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SAFETY SURVEILLANCE OF  
MEDICAL DEVICE-RELATED SURGICAL FIRES

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Thesis Committee Chair: Grant Baldwin, PhD, MPH

An abstract of  
A Thesis submitted to the Faculty of the  
Rollins School of Public Health of Emory University  
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Master of Public Health in the Career MPH program  
2012

## **Abstract**

### **SAFETY SURVEILLANCE OF MEDICAL DEVICE-RELATED SURGICAL FIRES**

**BY**

Stephanie Joseph

This thesis aimed to identify and analyze surgical fire reports submitted to FDA's Manufacturer and User Device Experience (MAUDE) database to support the Preventing Surgical Fires (PSF) initiative ([www.fda.gov/preventingsurgicalfires](http://www.fda.gov/preventingsurgicalfires)). Surgical fires occur on or in patients undergoing medical procedures and are preventable medical errors. They may occur when an ignition source, oxidizer, and fuel come together and can result in serious injury or death. FDA regulates elements of the fire triangle as either medical devices or drugs and therefore receives surgical fire reports submitted to MAUDE. The internal database was searched over two years (2008-2009), for keywords and devices implicated in surgical fires. The records were read individually to identify surgical fire reports. The data was analyzed to determine the number of reports, their severity, and how many referenced oxygen use, or use of alcohol-based skin preparation agents. The total number of surgical fire reports submitted to FDA in 2008 totaled 65, and those for 2009 totaled 47 (excluding reports from foreign sources, these totals are 48 and 39, respectively). Oxygen was involved in 29% of the 2008 total surgical fire reports and 30% for 2009. Alcohol-based skin preparation agents were involved in 4% of the 2008 reports, and 11% of the 2009 reports. Burns were reported in 35% of the 2008 reports and 52% of the 2009 reports. Surgical fires resulting in no injury were reported in 35% of the 2008 reports, and 38% of the 2009 reports. Outcomes were unknown in 22% of the 2008 reports, and 2% of the 2009 reports. One report involving death was reported in 2008 and one in 2009. After comparing these results to estimates in the literature, surgical fire reports in MAUDE likely underestimate what is happening on a national scale (largely due to underreporting). FDA and partners of the PSF initiative should develop a case definition for surgical fires so that data can be better compared. Actions to stimulate reporting of surgical fires should also be taken. Publication of these results may spur clinicians to reassess their risk of experiencing a surgical fire, and adopt best practices to mitigate this risk.

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# Introduction and Statement of and Context for the Problem

## ***Purpose statement***

The purpose of this study is to identify the number, and severity, of the surgical fire adverse event reports submitted to the U.S. Food and Drug Administration's (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database over a two year period from January 1, 2008 through December 31, 2009. This information will be used to support FDA's Preventing Surgical Fires Initiative ([www.fda.gov/preventingsurgicalfires](http://www.fda.gov/preventingsurgicalfires)) and may be used in public communications and to answer press inquiries.

## ***Introduction and rationale***

The Institute of Medicine (IOM) estimates that as many as 98,000 people die each year in the United States due to preventable medical errors (Institute of Medicine, 1999). The morbidity and mortality associated with these errors, coupled with the fact that they are preventable, makes their study a worthwhile public health endeavor.

Of particular interest to the author<sup>1</sup>, and to FDA, is the preventable medical error of surgical fires. These are fires that occur on, in, or in close proximity to a patient undergoing a medical procedure. Surgical fires can result in serious injury, including 2<sup>nd</sup> or 3<sup>rd</sup> degree burns. Some of these burns may lead to permanent scarring or disfigurement. They can also result in death, primarily in cases where the fire occurs in the patient's airway.

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<sup>1</sup> The author is currently employed by FDA.

**Figure 1: Surgical Fire Depiction (FDA, 2011)**



Surgical fires resulting in injury are believed to be relatively rare, and it is thought that the majority of fires are put out before the patient is injured. However, those that do occur have a significant financial cost associated with them. A review of closed malpractice claims for monitored anesthesia care (1990-2002) in the American Society of Anesthesiologists closed claims database revealed that payment was made in 89% of on-patient fires, with a median payment of \$71, 375 (Bhananker et al., 2006). Another closed claims review noted that payment was made in 100% of airway fires, which also had the highest median payment of \$167, 500 (Kressin, Posner, Lee, Cheney, & Domino, 2004).

In terms of indirect costs, patients with additional injuries may have additional hospitalization time, and lost work hours. Additionally, the surgical team and healthcare facility suffer the effects of negative publicity, loss of equipment and procedure space, and time spent reporting and preparing for court depositions instead of caring for patients (Pollock, 2004). Furthermore, there may be increased oversight from hospital

accreditation agencies such as the Joint Commission <sup>2</sup> or the Centers for Medicare and Medicaid (Hart, Yajnik, Ashford, Springer, & Harvey, 2011).

### *Etiology of a Surgical Fire*

The risk of a surgical fire exists when the three elements of the fire triangle (ignition source, fuel, oxidizer) are present in the surgical suite (see Figure 2). Ignition sources, such as electrosurgical units (ESUs) and lasers, are medical devices regulated by FDA. Similarly, some fuels (e.g. alcohol-based skin preparation agents, tracheal tubes, surgical drapes) and oxidizers (e.g. oxygen) are also regulated by the FDA as drugs or medical devices.

**Figure 2: The Fire Triangle (FDA, 2011)**



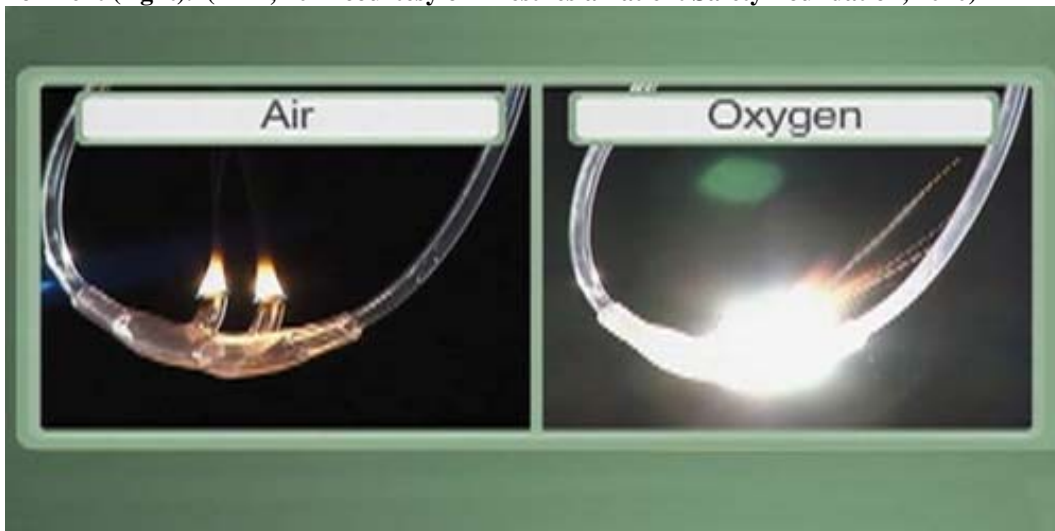
It should be noted that the oxidizer is a very important part of the fire triangle. Although some fires occur in ambient air (i.e. room air), most fires occur in the presence

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<sup>2</sup> The Joint Commission is a well recognized hospital accrediting agency. They have also published preventive recommendations for surgical fires (Joint Commission, 2003), which they deem “sentinel events” (i.e. an event that is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof).

of an oxygen-enriched environment (an atmosphere that contains more oxygen than is present in room air). Generally, ambient air contains 21% oxygen, 78% nitrogen, and trace amounts of carbon dioxide and other gases (Sheinbein & Loeb, 2010). Materials that will not burn in room air may burn more vigorously and spread more quickly in an oxygen-enriched environment (ECRI Institute, 2009c; Sheinbein & Loeb, 2010). In the surgical setting, an oxygen-enriched environment can be created when supplemental oxygen (>30% concentration) or nitrous oxide is being delivered to the patient.

**Figure 3: Photo showing a nasal cannula fire in room air (left) compared to an oxygen-enriched environment (right). (FDA, 2011 courtesy of Anesthesia Patient Safety Foundation, 2010)**



### *FDA's Role in Surgical Fire Prevention*

Since FDA has regulatory authority over the drugs and devices in the fire triangle, the agency receives adverse event reports related to surgical fires. The reports are most often submitted by medical device manufacturers and health care facilities (by law, manufacturers and user facilities are required to report medical device-related adverse events resulting in death or serious injury to FDA), but anyone can submit a report

through the MedWatch system<sup>3</sup>. As part of FDA’s regulatory authority, the agency oversees the adequacy of labeling for the products it regulates, and works to ensure the drugs and devices in the fire triangle are appropriately labeled with warnings to highlight flammability and fire concerns. However, the agency continues to receive adverse event reports of surgical fires each year.

**Figure 4: Example of alcohol-based skin preparation labeling containing fire warnings**



Other healthcare and clinical practice organizations (including ECRI Institute, Association of periOperative Registered Nurses, Anesthesia Patient Safety Foundation and American Society of Anesthesiologists) have published best practices for surgical fire prevention. Foremost among these recommendations is to evaluate the need for

<sup>3</sup> Medwatch is an FDA system whereby the public can voluntarily report a serious adverse event, product quality problem, product use error, or therapeutic inequivalence/failure that is suspected to be associated with the use of an FDA-regulated drug, biologic, medical device, dietary supplement or cosmetic. Available online: <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

supplemental oxygen delivery for each patient, and to deliver the minimum concentration necessary to maintain adequate oxygenation in the blood. Other recommendations include the safe use of medical devices and alcohol-based skin preparation agents, as well as increased communication among the surgical staff.

In an effort to engage stakeholders involved in surgical fire prevention, FDA held a meeting in October 2010 with other federal agencies and professional societies to identify ways to collaborate to prevent surgical fires<sup>4</sup>. Subsequently, in October 2011, FDA and its partners launched an initiative entitled “Preventing Surgical Fires” ([www.fda.gov/preventingsurgicalfires](http://www.fda.gov/preventingsurgicalfires)). The goals of the initiative are threefold: 1. to increase awareness of factors that contribute to surgical fires 2. to disseminate surgical fire prevention tools and 3. to promote the adoption of risk reduction practices throughout the healthcare community.

The research and information gathered in this thesis will be used to supplement FDA’s Preventing Surgical Fires initiative. FDA has not previously performed or published the results of an extensive search of the Manufacturer and User Device Experience (MAUDE) surveillance database for the number and severity of surgical fires reported to the agency. The purpose of this thesis is to review the adverse event reports related to surgical fires over a two year period and determine the number of surgical fires reported to MAUDE, as well as the severity of these events, and how often they involved the use of oxygen and/or alcohol-based skin preparation agents.

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<sup>4</sup> A summary of the FDA-Sponsored Stakeholder Meeting on Surgical Fire Prevention is available online: <http://www.fda.gov/Drugs/DrugSafety/ucm239511.htm>

## ***Problem statement***

The most cited estimate in the literature indicates that 550-650 surgical fires occur annually in the United States (ECRI Institute, 2009c). These figures are an extrapolation based on data reported to the Pennsylvania's Patient Safety Reporting System, which had estimated that 28 surgical fires occur each year in Pennsylvania (Pennsylvania Patient Safety Authority, 2007). To put this number in context, an estimated 50 million inpatient and outpatient surgical procedures occur in the United States each year (Joint Commission, 2003). Although surgical fires are relatively rare, they have resulted in serious injury and death, and they can be prevented. In fact, "patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility" is considered a "never event" by the Agency for Healthcare Research and Quality and the National Quality Forum<sup>5</sup>.

In summary, because FDA regulates the devices and drugs that are components of the fire triangle, the agency has a vested interest in promoting the prevention of surgical fires. However, FDA has not previously reviewed or published the number of surgical fire adverse event reports that have been reported to its medical device surveillance database (MAUDE)<sup>6</sup>. Given the recent launch of the Preventing Surgical Fires initiative, it is important to accurately track the baseline number of surgical fire adverse event reports, so that going forward, FDA may determine whether the number of surgical fire

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<sup>5</sup> The term "Never Event" was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify adverse events that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. (Agency for Healthcare Research and Quality, no date)

<sup>6</sup> Other researchers have performed analyses of surgical fire reports contained within the public version of the MAUDE database. These estimates and their limitations are discussed in the Review of the Literature that follows. None of these estimates have been validated by FDA.



reports are trending upwards or downwards, or identify patterns related to severity of the outcomes, and associations with the use of FDA-regulated products. Additionally, these figures will be helpful to FDA in answering press inquiries, and for developing public communications. The results of this thesis will help support FDA's activities in these areas.

## ***Theoretical Framework***

Surgical fire prevention efforts are informed by the health belief model. There are six main constructs of this theory, outlined below. Essentially, the theory states that a person may change their behavior if they perceive themselves to be at risk for a certain condition, and if they also believe they have the power to prevent this condition from occurring (i.e. that it can be prevented) (Healy & Zimmerman, 2010). By targeting health communications to surgeons and anesthesiologists, surgical fire prevention efforts aim to have these professionals recognized the real risk of surgical fires. We also hope they will recognize that they have the power to prevent these fires by adopting the best practice recommendations that have been published by several organizations, including FDA through its Preventing Surgical Fires Initiative. Additionally, by doing outreach to patients, the goal is that they may have a better informed perception of their risk of experiencing a surgical fire, and that they will learn appropriate discussion points to dialog with their care providers and better understand how the risk of surgical fire is being mitigated.

