INVESTIGATION REPORT

STERIGENICS

(4 Employees Injured)

STERIGENICS

ONTARIO, CALIFORNIA

AUGUST 19, 2004

KEY ISSUES

- PROCESS HAZARD ANALYSIS
- PROCESS DESIGN
- EMPLOYEE TRAINING
- LESSONS LEARNED

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Acronyms and Abbreviations

AIChE	American Institute of Chemical Engineers
CCPS	Center for Chemical Process Safety (AIChE)
CFR	Code of Federal Regulations
CSB	U.S. Chemical Safety and Hazard Investigation Board
EMS	Emergency medical services
EOSA	Ethylene Oxide Sterilization Association
EPA	U.S. Environmental Protection Agency
EO	Ethylene Oxide
HAZCOM	Hazard Communication Standard (OSHA)
HAZOP	Hazards and operability
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PHA	Process hazard analysis
PPE	Personal protective equipment
ppm	Parts per million
PSM	Process Safety Management of Highly Hazardous Chemicals (OSHA)
RMP	Risk Management Program (EPA)

Executive Summary

On August 19, 2004, an explosion at the Sterigenics International, Inc., ethylene oxide (EO) sterilization facility in Ontario, California, injured four workers and caused extensive damage to the 66,000 square-foot facility. Flying glass from the control room windows was responsible for all of the injuries, and both the facility structure and equipment sustained severe damage. The Sterigenics plant and neighboring facilities were evacuated, and plant operations were disrupted for 9 months.

Sterigenics is a contract medical sterilization services provider that specializes in various types of sterilization in the U.S. and around the world. Its EO facility in Ontario performs services for manufacturers of a variety of medical products such as disposable syringes, urinary tract catheters, and cardiovascular stints and valves.

The U.S. Chemical Safety and Hazard Investigation Board (CSB) determined that maintenance personnel overrode safety devices and EO flowed through the ventilation system from a sterilizer to an open-flame catalytic oxidizer (oxidizer) where it ignited. The flame traveled back to the sterilizer chamber through the ventilation system ducting and ignited a large volume of EO in the chamber.

The investigation identified the following root causes:

- Engineering controls installed at the facility did not prevent an explosive concentration of ethylene oxide (EO) from reaching the oxidizer.

- Employees did not understand the hazards associated with the process.

This CSB report makes recommendations to Sterigenics International, Inc., the National Fire Protection Association (NFPA), the National Institute for Occupational Safety and Health (NIOSH), and others.

1.0 INTRODUCTION

On August 19, 2004, an explosion inside an air pollution control device and medical products sterilization chamber at Sterigenics International, Inc., in Ontario, California, injured four workers and severely damaged the facility (see Figure 1). Neighboring businesses were evacuated for several hours and operations at the Ontario facility were disrupted for 9 months.

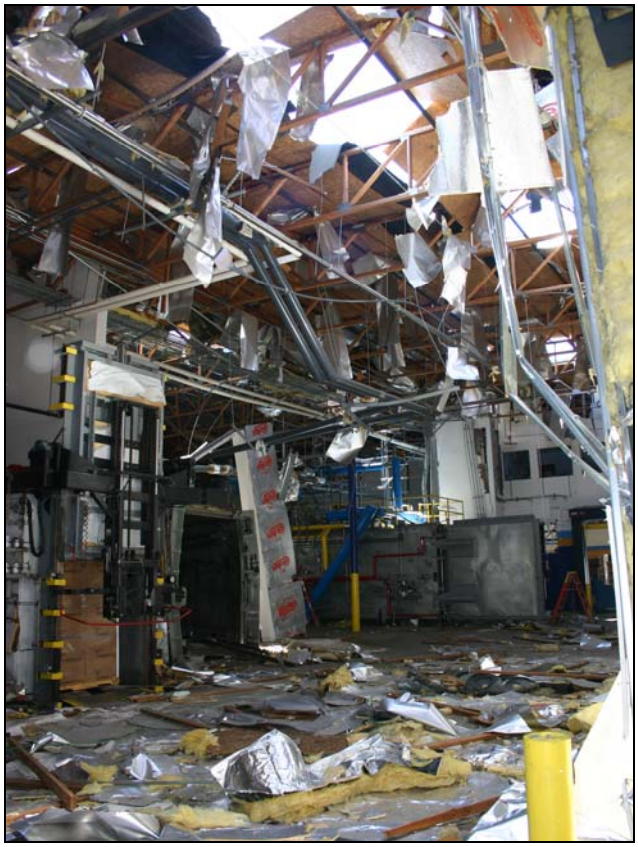

Figure 1 Facility Damage

The explosion occurred when maintenance personnel entered a password to override computer safeguards, allowing premature opening of the sterilizer door. This caused an explosive mixture of ethylene oxide (EO) to be evacuated to the open-flame catalytic oxidizer[1] (oxidizer) by the chamber ventilation system. The oxidizer is used to remove EO in compliance with California air quality regulations. When the EO reached the oxidizer it ignited and the flame quickly traveled back through the ducting to the sterilizer where approximately fifty pounds of EO ignited and exploded. Figure 2 is an illustration of the facility floor plan and location of key equipment involved in the explosion.

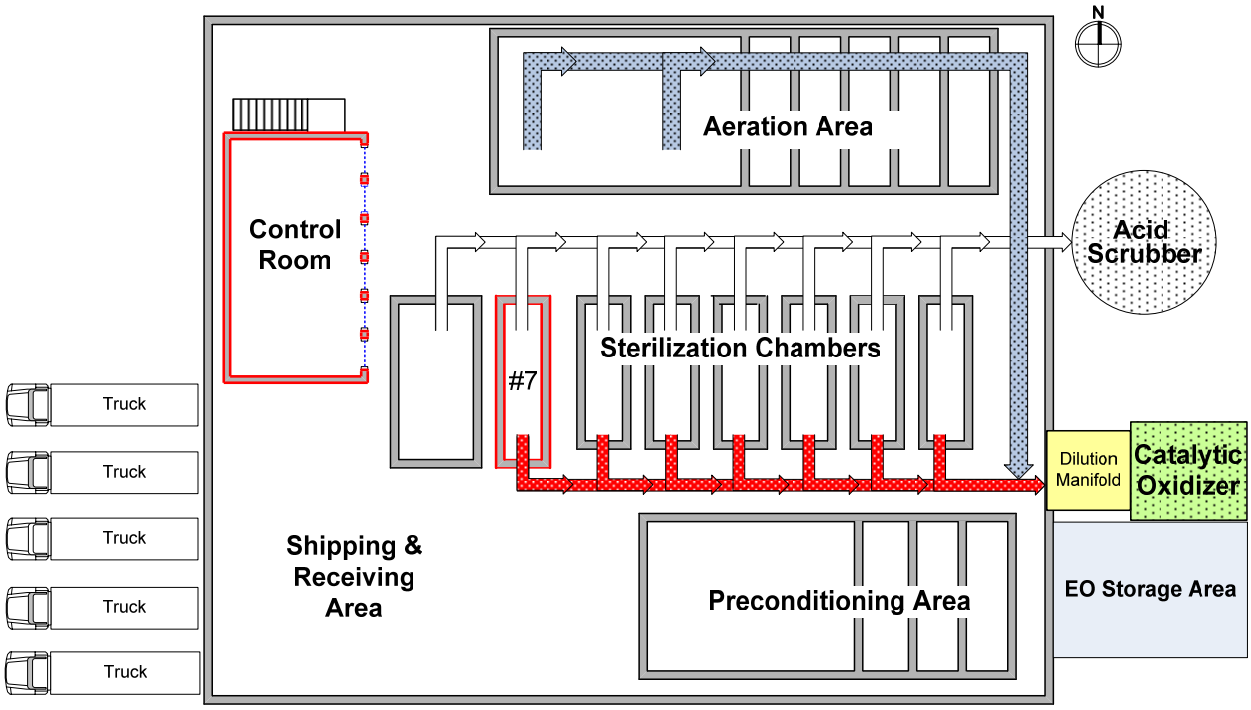

Figure 2 Ontario Plant Layout

[1] Oxidizers include both thermal and catalytic devices. Thermal oxidizers generally operate at higher temperatures and rely solely on heat to destroy pollutants, whereas catalytic oxidizers operate at lower temperatures and employ a catalyst bed to facilitate the destruction of pollutants.

U.S. Chemical Safety and Hazard Investigation Board (CSB) investigations result in safety recommendations targeted toward preventing similar incidents. CSB investigated this incident because it was a serious explosion that would have resulted in more serious injuries and possibly fatalities if workers had been in the sterilization area when the explosion occurred.

During the course of this investigation, CSB investigators examined physical evidence, interviewed Sterigenics employees, EO manufacturing industry and instrumentation experts, and reviewed relevant company documents. Investigators coordinated with California Occupational Safety and Health Administration (Cal/OSHA), South Coast Air Quality Management District (SCAQMD), San Bernardino County Fire Department, Hazard Materials Division, and the City of Ontario Fire Marshall's office.

2.0 STERIGENICS HISTORY

Sterigenics International, Inc. is a contract medical sterilization services provider that specializes in various types of sterilization in the U.S. and around the world. It began operation in 1979, but did not begin EO sterilization until 1999, when it merged with Ion Beam Applications (IBA); IBA had acquired Griffith Micro Science, Inc. (Griffith)—owner of the Ontario facility—in April of 1999. In June of 2004, PPM Capital Limited and PPM America Capital Partners (PPM)—private equity firms with worldwide assets totaling nearly $4 billion—acquired the IBA sterilization and ionization business and renamed it Sterigenics. PPM is owned by Prudential plc, a financial services group incorporated in the United Kingdom with over $300 billion in assets. Sterigenics International now operates at 40 locations around the world—including 9 EO sterilization facilities in the U.S.— and employs approximately 1,000 people. Figure 3 below is a timeline outlining the Ontario facility ownership.

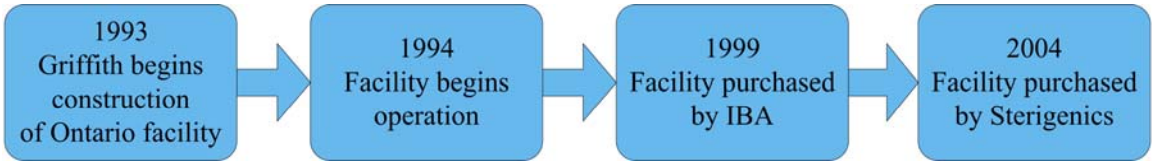

Figure 3 Ontario Plant Ownership

2.1 Ontario Facility

Griffith began construction on the Ontario facility in 1993, and commenced sterilization operations in 1994. The facility has eight sterilization chambers and operates 24 hours a day, seven days a week, with approximately 30 employees.

2.1.1 Continuity of Management

Although the facility changed ownership twice since its construction—first, when it was purchased by IBA in 1999, and again in 2004, when PPM purchased it and renamed it Sterigenics—many of the original management and engineering personnel remained on staff. They continued to oversee plant operations throughout these transitions, and were in charge at the time of the incident. CSB investigators interviewed many of these managers and engineers during this investigation.

