RESPONSE TO NEW MEXICO VETERANS AFFAIRS HEALTH CARE SERVICE, ALBUQUERQUE, NEW MEXICO:

REPORT TO THE OFFICE OF SPECIAL COUNSEL FILE NUMBER DI-15-2103

DATED 29 OCTOBER 2015

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June 21, 2016

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RE: OSC File No. DI-15-2103

June 21, 2016

Attorney Bradley:

I am responding to the findings from the Veterans Administration report: Report to the Office of Special Counsel, OSC File No. DI-15-2103. Albuquerque, NM: New Mexico Veterans Affairs Health Care System.

The report is adequate but not complete. I must emphasize again that this facility's Sterile Processing Service Unit operated outside of the governance of the United States government with the knowledge of its administrative leadership. I charge also that VISN-18 is also at fault for not correcting or calling to attention these questionable practices.

The gross mismanagement, complete disregard of aseptic techniques, and incompetence of this SPS Unit placed many veterans at risk. Many opportunities were presented to correct these deviations of industry protocol but this unit elected to continue to operate within their own aura of arrogant comfort. It should not be condoned.

When my attempts to resolve these matters internally proved futile, I turned to lawmakers at the local, state and federal levels, as well as, veterans groups and veterans congressional oversight committees. Labeled as a troublemaker, and with great personal sacrifice endured by me and my family, I was forced to leave my job of fifteen years and take this path in order to be heard. It should not have been this way.

I pray that my words make a difference.

Alfred Edward Smith III

1. Surgical technicians habitually fail to conduct point of use cleaning of reusable medical equipment (RME) and often commingle used RME.

Biofilm and Cross Contamination

Biofilm is the matrix that contains living and dead cells and a polysaccharide that is exuded by microorganisms when they grow in water or water solutions or in vivo (bloodstream). Biofilm prevents antimicrobial agents such as sterilants, disinfectants, and antibiotics from reaching microorganisms. (Lind, pg. 467).

Cross contamination is the *migration of contaminants from one person, object, or work location to another.* (Lind, pg. 473). As the report indicates, the surgery technicians acknowledged that they did/do commingle RME; this is in fact cross contamination. (OSC, 29 October 2015)

The Central Service Technical Manual, (CSTM), states in part "…*Point of use preparation (removal of gross soil*, (bio-burden), *should be removed immediately after use…*" (Lind, pg. 125). This is the responsibility of the end user, (surgery unit) not SPS personnel.

Referencing the Department of Veterans Affairs New Mexico Veterans Affairs Health Care System (NMVAHCS), *Report to the Office of Special Counsel*, dated October 29, 2015, (OSC, 2015 October 29) in less cases than most, photographs were taken of surgical case carts that were returned to the Sterile Processing Service (SPS) in haphazard condition, i.e. foreign fluids pooling and dried, visible bio-burden (blood, tissue, bone), with delicate instruments and bulky equipment crammed into a surgical case cart. It was not uncommon to see instrument strewn in and or missing.

Quality Feedback module

The Censitrac Quality Feedback module is a component that allows documentation of events that requires a corrective action. Broken, missing, in need of sharpening, requiring re-cleaning, or the general negative condition of RME could be documented by all SPS personnel with access. This module assigns an event number and generates an email daily to SPS managers for corrective action. I made use of this module on a daily basis and can attest to the fact that there were many times more instances of surgery case carts that were received in the Decontamination Unit than was photographed by SPS managers.

The report (OSC, 29 October 2015) makes reference to the use of a wetting agent, Prepzyme, to break down the contaminants on the RME. Documented also in the report is a reference to the fact that surgery case carts *are not reprocessed within the 4 hour period of time*; either they are awaiting transport at the transporters convenience or in a holding pattern in the Decontamination Unit. (OSC, 29 October 2015). On this premise, I suggest that the decontaminations and cleanings were questionable due to the buildup of biofilm and the time that it took to actually reprocess.