**Table 1: The 6 main constructs of the Health Belief Model (University of Twente, no date):**

<b>Concept</b>	<b>Definition</b>	<b>Surgical Fire Prevention Relevance</b>
<b>Perceived Susceptibility</b>	One's opinion of chances of getting a condition	Surgeons, anesthesiologists, and other healthcare professionals believe a surgical fire can happen at their healthcare facility.  Patients believe they may be at risk of experiencing a surgical fire, especially if undergoing a head and neck procedure.
<b>Perceived Severity</b>	One's opinion of how serious a condition and its consequences are	Surgeons, anesthesiologists and other healthcare professionals believe the outcomes of a surgical fire can be devastating enough that they try and avoid having them happen. Patients believe this too.
<b>Perceived Benefits</b>	One's belief in the efficacy of the advised action to reduce risk or seriousness of impact	Health care professionals believe that the recommendations outlined in the preventing surgical fires initiative (e.g. judicious use of supplemental oxygen, waiting for alcohol-based skin preparation agents to dry) would prevent a surgical fire. Patients believe that talking to their healthcare provider will help encourage their care provider to take steps to prevent fires.
<b>Perceived Barriers</b>	One's opinion of the tangible and psychological costs of the advised action	Because surgical fires are relatively rare events, surgeons and other healthcare professionals have a “this will not happen in my Operating Room” attitude. Publication of the number of surgical fire reports by a federal public agency, such as FDA, may spur these clinicians into believing surgical fires are a real world problem and pose a serious risk to patients.
<b>Cues to Action</b>	Strategies to activate "readiness"	Implementation of a fire risk-assessment checklist at the beginning of every surgical procedure.  By patients talking to their care providers about the risks of surgical fire and how to mitigate them, patients may encourage clinicians to learn more about these adverse events and take steps to prevent them.
<b>Self-Efficacy</b>	Confidence in one's ability to take action	Surgeons, anesthesiologists and other healthcare professionals are confident in surgical fire prevention practices. Patients are confident that open dialog with their care provider improves the quality of their care, and reduces their chances of experiencing an adverse event.

## ***Research question***

This study aims to answer the following questions:

- How many reports of surgical fires were submitted to MAUDE during the 2 year period in question, and how do these numbers compare to estimates in the literature?
  - Hypothesis: The number of surgical fires reported annually to FDA's database will be far lower than the estimated 550-650 fires per year that has been documented in the literature. This is suspected because it is well accepted that adverse events involving medical devices are widely underreported (U.S. Government Accountability Office, 2009) and also because MAUDE is a passive surveillance system that relies on people to recognize that a surgical fire is an event worth reporting, that is associated with a medical device, and that the FDA is the authority with whom reports should be filed.
- Of the surgical fire reports submitted to FDA, how many reports indicate a serious injury or death?
- Additionally, how many of these reports indicate that supplemental oxygen and/or alcohol-based skin preparation agents were being used?
- Where did the fire occur (e.g. on the patient, in the patient, elsewhere)?

## ***Significance statement***

Surgical fires are preventable medical errors that should never occur. Although it has recently launched a surgical fire prevention initiative, FDA has not previously published or extensively searched and analyzed the surgical fire event reports in its medical device surveillance database. Although there are existing estimates in the literature, publication of the number of documented reports of surgical fires received by a federal public health agency is likely to carry more weight, and add more significance to the problem than previously existed. It may also cause surgeons and anesthesiologists to reconsider their risk perception and adopt best practices for surgical fire prevention.

## ***Definition of terms***

**Surgical Fire:** A surgical fire is defined as a fire that occurs on or in a patient. (Caplan et al., 2008). For the purposes of this thesis, fires that occur within close proximity to the patient (e.g. on the surgical drapes) will also be included.

**Operating Room Fire:** operating room fires are defined as fires that occur on or near patients who are under anesthesia care, including surgical fires, airway fires, and fires within the airway circuit. (Caplan et al., 2008). For the purposes of this thesis, the requirement that the patient must be undergoing anesthesia care will be relaxed (i.e. any fire on or near patients will be included, even if the patient is not subjected to anesthesia).

Airway fire: is a specific type of surgical fire that occurs in a patient's airway. Airway fires may or may not include fire in the attached breathing circuit (Caplan et al., 2008).

Flash fire: For the purposes of this thesis flash fires will be defined as unexpected, sudden fires of very short duration (less than a few seconds).

High-risk procedure: is defined as one in which an ignition source (e.g., electrosurgical unit) may come in proximity to an oxidizer-enriched atmosphere (e.g., supplemental oxygen and/or nitrous oxide), thereby increasing the risk of fire. Examples of high-risk procedures include, but are not limited to, tonsillectomy, tracheostomy, removal of laryngeal papillomas, cataract or other eye surgery, burr hole surgery, or removal of lesions on the head, neck, or face (Caplan et al., 2008).

Oxygen-enriched environment: An environment containing a greater percentage of oxygen than is typically present in ambient air (i.e. room air). Ambient air contains 21% oxygen, 78% nitrogen, and trace amounts of carbon dioxide and other gases (Sheinbein & Loeb, 2010).

Early Warning signs of Fire: Unexpected flash, flame, smoke or heat, unusual sounds (e.g. a "pop," snap or "foomp") or odors, unexpected movement of drapes, discoloration of drapes or breathing circuit, unexpected patient movement or complaint (Caplan et al., 2008).

## Review of the Literature

A review of the literature was performed to identify articles and information that could be used to develop the search criteria and methodology for this study. The literature was also searched for any existing case definitions for surgical fires that could prove useful when reviewing adverse event reports. Finally, the literature was searched for information about the incidence or prevalence of surgical fires. The table below outlines the search terms that were used. Non-traditional sources, such as educational videos and publications from federal agencies, of which the author was aware, were also included.

**Table 2: Search Strategies and Results from Literature Review**

Objective	Search Strategy	Summary of Results
1. To identify literature related to surgical fires so that search criteria for the thesis could be developed	Pubmed searched for the past 3 years (August 2008-2011), for articles in English, using these search terms: - “operating room” and fire - “operating room” and fires - “surgical fire” - “surgical fires” - “surgical field” and fire - “surgical smoke” and fire - device and “operating room” and fire	33 unique articles were identified. Articles consisted of case reports, review articles, clinical practice recommendations, surveys and studies involving bench testing of medical devices.
2. To identify a case definition in the literature for a surgical fire	Pubmed searched for articles in English, using these search terms: - “case definition” and “surgical fires” - surveillance and “surgical fire” - surveillance and “operating room” and fire	No results returned
3. To identify literature summarizing the incidence and/or prevalence of surgical fires	Pubmed searched for the preceding 10 years for articles in English using these search terms: - “operating room fires” and prevalence - “operating room” and fires and prevalence - “surgical fire” and prevalence - “surgical fires” and prevalence - “surgical fires” and incidence	2 records already identified in search #1 above, were identified using the prevalence search terms.  4 articles were identified using the incidence search.

## ***Body of ROL***

The articles that were reviewed were comprised of case reports, surveys, reviews, non-clinical experiments involving bench testing or simulations using medical devices, letters to the editor (some of which described case reports), and clinical practice guidelines or recommendations.

The case reports describe fires occurring during a variety of surgical procedures, from taking biopsies to coronary bypass surgery, and describe outcomes ranging from no harm to the patient, to second degree burns, to a resulting 2 month stay in the Intensive Care Unit. The reports describe a variety of ignition sources and related medical devices, and cite oxygen use, alcohol-based skin preparation agents, and dry, easily ignitable surgical sponges as contributing factors.

Of the articles describing surveys, a recent internet-based questionnaire of head and neck surgeons (Smith & Roy, 2011) found that twenty-five percent (25%) of respondents had experienced at least one surgical fire in their careers. The survey results also indicated that electrosurgical units and lasers were the most common ignition sources, and that oxygen was involved in more than eighty percent (81%) of the cases. A key finding of another survey (Hart, Yajnik, Ashford, Springer, & Harvey, 2011) was that surgeons were involved in safety and education training involving surgical fires only thirty percent (30%) of the time at the healthcare facilities surveyed, and anesthesiologists involved forty-three percent (43%) of the time or less.

The reviews recapped the elements of the fire triangle, outcomes from case reports in the literature, and sometimes summarized clinical practice recommendations outlined by professional societies. They also described estimates in the literature for the

frequency of occurrence of surgical fires. Most often, ECRI Institute's estimates were cited. These include ECRI Institute's 2009 estimate of 550-650 reports per year, or their prior estimate of 100 surgical fires occurring annually in the US each year (ECRI Institute, 2009c). Other referenced estimates were from the American Society of Anesthesiologists who stated in their 2008 Practice Advisory that an estimated 50-200 operating room fires occur in the United States each year (Caplan et al., 2008).

The non-clinical experiments included bench tests to characterize whether or not, and how quickly a fiber optic cable connected to a light-source would melt a drape or set it on fire. In this article, the authors (Smith & Roy, 2008) also published a review of the public MAUDE database searching for surgical fires. From 1998 to 2006, the authors found 71 surgical fires associated with electrosurgical units, and 2 associated with fiber optic light cords. However, the authors excluded a number of types of surgical fires (like airway fires, and those not involving drapes), so this is not a true estimate of the surgical fires contained in the MAUDE database.

The clinical practice recommendations fall into three basic areas: judicious use of supplemental oxygen, safe use of medical devices, equipment, and alcohol-based skin preparation agents, and increased communication among the surgical team.

It should be noted that the literature review did not produce any information about a surgical fire case definition. Further details about the review of the literature are provided below.



### Case reports

Eight of the reviewed articles, contained specific case reports. Two of the case reports (Kuczkowski, 2008; Mirsaidi, 2008) reported device fires (an anesthesia unit's circuit board catching fire and battery pack setting a trash bin on fire, respectively) rather than surgical fires (i.e. they met the definition of operating room fires, rather than surgical fires). The remaining case reports were reviewed, and a list of the ignition sources, fuel sources, and oxidizers they described as causal factors were compiled.

Wikiel, Gemma, Yowler, Coffee, & Brandt (2011) described a surgical fire that occurred during a temporal artery biopsy, during which oxygen was being delivered through nasal cannula. The authors described a flash fire that occurred around the nasal cannula, with 2<sup>nd</sup> degree burns noted on the patient's face and ear. The burns ultimately healed and the patient was discharged after 19 days. An electrocautery unit was described as the ignition source.

Laudanski, Schwab, Bakuzonis, & Paulus (2010) described two separate case reports where the heated humidifier circuit of a ventilator caught fire. In one case, this occurred during set-up, and before the patient was connected (therefore, this would be deemed an operating room fire rather than a surgical fire). In the other case, the fire occurred while the patient was connected to the circuit, and the authors described visible flames in the inspiratory limbs of the breathing circuit. The event was described as lasting 30-45 seconds, and a chest radiograph was taken to confirm no injury to the patient, after the tracheal tube was removed and no evidence of soot noted.

Friedrich et al. (2010) described gauze going up in small flames in the thoracic cavity during coronary artery bypass grafting (CABG). An electrocautery unit was noted

as the ignition source and the fire was extinguished using saline. The patient was noted to leave the operating room in stable condition. The authors discuss the use of wet surgical sponges to reduce the risk of fire, as well as the use of alternate surgical devices (e.g. harmonic scalpel as an alternative to electrocautery). A similar case was described by Moskowitz (2009), who described a fire in the patient's chest cavity during dissection of the left internal mammary artery before CABG. The authors noted the electrosurgical device indirectly ignited gauze resulting in fire. Oxygen was provided via nasal cannula, and an endotracheal tube was subsequently placed. Sterile water used to douse the flames in the chest and the patient was noted to have a normal postoperative course, being discharged on day 5. Interestingly, the authors state the surgeon initially applied saline soaked gauze around the chest, but during the course of the procedure, it had dried enough to become a fuel source. The authors encourage increased communication among the surgical staff and a timeout to prevent fires.

Another case that was reviewed (Watson, 2009) described a muffled "pop" and smoke witnessed by staff as coming from under the surgical drapes. After the drapes were removed, the patient's head was seen as engulfed in flames. Contributing events were use of an electrosurgical monopolar pencil, having prepped the patient's skin using an isopropyl alcohol/iodoform mixture, and having placed the oxygen mask loosely on the patient's face. The fire was noted to last less than 15 seconds, but the patient was described as staying in the Intensive Care Unit (ICU) for 2 months before being discharged to rehab.

## Surveys

Two studies that employed surveys were reviewed. Smith & Roy (2011) conducted a prospective study, in the form of an internet-based questionnaire delivered to a convenience sample of members of the American Academy of Otolaryngologists (AAO) (i.e. head and neck surgeons). They noted a 15% response rate (349 responses of the 2300 people who typically open their email from AAO). Twenty-five percent (25%) of the physicians who completed the survey (88/349) reported having experienced one surgical fire. The authors stated concern that this may be an overestimate, however, given that head and neck surgeries are among the highest risk procedures for surgical fires, this may be accurate.

Of the surgeons who responded to the survey, 88 had experienced at least 1 fire, 10 experienced 2 fires, and 2 experienced 5 fires each. The most common ignition sources were an electrosurgical unit (59%), a laser (32%), and a light cord (7%), though the authors noted that the descriptions of the light cord fires indicated melting of the drapes rather than true surgical fires. Eighty-one percent (81%) of fires occurred while supplemental oxygen was in use. Common fuels included an endotracheal tube (31%), OR drapes/towels (18%), and flash fire (where no substrate burned) (11%). Less common fuels included alcohol-based preparation solution, gauze sponges, patient's hair or skin, electrosurgical unit with retrofitted insulation over the tip, tracheostomy tube, tonsil sponge, suction tubing, a cottonoid pledget, and a red rubber catheter. As for the surgical scenarios where the fire took place, most occurred during endoscopic airway surgery (27%), oropharyngeal surgeries (e.g. tonsillectomy) (24%), cutaneous/trancutaneous

surgery (23%), tracheostomy (18%). Other scenarios included the light cord melting drapes (7%), and that the anesthesia machine caught fire (1%).