3.0 Ethylene Oxide (EO) Hazards

EO is both flammable and toxic. OSHA regulates EO in two separate regulations: Ethylene Oxide (29 CFR 1910.1047) and Process Safety Management of Highly Hazardous Chemicals (PSM).[2] Likewise, EO is regulated by the Environmental Protection Agency (EPA). Most relevant to this investigation are the Hazardous Air Pollutant (HAP) regulations under the Clean Air Act (CAA), the National Emissions Standards for Hazardous Air Pollutants (NESHAP)[3], and the Risk Management Program (RMP).[4] See Section 8.0, Regulatory Review

3.1 Flammability

EO is a highly reactive compound represented by the chemical formula CH_2OCH_2. The lower flammable limit of EO/air mixtures is 2.6%, while the upper flammable limit is 100%, because pure EO will burn in the absence of air or oxygen. The flammable range of EO/air mixtures is accordingly 2.6-100%.

Once ignited, the velocity of an EO flame inside a gas enriched pipe or ventilation duct accelerates rapidly. As the flame continues to accelerate, the unburned EO just ahead of the flame front is compressed and heated, causing further ignition. Because EO flames can accelerate so rapidly (Thibault et al., 2000), designing and installing reliable explosion control systems is difficult, particularly when adding them to existing process equipment.

[2] Because Sterigenics stores more than 5,000 lbs of EO at its facility, it is covered by the OSHA PSM Standard (29 CFR § 1910.119). PSM covers processes containing threshold quantities of highly hazardous chemicals identified on a list contained in Appendix A of the standard, as well as other flammables present in quantities greater than 10,000 pounds.
[3] See Section 112 of the CAA and 40 CFR Part 61.
[4] The RMP program is detailed in Section 112(r) of the Clean Air Act and in 40 CFR Part 68.

In order to avoid explosions, facilities must maintain EO concentrations entering oxidizers below the lower flammable limit, also commonly referred to as the lower explosive limit (LEL).[5] National Fire Protection Association (NFPA) codes require facilities to dilute EO concentrations transported to oxidizers to less than 25% of the LEL, or 6,500 ppm.[6] Typical chamber concentrations during sterilization reach 400,000 ppm (40% by volume), which is a very explosive concentration.

3.2 Toxicity

The acute (short-term) effects of EO in humans consist mainly of central nervous system (CNS) depression and irritation of the eyes and mucous membranes. Chronic (long-term) exposure can cause irritation of the eyes, skin, and mucous membranes, and problems in the functioning of the brain and nerves. A recent study conducted by the National Institute for Occupational Safety and Health (NIOSH) concluded that long term exposures to EO increases the risk of bone cancer in men and breast cancer among women.[7] EPA has classified ethylene oxide as a probable human carcinogen, and the International Agency for Research on Cancer (IARC)—part of the World Health Organization—classifies EO as a Group 1 human carcinogen.[8]

[5] The Lower Explosive Limit (LEL) is the level at which there is enough oxygen and fuel to support combustion. The LEL for EO is 26,000 parts per million in air.
[6] See NFPA 86 Standard for Ovens and Furnaces 2003 Edition, Chapters 9.2.6.1. Chapter 9.2.8 allows $\leq$ 50% of the LEL when automated detection and response systems are used.
[7] The results of this study can be viewed at the NIOSH website: www.cdc.gov/niosh/
[8] This category is used by IARC when there is sufficient evidence of a cause and effect relationship between exposure to the material and cancer in humans. Such determination requires evidence from epidemiologic (demographic and statistical), clinical, and/or tissue/cell studies involving humans who were exposed to the substance in question.

The Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) is 1 ppm, averaged over an 8-hour workday. For shorter exposures to higher concentrations, OSHA has adopted a short-term exposure limit (STEL)—not to exceed 15 minutes—of 5 ppm. In addition, employers are required to take certain actions (e.g., conduct medical surveillance and periodically monitor worker exposures) when employee exposures exceed 0.5 ppm averaged over an 8-hour workday.[9]

4.0 EO STERILIZATION PROCESS

The Sterigenics facility in Ontario conducts sterilization by placing pallets of products inside a large stainless steel chamber, applying a vacuum, and injecting pure EO to achieve a sterilizing concentration of approximately 400,000 ppm. EO kills microbes by disrupting life-sustaining molecules. Commercially sterilized medical products must meet stringent U.S. Food and Drug Administration (FDA) safety regulations that address product sterility (i.e., microbial levels) and acceptable levels of EO residue. Because of the variability of products, packaging, load density, etc., each product type (e.g., tubing, catheters, containers, bandages) requires a unique treatment cycle to ensure sterilization. Cycle variables include EO concentration, duration of exposure, temperature, humidity, vacuum applied during sterilization, and gas washing and aeration required to remove residual EO. FDA requires that manufacturers "validate" (ensure successful sterilization) cycles for each product type. This entails using biological indicators[10] to ensure that residual EO is at or below standards deemed safe by the FDA. The

[9] See 29 CFR 1910.1047, Ethylene Oxide.
[10] Biological indicators are small devices containing microbes (germs) with known resistance to EO sterilization. They are strategically placed inside palletized product loads for the duration of a sterilization cycle, and afterwards, are transported to a laboratory for evaluation.

majority of the products sterilized at the Ontario facility are pre-conditioned, sterilized, and then aerated. (See Figure 4).

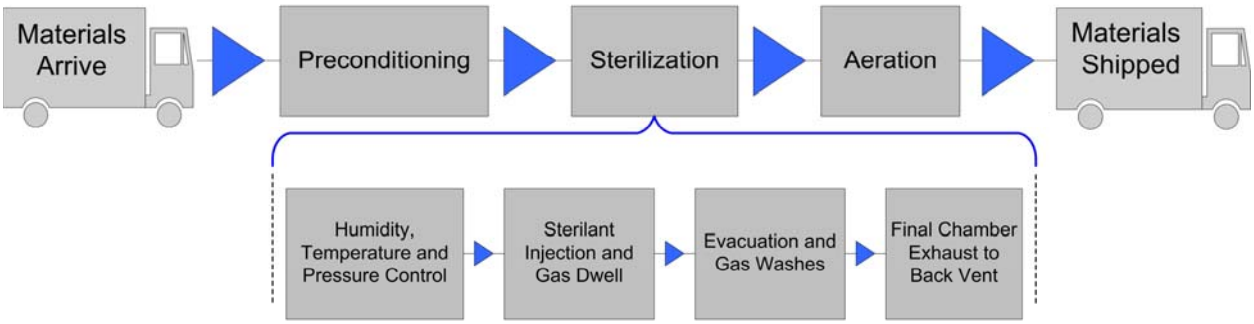

Figure 4 Sterilization Overview

4.1 Pre-conditioning

Pre-conditioning is the first stage of the medical product sterilization process. It lasts from 6 to 24 hours—depending on the products being conditioned—and involves subjecting products to high levels of humidity, and temperatures between 80^{o} and 120^{o} F (27-49^{o} C). This stage helps ensure effective EO penetration and warms products for the sterilization process. Pre-conditioning occurs in four environmentally controlled rooms along the north wall of the facility.

4.2 Sterilization

Operators use forklifts to move products to the sterilization chambers at the conclusion of pre-conditioning. The chambers are then sealed and prepared for sterilization. From the control room located at the west end of the facility, operators then input codes into the computerized process control system (the Antares system) that controls and monitors the sterilization cycle. The cycle takes from 6 to 15 hours, depending on the products being sterilized. See Section 4.2.2 Computerized Process Control below, for a detailed discussion of the Antares system.

4.2.1 Cycle Phases

The sterilization cycle begins by placing chambers under a vacuum, injecting some steam to further condition the products, and then injecting EO from pressurized 400-pound cylinders housed in cabinets located alongside each chamber. Products are exposed to EO while the chamber is maintained at a negative pressure for a pre-determined period, called the "dwell"[11] phase. At the end of this phase, the chamber gas mixture is evacuated to the acid scrubber that removes EO. Approximately 60% of the EO is exhausted from the chamber during this phase of the cycle. The chamber then undergoes a series of nitrogen and/or air washes to remove the remaining EO.[12] Figure 5 (below) illustrates the sterilization cycle sequencing described in this section.

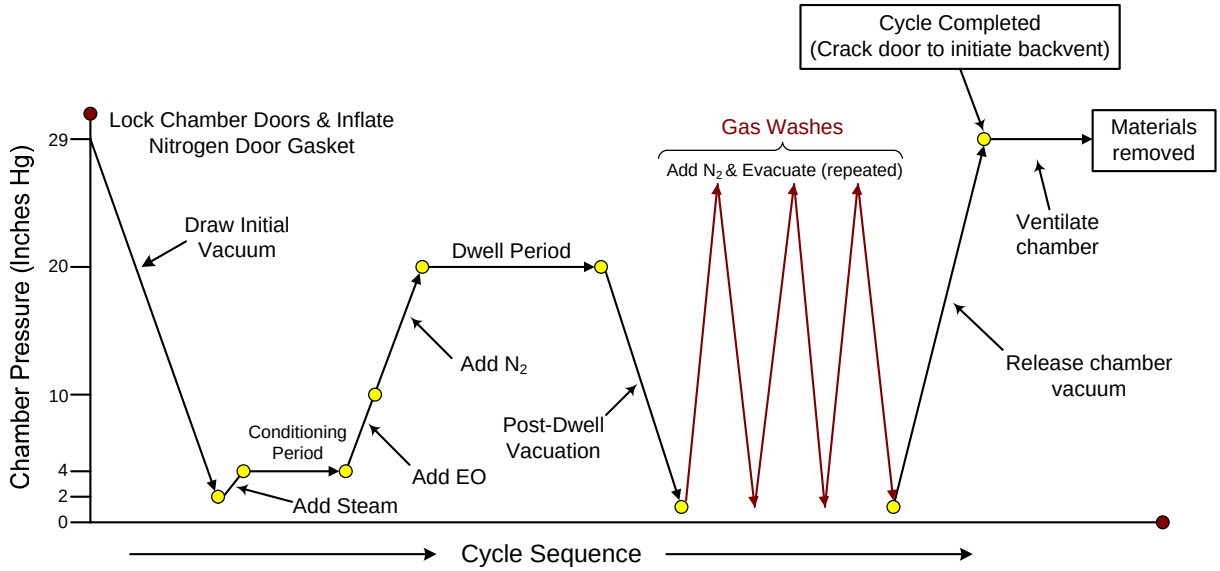

Figure 5 Sterilization Cycle Sequencing

[11] Dwell is the period during the sterilization cycle during which products are exposed to high concentrations of EO.

Despite efforts to remove all of the EO from sterilized products, potentially toxic (but normally not explosive) levels of EO remain in the chamber after gas washing. To purge this remaining EO, operators open the sterilizer door to approximately six inches, which automatically opens a ventilation duct—referred to as a "backvent"—located in the rear of the chamber. Operators leave the door in this position for several minutes to ventilate the chamber so that employees can safely enter to remove sterilized products. Air exhausted through the backvent flows to the oxidizer, which removes the remaining EO from the airstream. See Section 5.0 Facility Emissions Control (below) for more information about the emission control devices at the facility.

[12] Nitrogen/air washing involves decreasing the pressure inside the chamber relative to atmospheric pressure ("pulling a vacuum"), injecting nitrogen and/or air, and then evacuating the chamber.