Wetting Agent

Dr. Michelle J. Alfa, Ph.D., FCCM, Professor, University of Manitoba, Principal Investigator, St. Boniface Research Centre Winnipeg, Canada is a distinguished microbiologist and infectious disease specialist. Her area of expertise includes research in Clostridium difficile infections:

spore reservoirs in the healthcare environment Medical device associated infections: role of cleaning errors in infection transmission settings.

She notes that the consistent hydrating (wetting) of complex medical devices creates a biofilm that can transmit infectious disease to patients in a healthcare setting. (Alfa, 2012 September 19). She points out that in the case of complex surgical instruments and endoscopes; the healthcare industry continues to face challenges. (Interview, 2016).

Transport time

NMVAHCS Albuquerque surgery procedures number of cases varied daily, but a conservative estimate would be that there was an average of twenty (20) cases per day in the surgical unit. Procedures commenced at approximately 0730-0800 daily; the average time of each surgery varied, but one hour and thirty minutes (1.5) was the average time of a procedure; if the majority of the cases were transported to SPS within fifteen (15) minutes upon completion of the procedure, more than half of the case carts would have completed the decontamination phase of reprocessing and not have multiple required wettings (hydrating) by OR/SPS personnel. I believe it is safe to assume that SPS personnel did not reprocess delivered surgery case carts and other RME delivered by and from clinics throughout the facility in a timely manner.

Dental RME

The cleaning of the dental RME presented several problems: the dental cassettes (container) are not adequate to contain the different types of procedural trays. These cassettes permit sharp pointed tips to involuntarily protrude through that presents a poke risk to whoever handled them.

Additionally, after packaging, there is the on-going risk that the packaging can be compromised by handling by these sharp tips. In the sterile prep unit, SPS technicians do not wear gloves. Secondly, dentists were in the custom of customizing their dental trays (cassettes), so, inventory of the count sheet was time consuming and difficult. Third, closing the cassette was at times difficult, and again there always existed the "poke through" risk.

The report notes that during an inspection of stored dental RME "*we found over a dozen oil-stained packages containing sterilized dental hand pieces, a violation of MCM 129-2 and AORN* standards*."* (OSC, 29 October 2015).

Dental Hand piece

I possessed specialized training with dental equipment and availed myself numerous times, pointing out to my supervisor and lead technician that in the case of dental slow and high speed hand pieces, they were not being cleaned correctly. The hand pieces were not being disassembled and cleaned to remove the *dried coagulated blood* inside the hand pieces in accordance with the manufacturers' instructions. This was a procedure I was formally trained for and performed on a regular basis while assigned to VA Central Iowa Health Care Service Des Moines and Indianapolis VAMC. I also pointed out that the current SOP's did not indicate the proper cleaning of the hand pieces. These hand pieces came in direct contact (mouth) with multiple patients.

The majority of infections after surgical or diagnostic procedures are endogenous and is caused by the patients' own microorganisms derived from their skin or mucous membranes. However, there are infections that arise from exogenous sources such as contaminated medical devices.

These exogenous infections are preventable because reprocessing of medical devices should ensure that the device is safe for the next-patient use. Dr. Michelle J. Alfa

Collection of RME

Collection of clinic pickup of RME, presented its own issues as well. For administrative purposes, there was a posted schedule. This schedule included clinics that required daily pickups and clinics that were on-call for pickup. The pickup required an SPS technician to collect containers of contaminated scopes, individual and trays of instrument sets, and soiled equipment from various floors. The average time it took to go from floor to floor to collect was at least one (1) hour. It was not unusual to make two trips; the day shift SPS personnel would not routinely make pickups when the schedule indicated they should. This meant that evening shift personnel would minus one individual at the beginning of the shift to collect used RME from the entire day, which would require multiple trips, i.e. more time. To cut the time down, we would work in teams of two persons to collect the RME.