All of the above information is relevant to the current thesis, as these fuels and ignition sources can serve as search criteria for the surveillance of adverse events related to surgical fires. Furthermore, the relative frequency of the types of ignition sources and location of surgical fires can be used for comparison against the data that is obtained in this thesis. The strength of Smith & Roy's study (2011) is that it is a first of its kind. No other survey has polled head and neck surgeons for their experiences with surgical fires, or categorized responses to get an estimate of which ignition sources, fuels, and oxygen concentrations were prevalent. Limitations of the study include its poor response rate. Although the authors list a 15% response rate, they calculated this based on the number of people who actually open their AAO email. However, if this is calculated based on the number of people to whom the email was sent, the response rate drops considerably (to ~4%). Additionally, because this is a self-reported survey responses from respondent may be subject to recall errors, may not be truthful, and their definitions of surgical fires may vary from that of the authors.

Hart et al. (2011) also conducted a survey, but it was related to education of surgical fire prevention. Their phone survey study was a convenience sample of facilities in three tiers: those within their own healthcare system, those in their city, and those pulled from a list of national hospitals. Participants (either the surgical director of nursing, or charge nurse at the facility) were asked about fire drills, fire safety education, simulation or demonstration, frequency, the type of staff involved (i.e. anesthesiologists and surgeons included). The authors noted that surgeons were involved 30% of time or

less at each of the three tiers surveyed. Anesthesiologists involved 43% or less of time in safety/education training.

In addition to the external survey, the authors shared their own facility's experience with fire safety training. A pretest was conducted and participants were asked to identify the three components of the fire triangle. Only 81.8% of respondents correctly identified all 3 elements, which the authors suggest indicates a need for education. Additionally, only 92% correctly identified 4 digit phone number to call for fire emergency. Hart et al. (2011) also stated that fire safety was not a topic of priority at hospitals because of misinformed assumptions such as: 1. OR fires do not happen in today's hospitals, 2. if fires do occur, they were not preventable 3. fires only occur at inferior facilities and 4. all staff in the OR know what to do if a fire occurs. The authors included recommendations for what items to keep on hand in the event of a surgical fire, and provided tips for extinguishment.

#### Reviews:

The literature search also identified several review articles. Zahiri et al. (2011) reviewed literature from 1950-onward (in medline) for the terms patient safety and operating room. Of the 807 patient safety articles identified, 11% focused on fires (other topics included, retained foreign objects (6%), wrong site surgery (1%), and infections (26%). The authors cite estimates from the American Society of Anesthesiologists, of fires ranging from 50-200 cases annually, with significant morbidity resulting in 20% of cases. The authors also summarized a variety of preventive recommendations, and noted that a surgical safety checklist is advocated by many studies and experts and that they are beneficial for fostering effective communication among personnel and for OR safety.

The specific fire prevention recommendations that the authors list repeat what the ASA (Caplan et al., 2008) and ECRI Institute (2009c) have published, and which has been summarized by FDA (interested parties may refer to “Recommendations for Healthcare Professionals on Preventing Surgical Fires” found on the Preventing Surgical Fires website for details (FDA, 2011)).

Another review that was quite interesting was from the United Kingdom (Yardley & Donaldson, 2010). It was specific to surgical and operating room fires and the authors searched the internet, as well as pubmed and medline from 1948 onward using key words for operating room fires, surgical fires, and safety management. They identified 400 citations, many of which were case reports, while other were non-clinical experiments exploring the conditions required for ignition, and still others intended to provide advice to clinicians in order to prevent fires. Yardley & Donaldson discussed the history of surgical fires, noting that from the 1940s-1970s many surgical fires resulted from the use of flammable anesthetics. Once non-flammable anesthetics became available in the 1960s, flammable anesthetics were phased out, and this brought a decrease in awareness of the risks of surgical fires. The authors state that three instances of surgical fires were reported to the National Reporting and Learning System in the UK between 2006 and 2009. They also reference US estimates for incidence range from 20-650 surgical fires annually, many of which are noted to be minor fires causing no harm, but 20-30 causing disability and 1-2 being fatal. The authors list diathermy (i.e. electrosurgery) as the most common ignition source identified in their review. However, they also stated that lasers carried a greater risk. Another interesting finding was that nearly two in three qualified doctors had never heard of surgical fires.

Nishiyama, Komori, Kodaka, & Tomizawa (2010) cover much of the same information as the other reviews, but they provide unique detail about fires that occur in patient's bowels due to the accumulation of methane gas. The authors provide clinical practice recommendations for preventing surgical fires that are specific to the types of devices (i.e. alternatives to electrosurgery) that should be used to gain access to the intestines.

Sheinbein & Loeb's (2010) review succinctly summarized the outcomes of operating room fires, stating they "produce significant thermal injury, leading to partial-thickness or full-thickness burns, the latter requiring skin grafting. Destruction of the skin and mucous membranes predisposes the burnt victim to fluid and electrolyte loss, heat loss and infection. Swelling and edema of the airway are common after any degree of burn in the airway and can lead to life-threatening airway obstruction. Toxins released from burning plastics can also cause inhalation injuries and/or asphyxiation."

Other reviews by Rinder (2008) and Shapiro (2008) covered much of the same material as already presented above.

### *Non-clinical experiments*

Smith & Roy (2008) explored the fire and burn risk associated with fiberoptic cables and electrosurgical devices. They performed experiments to simulate the clinical environment, where ignition sources (fiberoptic cable or monopolar electrosurgical device) were inadvertently placed on the drape or in contact with a surgical towel. Their results indicate that the fiberoptic cable would melt a hole in the polypropylene drape within 15 seconds, and cause discoloration to a cotton towel (but no hole). They also

found that the electrosurgical device did not burn through the towel at any of the power levels tested, and would burn through the polypropylene drape only when the device was set to 30W. The study did not produce flame or fire in any trial. However, because polypropylene drapes melt at 160°C the authors note that melting of the drape from a fiber optic cable presents a significant burn risk to the patient.

Of note, the authors also searched the public MAUDE database from 1998 to 2006 for the keywords: “fiber optic light cable” “fiber optic cable” “operating room and fire” electrosurgical and fire” and “electrosurgical and burn.” They included any events involving flash fire, patient burn, drape fire or staff gown fire. However, because the authors excluded specific event types (i.e. those involving the electrosurgical grounding pad, OR sponges, endotracheal tubes and tracheostomy fires where the drapes did not catch fire), their results are not a comprehensive overview of the surgical fires contained in the MAUDE database. The MAUDE review revealed 2 fires involving fiberoptic cables and 71 fire-related incidents involving electrosurgical units. A table summarizing their findings is shown in Table 3 below.

In a more recent study (2011), Roy & Smith used a mechanical model of a whole chicken to simulate the oral cavity and assess the oxygen parameters necessary to cause an airway fire. Using electrocautery at 15W, the authors were unable to ignite any fire when the oxygen concentration was below 50%. They recommend physicians maintain their patients on the lowest oxygen concentration possible for which anesthesia can be safely maintained to reduce the risk of fire.



**Table 3: Results of public MAUDE search (Smith & Roy, 2008 )**

Table 2  
Fire and burn incidents involving fiberoptic light cables and electro-surgical devices reported to the FDA between 1998 and 2006

	Fiberoptic cable	Electrosurgical unit
<b>Fire</b>		
Flash fire (head and neck procedure, O <sub>2</sub> in use)	0	23
Flash fire with drape fire	0	12
Primary drape fire	2	18
Fire under drape (accumulation of flammable gases)	0	7
Primary device fire (spontaneous ignition of device)	0	1
Preparatory solution related fire (alcohol-based preparatory solution)	0	4
Staff gown fire	0	1
Tracheostomy procedure fire (drapes involved)	0	6
Total reported fire incidents	2	71
<b>Burn</b>		
Drape burn without patient injury	4	–
Drape burn with patient injury	3	–
Direct patient burn	12	–
Direct staff burn	3	–
Equipment (camera damaged by fiberoptic cable)	1	–
Total reported burn incidents	23	–
<b>Total</b>	<b>25</b>	<b>71</b>

A search of the MAUDE database at the FDA web site (<http://www.fda.gov/cdrh/maude.html>) revealed at least 25 incidents involving fiberoptic light cables and 71 incidents involving electro-surgical units.

*Clinical Practice Recommendations:*

Recommendations from healthcare organizations such as the American Society for Anesthesiology and ECRI Institute were identified in the traditional sources of the review of the literature (see nontraditional sources below for additional recommendations from healthcare organizations). The Association of periOperative Nurses has also

published recommendations, but these are typically summaries of what is recommended by ECRI Institute and others.

The ASA convened a “task force on operating room fires” and published a practice advisory in 2008 (Caplan et al., 2008). The advisory was a synthesis of scientific literature and analyses of expert opinion, clinical feasibility data, open forum commentary and consensus surveys (the advisory was also endorsed by the American Academy of Otolaryngology – Head and Neck Surgeons (ECRI, 2008)). The items most relevant to this thesis from the ASA advisory are the definitions described at the beginning of this paper. Also relevant are the ignition sources (including but not limited to electrosurgical or electrocautery devices, lasers, heated probes, drills and burrs, argon beam coagulators, fiberoptic light cables, and defibrillator paddles or pads) and fuel sources (including but not limited to tracheal tubes, sponges, drapes, gauze, alcohol-containing solutions, solutions containing other volatile compounds, such as ether or acetone; oxygen masks; nasal cannulae; the patient’s hair; dressings; ointments; gowns; gastrointestinal tract gases; blankets; suction catheters; flexible endoscopes; fiberoptic cable coverings; gloves and packaging materials) which can be used to inform the search criteria for the thesis. The article states that between 50 and 200 operating room fires occur in the United States every year, with as many as 20% of reported fires resulting in serious injury or death.

ECRI Institute is a non-profit healthcare research agency, and is widely considered expert in the area of surgical fire prevention. The organization performs forensic investigations and root cause analyses at hospitals after surgical fires have occurred. ECRI Institute has been publishing on surgical fire prevention and

management in their Health Devices journal for decades. In 2009, they update their estimates of the incidence of surgical fires, stating that the number of surgical fires in the US each year ranges from 550-650 per year (ECRI Institute, 2009c). Of these about 20-30 are serious with disfiguring or disabling injuries. One or two fatal fires occur each year, most of which are airway fires. This more recent estimate is an extrapolation of data from Pennsylvania's Patient Safety Authority (2007), which reported that in Pennsylvania 1 surgical fire occurs in every 86646 surgical procedures (or an average of 28 surgical fires per year in Pennsylvania). Although other states, such as Minnesota have mandatory reporting laws for death and disability associated with burns (Minnesota Department of Health, 2009), Pennsylvania appears to be the only state to have published their data specific to surgical fires. ECRI Institute also contracts for the Patient Safety Authority, and so they have access to the data as part of this contract. It should be noted that previous estimates from ECRI Institute indicated that approximately 100 surgical fires per year occurred in the United States.

With regard to the ignition sources involved in surgical fires, ECRI notes that 70% of surgical fires involve electrosurgical equipment as the ignition source, while 10% involve lasers. The balance of fires are ignited by a variety of other heat sources including electrocautery equipment and fiberoptic light sources. More rarely, other ignition sources include defibrillators and high speed burs (which can produce sparks), but only if an oxygen-enriched atmosphere is present.

ECRI notes that an oxygen-enriched environment is involved in 75% of surgical fires, while alcohol-based skin preparation agents are involved in 4% of reported fires. Furthermore, they state that about 21% of reported fires occur in the airway; 44% occur

on the head, face neck or upper chest; 26% occur elsewhere on the patient; 8% occur elsewhere IN the patient (ECRI Institute, 2009c). ECRI Institute also published detailed practice recommendations (interested parties may refer to their poster “Only You can Prevent Surgical Fires” for details, which can be found on the Preventing Surgical Fires website under the resources tab (FDA, 2011)).

### *Incidence of Surgical Fires*

The specific search for surgical fire incidence yielded several articles citing estimates of the frequency at which surgical fires occurred in the US. Pollock (2004) provided an overview of a team approach to surgical fire prevention, and noted that Federal Emergency Management Agency estimated in 1997 that 20-30 fires occur in operating rooms each year. Cady (2007) provided information for how a certified registered nurse anesthetist (CRNA) should prepare for a deposition and litigation involving a surgical fire and presented a case study. Also included was a reference to the Joint Commission stating that 66 surgical fire sentinel events had been reported to the organization from 1995-2006. Lastly, Bruley (2004), who is ECRI Institute’s surgical fire expert, discussed the institute’s 2003 estimate that 100 minor surgical fires occur annually in the US with approximately 10 being serious and 1-2 fatal. Bruley also presented the results of a public MAUDE search. The records in the database were searched over a 3.5 year period from January 1995-June 1998. It revealed 167 surgical fire reports, 56 of which (33%) occurred in the airway or were oropharyngeal fires. 47 (28%) were fires in the head and neck, 40 (24%) were ignited outside of the patient’s body, and 24 (14%) were fires in the patient, but not in the airway. The article does not

outline the search criteria, or note whether reports from foreign sources, or those with event dates outside the 3.5 years of interest were excluded from the results.

***Non-traditional sources:***

The causal factors surrounding surgical fires, namely the proximity and quantity of the elements of the fire triangle, are well understood and documented. Many healthcare organizations, such as the American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (APSF), Association of periOperative Registered Nurses (AORN), Christiana Care Health System and ECRI Institute have published best practices for the prevention and management of surgical fires. Those published by ECRI Institute and the American Society of Anesthesiologists were identified in the traditional sources of the literature review, and were described in detailed above. The other sources provide video content, posters, and risk assessment checklists. FDA has also developed an FDA expert commentary video in partnership with Medscape. All of these resources were compiled and can be accessed on FDA’s preventing surgical fires website (see “Resources and Tools for Preventing Surgical Fires” on the Preventing Surgical Fires website (FDA, 2011)). The specific recommendations in each of these sources were summarized and echoed in FDA’s preventing surgical fires recommendations for healthcare professionals as follows, which can also be found on the Preventing Surgical Fires website under the “Recommendations for Healthcare Professionals on Preventing Surgical Fires” tab (FDA, 2011).