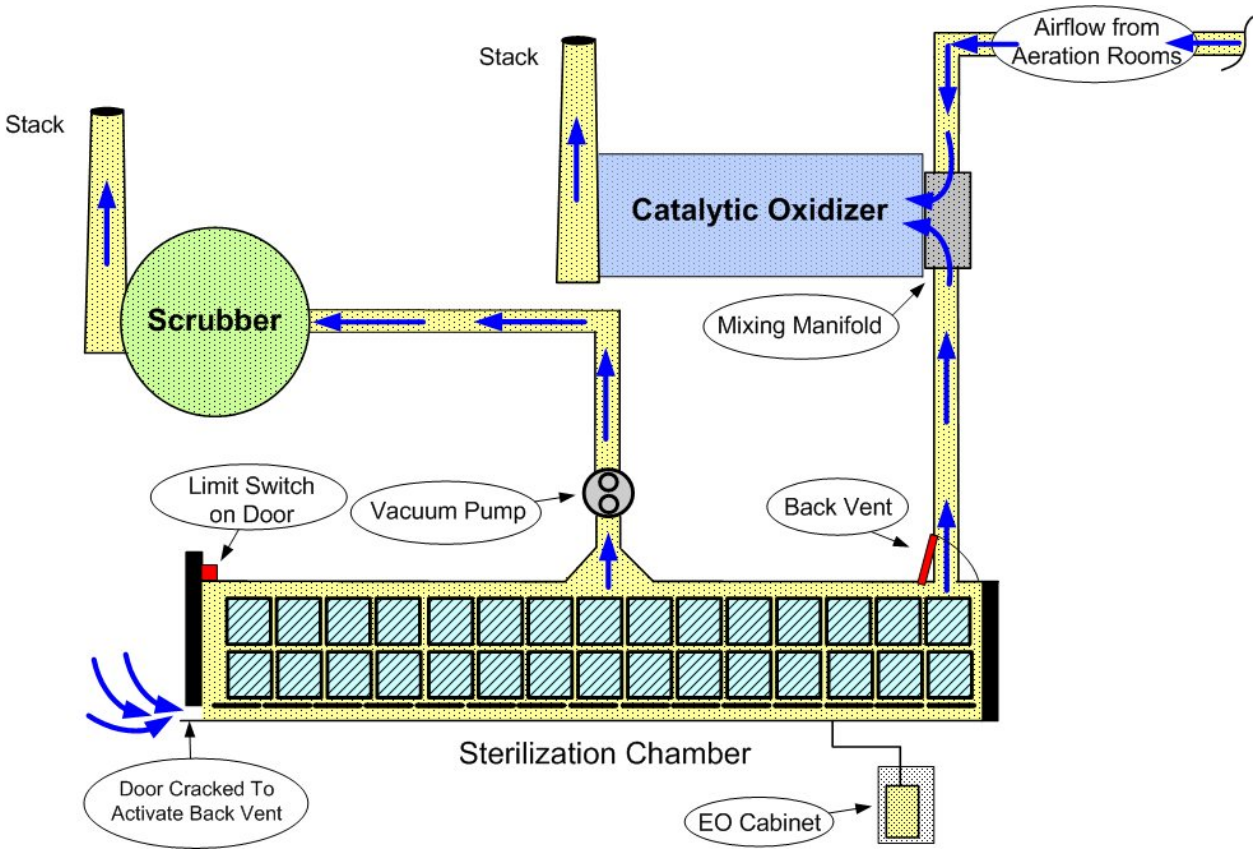

Figure 6 Facility Emission Control Devices

4.2.2 Computerized Process Control

The Antares[13] computerized process control system manages the sterilization process inside the chamber.

This includes automatically controlling levels of humidity, temperature, pressure, EO, and dwell time.

[13] Antares (manufactured by Digital Dynamics, Inc.) is the commercial name for the software used to control the process.

Facility management staff program cycle parameters and event sequencing into the Antares system during the cycle design phase, based on specifications to achieve FDA-mandated sterilization parameters. See Section 4.2.3, Cycle Design and Chamber Concentration Measurements, for a detailed discussion of cycle design.

To activate a particular sterilization cycle operators simply type the corresponding numeric code into the Antares system terminal located in the control room. The Antares system then controls the sequencing of that cycle from start to finish. Taking actions to manually intervene (advance or interrupt) a cycle sequence may present a considerable safety hazard.

If an unrecoverable problem occurs during the sterilization cycle, operators can immediately abort the cycle by activating a button located on the control room console. This initiates a pump that removes the high concentration gas from the sterilization chamber, followed by a sequence of gas washes that removes the remaining EO. Because of the explosion hazard potential, any modification to the Antares cycle sequence—other than an abort command—requires a manager's password.

4.2.3 Cycle Design and Chamber Concentration Measurements

The high EO concentration gas mixture evacuated after the dwell and gas wash phases goes to the acid scrubber for treatment, and is normally not an explosion safety concern, provided the cycle proceeds uninterrupted. Interrupting a cycle, by advancing it or otherwise, presents a considerable safety hazard because there is no monitoring or detection equipment to warn employees that an explosive concentration remains in the chamber. On the day of the explosion, after advancing the cycle and thereby bypassing gas washes, the technician who opened the sterilizer door did not know that the sterilizer contained an explosive gas mixture.

Gas washing to remove explosive levels of EO is the primary explosion-safety design feature of the sterilization process. As a backup, the engineering staff designed the ventilation system to dilute

backvent exhausts to less than 25% of the LEL before reaching the oxidizer. See Section 7.2.1.4, Vent Stream Dilution Air, for a more detailed discussion of this.

Mathematical calculations using the ideal gas law are used to design gas washes for the specific cycle during the initial cycle design. Thereafter, the pressure sensor system located inside the chambers predicts chamber concentrations. However, the sensor system does not measure EO concentration; it measures pressure inside the chamber at various phases of the cycle, such as during gas injection or removal. The sensor alerts the Antares system if a predetermined cycle pressure is not achieved. Such an alert indicates that the pressure is either too high or too low, which may indicate that too much or too little EO was injected. This system does not indicate the actual chamber EO concentration, or provide a warning to employees that a dangerous concentration may exist in the chamber. The Ontario facility used no other devices to measure explosive concentrations inside the chambers.

4.3 Aeration

After ventilating the chamber, operators completely open the sterilizer door and use forklifts to move products to the aeration rooms. Circulating air in the aeration rooms, also vented to the oxidizer, removes any remaining residual EO.

5.0 Facility Emissions Control

EPA and California Air Resources Board (CARB) emissions standards for EO—discussed more fully in Section 8.0 below—require sterilization facilities to remove EO from their gas emissions. When the Ontario facility was constructed in 1994, the oxidizer was installed to comply with these requirements. In 1998—after a series of oxidizer explosions involving EO at other sterilization facilities—Griffith installed an acid scrubber to treat high concentration chamber exhausts evacuated at the end of its sterilization and gas wash phases. However, the facility continued to use the oxidizer to treat the lower concentration

emissions from backvents and aeration rooms because the scrubber was unable to meet CARB emissions standards.

5.1 Acid Scrubber

The acid scrubber (manufactured and installed by Ceilcote Air Pollution Control) is safer to operate than the oxidizer, because it does not utilize an open flame or heat source. It contains a solution of water and sulfuric acid (H_2SO_4) that converts gaseous EO to an ethylene glycol solution. The ethylene glycol is transported to a waste treatment facility. The scrubber performs well for high concentration emissions, but cannot satisfy California emissions standards for the lower concentrations typical of backvents and aeration rooms. The Ontario facility continues to utilize its oxidizer to treat these emissions.

5.2 Catalytic Oxidizer (Oxidizer)

The oxidizer—just outside the eastern-most wall of the facility—was designed, manufactured, and installed by Donaldson, Inc., which worked closely with facility and corporate engineering personnel. A series of spiral wound steel ducts routed to a manifold connected to the oxidizer, transports EO-containing exhausts to the oxidizer. A heat exchanger and natural gas-fired (open flame) combustion chamber heats air entering the oxidizer to approximately 300^{o} F, the temperature required to initiate a reaction between the EO and the metal impregnated catalyst bed to destroy EO.[14] (See Figure 7)

[14] EO molecules are converted to carbon dioxide and water vapor when they contact the metal alloy in the catalyst bed.

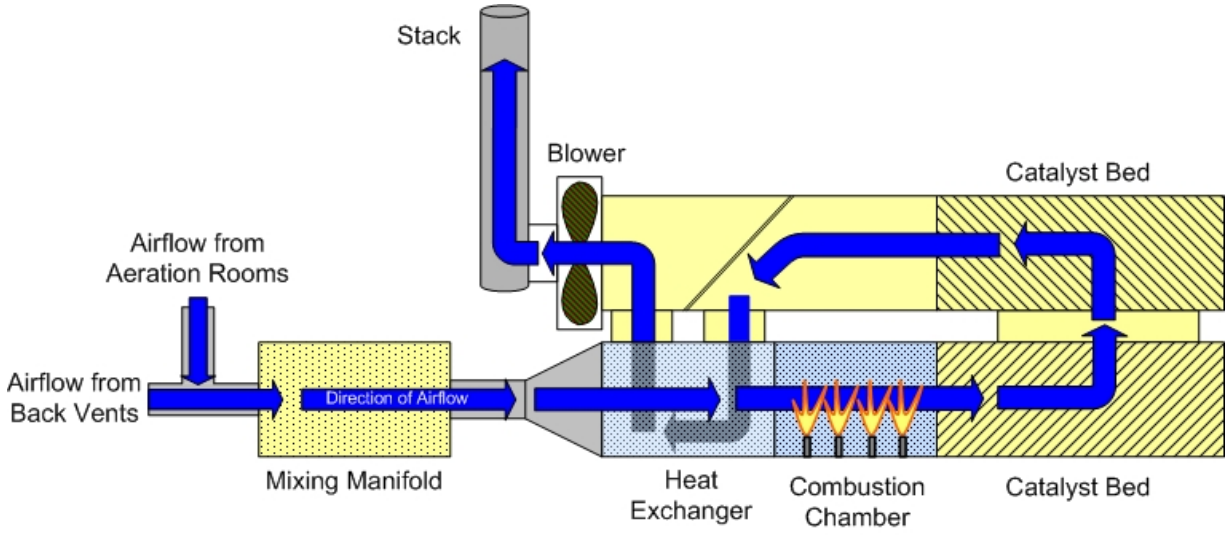

Figure 7 Diagram of Catalytic Oxidizer

The oxidizer has several safety features focused on preventing damage to the oxidizer, but none of these features prevent high concentration chamber exhausts from igniting. Likewise, there is nothing associated with the design of the oxidizer or ventilation system that can detect or stop a flame front from traveling from the oxidizer back to a chamber.

6.0 Incident Description

6.1 Pre-incident Events

On Thursday, August 19, 2004, at approximately 1:30 AM, the Antares control system alerted operators of an EO injection failure during a cycle in Chamber 7. The operator immediately ran several routine system checks in the control room to determine that the alert was accurate, but was unable to identify any problems. He then called in the lead operator, and together, they decided to abort the cycle. In accordance with company protocol, they used the cycle abort button on the control room console. Upon completion of the abort cycle, operators removed the chamber contents to an aeration room, and the chamber was left open awaiting maintenance personnel.

The maintenance supervisor arrived at the plant at approximately 7:30 AM and immediately assigned two technicians to work on the gas injection problem. The technicians ran a series of tests, including an abbreviated test cycle that injected approximately 4 pounds of EO. The cycle performed as designed, and the technicians did not identify any problems. Before returning the chamber to production, the technicians ran a final calibration cycle that utilized 125 pounds of EO.

