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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: April 16, 2019

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Stan Weisser, Licensee Member, Vice Chairperson
Victor Law, Licensee Member
Allen Schaad, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Shirley Kim, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Christine Acosta, Supervising Inspector
Laura Hendricks, Staff Analyst
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum and General Announcements**

   Chairperson Serpa called the meeting to order at 10:05 am. Board members present: Allen Schaad, Maria Serpa, Stan Weisser and Victor Law. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**

   There were no comments from the committee or the public.

3. **Presentation on the Proposed USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings**

   The committee heard a presentation on the current proposed revisions to USP General Chapter 800 regarding the handling of hazardous drugs by Supervising Inspector Christine Acosta.

Supervising Inspector Acosta provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and nonsterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Dr. Acosta updated the committee on the status of USP revising Chapter <797> and subsequent revisions. The committee was provided with a summary of the changes made in draft Chapter <797> based on the 18 sections.

Dr. Acosta stated that the National Institute for Occupational Safety and Health (NIOSH) is a division of Center for Disease Control and Prevention (CDC). She explained that NIOSH developed a list of antineoplastic and other hazardous drugs in healthcare settings. Dr. Acosta noted that the list has not been updated in 2016, but an updated list is expected to be released soon (typically it is updated every two years).

Dr. Acosta reviewed the following six characteristics that are used by NIOSH to determine if a drug is hazardous in humans or animals.

- Carcinogenicity
- Teratogenicity or fertility impairment
- Reproductive toxicity
- Organ toxicity
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous

Dr. Acosta explained that NIOSH organizes hazardous drugs into categories which are commonly referred to as “tables.” Dr. Acosta summarized the characteristics of each of the tables as provided below.

Table 1. Group 1: Antineoplastic drugs

- One or more of the NIOSH criteria for a hazardous drug.
- Many of these drugs are cytotoxic.
- Represent an occupational hazard to healthcare workers and should *always* be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation.

Table 2. Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug

- Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation.

Table 3. Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

- NIOSH criteria for reproductive hazards.
- Represent a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation.

Table 4

- Contains drugs that were deleted from the 2014 NIOSH hazardous drug list for the 2016 update; however, there are no deletions to report.

Table 5

- Provides general guidance for some of the possible scenarios that may be encountered in healthcare settings where hazardous drugs are handled.

Dr. Acosta explained that NIOSH defines the criteria and identifies hazardous drugs (HD), while USP develops the standards for handling these HDs to minimize the risk to public health. Dr. Acosta stated that the goals of the USP standards are to help increase awareness, provide uniform guidance to reduce the risk of managing HD, and help reduce the risk posed to patients and the healthcare workforce. Dr. Acosta noted that healthcare workers will become patients if they are exposed to these HDs without the proper precautions.

Dr. Acosta stated that there has been a delay in releasing the updated USP 800 due to the number of comments and stakeholders involved; however, it is expected that the updated USP 800 will be released and become enforceable on December 1, 2019.

Dr. Acosta recommended that interested parties visit the frequently asked questions section of USP's website because it contains a wealth of information broken down in an easy to search format.

Dr. Acosta reported that USP 800 is broken down into the following 18 sections. She noted that her presentation would also be broken down into these sections.

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding

14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance

Section 2. List of Hazardous Drugs

Dr. Acosta explained that NIOSH maintains a list of antineoplastic and other HDs used in healthcare. The entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. Dr. Acosta added that the list must be reviewed at least every 12 months and whenever a new agent or dosage form is used.

Dr. Acosta explained that section two contains the criteria that can be used by pharmacists to determine if containment requirements in USP 800 must be followed or when an "assessment of risk" can be conducted to determine alternative containment strategies.

Dr. Acosta explained that any HD active pharmaceutical ingredient (API) must follow the requirements in the chapter. She also provided the following definition of API: "any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body." Dr. Acosta stated that any antineoplastic requiring HD manipulation must also follow all of the requirements of the chapter.

Dr. Acosta explained that drugs on the NIOSH list that do not have to follow all of the containment requirements of this chapter if an assessment of risk (AOR) is performed and implemented include: final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer). Dr. Acosta stated that for dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and work practices.

Dr. Acosta reported that an AOR must document what alternative containment strategies and/or work practices are being employed for dosage forms to minimize occupational exposure. She added that it must be reviewed at least every 12 months and the review must be documented. Dr. Acosta also stated that the AOR must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

Dr. Acosta explained that an assessment of risk (AOR) may be performed for dosage forms to determine alternative containment strategies and/or work practices.