## ***Summary of Current Problem and Study Relevance***

After reviewing the literature, a comprehensive list of ignition sources, fuel sources, and oxidizers was developed. The ignition and fuel sources corresponding to medical devices will be used as search criteria to identify reports of surgical fires in FDA's MAUDE database. Knowing that Smith & Roy (2011) found that 91% of fires were started by either ESU or laser, and ECRI Institute note that 80% of all fires are started using these ignition sources, it is with good confidence that as long as these devices are included in the search criteria of the thesis, a majority of the surgical fire adverse event reports should be captured. The review of the literature noted that fuels in the operating room are ubiquitous. None the less, including the fuels identified in the literature as search criteria for the thesis study will also help target the search. Finally, the estimates in the literature for the frequency of occurrence or incidence of surgical fires will be used to compare the results obtained in the thesis study.

# Methodology

## Introduction

FDA's Manufacturer and User Device Experience (MAUDE) database represents reports of adverse events involving medical devices. De-identified reports are published in a publicly accessible online-version of the database (shown below). However, this publicly available database has more limited search and display capabilities than FDA's internal system.

**Figure 5: Screenshot of the online, publicly-accessible MAUDE database**  
(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>)

The screenshot shows the MAUDE search interface on the FDA website. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the FDA logo. Below the navigation bar, there is a search bar and a "Go" button. The main content area is titled "MAUDE - Manufacturer and User Facility Device Experience". Below the title, there is a list of bullet points providing information about the MAUDE database. The search form is titled "Search MAUDE Database" and includes the following fields: Product Problem (dropdown), Product Class (dropdown), Brand Name (text), Manufacturer (text), Event Type (dropdown), 510K Number (text), PMA Number (text), Product Code (text), and Date Report Received by FDA (mm/dd/yyyy) (calendar). Below the search form, there is a "Go to Simple Search" button, a "Records per Report Page" dropdown set to 10, and "Search" and "Clear" buttons. At the bottom of the page, there is a disclaimer about the Freedom of Information Act (FOIA).

Therefore, FDA's internal MAUDE system will be searched for surgical fire reports over a multi-year time period from January 1, 2008 to December 21, 2009 (no patient or hospital identifiers will be presented in the analysis of the data). FDA's Research Involving Human Subjects Committee (RIHSC) was contacted, and an exemption from

their review was granted (because the data is publicly available, and only existing records will be searched). Emory's Institutional Review Board (IRB) was also contacted about this study, and a determination of "No IRB Review Required" was given.

## ***Research design***

The study involves a retrospective review of existing records related to surgical fires in FDA's MAUDE database. The date range for the search will include adverse events reported to FDA between January 1, 2008, and December 31, 2009. The search criteria was further narrowed by device "product classification code"<sup>7</sup> and "product problem codes"<sup>8</sup> associated with fire or related problems. A total of 23 device problem codes were selected. The search was narrowed by the device product code. The types of devices that were included were the ignition and fuel sources identified in the literature review. For example, the device product code field was searched for "electrosurg" and all related product codes were included. This was repeated for laser, tracheal tube etc (implantable defibrillator product codes were excluded). A total of 229 product codes were included in the search criteria. Lastly, the keyword text searches applied were also informed by the review of the literature, and the definition for early warning signs of fire. Two separate searches were conducted for each year of data. Table 4 below summarizes the search criteria.

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<sup>7</sup> The "product code" is a three letter code that is associated with a "device class" that refers to the level of CDRH regulation of a given device. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.

<sup>8</sup> The "product problem code" is a descriptor assigned to a report that summarizes the problem or issue described in the report (e.g. fire, ignited).



**Table 4: MAUDE Search Criteria for Surgical Fire Reports**

Search Field	Search Criteria
<p>Date Report Received</p> <p>(Three separate searches were run for each date range using the same criteria below)</p>	<p>Between 01-JAN-2008 and 31-DEC-2008</p> <p>Between 01-JAN-2009 and 31-DEC-2009</p>
<p>Device Problem Code</p>	<p>1494 – user used incorrect product for intended use</p> <p>1670 – use of device issue</p> <p>UNK – unknown</p> <p>1335 – intraprocedure, fire or flash during</p> <p>1245 – fire</p> <p>1208 – endoscopic accessory fire or melt</p> <p>1585- smoking</p> <p>1303 – ignited</p> <p>2942 – flare or flash</p> <p>2943 – flashpoint threshold met</p> <p>1247 – flammable</p> <p>2595 – spark</p> <p>1071 – burn of device or device component</p> <p>1348 – lead(s), burn(s) from</p> <p>2305 – burn hole(s)</p> <p>1106 – component overheating of</p> <p>1285 – heath</p> <p>1385 – melted</p> <p>1437 – overheating of device or device component</p> <p>1605 – superheat</p> <p>1644 – transducer overheating</p> <p>1645 – transducer probe overheating</p> <p>2204 – unknown (for use when the device problem is not known)</p>
<p>Product Code</p>	<p>229 product codes were included. See Appendix A for details.</p>
<p>Text search keywords</p>	<p>fire, flame, flash, smoke, smoking, ignite, ignited, pop, smell, smoulder</p>

## ***Instruments***

FDA's MAUDE database will be searched using the criteria outlined above, and the results will be exported to Microsoft Excel and unduplicated<sup>9</sup>. The records will be read through manually to confirm surgical fire "near misses" (no known harm to patient or provider) and those reports involving injury (harm to the patient or provider).

## ***Plans for data analysis***

No patient or hospital identifiers will be presented in the analysis of the data. Only information that is accessible in the public MAUDE system will be presented. The reports will be analyzed to identify the number of reports related to surgical fires. Additionally, the number of reports resulting in injury or death, those that note the use of supplemental oxygen, the location of the surgical fire (on the patient, in the patient, elsewhere), and whether or not an alcohol-based skin preparation agent was referenced will be tallied. The data will also be compared to existing surgical fire estimates in the literature.

## ***Limitations***

The following limitations are noted:

- The "date of event" field is separate from the "date reported to FDA" field. Since the latter will be used in this thesis, it is possible that the records reviewed for a given year (i.e. from January 1, 200X to December 31, 200X) will actually

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<sup>9</sup> Because one report may have multiple device problem codes assigned to it, there may be several rows in excel for the same report, each line having a different problem code. "unduplication" refers to merging these identical reports into one row, with the device problem codes merged into one cell, and the different codes separated/delimited by semi-colons.

include adverse events that occurred in prior years, but were only later reported to FDA in 200X. However, given that the “date of event” field is not always submitted in FDA reports, the “date reported to FDA” field is the best choice to ensure a wide net for records is cast.

- Alcohol-based skin preparation agents are regulated by FDA’s Center for Drugs, and they have their own reporting Adverse Event Reporting (AERS) database that is separate from MAUDE. It is possible that additional or duplicate reports are contained in these databases. However, based on a presentation at the FDA sponsored stakeholder meeting in October, 2010, fewer than 10 reports related to surgical fires were identified in AERS for 2007, and this is true for 2008, and 2009 as well (i.e. fewer than 10 reports in 2008, and fewer than 10 reports for all of 2009). Additionally, only 1 report had been identified in AERS from January through October 2010.
- It is possible that some reports of surgical fires may be excluded from the results because they were coded with a device problem, or product code that is not in the search criteria. However, more than 100, 000 device-related adverse event reports are submitted to MAUDE each year (U.S. Government Accountability Office, 2009). This volume of reports would be too labor intensive to review manually without first narrowing the criteria.
- The quality and completeness of the information submitted in MAUDE reports is variable (i.e. there are often lots of “unknowns”). This often hampers the ability to fully understand the circumstances surrounding the event and to categorize reports (i.e. definitely state whether oxygen or an alcohol-based skin preparation

agent was used). It may also compromise our ability to determine the patient outcome.

- MAUDE contains reports submitted from countries outside the United States.

The analyses of the thesis will try and exclude these.

# Results

## *Introduction*

After searching the MAUDE database using the criteria specified in the methods chapter, the records were exported to excel and manually read through to identify surgical fire reports. It is important to note that these records contained reports from both US and foreign sources as well as reports for which the event date may have been earlier than the year of interest (e.g. event date of 2007 instead of 2008) or for which the event date was left blank. A detailed analysis was performed on all records submitted to FDA for the year of interest (whether foreign or not, and regardless of event date). Then, an analysis was performed on only reports from US sources, with event dates matching the year of interest. Although these figures were tabulated (with the foresight that these reports may some day be cross-referenced with data from state reporting agencies), the author believes that findings based on event date are not the best figures to report publicly. This is because reports may be submitted to FDA well after the actual date of the event. Consequently, this extends the time frame for which a search would have to be conducted to capture reports for a given year (i.e. since a handful of 2008 event date reports were submitted in 2009, you would have to search 2010 data to identify additional 2009 and 2008 reports). Additionally, the event date is not always reported, meaning there would reports that could not be categorized by event date. Instead, it makes more sense to discuss the total number of reports or total number of non-foreign reports submitted to the agency over a given time period.

A summary of the surgical fire report count, broken down by foreign/US reports and by event dates is provided in the table directly below. What follows in the

“findings” section is a detailed analysis of the data by year, with reference to the number of reports mentioning oxygen use or that of alcohol based skin preparation agents.

Other findings, such as a tally of the number of operating room fire reports, as well as the device product codes associated with the surgical fire reports are also presented.

**Table 5: Surgical Fire Report Counts**

<b>Surgical Fire Reports</b>	<b>YEAR 2008</b>	<b>YEAR 2009</b>
Total # Reports submitted to FDA	65	47
Total # Reports submitted from US sources	48	39
Total # Reports from US sources where the Event Date Year matches the Date Reported Year	38	32
Total # Reports from US sources with 2008 Event Dates where date reported may be either 2008 or 2009	40	---

Note: Since some reports submitted in 2009 were for events that occurred in 2008, these numbers were added back to the tally of 2008 reports (see row “Total # Reports from US sources with 2008 Event Dates where date reported may be either 2008 or 2009”). This information, and these particular reports, may be useful in the future if FDA’s data is cross-referenced with data from state or other agencies collecting adverse events.

### ***Findings: 2008 Data Analysis***

After applying the reported date range, device problem code, and product code criteria, a total of **1568 records** were returned. The text keyword search was then applied, narrowing the results to **230** reports containing any of those words. Records were exported to excel and unduplicated. The results were read through manually and **65 surgical fire reports** were identified (it should be noted that this total includes reports from foreign sources, and those with event dates that may be prior to 2008). A detailed analysis of those reports referencing oxygen, alcohol-based skin preparation agents, as well as the outcomes reported as a result of these fires is presented below. Additionally, the product codes associated with the surgical fire reports were also analyzed.

*2008 Surgical Fire Reports Mentioning Oxygen Use*

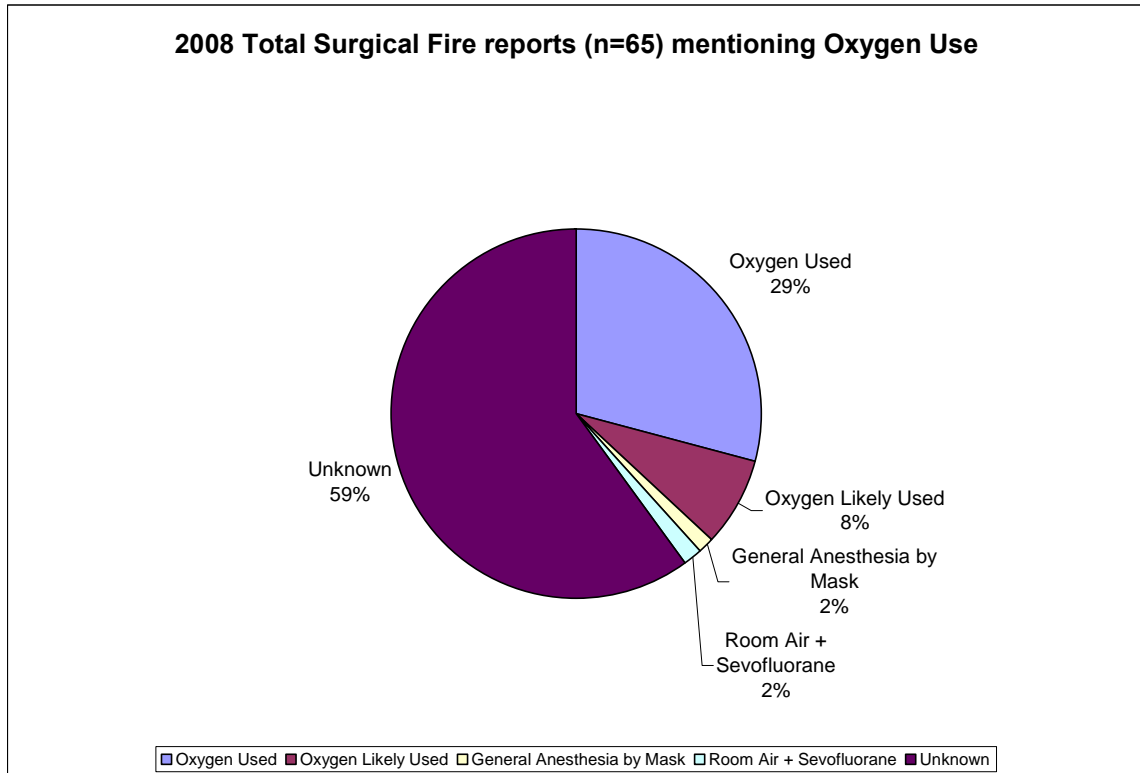
Of the sixty-five (65) surgical fire reports, nineteen (19) specifically mentioned the use of oxygen. Another five (5) were cases in which oxygen was likely used (e.g. oxygen was not mentioned specifically in the report, but devices such as ventilators or masks, which deliver oxygen were referenced). An additional (1) report mentioned that anesthetic gas (i.e. it may have been nitrous oxide) was delivered via mask. Figure 6 below graphically represents this information, while Table 6 provides summary data.