This cycle progressed through its gas injection phases with no problems. Thinking that they had ruled out the injection system as the problem, and eager to get the chamber back on line, the technicians asked the maintenance supervisor for permission to skip the final gas washes and advance the cycle to completion. Witness interviews indicated that the technicians believed—because the chamber was empty of products being sterilized—the single end of cycle evacuation had removed the explosive concentrations of EO, and therefore, there was no reason for the gas washes because no residual EO remained in the chamber. The maintenance supervisor agreed with their logic and agreed to advance the cycle to completion.

6.2 The Incident

To advance the cycle to completion the maintenance supervisor verbally gave the required password to a maintenance technician. The technician typed the command into the Antares system thereby skipping the gas wash phase. Minutes later, the technician cracked the sterilizer door to the pre-determined ventilation level, which automatically opened the backvent and caused approximately 50 pounds of EO remaining in the chamber to move into the ventilation system. EO immediately began to leak out of the chamber door into the building, causing nearby LEL monitors to alarm. The alarms, however, did not allow sufficient time to shut down the oxidizer or evacuate the facility before the EO-laden air reached the oxidizer and ignited. The flame flashed back through the duct to the chamber and ignited the remaining EO, resulting in a powerful explosion. The explosion occurred shortly after 2 PM on August 19, 2004. There were no employees working in the chamber area at the time of the explosion.

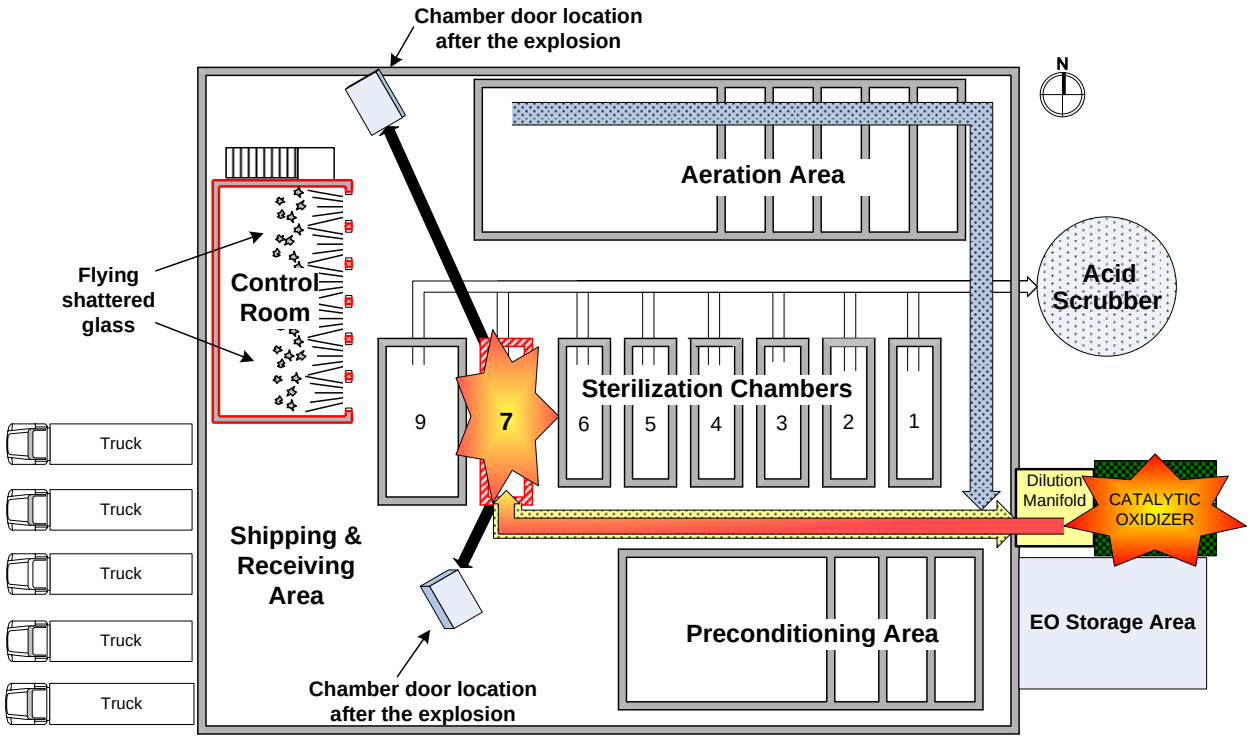

Figure 8 Explosion Overview

6.3 Incident Aftermath

6.3.1 Employee Injuries

Four employees in the facility's control room sustained minor cuts and lacerations from the shattered control room glass (see Figure 9). Three of these employees were transported to the hospital where they received minor medical treatment and were released the same day. Emergency responders treated and released one employee at the incident scene.

The normal course of duties for operator and maintenance employees involves various activities in the sterilization area. During a normal shift there are three to seven employees performing duties there. It

was a fortunate coincidence that there were no employees in the sterilization area at the time of this incident.

Figure 9 Blown Out Control Room Windows

6.3.2 Emergency Response

Employees exited the facility safely and called 911. The Ontario Fire Department and San Bernardino County Hazardous Materials unit arrived together at 2:47 PM and took control of the site. The Ontario Police Department immediately evacuated neighboring businesses and closed an approximately one quarter mile section of the street on the east side of the plant. Soon thereafter, the fire department began monitoring the air for EO and explosive gases using detector tubes and a direct-reading gas analyzer. No explosive concentrations were detected, but levels in the 1.0 ppm range were detected inside the building.

The incident response officially ended the following day at 2:05 PM, but because of elevated EO levels and structural damage, the fire department continued to monitor for EO and restrict access into the

facility. Once EO monitoring levels indicated it was safe and the remaining drums of EO were removed from the site, monitoring was suspended. Access to the building remained restricted until the structure was shored and a structural engineer approved the work. The structural support work was completed and access to the building was granted approximately two weeks after the incident.

7.0 Incident Analysis

CSB analyzed this incident by inspecting facility damage, reviewing company documents and industry accident data, and interviewing employees and other industry experts. In addition, several investigative techniques were used to analyze the incident, including establishing an event timeline (Appendix A) and developing a logic tree diagram (Appendix B). Key issues identified during the investigation included process design, control room design and construction, employee training, lessons learned from past incidents, and hazard identification and evaluation.

7.1 Origin of the Explosion

The location and magnitude of the damage to the ventilation system and Chamber 7 indicate that explosive EO-laden air was transported through the ventilation ducting to the oxidizer where it initially ignited. A large section of the manifold connecting the chamber ducts to the oxidizer was blown outward, on the upstream side of the oxidizer. This indicates that an explosive overpressure occurred inside the oxidizer (see Figure 10).

Figure 10 Oxidizer Manifold Damage

Once the explosive airflow was ignited, the flame traveled through the ventilation duct back to the chamber. The pressure created inside the duct as the flame front traveled back to the chamber destroyed a large section of the ventilation ducting from the oxidizer to the chamber (see Figure 11). The flame front, entering the chamber through the open backvent, initiated a powerful explosion.

Figure 11 Damage to Ventilation Ducting

Figure 12 Building Damage from Chamber Door

The force of the explosion sheared the hinges and propelled both chamber doors outward.[15] The loading (south) door came to rest approximately 15 feet away, after colliding with and damaging a steel column. The unloading (north) door came to rest approximately 75 feet from the chamber after striking and fracturing the south wall of the building (see Figure 12). The pressure flexed the entire chamber structure outward, leaving it permanently disfigured (Figure 13).

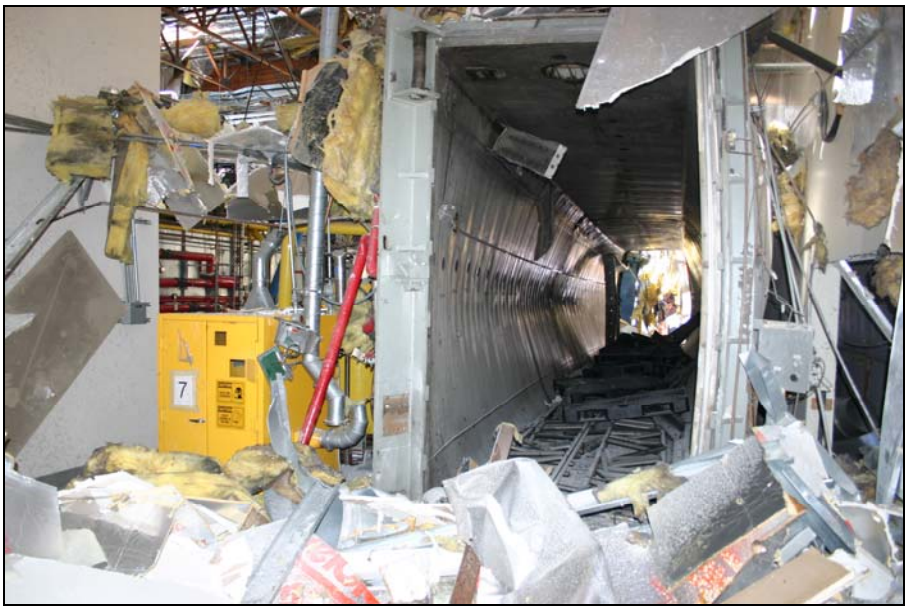

Figure 13 Damage to Sterilization Chamber 7

7.2 Engineering Controls

According to AIChE's Center for Chemical Process Safety (CCPS), process safety starts with the basic process design and includes control systems, alarms and interlocks, safety shutdown systems, response

[15] CSB estimates that the doors each weigh in excess of 4,000 pounds.

plans, and training (CCPS, 1993). Should primary protective systems fail, however, hazards must be controlled with reliable backup systems (CCPS, 2001).[16] Primary and backup safety systems are identified and evaluated during the process design phase, and again during the various Process Hazard Analysis (PHAs) conducted throughout the life cycle of the process. See Section 7.5, Hazard Analysis, for a detailed analysis of the PHAs conducted at this facility.

7.2.1 Concentration Control Design Measures

Key to preventing explosions at the Ontario facility is ensuring that high EO gas mixtures never reach a source of ignition, such as the oxidizer. The process design features that helped ensure this at the time of the incident were Antares-controlled chamber pressure monitoring, evacuation and gas washing, and a system of interlocks. The Antares system controls all of these through sequencing set points programmed into the system during the initial cycle design phase. The only backup was the ventilation system, designed to dilute chamber gas mixture produced from minor system upsets before it reached the oxidizer.

7.2.1.1 Chamber Monitoring

The facility indirectly monitored chamber concentrations to verify that the chamber achieved FDA prescribed EO levels; however, they did not monitor the chamber concentrations for explosivity, despite recommendations to the entire sterilization industry by NIOSH and NFPA. When the cycle sequence was interrupted just prior to the incident, employees were unable to determine if an explosive concentration remained in the chamber.

[16] Additional protective measures outlined by CCPS include post-release physical protection (dikes), plant emergency response, and community emergency response. These were excluded from this discussion because they were not relevant to this investigation.

7.2.1.2 Evacuation and Gas Washing

The evacuation and gas washing phases of the sterilization cycle remove high concentration chamber gas to the acid scrubber for treatment. The Antares system controls these phases, which, if allowed to proceed uninterrupted, will remove explosive concentrations of EO from the chamber.

7.2.1.3 Interlocks

Interlocks installed to prevent the inadvertent opening of a chamber door include nitrogen filled door gaskets and chamber pressure sensors. Employees, using a password supplied by managers, can override both interlocks. Without chamber concentration monitoring to inform them of the existence of explosive concentrations, this system is vulnerable to human error.

