Evaluation of Worker Exposures to Peracetic Acid-Based Sterilant during Endoscope Reprocessing

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Health Hazard Evaluation Report
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Centers for Disease Control and Prevention
NIOSH *National Institute for Occupational Safety and Health*

The employer shall post a copy of this report for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. [37 FR 23640, November 7, 1972, as amended at 45 FR 2653, January 14, 1980].

Contents

Report

Acknowledgments

ABBREVIATIONS

ACGIH®	American Conference of Governmental Industrial Hygienists
BGH	Buffalo General Hospital
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
FDA	United States Food and Drug Administration
HVAC	Heating, ventilating, and air-conditioning
HHE	Health hazard evaluation
LOD	Limit of detection
mL/min	milliliters per minute
NAICS	North American Industry Classification System
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational exposure limit
OPA	*ortho*-Phthalaldehyde
OSHA	Occupational Safety and Health Administration
PAA	Peracetic acid
PBZ	Personal breathing zone
PPE	Personal protective equipment
ppm	Parts per million
REL	Recommended exposure limit
RH	Relative humidity
SS1	Steris SYSTEM 1® Processing System
TWA	Time-weighted average

Highlights of the NIOSH Health Hazard Evaluation

In July 2006, the National Institute for Occupational Safety and Health (NIOSH) received a confidential health hazard evaluation (HHE) request from employees at Kaleida Health-Buffalo General Hospital in Buffalo, New York. The HHE request stated that inadequate ventilation was provided in the A2 GI Lab Steris Room where five employees clean and sterilize endoscopes using Klenzyme® Enzymatic Cleaner and Steris® 20 Sterilant Concentrate. Health problems identified in the request were headache, shortness of breath, eye irritation, and diminished sense of smell. We conducted a site visit on December 18–19, 2006.

What NIOSH Did

- We met with management, employees, and a union representative to discuss employee concerns.
- We toured the A2 GI Lab Steris Room and observed staff at work.
- We collected area and personal air samples for acetic and peracetic acids.
- We measured temperature and relative humidity.
- We used smoke tubes to observe airflow patterns in the A2 GI Lab Steris Room.
- We spoke with employees confidentially about possible work-related symptoms, safety and health training, use of personal protective equipment (PPE), chemical exposure incidents, and indoor environmental quality.
- We looked at Food and Drug Administration reports of sterilant spills, worker exposures, and injuries during endoscope reprocessing at other hospitals to identify possible causes of problems reported at this facility.

What NIOSH Found

- Concentrations of peracetic acid are thought to be low, although we could not measure current levels.
- Latex gloves worn while handling peracetic acid sterilant containers do not provide adequate protection.
- Some workers reported not using all available PPE (aprons and sleeve protectors) due to high temperatures in the A2 GI Lab Steris Room.
- Two workers reported prior chemical burns from contact with Steris 20 Sterilant Concentrate.
- Employees did not receive adequate training in chemical hazard communication and in standard operating procedures for chemical spills, leaks, and processor malfunctions.
- Ventilation in the A2 GI Lab Steris Room was inadequate.
- Exposure to peracetic acid sterilant is unlikely when Steris processors are maintained and operated properly and when technicians follow the manufacturer's operating procedures.

What Hospital Managers Can Do

- Require use of appropriate PPE to prevent eye, face, hand, arm, and body contact with concentrated peracetic acid as well as other cleaning chemicals and contaminated equipment.
- Provide hazard communication training for A2 GI Lab Steris Room employees.
- Train employees in standard operating procedures for spills, leaks, and processor malfunctions.
- Ask Steris Corporation to provide new employee and annual refresher inservice training.
- Make sure that processors are inspected periodically for worn parts that can cause leaks.
- Notify Steris Corporation of leaks and equipment problems.
- Increase ventilation in the A2 GI Lab Steris Room for odor control and the comfort of the workers.

What Steris Room Employees Can Do

- Wear tight-fitting splash-resistant goggles and acid-resistant gloves, sleeves, and apron when handling sealed Steris cups during normal operations.
- Wear a face shield over eye protection along with routine PPE when handling or disposing of a cup that is not completely empty.
- Follow the manufacturer's instructions for handling Steris cups and operating processors.
- Tell management about problems with processors or Steris cups, or if you notice worn processor seals or other parts.
- Follow standard operating procedures for processor problems, leaks, and sterilant spills.
- Participate in training when provided.