**Table 6: 2008 Surgical Fire Reports Referencing an Oxidizer**

<b>Oxygen Descriptor</b>	<b># Surgical Fire Reports (Includes foreign and event date &lt;2008 or blank)</b>	<b># Surgical Fire Reports (US Only, event date may be &lt;2008 or blank)</b>	<b># Surgical Fire Reports (US Only, 2008 Event Date only, reported in 2008)</b>	<b># Surgical Fire Reports (US Only, 2008 Event Date only, reported in either 2008 or 2009)</b>
Oxygen use mentioned	19	16	14	15
Oxygen use likely (i.e. ventilator or mask mentioned)	5	4	3	3
Anesthetic Gas delivered via mask	1	1	1	1
Room air + Sevofluorane <sup>10</sup> (non-flammable, general anesthetic agent)	1	1	1	1
Unknown	39	26	19	20
<i>Total # Reports</i>	<i>65</i>	<i>48</i>	<i>38</i>	<i>40</i>

<sup>10</sup> From report “NO OXYGEN USED DURING THE PROCEDURE, ONLY ROOM AIR AND SEVOFLURANE (USED WITH THE ANESTHETIC)”

**Figure 6: Percentage of 2008 Surgical Fire Reports Referencing Oxygen**



*2008 Surgical Fire Reports Mentioning use of Skin Preparation Agents*

With regard to alcohol-based skin preparation agents (“prep”), only six (6) of the reports mentioned the type of prep that was used. Three (3) reports mentioned preps known to contain or that alcohol was used in addition to another prep. Two (2) reports mentioned preps known to be alcohol-free, and one (1) report specifically stated that an alcohol prep was not used. An additional report mentioned that vapors from a barrier film pad were a contributing factor, however the product specified in the report corresponds to an alcohol-free product. Additionally, one other report mentioned that the patient had sprayed themselves with a flammable bug spray prior to surgery, and this was

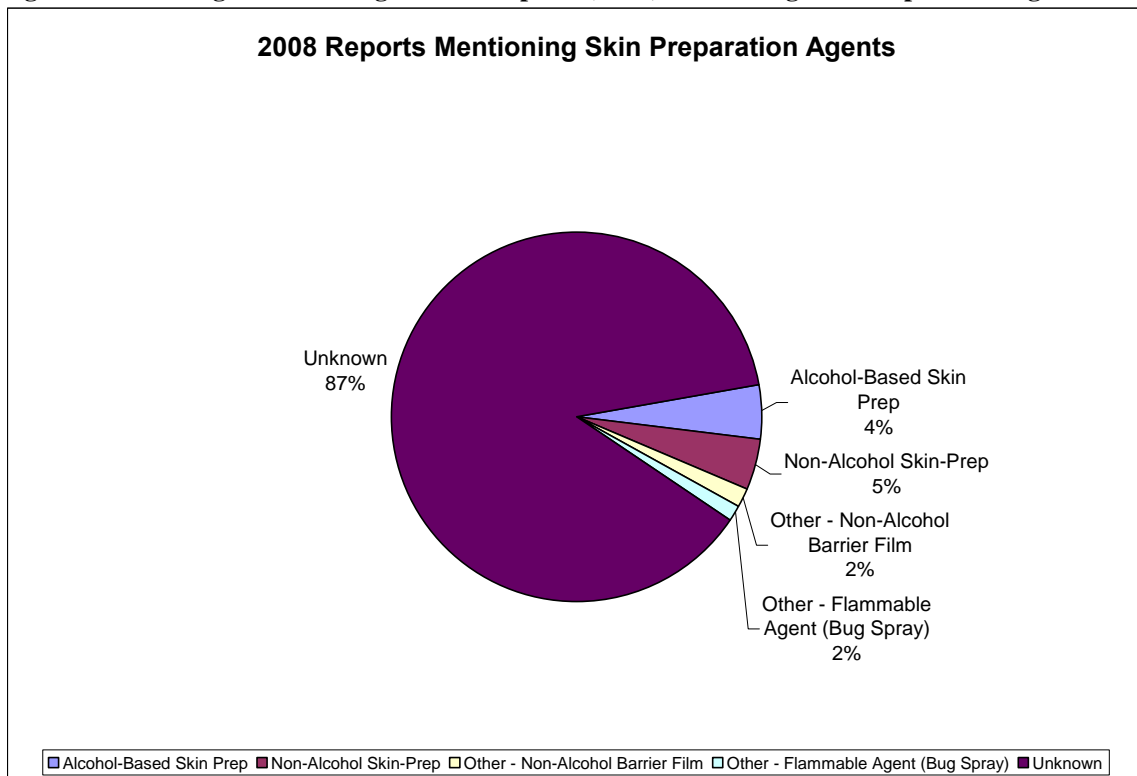


thought to have contributed to the fire. Table 7 and Figure 7 summarize this information.

**Table 7: 2008 Surgical Fire Reports Mentioning Skin Preparation Agent**

Skin Preparation Agent Descriptor	# Surgical Fire Reports (Includes foreign and event date <2008 or blank)	# Surgical Fire Reports (US Only, event date may be <2008 or blank)	# Surgical Fire Reports (US Only, 2008 Event Date only, reported in 2008)	# Surgical Fire Reports (US Only, 2008 Event Date only, reported in either 2008 or 2009)
Alcohol-based skin prep	3	3	3	4
Non-alcohol-based skin prep	3	2	2	2
Other –alcohol-free barrier film	1	1	1	1
Other – flammable product (DEET bug spray)	1	1	1	1
Unknown	57	41	31	32
<i>Total</i>	<i>65</i>	<i>48</i>	<i>38</i>	<i>40</i>

**Figure 7: Percentage of 2008 Surgical Fire Reports (n=65) Mentioning Skin Preparation Agents**



### *2008 Surgical Fire Reports - Outcomes*

The sixty-five (65) reports were reviewed for any adverse outcomes. Twenty-three (23) reports noted burns to the patient. Twenty-one (21) of these burns involved the patient only. In one of these reports involving an airway fire, the patient also underwent a bronchoscopy and laryngoscopy (i.e. additional medical procedures, with their associated risks) to assess damage to the airway. In another of the twenty-three burn reports, it was noted that the patient was recovering from the burns, but later expired due to an unrelated medical complication. In two of the twenty-three (2/23) reports the healthcare provider was also listed as being affected (in one case receiving a minor burn, and in the other the provider's glove was involved in the fire). Three (3) reports described the patient's hair being singed and two (2) reports indicate re-intubation of the patient was necessary (i.e. an additional medical procedure was required) but no other injury. In fourteen (14) reports the outcome was not described (i.e. unknown), and twenty-three reports (23) state specifically that no injury resulted. Figure 8, below, graphically summarizes this information. Table 8 summarizes this information for the total report count, as well as the tally if foreign reports or those with non-2008 event dates are excluded. To provide more context surrounding the impact of these outcomes excerpts of the event text from two surgical fire reports are also provided.

**Table 8: 2008 Surgical Fire Reports - Reported Outcomes**

<b>Outcomes Reported</b>	<b># Surgical Fire Reports (Includes foreign and event dates ≠2008)</b>	<b># Surgical Fire Reports (US Only, event date ≠2008)</b>	<b># Surgical Fire Reports (US Only, 2008 Event Date only, reported in 2008)</b>	<b># Surgical Fire Reports (US Only, 2008 Event Date only, reported in either 2008 or 2009)</b>
Burn	23	17	14	15
Hair singed	3	2	1	1
No Injury	23	18	17	17
Re-intubation	2	1	1	1
Airway assessment & lip discoloration	0	0	0	1
Unknown	14	10	5	5
<i>Total</i>	<i>65</i>	<i>48</i>	<i>38</i>	<i>40</i>

**2008 Exemplar Surgical Fire Reports**

Example 1: Excerpt from event description taken from public MAUDE database (Report 1717344-2008-00574)

**Event Date** 11/15/2008

**Event Type** Injury **Patient Outcome** Other;

**Event Description**

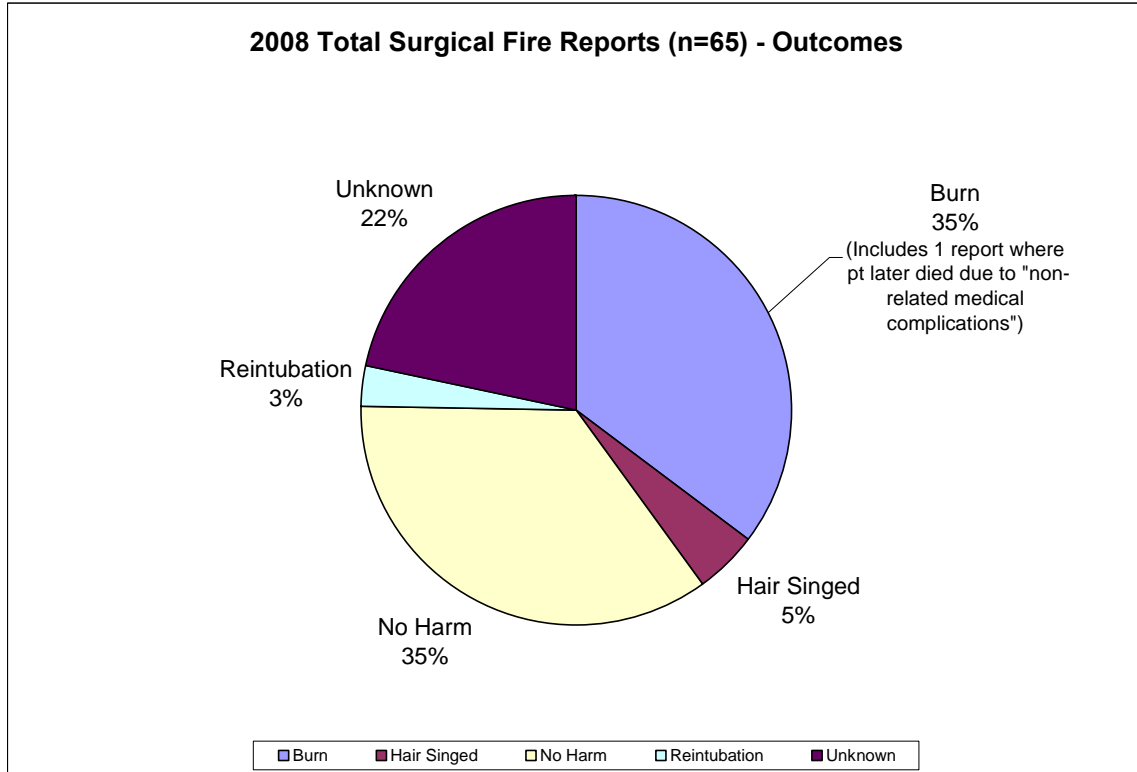
The report stated that the patient received 2nd degree burns to 1. 5% of his body during a wide lesion excision with possible graft or flap of the left cheek. The electrosurgical pencil arced and sparked from the tip to the oxygen mask and a fire ignited burning the patient's right eyebrow, right eye lashes, right cheek, right shoulder, upper lip, and deeper burns into the muscle. The electrosurgical pencil was not a covidien product. The patient was recovering from the burns but expired due to a non-related medical complication in 2008.

Example 2: Excerpt from event description taken from public MAUDE database (Report 1717344-2008-00029 event date 1/02/2008 US)

**Event Description**

The report stated that 1 min into a tracheostomy procedure, a fire occurred and the pts face received a 2nd/3rd degree burn. The pt was wearing a respironics bipap vision total face mask with 100% o2 being delivered at time of fire. Pt has burns under face mask with initial indication that there is no injury of airway. They had prepped the area with duraprep, the doctor left the room to scrub, came back and made initial incision into the trachea and then used a cautery pencil. It was during the activation of the pencil at the trach site that the fire occurred. A drape and drain sponge also caught fire. The hosp reports the pt's burns were to the face and partial neck and treatment has been skin grafting with the pt currently in stable condition.

**Figure 8: Percentage of Reported Outcomes associated with 2008 Surgical Fire Reports**



The severity of the reported burns was also analyzed. Eleven (11) of the reports did not mention the degree of the burns, while one (1) report mentioned a first degree burn, 9 mentioned second degree burns, and two (2) mentioned third degree burns. Table 9 below summarizes this data for the total report count, as well as the tally if foreign reports or those with event dates other than 2009 are excluded. Figure 9 graphically displays the burn severity information and breakdown for the total surgical fire report count. Figure 10 depicts the reported location of the burns.