7.2.1.4 Vent Stream Dilution Air

The engineering staff at the Ontario facility designed the ventilation system with a four-to-one dilution rate—four times more aeration room air than backvent air.[17] Using this dilution air, and ensuring final chamber concentrations are kept below 25% of the LEL through cycle design calculations, the engineering staff reasoned that it would be impossible for an explosive concentration to reach the oxidizer. However, they did not foresee a scenario that would leave a large volume of undetected EO in a chamber at the end of a cycle. CSB investigators estimate that the EO concentration inside the chamber, just prior to the explosion, was approximately 18% (180,000 ppm), or six times the LEL.

[17] Air concentrations of EO in the airflows from the aeration rooms to the oxidizer are less than 10 ppm and do not significantly affect the explosivity of the combined airflows to the oxidizer.

7.2.2 Backup Engineering Controls

Backup engineering control systems may be required at sterilization facilities if primary concentration control measures cannot reasonably ensure safe operation of the process. These systems can be grouped into two broad categories: those that monitor chamber exhausts in the ventilation ducting and divert explosive exhausts before they reach the oxidizer, and those that detect explosions that originate in the oxidizer and control them before they become destructive. According to industry guidance, however, the rapid flame speed of EO (Reference 11) is a central design consideration when retrofitting existing processes with reliable backup protection systems. Detection equipment must have adequate time to take protective actions, and this means ensuring safe minimum distances between detection and reaction devices and using devices that are fast acting. The most efficient addressing of reaction time issues is during the initial process design and engineering phases. There were no backup engineering controls to detect, prevent or mitigate an explosion at the Ontario facility.

7.2.3 Control Room Design and Location

The control room used to monitor and control the sterilization process is located approximately 75 feet from Chamber 7. Primarily constructed of drywall over metal stud frames, the control room includes six glass windows that provide a view of the sterilization chamber area. The explosion resulted in minor damage to the control room structure, but all windows were shattered. The windows were tempered window glass without any shatter-resistant treatments, and the walls were not designed to resist pressure from an explosion. All of the injuries resulted from flying glass from the shattered control room windows.

Staff engineering personnel involved in the original design of the facility indicated that windows were necessary because operators needed to view chamber operations. They further indicated that no explosion safety design measures were considered during the design and construction of the control room, and—

according to the PHA documents CSB investigators received from corporate staff—an evaluation of the control room was not included in the various PHAs conducted since the plant began operation.

Plant designers should avoid the use of normal or tempered window glass in areas with the potential for explosion overpressure. If proximity to the process is essential, and it is necessary to view the operation, good engineering design considerations would include substituting tempered window glass for something safer, such as video monitoring, or shatter-resistant glass. See the reference section at the end of this report for references to glass selection criteria provided by the American Society for Testing and Measurements (ASTM), the General Services Administration (GSA), and FM Global.

7.3 Training

According to the OSHA Hazard Communication (HAZCOM)[18] standard, all employees involved with hazardous chemicals require job-specific training on the particular chemical and physical hazards they encounter in the workplace. In addition, the OSHA PSM standard specifies that training must include an overview of the process and operating procedures, and safe work practices applicable to the employee's job tasks (OSHA, 1994). CSB investigated the training conducted at the Ontario facility by interviewing employees and reviewing training materials and records dating back to 1994, when the facility began operations.

[18] See 29 CFR 1910.1200

7.3.1 Process Understanding

The maintenance supervisor had an Antares system password in order to be able to perform his maintenance duties. Interviews with senior management and engineering staff at Sterigenics revealed that they assumed he possessed the requisite knowledge and experience to make appropriate decisions without additional supervision. Interviews with the supervisor and technician indicate that they both believed that the first evacuation after the dwell had removed all remaining EO, and that no dangerous levels of EO remained in the chamber when they made the decision to advance the cycle. Interviews with other employees confirmed this misconception. They each thought the only purpose of the gas wash cycle was to "wash out" residual EO that had been absorbed into the sterilized products. Because there were no products inside the chamber to absorb any EO, they thought the gas washes were unnecessary.

Of the ten employees interviewed in conjunction with this incident, only management and senior engineering staff personnel understood that the first evacuation after the dwell phase only removes 55-60% of the EO, and that gas washing is an essential safety measure, even if a chamber is operating without products in it.

7.3.2 Training Materials

The majority of the formalized employee training at the Ontario facility targets operations employees. Operators receive new-hire and refresher training that is formally administered and well documented; however, there is no job-specific maintenance-training program for maintenance personnel. Maintenance technicians at the Ontario facility are routinely promoted from operations, where they gain a working knowledge of the process through initial and refresher operator training and on the job experience.

CSB investigators reviewed all the training materials used at the Ontario facility since the plant began operations and found many references to the potential explosion hazard associated with skipping gas washes. The various materials make it clear that only managers have permission to modify a cycle

sequence. Operator training presented by a corporate staff member during a single training session in 1997 warned that the after vacuum only removed 60 percent of the EO, and that gas washes were always necessary. However, that training never distinguished between empty and full chambers. The maintenance supervisor on duty the day of the incident, hired afterwards, never received this training.

7.4 Past Incidents

7.4.1 General Industry Incidents

The use of oxidizers in the U.S. has grown since passage of the 1990 Clean Air Act Amendments (CAAA). They are now widely used to control air pollutants in many industries other than medical sterilization. As with those used to control EO, these oxidizers have demonstrated a similar propensity to cause explosions.

EPA reports that nearly 3,000 facilities employ approximately 4,000 oxidizers to treat volatile organic compounds (VOCs) in the United States. This number accounts for the largest emissions sources that are required to report facility information to the EPA, but falls far short of the total number in use.[19] Interviews with industry experts and device manufacturers indicate that there are approximately 25 oxidizer manufacturers making equipment for use in the U.S., and more than 10,000 devices in use.[20] A search of the major databases[21] for explosions involving oxidizers revealed very few reported injuries or deaths. However, there are numerous incidents and case studies outlined in various professional

[19] This information is submitted by air quality authorities in the various states and compiled in the National Emissions Inventory (NEI) in compliance with CAAA requirements.
[20] Many oxidizers do not require reporting/permitting by EPA, hence, there are no EPA records pertaining to them.
[21] Databases searched included OSHA's IMIS; EPA's NRC; and AIChE.

publications and papers,[22] and many of them describe incidents—similar to the Ontario explosion—involving management system failures, significant property damage, and a high potential for fatalities and serious injuries in high traffic areas.

The management system failures identified during this research included identification and evaluation of hazards and failure to install appropriate engineering controls.

7.4.2 Sterilization Industry

During the four years following EPA's 1994 EO emissions reduction rule, there was a series of approximately ten explosions involving EO and oxidizers (NIOSH, 2000).[23] These explosions drew the attention of the regulatory environment and led to a series of significant changes, including suspension of EPA's 1998 backvent EO emissions control rule, publication in 2000 of a NIOSH Alert regarding oxidizer/EO explosions, and modification of NFPA 560 language regarding EO/oxidizer safety.[24] See Section 8.0 Regulatory Review for more details regarding these standards.

7.4.2.1 1997 Griffith Abator Safety Review

As a result of these EO explosions at other facilities, Griffith—who built the plant ultimately acquired by Sterigenics—conducted a company-wide safety review of its emission control systems, and published a report in September of 1997, entitled "Abator Safety Review." That report identified specific process safety issues that "should" be addressed at the Ontario facility; specifically, dilution air calculations and interlock systems. It also identified issues at the Vernon (Los Angeles) facility; specifically, human error,

[22] CSB reviewed over 30 professional articles and papers for this portion of the investigation.
[23] One of these incidents was the 1997 Griffith Micro Science (Vernon) facility explosion in Los Angeles.

and the lack of LEL monitoring at the oxidizer. If the recommendations outlined in this report would have been implemented, both of the explosions that followed may have been prevented. It was distributed to all of Griffith's U.S. facilities approximately one month before an EO/oxidizer explosion at the Vernon facility.

7.4.2.2 1997 Vernon Plant Explosion

During November of 1997, an operator—confused as to which chamber was ready to be unloaded—opened the chamber door of a sterilizer during the dwell phase. According to the company investigation report, he discovered his mistake quickly and closed the door, but not before initiating the backvent and causing airflow to the oxidizer. An explosion followed, but no one was injured, and damage was limited to the oxidizer and ventilation ducting.

The Vernon incident investigation report contained specific corrective actions that were to be applied company-wide. These included alternative emission control devices, interlocks, automated controls, chamber monitoring tied to an alert system, and oxidizer explosion venting. Griffith communicated these corrective actions to the Ontario plant during an all-hands safety meeting conducted soon after the incident. According to company officials, however, Griffith—because of various operating differences—believed the lessons learned from the Vernon incident were of limited value to Ontario, and that the same incident could not happen there. For example, the sterilizers at Vernon were manually operated, and some cycles operated at atmosphere, allowing the chambers to be inadvertently opened mid-cycle by an operator in the production area. The sterilizers at Ontario, however, were automated and could not be opened mid-cycle because of air-filled gaskets and negative chamber pressures. According to company

[24] NFPA 560, *Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation*.

officials, despite wording in the incident report outlining company-wide application of corrective actions, they focused on correcting the deficiencies associated with the Vernon explosion. They did not rigorously evaluate the Ontario process to determine if it too, was vulnerable to an explosion.

7.5 Hazard Analysis

The hazard analysis process is an organized and systematic effort to identify and analyze the significance of potential hazards associated with the processing or handling of highly hazardous chemicals. It provides valuable information to employees and employers in making decisions for improving safety and reducing consequences of unwanted or unplanned releases of hazardous chemicals (OSHA, 1993). According to OSHA, conducting a thorough Process Hazard Analysis (PHA) is one of the most important elements of a process safety management (PSM) program. PHAs identify fire, explosion, and release scenarios resulting from equipment failures, and human and external factors that affect the safety of the process (OSHA, 1993). The ultimate objective of the PHA is to improve process safety by preventing incidents and mitigating effects of chemical incidents.

A typical PHA identifies and evaluates hazardous events in relation to the likelihood of occurrence and severity of consequences, to determine the risk to the employees, facility, neighboring community, and environment. Both OSHA and EPA require facilities to perform an initial PHA on every covered process, and revalidate it at least every 5 years to ensure it remains relevant. See Section 8.0, Regulatory Review for a more detailed analysis of the OSHA and EPA regulatory requirements.

7.5.1.1 Initial Process Hazard Analysis

Griffith conducted an initial PHA on its sterilization process in November 1993, just prior to the plant opening. It identified 16 various hazard scenarios and recommended 13 corrective actions. None of these scenarios identified or evaluated an explosion scenario involving the oxidizer. However, this PHA did identify “door opening with EO inside sterilizer” and “abator and software fails, causing high

temperature", but listed the consequences as "no effect", stating in both cases that automated controls (i.e., the Antares system, and the high temperature limit switches on the oxidizer) are in place to prevent harm. The PHA did not identify or evaluate other engineering controls or layers of protection.

7.5.1.2 Revalidations

The Ontario facility conducted two PHA revalidations after the initial PHA in 1993; one in 1996, and another in 2001.

