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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SIERRA NEVADA MEMORIAL HOSPITAL DBA SIERRA NEVADA MEMORIAL HOSPITAL PHARMACY; KATHERINE MEDEIROS, CEO** **JONATHAN STONE, PIC** **155 Glasson Way** **Grass Valley, CA 95945** **Hospital Pharmacy License No. HSP 20878** **Sterile Compounding Permit Number No. LSC 100095** **JONATHAN STONE** **15168 Brewer Road** **Grass Valley, CA 95949** **Pharmacist License No. RPH 33248** Respondents.	Case No. 6247 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about September 1, 1978, the Board of Pharmacy issued Hospital Pharmacy license number HSP 20878 to Sierra Nevada Memorial Hospital dba Sierra Nevada Memorial

Hospital Pharmacy; (Respondent Pharmacy). On or about August 29, 2006, Katherine Medeiros became the Chief Executive Officer (CEO) of Respondent Pharmacy. On or about April 21, 2008, Jonathan Stone became the Pharmacist in Charge (PIC) of Respondent Pharmacy. The Hospital Pharmacy license was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2018, unless renewed.

3. On or about June 21, 2014, the Board of Pharmacy issued Sterile Compounding Permit number LSC 100095 to Respondent Pharmacy. The Permit was in full force and effect at all times relevant to the charges brought herein and was suspended pursuant to a Cease and Desist Order issued on or about September 8, 2017.

4. On or about August 21, 1979, the Board of Pharmacy issued Pharmacist license number RPH 33248 to Jonathan Stone (Respondent Stone). The Pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2019, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4300 of the Code states in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

"...

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

7. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

8. Section 4301 of the Code states in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"...

"(b) Incompetence.

"...

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

9. Section 4306.5 of the Code states in pertinent part:

"Unprofessional conduct for a pharmacist may include any of the following:

"(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in

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the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board."

CALIFORNIA CODE OF REGULATIONS

10. California Code of Regulations, title 16, (Regulations) section 1735.1 states in pertinent part:

"...

"(ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

"...

"(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations."

11. Regulations section 1735.2, subdivision (i), states in pertinent part:

"(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

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12. Regulations section 1735.3 states in pertinent part:

"(a) For each compounded drug preparation, pharmacy records shall include:

"...

"(D) The identity of the pharmacist reviewing the final drug preparation.

"(E) The quantity of each ingredient used in compounding the drug preparation.

"...

"(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation."

13. Regulations section 1735.6, subdivision (d) states:

"Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs."

14. Regulations section 1751 states in pertinent part:

"...

"(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.7 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

"...

"(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-

(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3)."

15. Regulations section 1751.1 states in pertinent part:

"(a) In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:

"...

"(5) Video of smoke studies in all ISO certified spaces."

16. Regulations section 1751.3 states in pertinent part:

"(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

"...

"(11) Hand hygiene and garbing.

"...

"(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins."

17. Regulations section 1751.4 states in pertinent part:

"(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

"(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

"...

"(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or

area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years...

"...

"(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns."

18. Regulations section 1751.5 states:

"(a) When compounding sterile drug preparations the following standards must be met:

"(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

"(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area.

"(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

"(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

"(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

"(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied."

"(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator)."

19. Regulations section 1751.6 states:

"(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:

"(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

"(A) Aseptic technique.

"(B) Pharmaceutical calculations and terminology.

"(C) Sterile preparation compounding documentation.

"(D) Quality assurance procedures.

"(E) Aseptic preparation procedures.

"(F) Proper hand hygiene, gowning and gloving technique.

"(G) General conduct in the controlled area (aseptic area practices).

"(H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.

"(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

"(J) Container, equipment, and closure system selection.

"(2) Each person engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years."

20. Regulations section 1751.7, subdivision (b), states:

"(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is

detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

"(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

"(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

"(A) the quality assurance program yields an unacceptable result,

"(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

"(4) The pharmacy must document the validation and revalidation process.

21. Regulations section 1751.8 states:

"In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

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"(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures."

COST RECOVERY

22. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

BACKGROUND INFORMATION

23. On or about August 13, 2014, Inspector P. for the Board conducted a sterile compounding inspection at Respondent Pharmacy's premises. Inspector P. documented that there

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was a sink within three (3) inches of the hood used for hazardous compounding, that staff did not have sufficient training in hazardous compounding, that compounding worksheets needed to include quantities, lots, and expiration dates, and that policies and procedures (P&Ps) did not include cleaning and disinfection of the compounding area.

24. On or about July 30, 2015, Inspector W. for the Board conducted a sterile compounding inspection at Respondent Pharmacy's premises. Inspector W. documented that Respondent Pharmacy's pharmacists and technicians did not have adequate compounding training.

25. On or about August 3, 2016, Inspector W. for the Board conducted a sterile compounding inspection at Respondent Pharmacy's premises. Inspector W. documented that Respondents failed to have lot numbers on log sheets, that staff failed to garb for either hazardous or non-hazardous compounding, and that pharmacist staff competencies were pending.

26. On or about July 18, 2017, Inspector P. conducted a sterile compounding inspection at Respondent Pharmacy's premises. This inspection found multiple violations of pharmacy laws and regulations as set forth below.