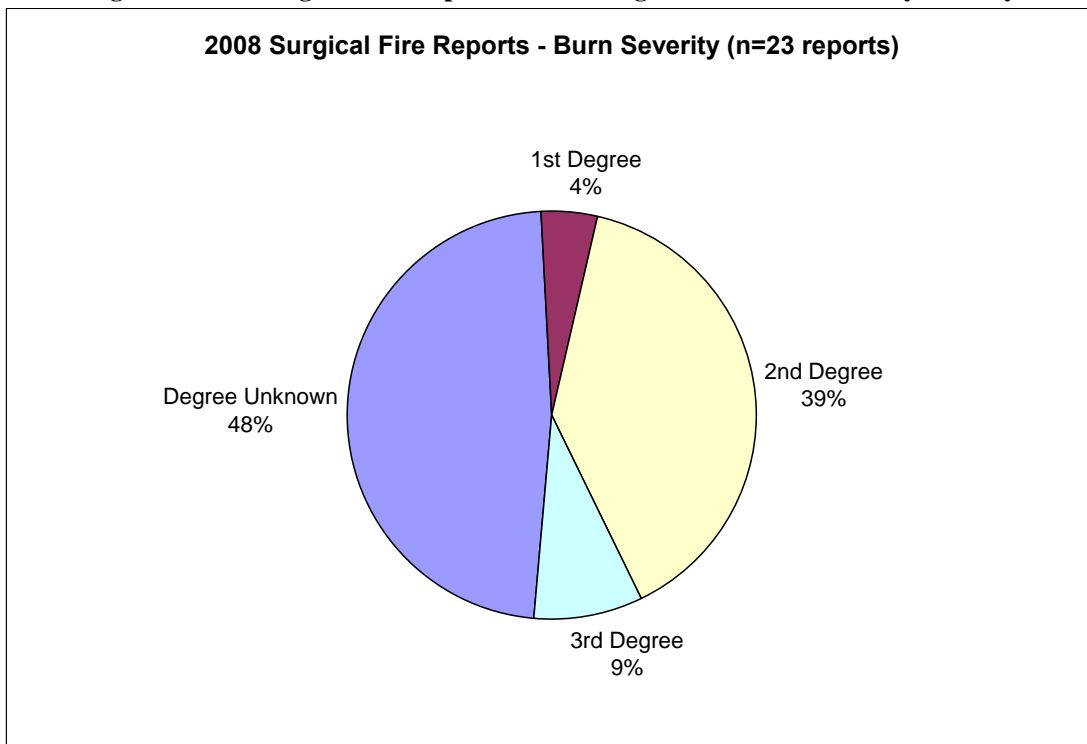
**Table 9: 2008 Surgical Fire Burn Reports - Severity of Burns**

Burn Severity	# Surgical Fire Burn Reports (Includes foreign and event dates ≠ 2008)	# Surgical Fire Burn Reports (US Only, event date ≠ 2008)	# Surgical Fire Burn Reports (US Only, 2008 Event Date only, reported in 2008)	# Surgical Fire Burn Reports (US Only, 2008 Event Date only, reported in either 2008 or 2009)
Burn degree not mentioned	11	7	4	4
First Degree Burn	1	1	1	1
2 <sup>nd</sup> Degree Burn	9*, **	8*, **	8*, **	8*, **
3 <sup>rd</sup> Degree Burn - one report notes that skin grafting was required	2	1	1	2
<i>Total</i>	<i>23</i>	<i>17</i>	<i>14</i>	<i>15</i>

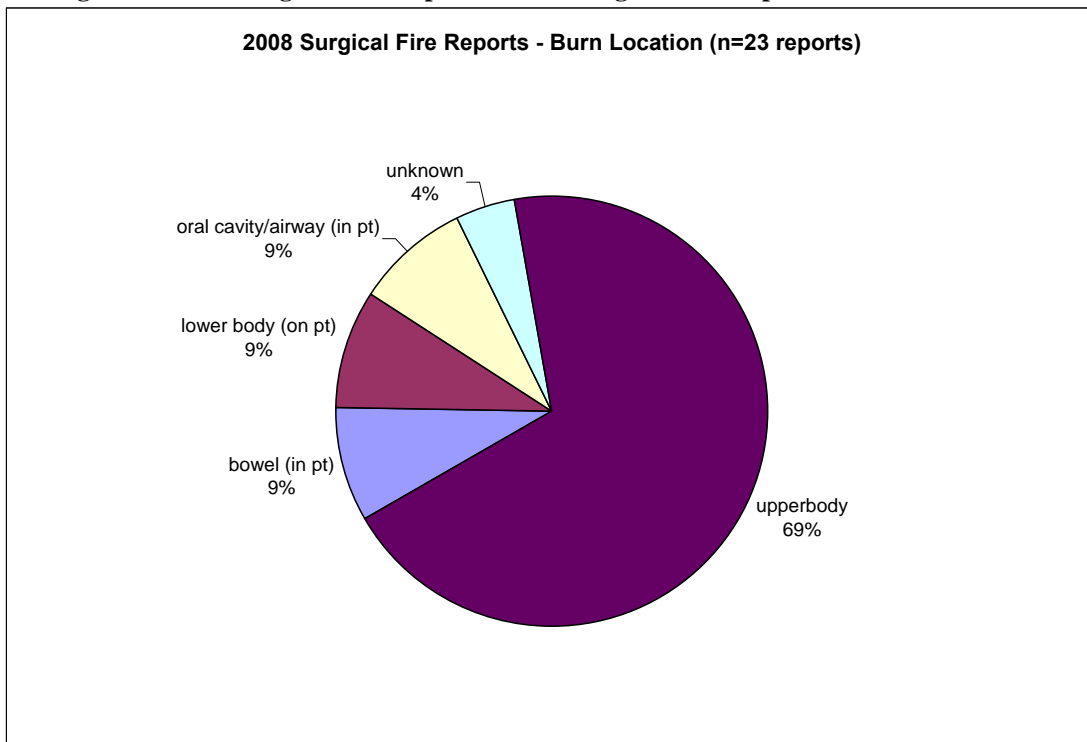
\* one report mentions 2<sup>nd</sup> degree plus permanent discoloration

\*\* one report mentions 2<sup>nd</sup> degree burn and also states that the patient later died due to a non-related medical complication while recovering from burns.

**Figure 9: 2008 Surgical Fire Reports Referencing Burns – Breakdown by Severity**



**Figure 10: 2008 Surgical Fire Reports Referencing Burns – Reported Location of Burns**



Note: Upper body includes burns to the face, head, neck and chest. Seventy-five percent (or 12 of the 16 upper body burn reports) involved the face or head.

### ***Other Findings: 2008 Data Analysis***

**Twenty-two (22) operating room fire reports** were identified in the 2008 search. These included trash bin fires, fires occurring on the electrical cords connected to devices, and one report of a defibrillator catching fire in an ambulance. After excluding foreign reports and those with event dates whose year did not match 2008, the number of operating room fire reports totaled 19.

It should be noted that **thirteen (13) reports noting flames at the tip of an electrosurgical device were identified and categorized as “early warning signs – flame”**. These were not categorized as surgical fires because of the inherent nature of electrosurgery (i.e. the devices are intended to be ignition sources, and if there is a build-

up of tissue on the device tip, small flames are common). Only reports noting flame at the device tip that occurred during oral surgery (e.g. tonsillectomy etc.), laparoscopically, or in the surgical cavity (i.e. the flame occurred within the patient) were considered surgical fires. In eight (8) of the “early warning – flame” reports, no harm was denoted, and in the other five (5) reports no outcome was listed.

Lastly, the product codes associated with the surgical fire reports were also tallied. Table 10, below, summarizes these results. The majority of surgical fires (78%) were reported for electrosurgical devices (product codes GEI and KNS). Three percent (3%) of surgical fire reports were associated with lasers (product code GEX).

**Table 10: Device Product Codes associated with 2008 Surgical Fire Reports**

<b>Product Code</b>	<b>Code Description</b>	<b># Surgical Fire Reports</b>
BTR	TUBE, TRACHEAL (W/WO CONNECTOR)	2
BYG	MASK, OXYGEN	1
BZO; GEI; BYG	SET, TUBING AND SUPPORT, VENTILATOR (W HARNESS); ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES; MASK, OXYGEN	1
CAI	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)	1
FFS	IMAGE, ILLUMINATION, FIBEROPTIC, FOR ENDOSCOPE	2
GCT	LIGHT SOURCE, ENDOSCOPE, XENON ARC	1
GEI	ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES	48
GEX	POWERED LASER SURGICAL INSTRUMENT	2
KNS	UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)	2
KOY	DEGREASER, SKIN, SURGICAL	2
MKJ	AUTOMATED EXTERNAL DEFIBRILLATORS (NON-WEARABLE)	1
MLN; MKJ	ELECTRODE, ELECTRODCARDIOGRAPH, MULTI-FUNCTION; AUTOMATED EXTERNAL DEFIBRILLATORS (NON-WEARABLE)	1
ODR	ELECTROSURGICAL PATIENT RETURN ELECTRODE	1
Total		65

### ***Findings: 2009 Data Analysis***

After applying the reported date range, device problem code, and product code criteria, a total of **1290 records** were returned. The text keyword search was then

applied, narrowing the results to **248** reports containing any of those words. Records were exported to excel and unduplicated. The results were read through manually and **47 surgical fire reports** were identified (It should be noted that this total includes reports from foreign sources, and those with event dates that may be prior to 2009). A detailed analysis of those reports referencing oxygen, alcohol-based skin preparation agents, as well as the outcomes reported as a result of these fires is presented below. Additionally, the product codes associated with the surgical fire reports were analyzed.

*2009 Surgical Fire Reports Mentioning Oxygen Use*

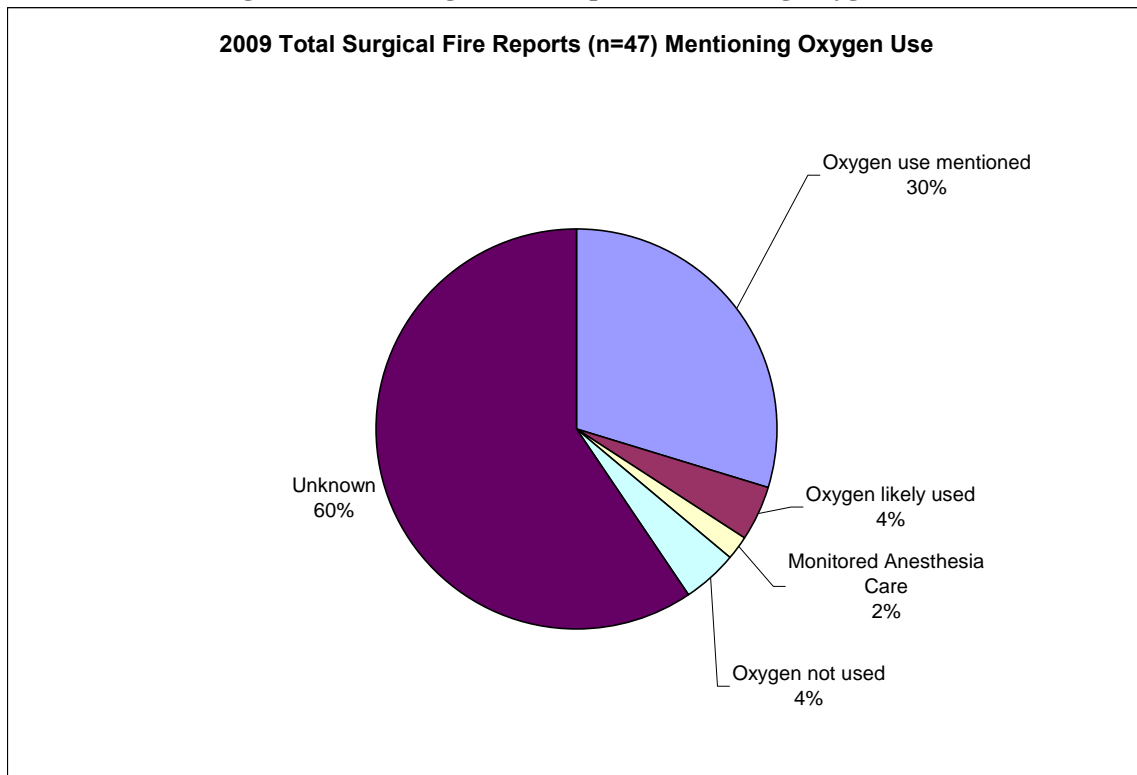
Of the forty-seven (47) total surgical fire reports, fourteen (14) referenced oxygen use and another two (2) were cases in which oxygen was likely used (e.g. oxygen was not mentioned specifically in the report, but devices such as ventilators or masks, which typically deliver oxygen were referenced). An additional report mentioned that monitored anesthesia care was being provided, but provided no other specifics. Figure 11 below graphically represents this information, while Table 11 provides summary data of the total reports, as well as the tally if foreign reports or reports excluding non-2009 event dates are excluded.

**Table 11: 2009 Surgical Fire Reports Referencing an Oxidizer**

<b>Oxygen Descriptor</b>	<b># Surgical Fire Reports (Includes foreign and event dates &lt; 2009 or blank)</b>	<b># Surgical Fire Reports (US Only, includes event dates &lt;2009 or blank)</b>	<b># Surgical Fire Reports (US Only, 2009 Event Date only, reported in 2009)</b>
Oxygen use mentioned	14	11	7
Oxygen use likely (ventilator, mask mentioned)	2	2	1
Monitored Anesthesia Care	1	1	1
Oxygen not used	2	1	1
Unknown	28	24	
<i>Total # Reports</i>	<b>47</b>	<b>39</b>	<b>32</b>



**Figure 11: 2009 Surgical Fire Reports Referencing Oxygen Use**



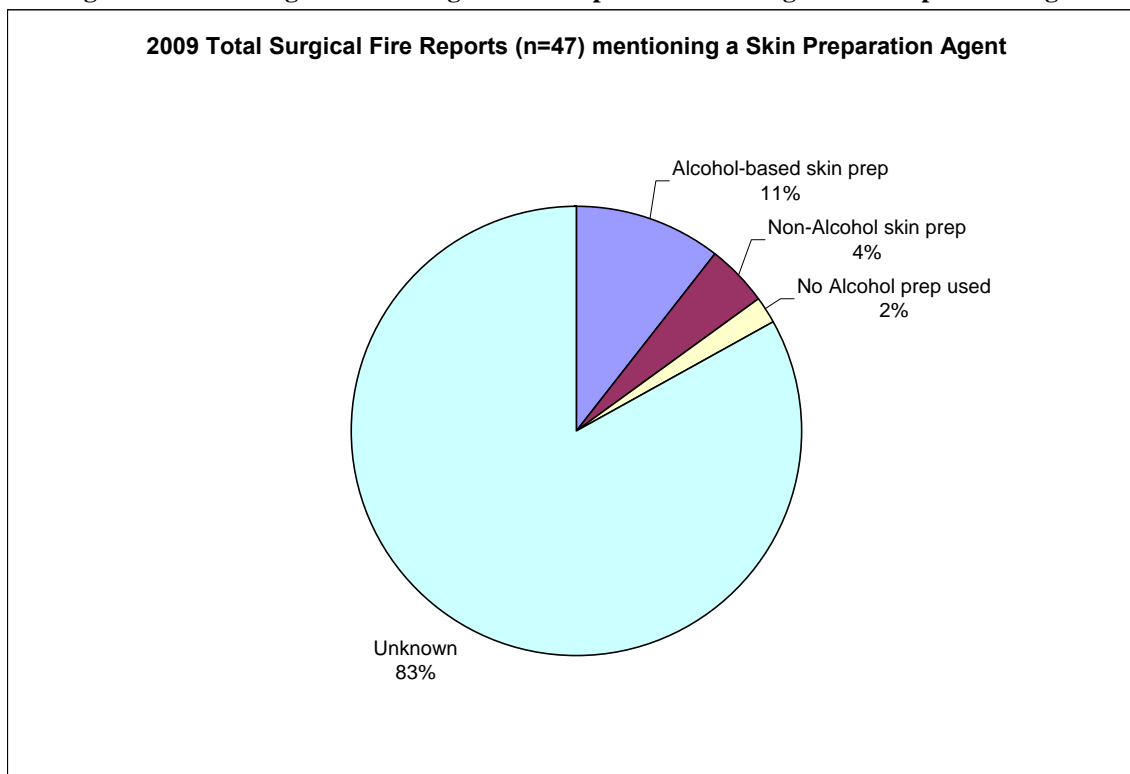
*2009 Surgical Fire Reports Mentioning use of Skin Preparation Agents*

With regard to alcohol-based skin preparation agents (“prep”), eight (8) reports mentioned the type of prep used. Five (5) reports mentioned preps known to contain alcohol. Two (2) reports mentioned preps known to be alcohol-free, and one (1) report specifically stated that an alcohol prep was not used. In thirty-nine (39) records, no reference to a prep solution was made. Table 12 and Figure 12 summarize this information.