1996 Revalidation—This focused specifically on the oxidizer, but also did not identify any explosion hazard scenarios. Because of the potential to overheat and damage the catalyst bed inside the oxidizer, the team recommended the installation of a "LFL [Lower Flammability Level] monitor and alarm".[25] When CSB asked various management officials at Sterigenics about the status of that recommendation, each responded that accurate and safe monitoring technology did not exist; therefore, Sterigenics did not act upon the recommendation. See Section 9.2.1, Monitoring, for a discussion on chamber monitoring equipment.

2001 Revalidation—This was the most recent revalidation prior to the incident. It identified a catastrophic explosion scenario involving the oxidizer, but recommended only that the facility investigate the prospect of equipping the oxidizer with explosion relief equipment. It did not specifically address the cause of the explosion or any other potential failures or solutions. At the time of the incident, the facility had not installed this equipment. See Section 9.2.2, Damage Prevention and Protection, for a discussion on explosion relief devices.

[25] The terms "LFL" and "LEL" are synonymous for the purposes of this discussion.

The written report of this evaluation of potential explosion scenarios failed to identify or address the recent history of sterilization industry EO/oxidizer explosions, including an explosion in 1997 at a nearby Griffith plant (Vernon) that resulted in specific recommendations for additional engineering controls at "…other Griffith Micro Science facilities." Company officials told CSB that these incidents were reviewed, but did not result in written action items.

8.0 Regulatory Review

8.1 Process Safety Management of Highly Hazardous Chemicals (PSM)

Because the Ontario facility stores more than 5,000 lbs of EO at its facility, it is covered by the OSHA PSM Standard (29 CFR § 1910.119). PSM provides a structure for a systematic approach to process safety and the prevention of catastrophic incidents. It covers processes containing threshold quantities of highly hazardous chemicals identified on a list contained in Appendix A of the standard, as well as other flammables present in quantities greater than 10,000 pounds. PSM-covered processes require adherence to 14 elements of good safety management.

Cal/OSHA enforces PSM[26] by conducting workplace inspections in response to accidents, complaints, or as part of a targeted (planned) inspection program that focuses on particularly hazardous businesses (e.g., PSM-covered facilities), or those with high rates of fatalities, injuries or illnesses. A specialized PSM

[26] See Division 1. Department of Industrial Relations, Chapter 4. Division of Industrial Safety, Subchapter 7. General Industry Safety Orders, Group 16. Control of Hazardous Substances; Article 109. Hazardous Substances and Processes; §5189. Process Safety Management of Acutely Hazardous Materials.

enforcement unit located in Torrance investigates accidents and complaints, and conducts planned inspections of PSM-covered facilities in the Ontario region.

8.1.1 Cal/OSHA Inspections

During September 2004—after the explosion—the Cal/OSHA PSM enforcement unit conducted a post incident inspection at the Ontario facility that resulted in three citations, two of which were classified as "Serious". These citations were for failures to follow operating procedures and conduct training. The facility was assessed a combined fine amount of $36,000 for these two citations.[27]

8.2 Environmental Regulations

8.2.1 Hazardous Air Pollutant (HAP) Control

Because EO is a toxic substance, EPA regulates it as a Hazardous Air Pollutant (HAP) under the Clean Air Act Amendments (CAAA) of 1990.[28] In 1994, EPA promulgated specific emissions standards for sterilization facilities that required facilities that used 10,000 pounds or more to eliminate 99 percent of their EO emissions by applying the "maximum achievable control technology" (MACT) to each distinct emission source (i.e., chamber exhausts, backvents, and aeration room exhausts).[29] For the vast majority of EO facilities, oxidizer units were the compliance solution of choice.

[27] As of September 18, 2005, Sterigenics was still appealing this citation.
[28] See U.S. Code Title 42, Chapter 85, Subchapter I, Part A §7412 Hazardous Air Pollutants.
[29] See 40 CFR Part 63, Subpart O— Final Air Toxics Rule For Controlling Ethylene Oxide Emissions From Commercial Sterilization And Fumigation Operations, November 15, 1994.

Following the 1994 MACT rule, a series of EO/oxidizer explosions prompted EPA (in 1997) to temporarily suspend the portion of the rule pertaining to backvents.[30] In 2001 EPA made the suspension permanent.[31] In April 2000, EPA co-authored—with NIOSH and the Ethylene Oxide Sterilization Association (EOSA)[32]—a NIOSH Alert detailing the hazards associated with oxidizers and EO. (See Section 9.2. for more details regarding this collaboration.) Despite EPA's suspension of the rule, the California Air Resources Board (CARB)—and other State and air quality districts—continue to require backvent emission treatment.[33]

According to CARB regulations, any source such as the Ontario facility that uses 20,000 pounds or more of EO over a consecutive 12-month period, must remove 99.0% of its backvent emissions.[34] The CARB regulation does not specify mandatory equipment, but interviews with CARB and EOSA officials—as well as other sterilization facility managers—indicate that sterilization facilities in California utilize oxidizer technology to control their backvent emissions.

Despite EPA's suspension of Federal backvent emission rules—based largely on explosion safety concerns—the CARB rules do not contain any requirements, precautionary language or references to safety codes or standards regarding the explosive hazards associated with EO and oxidizers.

[30] See 62 FR 64736, December 9, 1997.
[31] See 66 FR 55577, November 2, 2001.
[32] EOSA is a non-profit industry organization whose members share a common interest in promoting ethylene oxide sterilization. Its stated mission is to promote the safe use and handling of ethylene oxide for sterilization purposes. Sterigenics is an active member of EOSA.
[33] Air quality boards in California, Michigan, North Carolina, and New York require some form of control of backvent emissions. Other States may also require backvent emission treatment.
[34] See California Air Resources Board Final Regulation Order—§93108.5 Ethylene Oxide Airborne Toxic Control Measure – Part 2 Commercial Sterilizers and Aerators Using 20,000 Pounds or more of Ethylene Oxide per 12 Consecutive Months.

9.0 Industry Standard Analysis

This portion of the incident evaluation includes a review of the industry standards and guidance applicable to this incident.

9.1 NFPA 560, 2002 Edition

The National Fire Protection Association (NFPA) serves as a leading advocate of fire prevention and is an authoritative source on public safety. NFPA develops standards by consensus, enlisting regulators, industry, the scientific community, and other parties in the development process. This standard-development process has earned accreditation from the American National Standards Institute (ANSI).

NFPA 560, *Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation, 2002 Edition,* has been adopted as an industry standard by the Ethylene Oxide Sterilization Association (EOSA) and is used as a compliance reference by the Ontario Fire Department when inspecting the sterilization facilities in its jurisdiction. The Ontario facility maintained and referenced a copy of this standard.

NFPA 560 was first published in 1995 at the behest of EO manufacturers, following the phase out of chlorofluorocarbons (CFCs)[35] called for by the Montreal Protocol.[36] Prior to the phase out, CFCs were added to EO to reduce flammability and the risk of explosion. Most sterilization facilities used an

[35] CFCs are nontoxic, nonflammable chemicals containing atoms of carbon, chlorine, and fluorine. They are classified as halocarbons.

[36] The Montreal Protocol on Substances that Deplete the Ozone Layer is a 1987 international treaty intended to stop the depletion of the stratospheric ozone layer. Such depletion allows harmful ultraviolet radiation to reach the

"88:12" (88% CFCs, 12% EO) blend. According to EO manufacturer safety personnel, hospitals and commercial sterilization facilities needed guidance because they were unaccustomed to dealing with the explosion hazards created by the shift from 88:12 to pure EO.

During the period from 1994 to 1998, approximately ten sterilization facilities experienced explosions. In 2002, the NFPA 560 committee took action by adding some of the explosion prevention language outlined in the 2000 NIOSH Safety Alert. See Section 9.2, NIOSH Guidance, for a more detailed discussion of the NIOSH Safety Alert.

The following is the CSB analysis of two relevant sections of the 2002 Edition of NFPA 560.

9.1.1 Disposal and Emissions, NFPA 560, Section 11.5 Oxidizing Emissions Control Devices (Chapter 11)

This section requires monitoring of the EO chamber concentration to avoid venting an explosive concentration to the oxidizer. It does not specify what type of monitoring is required. The Ontario facility uses pressure-sensing devices to ensure the injection of target quantities of EO, but conducts no real-time concentration monitoring. Pressure readings provide no real-time concentration information during the cycle or during system upsets or abnormal operating conditions. The language outlining the requirement for monitoring in this section is ambiguous, and does not communicate the intent of the NIOSH Safety Alert: that monitoring should include direct reading devices (e.g., EO or combustible gas detection) capable of determining chamber vapor concentrations.

Earth's surface. It was ratified by the United States on April 21, 1988, and the phase out of CFCs was to be completed by 2000.

In 2001 an industry group proposed removing the chamber-monitoring requirement altogether, based on claims that monitoring equipment is expensive and unreliable. The NFPA 560 committee rejected this proposal, however, and retained the requirement to monitor EO concentrations. See Section 9.2.1, Monitoring, for a detailed discussion of chamber monitoring.

9.1.2 Annex C – Informational References

Because local municipalities and sterilization facilities reference NFPA 560 and it may be the only fire prevention design guidance used, it is important for it to contain references to other relevant fire and explosion safety codes. This section does not include references to NFPA 69 or 86, which are important fire and explosion safety standards. In addition, despite having incorporated its recommendations, this section has no reference to the 2000 NIOSH Alert.

9.1.2.1 NFPA 69, Standard on Explosion Prevention Systems

NFPA 69 applies to systems and equipment used to prevent and/or control deflagrations,[37] and covers the minimum requirements for installing explosion prevention systems in enclosures that contain flammable concentrations of gases, vapors, mists, dusts, or hybrid mixtures. NFPA 69 is a companion guide to NFPA 68, *Guide for Venting Deflagrations*, which is referenced in Annex A *Explanatory Information,* and in Annex C of NFPA 560.

9.1.2.2 NFPA 86, Ovens and Furnaces

This standard provides the requirements for prevention of fire and explosion hazards associated with heat processing of materials in ovens, furnaces, and related equipment (e.g., Thermal Oxidizers, Chapter 8). It

also provides an oven/furnace classification for oxidizers (i.e., Class A), and contains the recognized industry standard for maximum solvent vapor levels in ventilation (i.e., ≤ 25% of the LEL),[38] and an exception when automated detection and response systems are used (i.e., ≤ 50% of the LEL).[39]

9.2 NIOSH Guidance

Between 1994 and 1998, EO was involved in 10 explosions at industrial EO sterilization facilities and EO repackaging plants. One of these incidents resulted in a fatality, all caused damage to the plants, and most of the facilities involved used oxidizers to control EO emissions. In April of 2000—in response to these explosions—the National Institute for Occupational Safety and Health (NIOSH) published a 32-page Safety Alert entitled *Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities*.[40] EPA and industry representatives from the Ethylene Oxide Sterilization Association (EOSA)[41] collaborated with NIOSH to produce this alert.[42] It warns EO sterilization facility employees and managers about the explosion hazards associated with oxidizers, and it makes comprehensive recommendations for preventing future incidents. CSB evaluated recommendations made by NIOSH pertaining to monitoring and damage protection.