Summary

In July 2006, NIOSH received a confidential HHE request from employees at Kaleida Health-Buffalo General Hospital in Buffalo, New York. The HHE request stated that inadequate ventilation was provided in the A2 GI Lab Steris Room where five employees clean and sterilize endoscopes with Klenzyme® Enzymatic Cleaner and Steris® 20 Sterilant Concentrate. Health problems identified in the request were headache, shortness of breath, eye irritation, and diminished sense of smell.

On December 18–19, 2006, we conducted a site visit that included an opening conference, a walk-through of the A2 GI Lab Steris Room, air sampling for peracetic and acetic acids, measurements of temperature and RH, smoke tube visualization of airflow, and confidential informal interviews with several employees.

Exposure to peracetic acid sterilant is unlikely when SS1 processors are maintained and operated properly and when technicians follow the manufacturer's operating procedures. Processor malfunctions, and improper handling and disposal of Steris 20 Sterilant Concentrate containers can result in dermal or inhalation exposures.

Air samples did not contain detectable concentrations of acetic acid. Sampling results and our onsite observations indicate very little, if any, airborne exposure to peracetic acid sterilant on the sampling date. The temperature was 74°F to 76°F, and the RH was 17% to 20%. Smoke tube visualization of airflow at the ceiling-mounted ventilation supply diffusers and return grilles in the Steris room indicated that the HVAC system provided insufficient airflow. Ventilation in the Steris room appeared to be inadequate for providing reliable odor control and maintaining the work environment within an acceptable range of temperature and RH.

Employees reported periodic headaches and burning eyes that were more noticeable when SS1 processors malfunctioned and leaked. Poor ventilation and high environmental temperatures were noted by workers. Although gloves, sleeves and aprons are provided, some workers reported not using all available PPE due to high environmental temperatures. Two workers reported prior chemical burns from occupational exposure to Steris 20 Sterilant Concentrate. Several workers reported that they had not received formal chemical hazard communication training for Steris room operations.

A review of FDA CDRH data files indicated that occupational exposure to peracetic acid sterilant should be unlikely when SS1 processors are maintained and operated properly and when technicians follow the manufacturer's operating procedures. However, processor malfunctions and improper handling and disposal of Steris 20 Sterilant Concentrate containers can result in dermal or inhalation exposures. Appropriate employee training,

use of adequate PPE, and routine maintenance of processors should help reduce the likelihood of worker exposures, as well as the risk of employee illness or injury if a spill or leak does occur.

Keywords: NAICS 622110 (General Medical and Surgical Hospitals), endoscope reprocessing, endoscope sterilization, peracetic acid, anosmia, chemical burns, dyspnea, eye irritation, sense of smell, shortness of breath.

In July 2006, NIOSH received a confidential HHE request from employees at Kaleida Health-Buffalo General Hospital in Buffalo, New York. The HHE request stated that inadequate ventilation was provided in the A2 GI Lab Steris Room where five employees clean and sterilize endoscopes using Klenzyme® Enzymatic Cleaner and Steris® 20 Sterilant Concentrate. Health problems identified in the request were headache, shortness of breath, eye irritation, and diminished sense of smell.

Background

Management representatives told us that SS1 had been used at BGH for approximately 10 years prior to our site visit. SS1 was introduced into BGH as a replacement for ethylene oxide sterilization. During the opening conference, management noted that health complaints from employees in the A2 GI Lab Steris Room began in approximately May 2006, following renovations in that area. Full-shift air sampling conducted by a consultant in June 2006 indicated that airborne concentrations of acetic acid were less than 0.2 ppm. Although management was not aware of spills involving SS1 processors, employees had reported occasional leaks. In November 2006, SS1 processors were inspected by a representative from Steris Corporation who identified no problems.