**Table 12: 2009 Surgical Fire Reports Referencing a Skin Preparation Agent**

Skin Preparation Agent Description	# Surgical Fire Reports (Includes foreign and event dates ≠ 2009)	# Surgical Fire Reports (US Only, includes event date ≠ 2009)	# Surgical Fire Reports (US Only, 2009 Event Date only, reported in 2009)
Alcohol-based skin prep	5	5	4
Non-Alcohol skin prep	2	2	3
No Alcohol prep used	1	0	0
Unknown	39	32	26
<i>Total # Reports</i>	<i>47</i>	<i>39</i>	<i>32</i>

**Figure 12: Percentage of 2009 Surgical Fire Reports Referencing a Skin Preparation Agent**



*2009 Surgical Fire Reports - Outcomes*

The forty-seven (47) reports were reviewed for any adverse outcomes. In one (1) report involving airway fire, the patient’s air passage was burnt, and the patient died as a result of respiratory complications (i.e. a death directly associated with a surgical fire). In addition, twenty-three (23) reports noted burns. The severity of the burns ranged from minor first degree burns to 3<sup>rd</sup> degree burns, and those resulting in permanent disfigurement (see Table 14 below for details). Twenty-two (22) of these burns involved

the patient only. In one (1) of these reports involving an airway fire, the patient also underwent a bronchoscopy and laryngoscopy (i.e. additional medical procedures with their associated risks) to assess damage. The patient in this report was also re-intubated. In one report, only the provider was burned. Two (2) of the burn reports noted that the patient's hair was also singed, and an additional two reports noted that only the patient's hair was singed. Two (2) reports stated the patient was subjected to an airway assessment such as bronchoscopy (i.e. an additional medical procedure) but did not list any injury. Eighteen (18) reports mentioned no injury to the patient, and one (1) report did not list any outcomes. Table 13 and Figure 13 below provide a summary of this information. To provide further perspective about the impact of these outcomes, an excerpt from a surgical fire report is presented below.

**Table 13: 2009 Surgical Fire Reports - Outcomes**

<b>Outcome Descriptor</b>	<b># Surgical Fire Reports (Includes foreign and event dates ≠ 2009)</b>	<b># Surgical Fire Reports (US Only, includes event date ≠ 2009)</b>	<b># Surgical Fire Reports (US Only, 2009 Event Date only, reported in 2009)</b>
Death (air passage burnt)	1	0	0
Burn	23+	21+	15++
Hair Singed	2	1	1
No Injury	18	14	14
Airway Assessment (e.g. bronchoscopy)	2	2	1
Unknown	1	1	1
<i>Total # Reports</i>	<i>47</i>	<i>39</i>	<i>32</i>

**2009 Surgical Fire Report Example**

Example 1: Excerpt from event description taken from public MAUDE database (Report 1717344-2009-00336)

**Event Date** 04/07/2009

**Event Type** Injury **Patient Outcome** Disability; Other

**Manufacturer Narrative**

The return of the incident sample has been requested. To date, it has not been received for eval. Additional questions in regard to the incident have also been asked. If the sample is received or if additional info pertinent to the incident is obtained, a f/u report will be submitted.

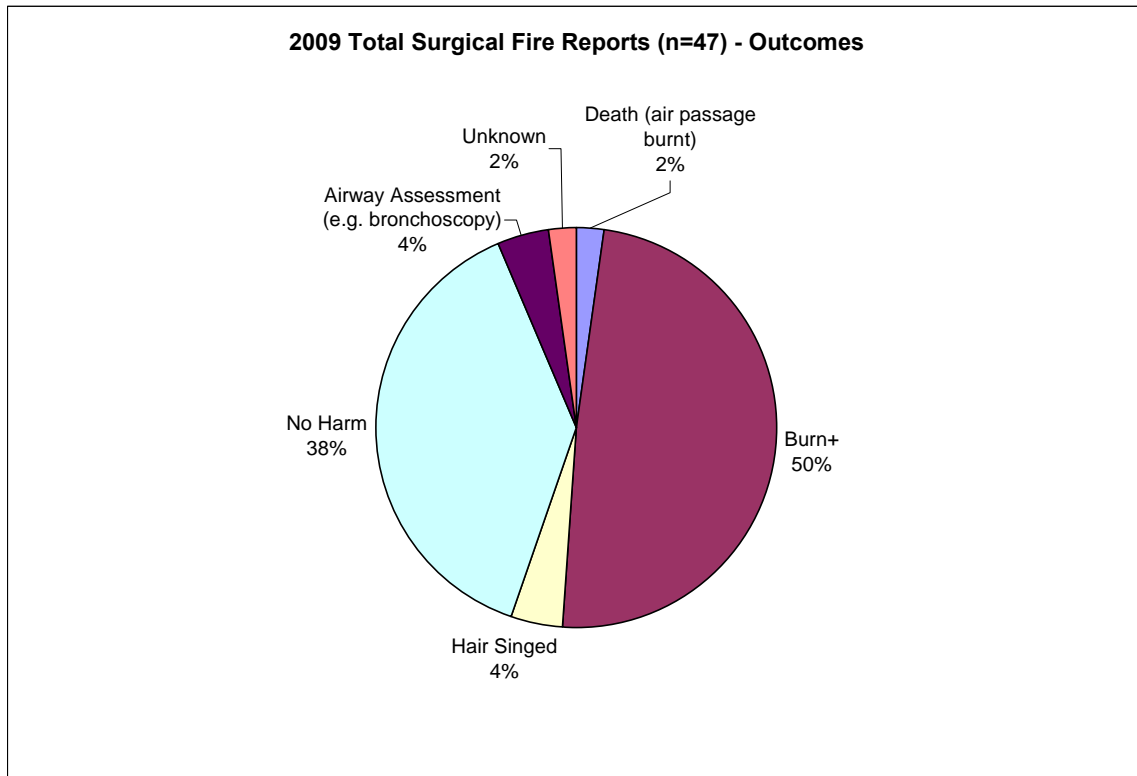
**Event Description**

According to the complaint, the pt was undergoing a right temporal artery biopsy when a flash fire occurred causing severe burns to the pt's face. The pt suffered significant, life-long injuries to her face. The pt has withstood intensive and repeated debridement for burns to a large percentage of her face and is permanently disfigured.

+ includes 2 reports of burn plus singed hair, and 1 report of burn plus re-intubation and bronchoscopy

+ +includes 1 reports of burn plus singed hair, and 1 report of burn plus re-intubation and bronchoscopy

**Figure 13: 2009 Total Surgical Fire Reports – Breakdown of Reported Outcomes**

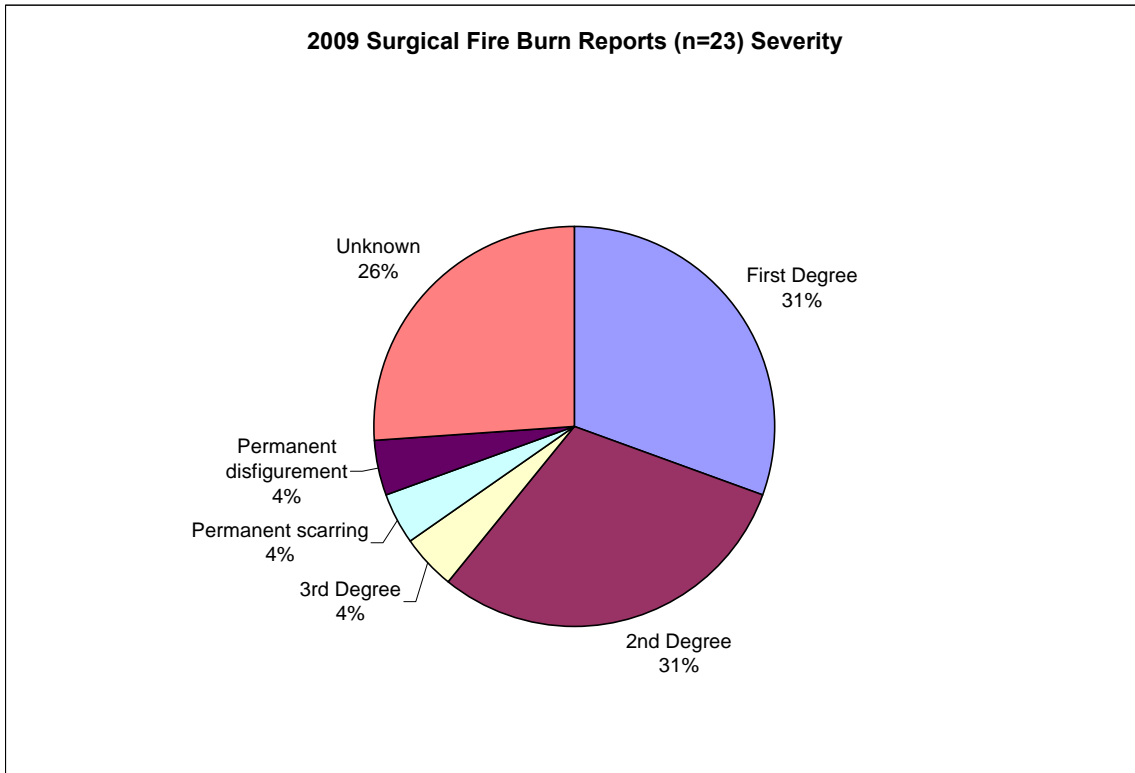


The severity of the reported burns was also analyzed. Six (6) of the reports did not mention the degree of the burns, while seven (7) report mentioned a first degree burn, seven (7) mentioned second degree burns, and one (1) mentioned third degree burns. An additional report mentioned permanent scarring, and one report stated the patient would be permanently disfigured. Table 14 below summarizes this data for the total report count, as well as the tally if foreign reports or those with event dates other than 2009 are excluded. Figure 14 graphically displays the information and breakdown by severity for the burn reports. Figure 15 depicts the reported location of the burns.

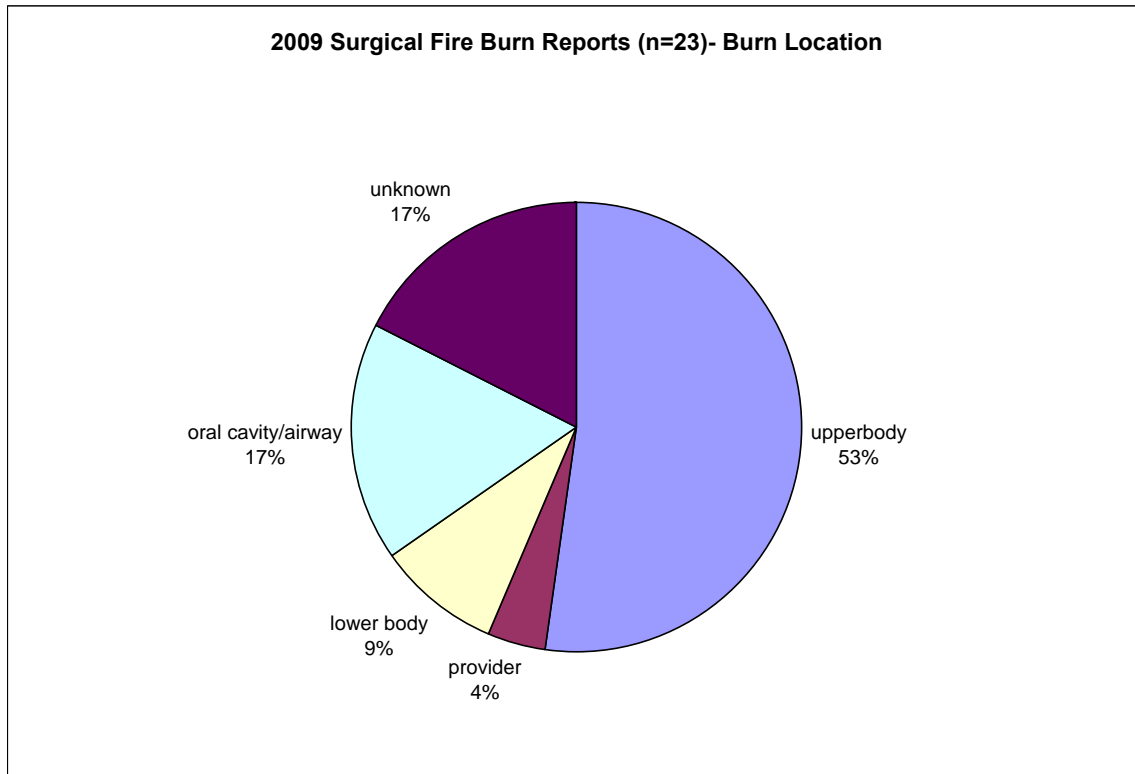
**Table 14: 2009 Surgical Fire Reports – Burn Severity**

<b>Burn Descriptor</b>	<b># Surgical Fire Reports (Includes foreign and event dates ≠ 2009)</b>	<b># Surgical Fire Reports (US Only, includes event date ≠ 2009)</b>	<b># Surgical Fire Reports (US Only, 2009 Event Date only, reported in 2009)</b>
First Degree	7	6	3
2 <sup>nd</sup> Degree	7	7	7
3 <sup>rd</sup> Degree	1	1	0
Permanent scarring	1	1	0
Permanent disfigurement	1	1	1
Unknown	6	5	4
<i>Total # Reports</i>	<i>23</i>	<i>21</i>	<i>15</i>

**Figure 14: 2009 Surgical Fire Reports Referencing Burns – Breakdown by Severity**



**Figure 15: 2009 Surgical Fire Reports Referencing Burns – Reported Location of Burns**



Note: Upper body denotes burns to the face, neck, and chest, while lower body indicates burns to the thigh. Ninety-two percent (or 11 of the 12 upper body reports) involved burns to the patient's face.