Section 3. Types of Exposure

Dr. Acosta highlighted the potential opportunities of exposure based on activity as provided in Section 3. For example, the risk of exposure that can occur while transporting HDs within a healthcare setting.

Section 4. Responsibility of Personnel Handling Hazardous Drugs

Dr. Acosta explained that each facility must have a designated person who:

- is qualified and trained to be responsible for developing and implementing appropriate procedures;
- oversees compliance with this chapter and other applicable laws, regulations, and standards;
- ensures competency of personnel;
- ensures environmental control of the storage and compounding areas.
- thoroughly understands:
  - rationale for risk-prevention policies,
  - risks to themselves and others,
  - risks of noncompliance that may compromise safety,
  - the responsibility to report potentially hazardous situations to the management team.
- Is responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities and acting on the results.

Section 5. Facilities and Engineering Controls

Dr. Acosta stated that HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. She explained that access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling.

Dr. Acosta also reported that HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure. There must be designated areas available for: receipt and unpacking, storage of HDs, nonsterile HD compounding, and sterile HD compounding. Dr. Acosta reviewed the following criterial for the designated areas.

- Designated areas:
  - Receipt and unpacking: (Antineoplastic HDs and all HD APIs)
    - neutral/normal or negative pressure relative to the surrounding areas.
- Storage of HDs:
  - Not on floor

- Antineoplastic HDs (requiring manipulation) and all HD APIs:
  - stored separately from non-HDs
  - stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).
- Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs:
  - may be stored with other inventory if permitted by entity policy.
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.

Dr. Acosta explained that a containment primary engineering control (C-PEC) is a ventilated device to minimize worker and environmental HD exposure and it must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.

Dr. Acosta stated that a containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed and must:

- be externally vented,
- be physically separated (a different room from other areas),
- have an appropriate air exchange (ACPH); and
- have a negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas.

Dr. Acosta reported that supplemental engineering controls (closed-system drug-transfer device (CSTD)) are adjunct controls to offer additional levels of protection.

Dr. Acosta noted that a sink must be available for hand washing and the water source and drain must be located at least one-meter way from the C-PEC.

Dr. Acosta explained that C-PECs must be placed in separate rooms, unless the C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. She added that if they are in the same room they must be placed at least one-meter apart and particle-generating activity must not be performed when sterile compounding is in process.

Dr. Acosta stated that nonsterile HD compounding must be performed in a C-PEC within a C-SEC. she added that the C-SEC surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Dr. Acosta reviewed the following requirements for C-PECs (Class II or III Biological Safety cabinet or compounding aseptic containment isolator):

- must be externally vented
- must provide an ISO Class 5 or better air quality
- must not be used for the preparation of a non-HD unless:

    - non-HD is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.
- must be located in a C-SEC

Dr. Acosta explained that in the HD cleanroom suite the C-SEC (clean/buffer room) must have:

- fixed walls,
- minimum of 30 ACPH of HEPA-filtered supply air,
- air quality of ISO Class 7 or better; and
- negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas

Dr. Acosta also explained that the C-SEC (Anteroom) must have:

- Fixed walls,
- Minimum of 30 ACPH of HEPA-filtered supply air
- Positive pressure of at **least** 0.02 inches of water column relative to all adjacent unclassified areas
- Air quality of ISO Class 7 or better
- Hand-washing sink **must** be placed in the ante-room at least 1 meter from the entrance to the HD buffer room

Dr. Acosta stated that if the HD buffer room is entered through the positive-pressure non-HD buffer room, the following is also required: (Not a recommended facility design)

- Line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE
- Method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination.
    - If using a pass-through chamber (buffer area and adjacent space).
        - must be included in the facility's certification (particles and pressure)
        - refrigerator pass-through must not be used.

Dr. Acosta reported that containment segregated compounding areas (C-SCA) must have:

- Fixed walls,
- Negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas,
- 12 ACPH
- Externally vented
- hand-washing sink must be placed at least 1 meter from C-PEC
    - either inside the C-SCA or directly outside the C-SCA.
- Only low-and medium-risk HD CSPs may be prepared in a C-SCA.

Dr. Acosta explained that a closed-system drug-transfer device (CSTD) may limit the potential of generating aerosols during compounding. She also stated that it must not be used as a substitute for a C-PEC when compounding. Dr. Acosta explained that a CSTD should be used when compounding HDs when the dosage form allows and when administering antineoplastic HDs when the dosage form allows.