The A2 GI Lab Steris Room is one of several Steris rooms at BGH. Although referred to as a single room, the A2 GI Lab Steris Room is divided into two small rooms ("dirty side" and "clean side," which are separated by a floor-to-ceiling wall with a sliding window. The dirty side adjoins a hospital corridor along a 6-foot wall, which has a single doorway for entry. The length of the room extends approximately 15 feet from the corridor. The dirty side contains a stainless steel counter and sink along the 15-foot wall that separates the dirty and clean sides. The window between these rooms is located a few feet from the most interior wall. Each of these rooms has a plumbed eyewash station.

The clean side is approximately 10 feet wide by 15 feet long, with a single doorway to the corridor. Three SS1 processors are installed on a stainless steel counter near the window between the dirty and clean sides. Two processors are located along the back wall and one along the wall opposite the window. Also along this wall is a GUS® Model G17HS endoscope immersion unit, which contains approximately one-half gallon of Cidex® OPA Solution. The GUS unit is a compact, ductless vapor control system that exhausts into the room via a carbon filter. It is our understanding that the GUS

unit is used infrequently for endoscope disinfection; however, Cidex OPA remains in the unit at all times.

A canopy hood is mounted on the ceiling of the clean side against the wall separating the two small rooms and the most interior (back) wall (the hood is open on two sides). The sides of the hood extend downward to within approximately 4 feet above four of the six processors. The Steris room is provided with ceiling diffusers and returns for general ventilation. Facilities staff informed us that the Steris room is supplied with 100% outside air.

When an endoscopic procedure is completed, the endoscope is brought to the dirty side where a technician manually cleans it using Klenzyme® enzymatic cleaner. After cleaning, the endoscope is passed through the sliding window to a technician in the clean side. The clean side technician installs the appropriate channel connectors, places the endoscope in a processing tray in one of the SS1 processors along with a sealed container of Steris 20 Sterilant Concentrate, closes the processor lid, and starts the microprocessor-controlled operating cycle. When the approximately 30-minute sterilization cycle is finished, the technician opens the processor, removes the endoscope, flushes it with 120 milliliters of isopropyl alcohol, and purges cavities within the endoscope with forced air to remove the alcohol. This procedure is repeated for each endoscope that is returned for cleaning and sterilization. More than one processor may be operating at any given time. The

