder spills with water wet toweling. Dispose of it in waste disposal bag
- 8.7. Wash entire area with approved detergent solution
- 8.8. Rinse well with distilled water
- 8.9. Repeat washing and rinsing until all of the medication has been removed
- 8.10. Place toweling in the waste disposal bag
- 8.11. Remove outer utility gloves and shoe covers. Place them in waste disposal bag
- 8.12. Seal the bag and place it in the second waste disposal bag
- 8.13. Remove protective clothing and place them in the second waste disposal bag

8.14. Tie the waste disposal bag securely and dispose of it as required by workplace policy

8.15. Wash hands thoroughly

8.16. Fill out accident report form as required by your workplace

## 9. **Personal Contamination**

9.1 All preparation areas should have chemotherapy emergency kit on hand in the event of hazardous drugs coming in direct contact with the skin. Kit should consist of:

- 500 ml of Normal Saline
- 30 ml of sterile eyewash solution/eyewash station
- 120 ml of liquid soap
- 500 ml of a 5% bleach solution
- 500 ml of a 3% Hydrogen Peroxide solution

9.2 For direct contact with skin, wash immediately with soap and warm water. Using a gauze pad wipe with bleach solution. If skin is broken, use Hydrogen Peroxide

9.3 For direct contact with eye(s), flush immediately with warm water or eyewash for at least 5 minutes

9.4 Seek immediate medical attention

**ATTACHMENT(S):** None

**REFERENCE(S):**

Oncology, A. S. (2012). Chemotherapy Administration Safety Standards. American Society of Clinical Oncology/Oncology Nursing Society, 1-13.

Power, L. (2006). Drug Distribution and Control: Preparation and Handling - Guidelines. American Society of Health-System Pharmacists, 1172-1193.

Germfree. (2013, 04 22). LFGI (Laminar Flow Glovebox/Isolator). Retrieved from Germfree: <http://www.germfree.com/product-lines/pharmacy-equipment/compounding-aseptic-isolators/laminar-flow-glovebox-isolator-series/>

**PERFORMANCE CHECKLIST:**

**PREPARE CYTOTOXIC & BIOLOGICAL AGENTS**

<b>PERFORMANCE ITEMS</b>	<b>SAT</b>	<b>UNSAT</b>
<b>RISK OF EXPOSURE TO CHEMOTHERAPEUTIC DRUGS</b>		
1. Identify health risk associated with preparing chemotherapeutic medications		
2. List 4 methods exposure can occur		
3. Identify ways to reduce risk of exposure		
4. Explain the purpose of the Biological Safety Cabinet		
5. Identify protective clothing worn when preparing chemotherapeutic admixtures		
6. State why Luer-lock syringes are used		
7. List 2 additional safety devices		
<b>PREPARE WORK AREA</b>		
1. Identify hazards associated with medication using Material Safety Data Sheet		
2. Double-check calculations		
3. Assemble supplies		
4. Don protective clothing		
5. Clean Biological Safety Cabinet		
6. Wiped vials, amps, ports of injection with 70% alcohol		
<b>PREPARE THE ADMIXTURE</b>		
1. Reconstitute powders using negative pressure technique		
2. Withdraw solution from vial or amp		
3. Inject solution into bag/bottle using negative pressure technique		
4. Seal bag/bottle		
5. Work double-checked		
6. Pharmacy and Caution labels attached		
7. Finished product ready for safe transport		
<b>CLEAN WORK AREA</b>		
1. Properly dispose of waste materials		
2. Disinfect Biological Safety Cabinet with 70% alcohol		
3. Properly remove and dispose of protective clothing		
4. Wash hands thoroughly		

<b>PERFORMANCE ITEM</b>	<b>SAT</b>	<b>UNSAT</b>
<b>CLEAN SPILL INSIDE THE BIOLOGICAL SAFETY CABINET</b>		
1. Don protective clothing		
2. Contain the spill with gauze (liquid spill) or water wet toweling (powder spill)		
3. Remove/dispose of gloves, and don two fresh pair		
4. Carefully remove fragments and glass pieces with cardboard. Place in the chemotherapy waste container		
5. Absorb the spill with gauze and dispose of it in a sealable bag		
6. Decontaminate Biological Safety Cabinet by washing with detergent		
7. Rinse the surface, walls, and shield with gauze saturated with distilled water		
8. Repeat washing and rinsing three times then dry with fresh gauze		
9. Dispose of protective clothing/waste in chemotherapy waste container		
<b>CLEAN SPILL OUTSIDE BIOLOGICAL SAFETY CABINET</b>		
1. Obtain chemotherapy drug spill kit		
2. Seal off area		
3. Don protective clothing and equipment		
4. Remove debris using spill kit scoop		
5. Absorb liquid spill w/absorb pad/powder		
6. Absorb powder spill with wet toweling		
7. Wash area w/detergent solution and rinse w/distilled water, repeat till spill is clear		
8. Dispose of all materials used in clean up		
9. Dispose of protective clothing/respirator		
10. Wash hands thoroughly		
<b>PERSONAL CONTAMINATION</b>		
1. Prepare chemotherapy emergency kit		
2. Explains steps taken if chemotherapeutic agent come in direct contact with skin		
3. Explains steps taken if chemotherapeutic agent come in direct contact with eye		
<b>FINAL RESULTS:</b>		
<b>Trainee:</b>		
<b>Trainer:</b>		
<b>Certifier:</b>		
<b>Date:</b>		

**FEEDBACK:** Using this checklist as a source of information, discuss the trainee's performance indication strengths, weaknesses, suggested improvements, etc. If the trainee performed all steps of the task satisfactorily, document the results in the trainee's AFTR record.