Section 6. Environmental Quality and Control

Dr. Acosta stated that environmental wipe sampling for HD surface residue should be performed routinely.
Dr. Acosta explained that surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near C-PEC
- Areas adjacent to C-PECs (floors, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas

Dr. Acosta stated that if any measurable contamination is found, the designated person **must** identify, document, and contain the cause of contamination.

Section 7. Personal Protective Equipment (PPE)

Dr. Acosta reviewed the types of personal protective equipment must be used by the staff.

- Gloves:
  - Must meet American Society for Testing and Materials (ASTM) standard D6978
  - worn for handling all HDs
  - must be powder-free
  - must be inspected for physical defects before use.
  - for sterile compounding: two pairs required
    - the outer chemotherapy gloves must be sterile
    - changed every 30 minutes
    - must be changed when torn, punctured, or contaminated
- Gowns:
  - must be disposable and shown to resist permeability by HDs
  - must be selected based on the HDs handled
  - must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit
  - must not have seams or closures
  - must be changed per the manufacturer's information for permeation of the gown. If none every 2–3 hours
  - must not be worn to other areas

- Respiratory Protection:
  - Surgical masks must not be used when respiratory protection is required.
  - For most activities, a fit-tested NIOSH-certified N95 or more is sufficient to protect against airborne particles.
    - no protection against gases and vapors and little protection against direct liquid splashes

- Appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:
  - Attending to HD spills larger than what can be contained with a spill kit
  - Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
  - There is a known or suspected airborne exposure to powders or vapors

- Disposal of Used Personal Protective Equipment:
  - All PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.
  - All PPE worn be disposed of in the proper waste container before leaving the C-SEC.
  - Chemotherapy gloves and sleeve covers worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

Section 8. Hazard Communication Program

Dr. Acosta reviewed the requirements for hazard communication programs as provided below.

- Required to establish P&Ps that ensure worker safety during all aspects of HD handling.
- Must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- Elements of the hazard communication program plan must include:
  - Written plan that describes how the standard will be implemented
  - All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
  - must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
  - must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
  - Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
  - Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

Section 9. Personnel Training

Dr. Acosta informed the committee that all personnel must be trained based on their job functions. She added that the training must occur before the employee handles any HDs and each employee must demonstrate the effectiveness of the training. Dr. Acosta stated that the training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE

- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

Dr. Acosta explained that all training must be documented and must be reassessed every 12 months.

Section 10. Receiving

Dr. Acosta provided the following requirements for receiving of HD products.

- HD products should be received from the supplier in impervious plastic to segregate them from other drugs.
- HD products must be delivered to the HD storage area immediately after unpacking.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- A spill kit must be accessible in the receiving area.
- The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).
- Damaged shipping containers: transported to a C-PEC designated for nonsterile compounding.
    - Damaged containers are considered spills and must be reported to the designated person and managed.

Section 11. Labeling, Packaging, Transport and Disposal

Dr. Acosta provided a summary of each section as provided below.

- Labeling
    - HDs identified must be clearly labeled at all times during their transport.
    - Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.
- Packaging
    - must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
    - must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs.
    - must have written SOPs to describe appropriate shipping containers and insulating materials.
- Transport
    - must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.
    - must be in containers that minimize the risk of breakage or leakage.
    - must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.
- Disposal

- All personnel performing custodial waste removal and cleaning activities must be trained in appropriate procedures.
- Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

Section 12. Dispensing Final Dosage Forms

Dr. Acosta explained that HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). She added that clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Dr. Acosta also noted that tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines.

Section 13. Compounding

Dr. Acosta stated that all compounding must be compliant with the appropriate USP standards for compounding including <795> and <797> and must be done in proper engineering controls.

Dr. Acosta explained that when compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC and the back should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity.

Dr. Acosta reported that bulk containers of liquid and API HD must be handled carefully to avoid spills. She also explained that APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities

Section 14. Administering

Dr. Acosta explained that HDs must be administered safely using protective medical devices and techniques and appropriate PPE must be worn. She added that PPE must be removed and disposed of in a waste container approved for trace contaminated HD waste at the site of drug administration.

Dr. Acosta stated that equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.

Dr. Acosta explained that If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel **must** don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting

Dr. Acosta explained that all areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. She noted that sterile

compounding areas and devices must be subsequently disinfected.

Dr. Acosta stated that policies and procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.

Dr. Acosta described appropriate PPE as follows:

- resistant to the cleaning agents used,
- two pairs of chemotherapy gloves
- impermeable disposable gowns
- eye protection and face shields must if splashing is likely
- respiratory protection must be used, if warranted

Dr. Acosta explained that agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and all disposable materials must be discarded to meet EPA regulations and the entity's policies.