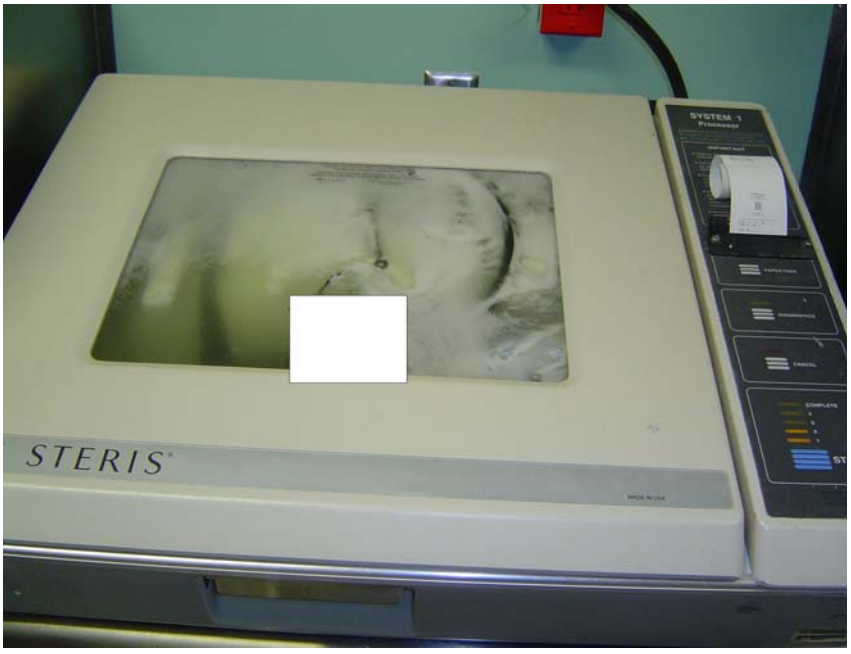

Figure 1. Steris System 1® processor in operation

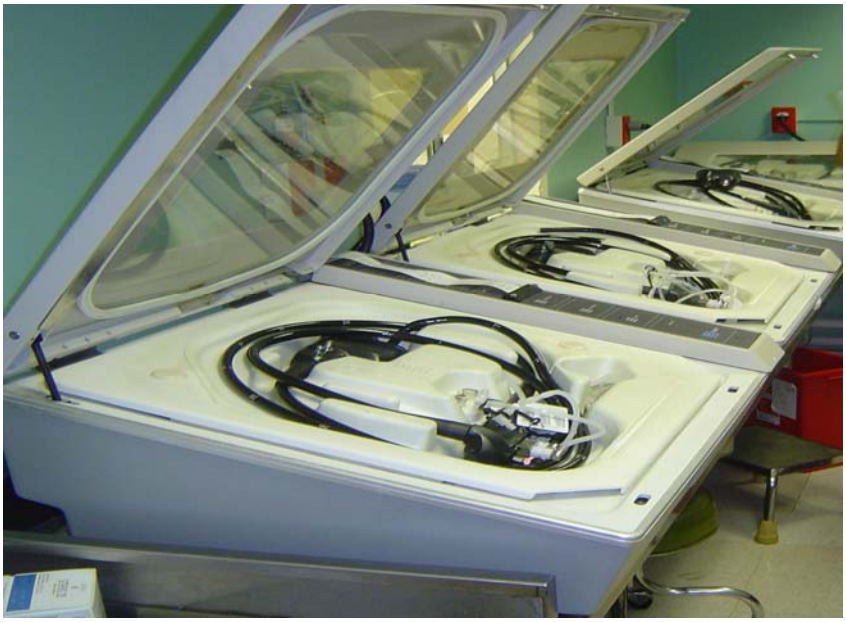

Figure 2. Row of Steris System 1® processors

only PPE that we observed being worn in the clean side during our site visit was latex gloves.

Each SS1 processor is a fully-enclosed tabletop unit. Steris 20 Sterilant Concentrate is provided in sealed single-use containers ("cups") that hold 2.02 fluid ounces (67.5 grams) of liquid and 163.7 grams of powder. The composition of the liquid (% by volume) is 35.5% peracetic acid, 40.0% acetic acid, 6.5% hydrogen peroxide, and 1.0% sulfuric acid [Steris 1995]. The solid powder consists of proprietary builders and buffers [Alfa 2004; Steris 2007]. During the sterilization cycle, the processor aspirates the concentrated liquid sterilant, and dilutes it to a working concentration of 0.2% PAA at a pH of 6.4 and a temperature of 50°C to 56°C [Alfa 2004; Steris 2007]. When diluted, PAA hydrolyzes to acetic acid and hydrogen peroxide with a half-life of less than 20 minutes at 50°C [Steris 1995]. The 0.2 % PAA solution circulates around and through the endoscope for 12 minutes before being discharged into the sewer system. After the sterilant has been discharged from the processor, the processor flushes the endoscope four times with filtered water [Alfa 2004; Steris 2007; Steris 2008]. The technician can open the processor after the final rinse water has been discharged down the drain.