9.2.1 Monitoring

The Alert instructs employers to monitor concentrations in the sterilizer before opening the backvents, to avoid venting high EO concentrations to the oxidizer. This warning appears in the section designed for

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[37] A deflagration is a rapid burning at a velocity that is less than the speed of sound.
[38] See Chapter 9, § 9.2.6.1.
[39] See Chapter 9, § 9.2.8.
[40] DHHS (NIOSH) Publication No. 2000-119, April 2000.
[41] Sterigenics was a member and active participant in EOSA at the time the NIOSH Safety Alert was being prepared, and provided technical input into its publication.

posting in the workplace, as well as in the Recommendations section (p. 8). Appendix C (p. 22), a work product of the EOSA safety committee, provides more detail pertaining to monitoring. It states that facilities should use direct analysis of the sterilizer gas content in conjunction with backvent lockout, but adds the caveat that "[t]he accuracy, reliability, resolution, and availability of current EO measurement devices is questionable" (NIOSH, p. 22).

CSB investigators collected and reviewed monitoring device literature and conducted interviews with leading device manufacturers and process instrumentation consultants. While some of the devices reviewed—without some modification—would not meet the safety demands of commercial EO sterilization facilities, CSB identified one manufacturer with a commercially available instrument that will accurately, reliably, and safely determine explosive concentrations of EO inside sterilization chambers. Other devices reviewed might also perform this monitoring, but would require some modification to ensure the safety of the process. Sterigenics uses a proprietary microwave monitoring device on some of its sterilizers that is capable of determining the explosivity of chamber gases at the end of a cycle. However, this device was not installed on chamber 7 at the time of the incident.

9.2.2 Damage Prevention and Protection

Recommendation Number 5, entitled "Implement engineering controls," located on page 11 of the NIOSH Alert, advises employers to "[u]se damage control devices in the EO supply lines and oxidizer feed lines to limit explosion damage." Further discussion of this issue is in the Recommendations section (p. 11 of the Alert) but does not specifically address pressure, temperature or gas detection methodology for ventilation systems connected directly to oxidizers. The vulnerability of ventilation systems and

[42] See DHHS (NIOSH) Publication No. 2000-119, April 2000.

relevant engineering methodologies are widely discussed in professional journals, and in NFPA, 68, 69 and 86; the NIOSH Alert should reference them.

10.0 KEY FINDINGS

1. The maintenance supervisor entrusted with the password for bypassing gas washes did not fully understand the hazards associated with the process.

2. A maintenance employee, unaware of the explosion hazard inside the chamber, opened the chamber door and activated the backvent, sending an explosive mixture of EO to the oxidizer, which ignited it.

3. Sterigenics management did not implement company-wide engineering control recommendations that could have prevented this explosion.

4. Despite recommendations directed to the sterilization industry by NIOSH and NFPA, Sterigenics management did not monitor sterilization chamber concentrations for explosivity.

5. The initial and subsequent revalidation Process Hazard Analysis (PHAs) did not thoroughly evaluate the explosion hazard presented by the oxidizer.

6. The design of the control room did not include blast or shatter resistant window glass.

7. Federal EPA permanently suspended its requirement to treat backvent EO emissions in 2001, although California and at least four other states continue to require some form of treatment.

8. Catalytic oxidizers are commonly used to treat backvent emissions by sterilization plants located in states that continue to require it.

11.0 Root and Contributing Causes

11.1 Root Causes

11.1.1 Engineering controls installed at the facility did not prevent an explosive concentration of ethylene oxide (EO) from reaching the oxidizer.

- Sterigenics management did not implement company-wide engineering control recommendations that, if implemented, would have likely prevented this incident.

- Sterigenics management did not implement design recommendations for chamber monitoring issued by NIOSH and NFPA that, if implemented, would have likely prevented this incident.

11.1.2 The maintenance supervisor did not fully understand the hazards associated with the process.

- The maintenance supervisor did not understand that bypassing gas washes during a maintenance procedure involving an empty sterilization chamber could lead to an explosion.

11.2 Contributing Causes

11.2.1 The Process Hazard Analysis program at the Ontario facility did not fully identify and evaluate the hazard associated with an explosive concentration of EO reaching the oxidizer.

- The initial PHA did not identify any explosion scenarios or evaluate any engineering or administrative controls that may have prevented an explosion.

- PHA revalidations narrowly addressed the potential for an explosion, but did not comprehensively evaluate the need for additional engineering controls, or apply lessons learned from past incidents in the sterilization industry and at its own facilities.

11.2.2 The control room was not designed to protect workers from an explosion.

- Griffith located the control room within proximity of explosion impact and installed windows that were not blast or shatter resistant.

11.2.3 California Air Resources Board (CARB) did not help ensure that sterilization facilities covered by its EO backvent emission treatment rule design and operate their facilities to prevent explosions.

- In 1997, following a series of EO/oxidizer explosions at sterilization facilities, Federal EPA suspended the NESHAP rule requiring backvent emission treatment so as to "eliminate safety problems associated with the existing requirements." This suspension was made permanent in 2001.

- Despite the EPA rule suspension, CARB continues to require backvent EO emission treatment.

- Oxidizers, which pose a serious explosion hazard, continue to be used in California to comply with this rule.

12.0 **Recommendations**

Sterigenics International

Audit all Sterigenics ethylene oxide sterilization facilities using oxidizing emissions control devices. Ensure that audits assess the issues detailed below, under "Sterigenics International– Ontario Facility," and that necessary corrective measures are promptly implemented. Communicate results of these audits to your workforce. (2004-11-I-CA-R1)

Sterigenics International - Ontario Facility

1. Review and revise the Process Hazard Analysis (PHA) program to ensure that: (2004-11-I-CA-R2)

    - Hazardous scenarios are identified, evaluated, and documented.

    - Lessons learned from past incidents are applied, where appropriate.

2. Evaluate current process controls and install appropriate safeguards, such as: (2004-11-I-CA-R3)

    - Real-time chamber and/or effluent concentration monitoring connected to alarms, interlocks, and/or fast acting control devices.

    - Post-ignition deflagration detection and damage control devices.

3. Ensure that all employees with passwords capable of modifying the sterilization cycle sequence have process experience and training that enables them to make safe process decisions. Training should emphasize flammability hazards and the need for gas washes when the chamber is empty of products to be sterilized. (2004-11-I-CA-R4)

4. Ensure that the control room, and any other room where employees congregate in dangerous proximity to the sterilization area, is located and/or designed to protect workers from an explosion. (2004-11-I-CA-R5)

5. Communicate the findings and recommendations of this report to all employees, including operators and maintenance staff. (2004-11-I-CA-R6)

California Air Resources Board (CARB)

In collaboration with other state/regional agencies as necessary, such as California Occupational Safety and Health Administration, recommend to facilities that treat ethylene oxide backvent emissions with oxidizing emissions control devices to evaluate current process controls and install appropriate safeguards, such as: (2004-11-I-CA-R7)

- Real-time chamber and/or effluent concentration monitoring connected to alarms, interlocks, and/or fast acting control devices.

- Post-ignition deflagration detection and damage control devices.

California Occupational Safety and Health Administration (Cal/OSHA)

In collaboration with other state/regional agencies as necessary, such as California Environmental Protection Agency, identify the ethylene oxide sterilization facilities in California that utilize oxidizing emissions control devices and conduct inspections of those facilities (including the Sterigenics Ontario facility) in terms of the findings of this report. Ensure prompt correction of all violations identified during these inspections. (2004-11-I-CA-R8)

National Fire Protection Association (NFPA)

Review and revise NFPA 560, Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation in terms of the findings of this report. Specifically:

- Include references to the following: (2004-11-I-CA-R9)
    - NFPA 69, Standard on Explosion Prevention Systems.
    - NFPA 86, Ovens and Furnaces.

  - NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions in Industrial Ethylene Oxide Sterilization Facilities.

- Include requirements for appropriate safeguards, such as: (2004-11-I-CA-R10)
  - Real-time chamber and/or effluent concentration monitoring connected to alarms, interlocks, and/or fast acting control devices.
  - Post-ignition deflagration detection and damage control devices.

National Institute for Occupational Safety and Health (NIOSH)

Revise and reissue the NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions at Industrial Ethylene Oxide Facilities (Publication No. 2002-119) in terms of the findings of this report. Specifically:

- Include industry guidance materials on Process Hazard Analysis (PHA), such as those published by the Center for Chemical Process Safety (CCPS). (2004-11-I-CA-R11)
- Add references to NFPA 68 Guide for Venting of Deflagrations; NFPA 69 Standard on Explosion Prevention Systems; NFPA 86 Ovens and Furnaces; and NFPA 560 Standard for the Storage, Handling, and Use of Ethylene Oxide for Sterilization and Fumigation. (2004-11-I-CA-R12)
- Coordinate with the Ethylene Oxide Sterilization Association (EOSA) to remove the portion of paragraph D of Appendix C that states, “[t]he accuracy, reliability, resolution, and availability of current ethylene oxide measurement devices is questionable.” (2004-11-I-CA-R13)

Ethylene Oxide Sterilization Association (EOSA)

1. Coordinate with NIOSH to revise and reissue Appendix C of the NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions at Industrial Ethylene Oxide Facilities (Publication No. 2002-119) in terms of the findings of this report. Specifically, remove the portion of paragraph D that states, "[t]he accuracy, reliability, resolution, and availability of current ethylene oxide measurement devices is questionable." (2004-11-I-CA-R14)

2. Conduct outreach to communicate the findings and recommendations of this report, and the contents of the NIOSH Alert: Preventing Worker Injuries and Deaths from Explosions at Industrial Ethylene Oxide Facilities, to your membership. (2004-11-I-CA-R15)

Recommendations to Communicate the Findings from the Investigation

In an effort to distribute lessons learned from investigations as widely as possible, CSB recommends that organizations communicate relevant findings and recommendations to their membership and stakeholders. CSB intends for those organizations to use multiple avenues to communicate, such as having presentations at conferences, placing summaries of a report and links to full CSB reports on their websites, developing and holding training sessions that highlight the report findings, and summarizing relevant findings in newsletters or direct mailings to members. CSB encourages the organizations to use all their existing methods of communication and explore new ways to distribute these messages more widely.

U.S. Environmental Protection Agency

Communicate the findings and recommendations of this report to the states that require EO backvent emissions treatment. Emphasize the need for facilities to evaluate current process controls and install appropriate safeguards, such as: (2004-11-I-CA-R16)

- Real-time chamber and/or effluent concentration monitoring connected to alarms, interlocks, and/or fast acting control devices.
- Post-ignition deflagration detection and damage control devices.