27. On September 8, 2017, the Board issued a cease and desist letter to Respondent Pharmacy which required the Pharmacy to cease sterile and hazardous compounding.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Incompetence)

28. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (b), in that they demonstrated acts of incompetence as follows:

a. Between January 1, 2017 and September 8, 2017, Respondents knowingly compounded dangerous drugs in compounding units which were unsafe and not compliant with regulations.

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b. On or about July 19, 2017, the Board directed Respondents to only compound low risk[1] drug products. Respondents knowingly compounded medium risk drug products despite this directive.

c. After July 19, 2017, Respondents knowingly continued to compound hazardous drugs in a compounding unit which was both unsafe and non-compliant with regulations. Specifically, on July 19, 2017, Respondent Stone asked permission from the Board to compound Vidaza for one (1) patient, which the Board allowed. However, Respondents then continued to compound hazardous drugs for multiple patients for several weeks.

d. Respondents documented cleaning the compounding area weekly when in fact cleaning was conducted monthly.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Misuse of Education)

29. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that in and between January 1, 2017, and September 8, 2017, pharmacists, while employed by Respondent Pharmacy and under the direction of Respondent Stone, committed acts or omissions involving the inappropriate exercise of their education, training, or experience as a pharmacist. The circumstances are as follows:

a. Pharmacists failed to ensure aseptic procedures were followed by all compounding staff.

b. Pharmacists knowingly and purposely used non-compliant compounding units for the purpose of compounding dangerous drugs.

c. Pharmacists failed to fully maintain patient specific information pertaining to compounding worksheets. Pharmacists were directed on several occasions to provide a lot or patient-specific reference number for each compounded drug product, but they failed to do so. This resulted in an inability to identify patients who received the product.

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[1] High, Medium and Low risk compounding products are defined by the United States Pharmacopeia Convention (USP) Chapter 797.

d. Pharmacists continued to use compounding hoods even after they knew the hoods were unable to be certified pursuant to regulations.

e. Pharmacists continued to compound medium risk drug products after being instructed by the Board to only compound low risk drug products.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Beyond Use Dates)

30. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations sections 1735.2, subdivision (i), and 1751.8, subdivision (e), by extending Beyond Use Dates (BUDs) past the appropriate safety limitations. The circumstances are that between January 1, 2017, and July 18, 2017, Respondents gave up to twelve (12) hour BUDs on compounded drug products compounded in non-compliant compounding units. The compounded drug product BUD should not have exceeded immediate risk[2] compounding, which requires a one (1) hour BUD.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Smoke Studies)

31. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations sections 1751.1, subdivision (a)(5), and 1751.4, subdivision (i), by failing to complete required smoke studies. The circumstances are as follows:

a. Respondents failed to conduct smoke studies to demonstrate proof of unidirectional airflow in their compounding hoods, and no smoke study was available within the pharmacy records.

b. On or about July 18, 2017, Respondents informed Inspector P. that smoke studies had been completed when in fact they had not been, and Respondents were made aware

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[2] Immediate Risk compounding is an exemption to USP 797 that allows certain sterile products to be compounded without full compounding practices and facilities. Immediate risk compounding requires administration of the drug compound to occur within one (1) hour.

that the smoke studies had not been completed because the compounding hoods would have failed if such a study was performed.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Substandard Facility Equipment)

32. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations sections 1751.4, subdivisions (a), (b), and (f), and 1735.6, subdivision (d), by using substandard facility equipment. The circumstances are as follows:

a. Respondents used compounding hoods which did not meet certification guidelines. Respondents' compounding hoods used turbulent air flow instead of the required unidirectional flow.

b. Respondents failed to provide compounding staff with proper attire for compounding and failed to restrict the designated compounding area to individuals who were properly attired for compounding. In addition, Respondents' compounding staff were unaware and untrained regarding proper garbing and handwashing techniques.

c. Respondents failed to clean or maintain cleaning logs for compounding hood #3 for the month of August 2017, when the hood was in use during that month.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Location of Sink in Compounding Area)

33. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations sections 1735.1, subdivision (af), and 1751, subdivision (b)(3), by having a sink in the compounding area. The circumstances are that Respondents had a sink directly next to and less than three (3) feet away from a compounding hood used for hazardous compounding.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Sterile Compounding Policies and Procedures)

34. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations section 1751.3,

subdivision (a), by failing to have and ensure compliance with compounding policies and procedures (P&Ps) that comply with Regulations. The circumstances are as follows:

a. Respondents failed to have an adequate and complete P&Ps with appropriate garbing and handwashing procedures.

b. Respondents failed to ensure that pharmacists and technicians had knowledge of appropriate garbing and handwashing techniques.

c. Respondents' P&Ps stated that process validation shall be conducted for any type of procedure or technique. Respondents' staff failed to conduct any process validation prior to compounding hazardous drugs.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Media Fill and Fingertip Process Validation)

35. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations section 1751.7, subdivision (b)(1), by failing to complete media fill and fingertip process validation prior to conducting hazardous compounding. The circumstances are as follows:

a. Respondents conducted sterile compounding in a compounding hood specified for hazardous compounding.

b. Several of Respondents' employees conducting compounding had not completed process validation or finger-tip testing prior to conducting hazardous compounding in the hazardous compounding hood.

c. Respondents failed to revalidate their process on aseptic technique and aseptic area practices after conducting sterile compounding in the hazardous compounding hood.

NINTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Garbing and Handwashing)

36. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations section 1751.5, subdivision (a), by ensuring that all staff were trained and completed appropriate garbing and handwashing prior to compounding. The circumstances are as follows:

a. On or about July 18, 2017, Respondents' staff demonstrated lack of knowledge and training relating to garbing and aseptic techniques. Staff demonstrated garbing by donning a gown prior to hand washing, donning dirtiest garb after cleanest, and failing to wear face masks.

b. Respondents failed to provide face masks to their staff for use during compounding.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Compounding Training)

37. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations section 1751.6, subdivision (e), by failing to complete compounding training prior to conducting sterile compounding. The circumstances are as follows:

a. Respondent Stone was not trained in all aspects of sterile compounding, yet Respondent Stone reviewed training for the pharmacist supervisor of sterile compounding.

b. Respondents failed to grade compounding training tests completed by staff members, and when graded, several test answers were incorrect.

c. There was no documentation that Staff completed didactic hazardous compounding training prior to conducting hazardous compounding.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Pharmacist Review Prior to Compounding)

38. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulation section 1751.3, subdivision (a)(22), by failing to have a pharmacist review compounding information prior to compounding. The circumstances are as follows:

a. Respondents failed to have a P&P requiring pharmacists to review, determine, and approve ingredients and compounding processes for each compounded drug prior to commencing compounding.

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b. Respondents failed to show that pharmacists completed a review, determination, and approval of ingredients and compounding processes for each compounded drug prior to commencing compounding.

TWELFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Records of Compounded Products)

39. Respondents, and each of them, are subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondents failed to comply with Regulations section 1735.3, subdivisions (a)(D), (a)(E), and (a)(G), by failing to record completion of compounded drug products in a manner compliant with regulations. The circumstances are as follows:

a. Subdivision (a)(D): Respondents failed to have pharmacists conduct verification of compounded drug products on the following dates:

April 25, 2017	Ferumoxytol
July 4, 2017	Ondansetron 8mg/Dexamethasone 8mg
July 14, 2017	Pemetrexed Paclitaxel Gemcitabine
July 17, 2017	Paclitaxel Carboplatin
July 18, 2017	Azacytidine
July 24, 2017	Ferric Carboxymaltose
July 29, 2017	Infliximab 400mg
August 5, 2017	Furosemide 100mg
August 11, 2017	Folic Acid 0.2mg/Thiamine 100mg
August 17, 2017	Iron Dextran 1000mg
August 18, 2017	Pembrolizumab 200mg Trastuzumab-herceptin 240mg
August 20, 2017	Ascorbic Acid + Calcium Gluconate Magnesium 2gm Ondansetron 8mg
August 21, 2017	Aztreonam 500mg Fosaprepitant 150mg

b. Subdivision (a)(E): Respondents' compounding worksheets did not contain all ingredients used in compounding the drug preparation. Respondents' compounding worksheets and logs failed to identify the reconstitution ingredients and failed to state the quantity of each ingredient.

c. Subdivision (a)(G): Respondents' compounding worksheets and logs failed to contain a pharmacy-assigned unique reference or lot number for the compounded drug preparation.

DISCIPLINE CONSIDERATIONS

40. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about August 5, 1996, in a prior disciplinary action entitled *In the Matter of the Accusation Against Sierra Nevada Memorial Hospital Pharmacy and William Turiace, PIC*, before the Board of Pharmacy, in Case Number 1823, Respondent Pharmacy's license was revoked, with the revocation stayed for a probation term of three (3) years during which time Respondent Pharmacy was required to comply with specified conditions of probation. The causes for discipline included: 1) unprofessional conduct for failing to maintain a current inventory of controlled substances; 2) unprofessional conduct for failing to maintain records of purchase, receiving, and distribution records, and 3) unprofessional conduct for failing to provide effective controls and procedures to guard against theft and diversion of controlled substances. These failures caused unexplained discrepancies in Respondents' actual inventory of controlled substances. That decision is now final and is incorporated by reference as if fully set forth.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Hospital Pharmacy License number HSP 20878, issued to Sierra Nevada Memorial Hospital dba Sierra Nevada Memorial Hospital Pharmacy; Katherine Medeiros, CEO;

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2. Revoking or suspending Sterile Compounding Permit number LSC 100095, issued to Sierra Nevada Memorial Hospital dba Sierra Nevada Memorial Hospital Pharmacy; Katherine Medeiros, CEO;

3. Revoking or suspending Pharmacist License number RPH 33248, issued to Jonathan Stone;

4. Ordering Sierra Nevada Memorial Hospital dba Sierra Nevada Memorial Hospital Pharmacy; Katherine Medeiros, CEO and Jonathan Stone to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

5. Taking such other and further action as deemed necessary and proper.

DATED: 3/30/18

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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