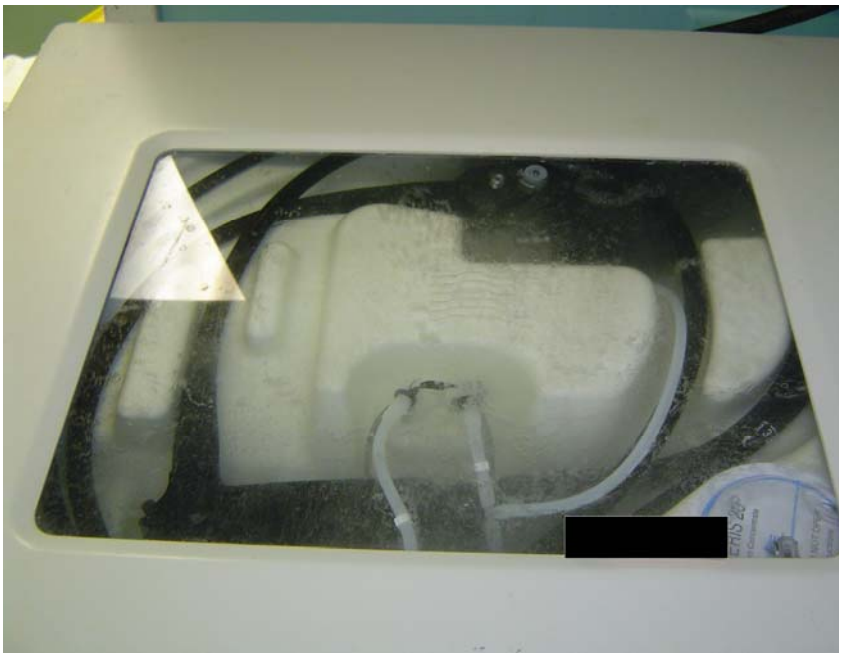

Figure 3. Steris System 1® processor in operation showing Steris 20 Sterilant Concentrate container in lower right corner of the processor.

Contact with Steris 20 Sterilant Concentrate can cause severe irritation and burns to eyes and skin. Animal studies indicate that Steris 20 Sterilant Concentrate may be a sensitizer [Steris 1995]. Inhalation of PAA vapor may cause pulmonary edema and sensitization [IPCS 1994a; Sciencelab.com 2005]. No OELs have been established for PAA [NJDHSS 1998a].

Contact with acetic acid can cause severe irritation and burns to the eyes and skin. Inhalation exposure can cause respiratory irritation, bronchitis, pharyngeal edema, and pulmonary edema [IPCS 1994b; Hathaway et al. 1996; NJDHSS 1998b]. The NIOSH REL for acetic acid is 10 ppm for up to 10 hours per workday during a 40-hour workweek. OSHA and ACGIH have established 8-hour TWA OELs of 10 ppm for acetic acid. In addition, NIOSH and ACGIH recommend that exposures to acetic acid not exceed 15 ppm during any 15-minute exposure during the course of the day (short-term exposure limit) [ACGIH 2009; NIOSH 1992]. The odor threshold for acetic acid is reported to be approximately 0.48 to 1.0 ppm [NJDHSS 1998b].

ASSESSMENT

In response to the HHE request, we conducted a site visit on December 18–19, 2006. The evaluation included an opening conference, a walk-through of the A2 GI Lab Steris Room,

ASSESSMENT (CONTINUED)

air sampling for peracetic and acetic acids, measurements of temperature and RH, and confidential informal interviews with several employees.

Full-shift PBZ air samples were collected for each of the three technicians who were working in the Steris room on December 19. Two area air samples were collected in the clean side. One area air sample was collected in the dirty side at the open window between the dirty and clean sides. Air samples were collected on ORBO™ 53 activated silica gel tubes at a nominal flow rate of 100 mL/min. Samples were analyzed for PAA and acetic acid by high performance liquid chromatography according to a NIOSH draft method. Draeger® short-term colorimetric detection tubes were used to measure the airborne concentration of acetic acid in the clean side while four processors were in operation. These tubes have a standard measurement range of 5 to 80 ppm during a 30 second sampling period [Draeger 2009].

Temperature and RH were measured in the clean side using a hand-held, battery operated, TSI Model 8722 TH-Calc™ Thermal Hygrometer (TSI Inc., Shoreview, Minnesota). This instrument measures temperature and RH in the ranges of 32°F to 140°F and 5% to 95% RH. A ventilation smoke tube was used to visualize airflow patterns within the Steris room and to determine if the clean and dirty sides were under positive or negative pressure relative to each other and to the adjoining corridor.

Confidential, voluntary interviews were conducted with employees who work in the A2 GI Lab Steris Room. Employees were asked about potential work-related health symptoms, safety and health training, PPE use, chemical exposure incidents, and indoor environmental quality.

RESULTS

Industrial Hygiene

Air samples did not contain detectable concentrations of acetic acid. The analytical LOD for acetic acid in the air samples was approximately 25 micrograms of acetic acid per sample [Neumeister 2009]. Based on the LOD and the average volume of the PBZ samples (20.1 liters), acetic acid concentrations in these samples were no greater than 0.5 ppm. The three area air samples, which had an average sample volume of 43 liters, indicated that acetic acid concentrations were no greater than 0.24 ppm. Draeger colorimetric detector tubes did not detect acetic acid in the clean side.