RME Collection Compromise

At a monthly staff meeting, I suggested that the day shift add an afternoon pickup shortly before the arrival of the evening shift (2:30); I reasoned that if one person could pick up the dental and specialty clinics, and place them in the sink to soak, we could have them reprocessed first. The day shift supervisor/assistant chief was not in agreement with this concept and she voiced to me that she was against this proposal. I explained that the current clinic collection schedule worked

against us all as a team. Something had to be done to make better use of time. The chief set a compromise, stating that we would 'try" this method for a period of six (6) months.

Daily, at shift change meetings, we would ask if the pickup was done, and were told no, there had not been time, or some variation of there was nothing to collect. After a month, I inquired to a couple of members of the day shift and was told that the chief had rescinded this plan. Apparently our supervisor was made aware of this but he failed to pass the information on to the shift, even though we clearly asked about this in the daily report change over meetings.

RME that was collected by the Logistics staff *sat for days* in the Decontamination Unit in plain sight for shift to work. This equipment was not cleaned in a timely manner. This included pain pumps, SCD machines, monitors, poles, etc. The reasoning was that the day shift were not compelled to clean them because they were not asked to, the evening shift was busy reprocessing surgery case carts and clinic RME and the night shift was tasked with ensuring that the last minute details for the surgery cases for the upcoming days procedures were correct. It was not unusual to see them come into the Decontamination Unit and ask or pick out what they needed and clean it themselves.

Clarification of HIV/vCJD

My inference in the report regarding Variant Creutzfeldt-Jakob Disease (vCJD) a rare, degenerative, fatal brain disorder in humans and Human Immunodeficiency Virus infection and Acquired Immune Deficiency syndrome (HIV-AIDS) a spectrum of conditions caused by infection with the human immunodeficiency virus, was taken slightly out of context. As Sterile

Processing Technicians, *the nature of our job duties places us in harm's way for exposure to harmful microorganisms.* (Lind, pg. 60).

The CSTM states that the only way an individual can acquire this disease is if the AIDS virus invades the individuals' bloodstream. (Lind, pg. 135). I questioned this due to the poke risk associated on the sterile prep side and the questionable cleanliness of the RME as I have recently outlined in this document.

I am apprehensive of the notion that even though commingling of RME existed, that there existed no risk due to the conditions that existed during my employment there as outlined by the report and by my own observations. Universal precautions were not routinely observed or enforced. Changing of gloves in decontamination area was not a routine. Techs routinely cleaned RME in the same unmonitored sinks with the same enzymatic wash detergents as long as it did not appear too contaminated to work with; the same is true of the ultra-sonic washers as well. Solutions were not used in accordance with IFU's. SPS techs routinely left the area for breaks and returned and resumed work in the sterile area without so much as washing their hands. The hand washing station was removed from the sterile prep area to make room for the new SPS workstations. Documentation of daily, weekly and semi-annual cleaning and maintenance of sterilizers, per manufacturer and industry standard was virtually non-existent because it did not happen as it was supposed to.

Training

The rescinding of VHA Handbook and Directive 7176 did not leave SPS blind, in regards to protocols and procedures. The Central Service Technical Manual (Lind, 2007) published by the

International Association of Healthcare Central Service Material Management (IAHCSMM) also served SPS professionals exclusively. It continues to provide quality education to SPS personnel from the basics, specialty sessions and management level. Certification through IAHCSMM is the standard.

I communicated to SPS management verbally and in writing the need for more formal education for myself and colleagues. Due to the pressure to reprocess within time and resources constraints, training consisted of stopping at a break interval, reading outdated SOP's, signing and continuing the work to meet requirements for the next day. This was continuous for the years I was there. Only a select few personnel were permitted to represent NMVAHCS Albuquerque. From this, information was not disseminated to the staff. Not even a handout. I communicated this to the VA- on July 29, 2015 (teleconference) and a subsequent personal interview at NMVAHCS, Albuquerque on August 4, 2015.

2. Sterile Processing Service (SPS) employees regularly fail to use tracking software to account for individual trays of RME and do not follow SPS protocols.