Institute of Clean Air Companies (ICAC)

Communicate the findings and recommendations of this report to your membership. (2004-11-I-CA-R17)

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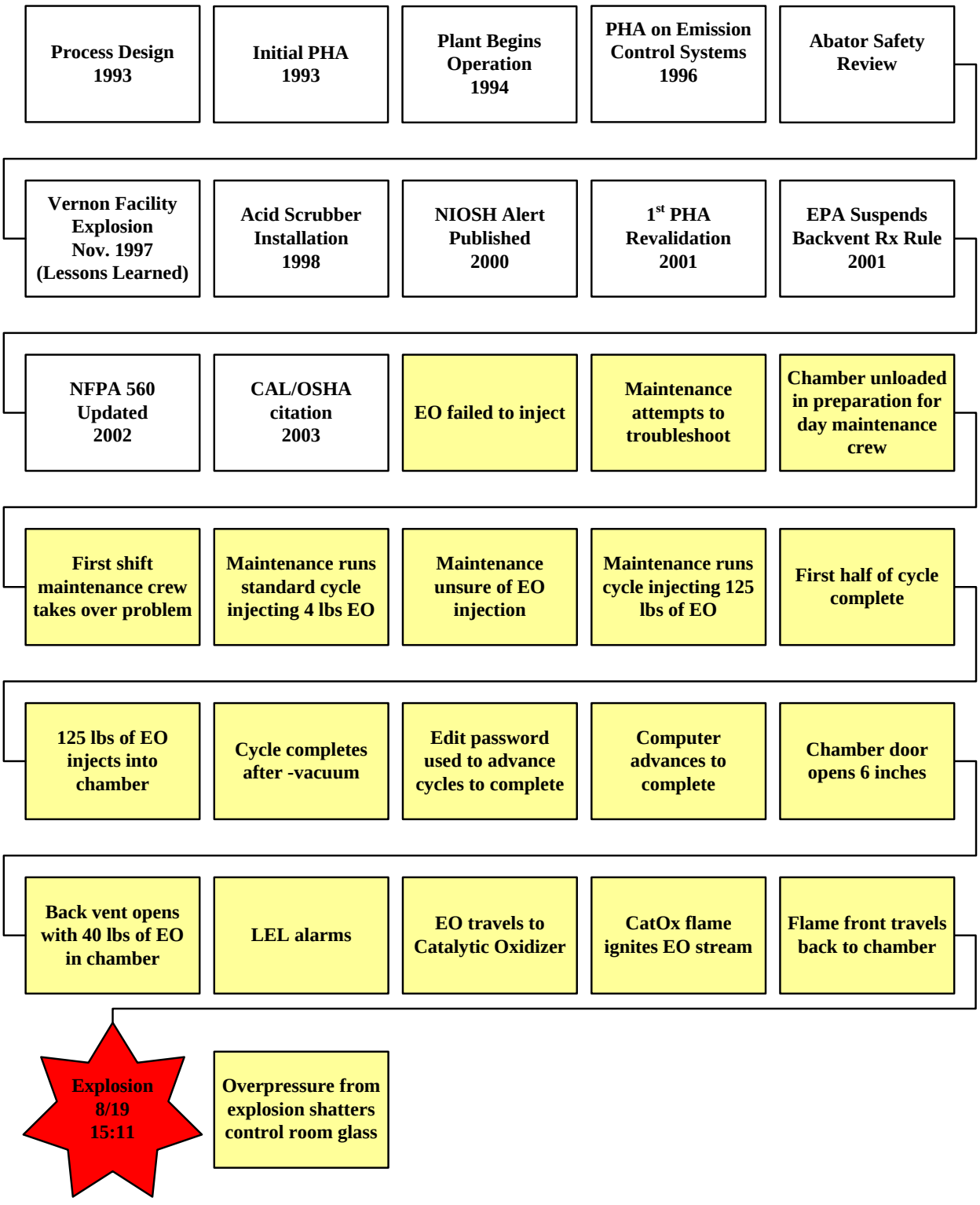
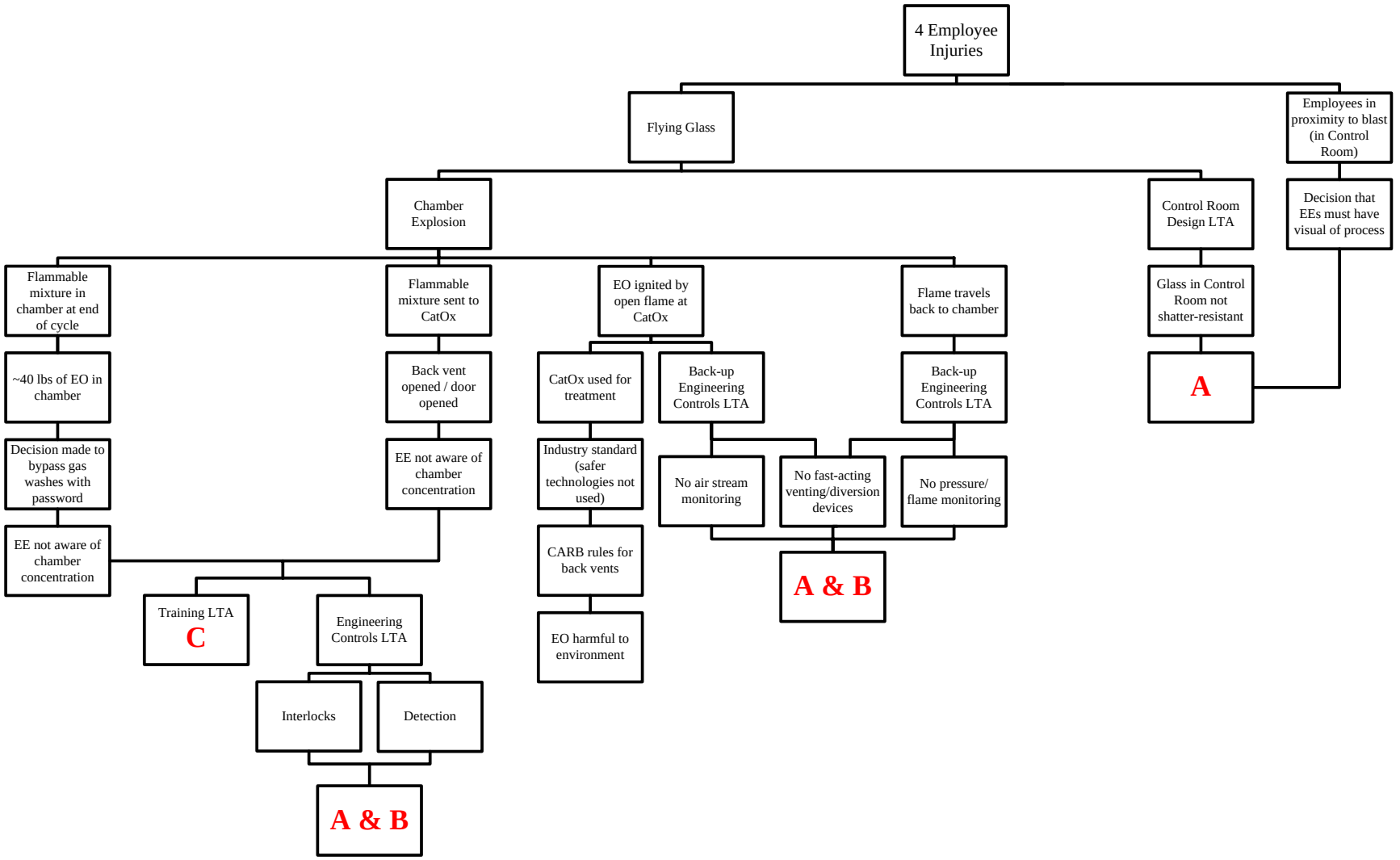
Thibault, Paul; Britton, Laurence G.; Zhang, Fan, 2000. *Deflagration and detonation of ethylene oxide vapor in pipelines,* Process Safety Progress, Volume 19, No. 3, pp. 125-139, American Institute of Chemical Engineers.

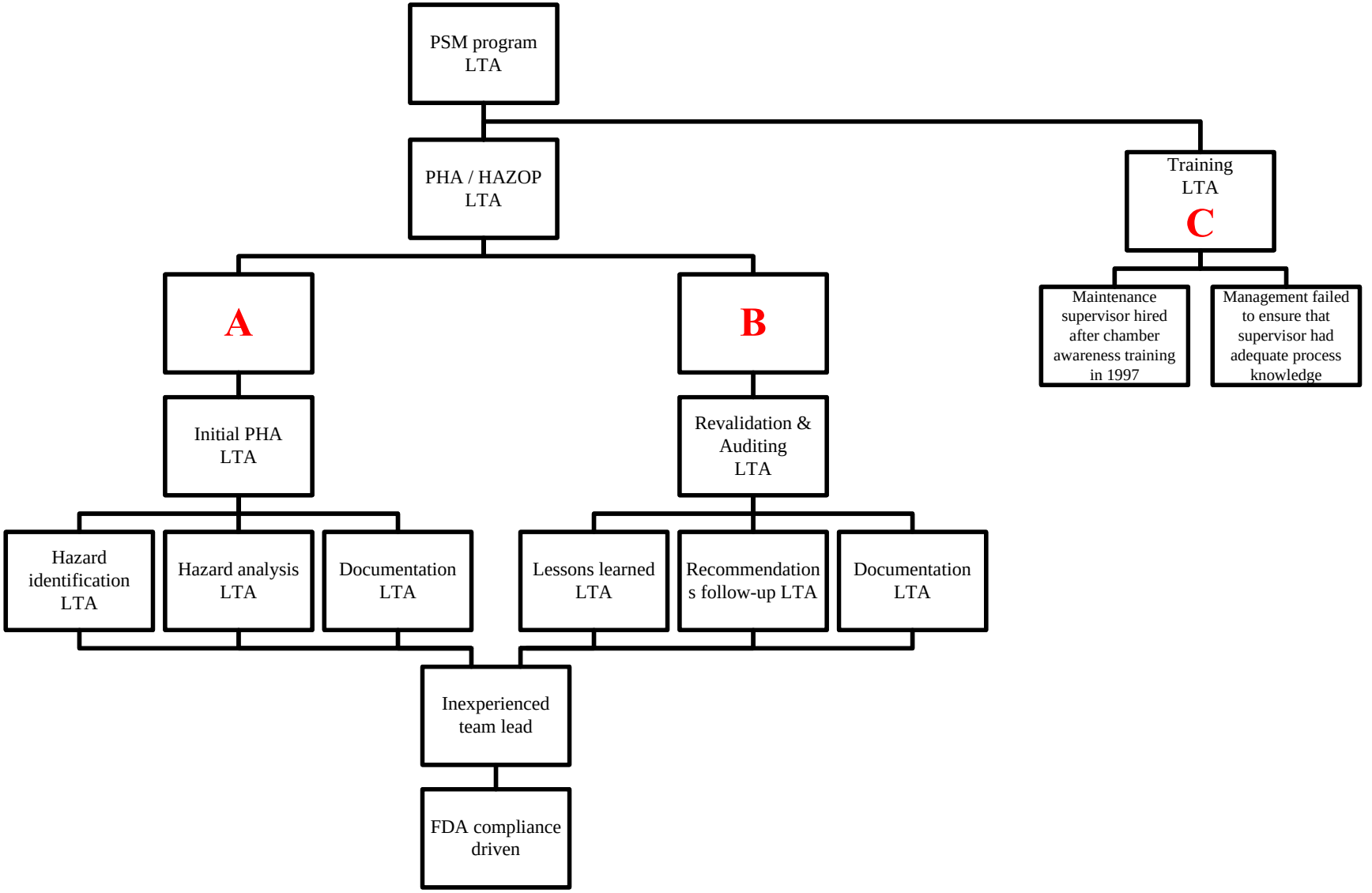
U.S. General Services Administration (GSA), 2003. *U.S. General Services Administration Standard Test Method for Glazing and Window Systems Subject to Dynamic Overpressure Loadings,* GSA TS01 (2003).

Appendix A: Event Timeline



Appendix B: Logic Tree Diagram




PSM program LTA
PHA / HAZOP LTA
Training LTA
C
Maintenance supervisor hired after chamber awareness training in 1997
Management failed to ensure that supervisor had adequate process knowledge
A
B
Initial PHA LTA
Revalidation & Auditing LTA
Hazard identification LTA
Hazard analysis LTA
Documentation LTA
Lessons learned LTA
Recommendations follow-up LTA
Documentation LTA
Inexperienced team lead
FDA compliance driven