We attempted to quantitate PAA using a draft NIOSH method originally intended for acetic acid; however, PAA coeluted with the solvent front during analysis, which prevented separation and quantitation of PAA. Further efforts to resolve PAA in the samples were not made because (1) acetic acid (a major component of Steris 20 sterilant) was not detected above the LOD; (2) although PAA coeleuted with the solvent front, the area of the chromatogram peak was consistent with the area of the blank samples, indicating that PAA was not present in large quantity; and (3) no acid odor was detected during the sampling visit [Neumeister 2009].

Temperatures in the clean side between 8:50 a.m. and 1:15 p.m. were 74°F to 76°F, and RH was between 17% and 20%. Smoke tube visualization of airflow at the ceiling-mounted ventilation supply diffusers and return grilles in the clean side indicated that the HVAC system provided insufficient airflow. No air appeared to be coming from the supply diffusers. The open doors between the Steris room and the corridor served as the source of make-up air for the canopy hood; there was no other source of outside air. The dirty side appeared to be under slight negative pressure relative to the corridor, while the clean side was under negative pressure relative to the corridor and the dirty side, causing air to flow toward the clean side and out through the canopy hood. Turbulence beneath the canopy hood in the clean side caused smoke to drift away from the Steris processors, rather than being immediately captured and exhausted by the hood.

Interviews

Confidential, voluntary interviews were conducted with four of five employees who work in the A2 GI Lab Steris Room; one employee was on extended family leave and not available to participate. The median length of employment at BGH was 14 years; however, the median length of employment in the A2 GI Lab Steris Room was 13 months, and three of the four employees had worked in the department less than 14 months. Workers reported no formalized, documented initial or refresher hazard communication training in their current assignment at BGH; however, such training had been provided when they were employed in other sections of the hospital. On-the-job training was provided by coworkers with longer tenure in the department; however, two of four employees did not know the proper procedures for responding to a chemical spill or SS1 processor malfunction and overflow.

RESULTS (CONTINUED)

Three employees reported periodic headaches and burning eyes; these symptoms were worse when the processors malfunctioned and overflowed, or when excessive liquid was left in the bottom of the machine after completion of a sterilization cycle. Poor ventilation and high environmental temperatures were common complaints among workers; these conditions were reportedly worse during the summer. Workers reported leaving the doors between both sides of the Steris rooms and the corridor open to improve ventilation, but are instructed by supervisors to keep these doors closed, reportedly due to odor complaints from patients and nursing staff. PPE in the form of chemically resistant, sleeve protectors and aprons are provided by management; however, some workers reported not using all available PPE due to high environmental temperatures. Two workers reported having had chemical burns from prior use of Steris 20 Sterilant Concentrate.

DISCUSSION

On the day of our site visit, we did not smell an acid odor, which we would have noticed if airborne acid vapor concentrations had approached the OELs for acetic acid. This observation is consistent with air sampling results, which indicate that airborne levels of acetic acid were below the analytical LOD. Although exposure limits have not been established for PAA, the sampling results and our onsite observations indicated little, if any, airborne exposure to PAA on the sampling date.

Although we do not know the specific sources of odors reportedly emitted from the Steris room, odor complaints from patients and nursing staff suggest that the ventilation in the Steris room is inadequate. Odor complaints, worker reports of uncomfortably warm temperatures especially during the summer, and our observations during the site visit point to a need for increasing the general ventilation in the Steris room.

While Klenzyme Concentrate Plus Enzymatic Cleaner and Cidex OPA Solution were not the focus of this investigation, it is important to note hazards associated with these products. Klenzyme, which can irritate the skin and eyes, contains proteolytic enzymes, also known as subtilisins. Subtilisins in powder form are a known respiratory sensitizer. In 2001, researchers reported a case of extrinsic allergic alveolitis in a hospital worker who was exposed to subtilisins in Klenzyme that the worker used to wash surgical instruments and clean operating room surfaces [Tripathi and Grammer 2001]. OPA is an eye, skin, and respiratory irritant that may also cause sensitization [Advanced Sterilization Products 2007]. A 2006 article describes a case of occupational asthma and

dermatitis that is believed to be due to exposure to OPA in an endoscopy unit [Fujita et al. 2006]. BGH employees and managers should be aware of the hazards associated with these materials.