When the Censes Implementation Team was onsite to install Censitrac, I, as well as SPS Technician Will Torres volunteered to assist. We both came from facilities that had been using this software and we were both eager to assist NMVAHCS Albuquerque. There were many lessons learned from our experiences and we both wanted to own this project to make our service successful. We were not utilized. The substantiated findings by VA are adequate.

3. SPS employees improperly alter cleaning test data for endoscope and dental equipment to show negative test results.

Censitrac Records Altering

Censis Censitrac Tracking System Biological tests results *were altered* by SPS management to meet and accommodate the demands of the OR (customer). Instead of reprocessing the questionable loads, SPS simply annotated in Censitrac (Recording Load Information) a justifiable reason for the change, i.e. forgot to crush the exposed vial (prior to incubation). There were instances additionally where loads were run without a biological control as well. To my knowledge, complaints were referred to The Joint Commission, an independent non-profit organization. (The Joint, 21 June 2016). There was at least one site visit (inspection) conducted but the staff was not made aware of the findings.

According to the Society of Gastroenterology Nurses and Associates (SGNA), every reported case of hospital acquired infection associated with a contaminated GI endoscope has been linked to a breach or violation of at least one of several requisite reprocessing steps. “Failure to adhere to established reprocessing guidelines or the use of defective equipment accounts for all of the reported cases of bacterial and viral transmissions.” (Patient Safety, 21 June 2016).

4. SPS decontamination and sterile processing areas are not cleaned on a regular basis.

EMS

The daily cleaning of the SPS department required an EMS technician as specialized as we were. During the time of my employment, there was such a person assigned, EMS Technician George Halona. George Halona provided us with extremely good service.

When this individual was not present for duty we suffered. Because he was pulled away to other duties or not present for duties, when we did receive another EMS technician, he/she was not trained. I can recall vividly reporting for work in the evening and our trash bins were already full, meaning no one had come to collect the trash. Housekeeping is important in a healthcare facility, but even more so in SPS. At the time of my communication of my concerns to the VA, it was lacking. I appreciate the information provided in the report regarding the quality of service being received.

For consideration

The June 2009 report by the Department of Veterans Affairs leadership to the Sub Committee on Oversight and Investigations 111th Congress (Hearing, 2009 June, 16) serves as a stark reminder to what happens when healthcare professionals fail. Unfortunately, the questions asked at that time to correct the deficient conditions that existed at that time prior, could and should be utilized again to demonstrate that Department of Veterans Affairs willingness to listen to its professionals and learn from the mistakes that are made time and time again.

I started working in Sterile Processing as a Medical Supply Technician Aide, in September 2008 at the Indianapolis VAMC (Richard L. Roudebush). I was mentored by the best this occupational field has to offer. I witnessed the fallout of the failings of the colonoscope scandal of 2009. (VAOIG, September 17, 2009) As I struggled to comprehend and put to use my Level I

and Level II training, I was afforded the opportunity to see the severe negative impact of what happens when SPD fails. I vowed this would not happen on my watch.

I am at a loss to comprehend, as a retired veteran, and former government employee how the issues I have raised were allowed to grow at the rate they have, yet be ignored by the very persons charged with ensuring that this facility operate daily as a lifeline for the veterans who are more than deserving of healthcare services.

New Mexico Health Care Service Albuquerque is named after a Marine Medal of Honor recipient Captain Raymond G. Murphy, who dedicated his life after his distinguished military career as an employee and volunteer for the Veterans Administration. It is also supposed to be an example of the benefits of American freedom. There needs to be a complete public accounting of these matters for the persons who were placed at risk and who have suffered as a result of this disregard for public safety.

I would hope that my clarification(s) assist in creating and fostering a better work environment that is deserving of the people who have dedicated themselves to make this their life's work for the veterans and American people.

Semper Fidelis

Alfred Edward Smith III

USMCR Retired

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Attachments area

Preview YouTube video Interview Dr. Michelle Alfa : The critical role of biofilm


Can failure to clean endoscopes potentially lead to infection transmission ?