Dr. Acosta also reminded that committee that all cleaning must be performed in areas that are sufficiently ventilated.

Dr. Acosta provided the committee with the following definitions of deactivating, decontaminating, cleaning and disinfecting.

- Deactivation
  - renders a compound inert or inactive.
  - Residue must be removed by decontaminating the surface.
  - There is no one proven method for deactivating all compounds. (EPA-registered oxidizing agents that are appropriate for the intended use
- Decontamination
  - inactivating, neutralizing, or physically removing HD residue and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned.
  - The work surface of the C-PEC must be decontaminated between compounding of different HDs.
  - The C-PEC must be decontaminated at least daily, any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
    - areas under the work tray must be deactivated, decontaminated, and cleaned at least monthly
- Cleaning
  - a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.
  - Cleaning agents used on compounding equipment should not introduce microbial contamination.
- Disinfection
  - a process of inhibiting or destroying microorganisms.
  - must be done for areas intended to be sterile, including the sterile compounding areas.

Section 16. Spill Control

Dr. Acosta provided the committee with the following information regarding spill control.

- personnel must receive proper training in spill management and the use of PPE and NIOSH-certified respirators
- Spills must be contained and cleaned immediately by qualified personnel with appropriate PPE.
- Qualified personnel must be available at all times while HDs are being handled.
- Signs must be available for restricting access to the spill area.
- Spill kits must be readily available in all areas where HDs are handled.
- All spill materials must be disposed of as hazardous waste.
- The circumstances and management of spills must be documented.
- Personnel potentially exposed during the spill or spill cleanup or who have direct skin or eye contact with HDs require immediate evaluation.
- Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.
- SOPs must:
  - be developed to prevent spills and to direct the cleanup of HD spills.
  - address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required.
  - address the location of spill kits and clean-up materials as well as the capacity of the spill kit.

Section 17. Documentation and Standard Operating Procedures (SOP)

Dr. Acosta explained that standard operating procedures must be reviewed (and documented) at least every 12 months and should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls
- Hand hygiene and use of PPE based on activity
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance

Dr. Acosta stated that personnel who transport, compound, or administer HDs must document their training according to OSHA standards (OSHA Standard 1910.120) and other applicable laws and regulations.

Section 18. Medical Surveillance

Dr. Acosta explained that Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. She added that healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.

The committee thanked Dr. Acosta for her presentation and asked for public comments.

A pharmacist that compounds exclusively for veterinary practices asked if the board would be creating an exception that would allow certain veterinary HD products to be handled in a room that is not USP 800 complaint. Dr. Acosta recommended contacting the CDC as they create the NIOSH list which is used to determine how HD products must be handled.

A member of the public asked if the committee could make Dr. Acosta's slides available in an electronic format or in larger printed sizes. Chairperson Serpa reminded the public that the it is the responsibility of the PIC and designated staff to review the USP standards, the slides are only a high-level review of the standards.

A compounding pharmacist asked if a pharmacy what provides patient specific HDs to a hospital is responsible to make sure that the HDs are handled appropriately by hospital staff when it is administered (i.e. wearing proper PPE and proper disposal). Chairperson Serpa responded that in some healthcare systems the pharmacy is responsible to oversee the HDs from compounding to administration; however, an independent pharmacy would have different requirements. DCA legal counsel Laura Freedman stated that this question goes beyond the agenda item and should be placed on a future agenda for future discussion.

Interim Executive Officer Anne Sodergren reminded the committee that there is pending legislation that will set the relevant USP chapters as the floor for the board's compounding regulations. After the floor is set the board will have the opportunity to develop additional regulations if nessecary.

4. Approval of the February 20, 2019 Meeting Minutes

Chairperson Serpa noted that in both the February and March minutes on page 2 the term "<825> – Preparation" should be corrected to read "<825> – Radiopharmaceuticals Preparation."

The committee agreed with the changes to both minutes.

Motion: Approve the February 20, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Weisser/Law

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			
Serpa	x			
Weisser	x			

5. Approval of the March 13, 2019 Meeting Minutes

Motion: Approve the March 13, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Schaad/Weisser

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			
Serpa	x			
Weisser	x			

6. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for June 4, 2019, in Sacramento. She added that the July meeting has been rescheduled to July 11, 2019, in Sacramento. Chairperson Serpa noted that the board's website has been updated to reflect the new meeting date.

7. Adjournment

Chairperson Serpa adjourned the meeting at 11:25 a.m.