The FDA CDRH maintains Adverse Event Reporting Data Files that consist of voluntary reports, user facility reports, distributor reports, and manufacturer reports of medical devices that may have malfunctioned or caused a death or serious injury [USFDA 2009]. To better understand workplace hazards during endoscope reprocessing, we searched the online CDRH data files for adverse event reports received in 1996 through 2008 that involved SS1. Reports involving SS1 were reviewed to identify factors related to worker safety and health at all medical facilities that had submitted reports, or that were described in reports.

Steris 20 Sterilant Concentrate was involved in approximately 50% of the 63 adverse event reports identified during our review. Worker exposure was noted in all but one of these reports. More than 80% of reported exposures to concentrated PAA sterilant resulted in worker injury; most of these incidents occurred while handling a sealed Steris 20 Sterilant Concentrate cup prior to placing the cup into a processor, or while disposing of incompletely emptied cups at the end of a sterilization cycle. The most common type of injury was a chemical burn of the skin, which varied from what appeared to be minor burns, to several reports of second degree burns, and at least one report of a third degree burn. Several instances of eye contact that reportedly resulted in burns and pain were identified. Respiratory exposures to concentrated PAA sterilant resulted in reports of shortness of breath; nasal irritation and scabbing of nasal passages; and rare events, including lung hypertension and pneumonia, and an asthmatic-like reaction in a hospital receptionist.

Eight reports noted that hospital workers were burned when the seal on unopened cups ruptured as the workers squeezed the cups to break up powdered buffers. As reported in three manufacturer narratives, the manufacturer's instructions state that "powders can be broken up by gently squeezing the bottom portion of the Steris 20 container." The manufacturer narratives attributed these incidents to improper handling by the workers. These incidents resulted in reports of burns on hands, arm, eyes, face, neck, and abdomen. In one instance, concentrated PAA sterilant was reportedly splashed onto the eyes, face, and neck of a bystander. In two instances, a cup lid "popped" or leaked as a cup was being removed from its carton.

Discussion (continued)

Ten reports described incidents involving disposal of cups that had expired, or that had not been completely emptied during a sterilization cycle. In most cases, the exposure occurred to the worker who was disposing of the cup; however, two reports noted burns due to contact with concentrated sterilant spilled on work surfaces or furniture, and in one instance, a housekeeping employee reported shortness of breath that was attributed to a Steris cup that had been thrown in the trash. Other reports describe skin and eye contact with concentrated sterilant as a result of cup leaks, improper sterilant storage, and spray released while inserting or removing the SS1 aspirator into/from the sterilant cup.

Only eight reports were identified in which PPE was mentioned. Of these, five noted that PPE had not been used by the exposed worker, and two indicated that the PPE was inadequate. Based on the descriptions of dermal and eye exposures to concentrated PAA sterilant, it appears that worker injuries could have been prevented if appropriate PPE had been used.

Twenty-five reports appear to involve releases of 0.2% PAA sterilant ("use dilution") from SS1 processors. Failure of the inflatable processor lid seal was reported as the cause of most processor leaks. Other leaks occurred when the processor lid opened suddenly during a sterilization cycle, or when defective endoscope trays were used. Only six releases of dilute sterilant resulted in reports of worker exposure. Four reports identified health effects such as eye, skin, or respiratory irritation. Two reports of exposure during cleanup of dilute sterilant described respiratory difficulties: in one instance, a worker was treated with a nebulizer after cleaning a dilute sterilant spill for 10 minutes, and in the second instance, a worker was treated for reactive airways dysfunction syndrome after cleaning a spill for 15 minutes.

Conclusions

Exposure to peracetic acid sterilant is unlikely when SS1 processors are maintained and operated properly, and technicians follow the manufacturer's operating procedures; however, processor malfunctions, improper handling and disposal of Steris 20 Sterilant Concentrate containers, and nonroutine events can result in dermal or inhalation exposures. Even though the sterilant cups are designed to prevent exposure to PAA sterilant, rough handling and accidental or forceful squeezing can result in exposure to the concentrated acid. Appropriate employee training, use of adequate PPE, and routine maintenance of equipment should help reduce the likelihood that such events will occur, and also

DISCUSSION (CONTINUED)

reduce the risk of employee illness or injury if a spill or leak does occur. Ventilation in the Steris room appears to be insufficient for providing reliable odor control and maintaining the work environment within an acceptable range of temperature and RH.

RECOMMENDATIONS

The following recommendations are provided to improve the safety and health of hospital staff that clean and sterilize endoscopes at in the A2 GI Lab Steris Room.

Training

- Conduct and document hazard communication training required by the OSHA Hazard Communication Standard (29 CFR 1910.1200). Training should be provided for new and current employees, and should be designed specifically for A2 GI Lab Steris Room workers. Training should address chemical hazards, exposure controls, and PPE for all chemicals used to process endoscopes, including Steris 20 Sterilant Concentrate, Klenzyme Concentrate Plus Enzymatic Cleaner and Cidex OPA Solution.
- Conduct training for Steris room employees that addresses standard operating procedures in the event of chemical spills, processor malfunctions, and processor leaks. Training should include notification procedures for contacting Environmental Services for spill cleanup.
- Contact Steris Corporation to request new employee initial and annual refresher inservice training for SS1 processor operators. Training should include routine and nonroutine processor operations, handling of unopened sterilant cups, and disposal of incompletely aspirated and expired cups. Annual refresher training would allow a Steris representative to review technicians' technique, and to provide instructions for the proper use and handling of Steris 20 Sterilant Concentrate.

Personal Protective Equipment

- Given the serious nature of injuries that may result from exposure to Steris 20 Sterilant Concentrate, appropriate PPE should be worn by workers when handling both sealed and used containers of Steris 20 Sterilant Concentrate.

- Minimum PPE worn while performing routine tasks involving the handling of sealed Steris cups should include tight-fitting splash-resistant goggles, acid-resistant sleeves and apron, and gloves made of butyl rubber, neoprene rubber, Viton®, or Barrier® [Forsberg and Mansdorf 2007]. Very thin gloves, as typically worn in healthcare settings, provide poor chemical resistance and mechanical strength, and should not be the only barrier between the wearer and a chemical hazard, such as PAA [Forsberg and Mansdorf 2007]. Latex gloves do not provide appropriate protection and introduce a known allergen into the workplace [NIOSH 1997].
- If sterilant remains in a cup at the end of a sterilization cycle, the technician should don additional face protection (e.g., face shield in addition to gloves, sleeves, apron, and eye protection used during normal operations). This PPE should be worn when handling unsealed cups containing any sterilant concentrate, and when disposing of expired sterilant.

Preventive Maintenance and Equipment Malfunctions

- SS1 processors should be inspected periodically for components that can fail due to normal wear, resulting in a leak or worker exposure. These components include aspirator tubing, processor lid seal, and endoscope trays.
- Employees should notify management of all spills, leaks, and equipment malfunctions so that the causes of these events can be identified and appropriate corrective actions can be taken. BGH should notify Steris Corporation of equipment malfunctions and request assistance from Steris in diagnosing and correcting problems.

Ventilation and Indoor Environmental Quality

- The Steris room must be under negative pressure relative to all surrounding areas in order to control odors. The HVAC system serving the Steris room should exhaust completely to the outdoors, i.e., no recirculation. The dirty side should be under negative pressure relative to the clean side to help prevent migration of bioaerosols from the dirty side to the clean side.

Recommendations (continued)

- A minimum of 10 air changes per hour should be provided in the Steris room, with a minimum of 2 air changes of outside air per hour [ASHRAE 2003; ACGIH 2007; ASHRAE 2007].
- Supply diffusers and return grilles need to be located so that supply air reaches room occupants without "short circuiting," i.e., flowing directly from supply diffusers to return ducts without ventilating the occupied space.
- ASHRAE recommends maintaining sterilizer equipment rooms between 72°F and 76°F, with RH between 30% and 60% [ASHRAE 2007].
- Ensure that the GUS Vapor Control System is operating whenever it contains OPA, and that the charcoal filters are changed every 6 months or as advised by PCI Medical, Inc [PCI 2009].

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