### ***Other Findings: 2009 Data Analysis***

**Twenty-one (21) operating room fire reports** were identified in the 2009 search. These included trash bin fires, fires occurring in the electrical cords connected to devices, and defibrillators catching fire. Fourteen (14) reports noted no injuries, and seven (7) reports did not list the outcome. After excluding foreign reports, and those with event dates whose year did not match 2008, the number of operating room fire reports totaled 16. An additional (1) report was identified involving a patient using a medical

device (for treating tinnitus), presumably in their home (this was not categorized as an operating room fire report).

It should also be noted that twenty-two (22) reports noting flames or fire at the tip of an electrosurgical device were identified and categorized as “early warning signs – flame/fire”. These were not categorized as surgical fires because of the inherent nature of electrosurgery (i.e. the devices are intended to be ignition sources, and if there is a build-up of tissue on the device tip, flames are common). Only reports noting flame at the device tip that occurred during oral surgery (tonsillectomy etc), laparoscopically, or in the surgical cavity (i.e. the flame occurred within the patient) were considered surgical fires. In eight (8) of the reports, no harm was denoted, and in the other five (5) reports no outcome was listed.

Lastly, the product codes associated with the surgical fire reports were tallied. Table 15 below summarizes these results. The majority of surgical fires (87%) were reported for electrosurgical devices (product codes GEI and KNS). Six percent (6%) of surgical fire reports were associated with lasers (product code GEX).

**Table 15: Device Product Codes Associated with 2009 Surgical Fire Reports**

<b>Product Code</b>	<b>Code Description</b>	<b># Surgical Fire Reports</b>
BYG	MASK, OXYGEN	1
CAT	CANNULA, NASAL, OXYGEN	1
FFS	IMAGE, ILLUMINATION, FIBEROPTIC, FOR ENDOSCOPE	1
GEI	ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES	39
GEX	POWERED LASER SURGICAL INSTRUMENT	3
KNS	UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)	1
LOP; ODR; GEI; BTR; KOD	SOLUTION, ANTIMICROBIAL; ELECTROSURGICAL PATIENT RETURN ELECTRODE; ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES; TUBE, TRACHEAL (W/WO CONNECTOR); CATHETER, UROLOGICAL	1
Total		47



## Summary of Results

The total number of surgical fire reports submitted to FDA in 2008 totaled 65, while those submitted in 2009 totaled 47. Oxygen was involved in 29% of the 2008 surgical fire reports and 30% of the 2009 reports. Alcohol-based skin preparation agents were involved in 4% of the 2008 reports, and 11% of the 2009 reports. Burns were reported outcomes in 35% of the 2008 reports and 52% of the 2009 reports. For both years, the majority of burns affected the patient's upper body (69% of cases for 2008 and 53% for 2009), with the face being the most common location affected. Burns to the patient's airway or oral cavity were reported in 9% of 2008 reports and 17% of 2009 reports. Surgical fires resulting in no injury were reported in 35% of the 2008 reports, and 38% of the 2009 reports. Outcomes were not specified (i.e. unknown) in 22% of the 2008 reports, and 2% of the 2009 reports. The severity of the surgical fire outcomes ranged from no harm to permanent disfigurement and even death. Table 16 below summarizes this information.

**Table 16: Summary of Results from Surgical Fire Reports Submitted to FDA's MAUDE database**

<b>Surgical Fire Reports</b>	<b>YEAR 2008</b>	<b>YEAR 2009</b>
Total # Reports submitted to FDA	65	47
Total Surgical Fire Report Analysis Summary	Percentage of Reports	Percentage of Reports
Oxygen Use Mentioned	29%	30%
Oxygen Use Mentioned or Likely	37%	34%
Alcohol-Based Skin Preparation Agents Used	4%	11%
Burns reported	35% **	52% ***
Burn Location – upper body	69%	53%
Burn Location – in patient's airway or oral cavity	9%	17%
No harm	35%	38%
Electrosurgical Device (by product code) reported	78%	87%
Laser (by product code) reported	3%	6%

\*\* includes one burn report which states that the patient later died due to a non-related medical complication while recovering from burns.

\*\*\* includes one report of patient death after respiratory complications resulting from the patient's air passage being burnt.

The number of operating room fire reports was also tallied. For 2008, twenty-two (22) operating room fire reports were identified, while twenty-one (21) were identified for 2009.

# Conclusions, Implications and Recommendations

## *Introduction*

Surgical fires are preventable medical errors that are defined as fires occurring on, in or in close proximity to a patient undergoing a medical procedure. These fires have the potential to result in permanent disabling injury or disfigurement and on rare occasion they can result in death. There are three elements of the fire triangle (ignition source, fuel, oxidizer), and in the context of surgical fires, many of the items that make-up this triangle are medical devices or drugs regulated by FDA. As a result of its regulatory authority over these products, FDA receives adverse event reports of surgical fires, which are submitted to its surveillance databases for medical devices and drug products.

Despite improvements to device and drug labeling to warn of the risks of fire, FDA continues to receive adverse event reports of surgical fires. Consequently, FDA partnered with organizations representing healthcare professionals and patient safety and advocacy organizations to launch the Preventing Surgical Fires initiative in October, 2011. Up to this point, FDA has not published, or previously performed an extensive review or analyses of the surgical fire reports contained in the Manufacturing and User Device Experience (MAUDE) database (i.e. its medical device surveillance database). Hence, the purpose of this thesis was to search, identify and analyze the surgical fire reports submitted to MAUDE over a two year period covering 2008 and 2009. In addition to being useful for answering press inquiries and supporting public communications, these numbers will serve as a baseline to help FDA identify any increasing or decreasing trends in the number of surgical fires reported to the agency

moving forward. It is also hoped that if FDA should publish these results, because it is a respected federal public health agency, credibility and awareness surrounding the issue will be raised. It is also hoped that this will impact the risk perception of surgeons, anesthesiologists and other health care professionals, and encourage them to adopt prevention practices to mitigate the risk of surgical fire.

### ***Summary of Study***

The internal MAUDE database was searched by reported date range, for a list of device product codes that was informed by the literature review, and for a set of product problem codes related to surgical fires. The results were then narrowed by keyword terms also informed by the literature review. The records were exported to a spreadsheet and each was read through manually to identify reports of surgical fire. The data was then analyzed to determine the number of surgical fire reports referencing oxygen use, or the use of an alcohol-based skin preparation agent. The severity of the outcomes and the devices associated with surgical fires were also analyzed.

### ***Conclusions***

Less than 100 surgical fire reports per year were submitted to FDA's MAUDE database during two year period in question (2008-2009). Specifically, sixty-five (65) surgical fire reports from US and non-US sources were submitted in 2008 and forty-seven (47) in 2009. If we look only at reports submitted from US sources, there were forty-eight (48) surgical fire reports submitted in 2008 and thirty-nine (39) submitted in 2009. These figures include events that may have occurred in previous years (refer to

Table 4 in the Results section for details). It is important to put the number of surgical fires reported to FDA in context by comparing them to estimates in the literature.

*Comparisons to published searches of the public MAUDE database*

Bruley (2004) published results from a search of the public MAUDE database over a 3.5 year period from January 1995 to June 1998. He identified 167 reports of surgical fire, which corresponds to an average of 48 reports per year (it is unclear whether reports were excluded if the report source was listed as foreign or if the event date did not match the year in question). This compares well with the results of this thesis, for which 47 total surgical fire reports were identified in 2009 and 65 in 2008 (or an average of 56 reports per year). However, it should be noted that a challenge with any of these comparisons is as follows: because there is no published case definition of a surgical fire, what one researcher or organization may consider a surgical fire may vary from one researcher to the next. In a personal correspondence with Bruley (November 7, 2011), he indicated that he would not consider flames from the tips of electrosurgical devices to be surgical fires -- unless they occurred during a tonsillectomy. This is fairly consistent with the classification used in the present thesis, as reports noting flames at an electrosurgical device tip were classified separately as “early warning signs” of fire, rather than surgical fires, unless they occurred in the oral cavity or surgical site (whether open or laparoscopically).

Smith & Roy (2008) also published the results of their public MAUDE search for surgical fire reports. They searched the database from 1998 to 2006 for keywords related to electrosurgical devices and fiber optic cables and fire. They included results involving

flash fires, patient burns, drape fires, or staff gown fire. Their search revealed 71 fires associated with electrosurgical units and 2 fires associated with fiber optic light cords. However, because the authors excluded events involving the electrosurgical grounding pad, OR sponges, endotracheal tubes and tracheostomy fires where the drapes did not catch fire, their results cannot be accurately compared to the results of the present thesis.

### *Comparisons to State-wide estimates*

Looking at the data from Pennsylvania, the Patient Safety Authority (2007) published a review of their data, which identified 83 surgical fires occurring in over a 36 month period, which they listed as corresponding to an average of ~28 fires per year. If we compare this to the reports submitted to MAUDE for 2008 and 2009 there were 87 reports from US sources submitted over 24 months (48 from 2008 and 39 from 2009), or an average of ~ 44 per year. The scale of these numbers indicates that the number of surgical fires reported to FDA aligns with the number of surgical fire reports being submitted by one state (as opposed to a national estimate). If we assume that 28 reports were submitted to FDA in 2008 from Pennsylvania that would leave 20 surgical fire reports that were submitted by the remaining 49 states in the nation. Because the state from which a report was submitted is considered a sensitive and identifying piece of information, it is outside the scope of this thesis to actually analyze and compare the number of reports submitted from Pennsylvania (to determine whether the surgical fires reported to Pennsylvania are also reported to FDA). However, this would be a valuable exercise for FDA to complete moving forward, to better understand why the reports

submitted to a state are not submitted to federal databases, and to partner with state reporting agencies to better share and understand adverse event data.

Minnesota also requires reporting of the burn “never event” (i.e. death or serious disability associated with a burn incurred while being cared for at a health care facility). From October 7, 2007 – October 6, 2008, there were 3 reports of serious disabilities resulting from such burns and no reports of death (Minnesota Department of Health, 2009). It should be noted that the report does not specify whether or not the burns were the result of a surgical fire so no true comparisons can be made. This presents an opportunity to work with the National Quality Forum, who outline the “never events” to find a way to specify which of these events are due to surgical fires.

#### *Comparisons to national Estimates*

ECRI Institute’s 2009 estimate was that 550-650 surgical fires occur each year in the United States (ECRI Institute, 2009c). This updates their previous estimate of 100 surgical fires per year in the US, of which approximately 10 result in serious injury, with 1-2 being fatal (Bruley, 2004). The organization developed the 550-650 estimate by extrapolating the previously described data from Pennsylvania’s Patient Safety Authority. ECRI Institute’s current estimate suggests that 20-30 surgical fires per year cause serious, disabling or disfiguring injuries, and that one to two fatal fires occur each year (mostly occurring in the airway).

The results from this thesis do not support hundreds of surgical fires being reported each year to FDA. They do compare well to the ECRI Institute estimate of fatalities, as 1 death report each was identified in 2008 and 2009 (although the 2008 death

case reported that the cause was due to non-related medical complications, and the 2009 report was from a foreign source). Regarding injuries, the thesis results found twenty-three (23) reports of burns in 2008 (22 if the death report is excluded) and twenty-three (23) in 2009 (not including the death report). As some of these were minor burns, it means that the results do not support 20-30 serious injuries per year. However, since outcomes were not reported in some cases this may result for some of the discrepancy.

The thesis hypothesis was that the number of surgical fires identified in the search would indeed be far fewer than the estimate of 550-650. This was suspected because it is generally known that adverse events involving medical devices are widely underreported (US Government Accountability Office, 2009; Smith & Roy, 2008; CDRH, 2006). The database is also a passive surveillance system, meaning that people must recognize that the event merits reporting, and they must also recognize that FDA is the authority with whom a report should be filed. Additionally, surgical fires are a type of event that is not immediately associated with a medical device or drug, so it is likely that a number of cases go unreported. Additionally, liability concerns are one known reason why adverse events are not reported. Another possible explanation for the underestimate is that surgical fire events that cause no harm may not be reported because they do not meet the threshold of mandatory reporting requirements for events resulting in death or serious injury. However, from the present study, we know that at least some of these “no harm” surgical fire reports are being submitted, as 23 such reports were submitted in 2008 and 18 in 2009. It should also be noted that the vast majority of reports that are submitted to MAUDE come from device manufacturers, as opposed to user facilities or voluntary



reporters (and this is true of surgical fire reports as well). This means there is the potential for bias for the reports that are received.

It is interesting to note that the devices associated with the surgical fire reports of this thesis match up well with what ECRI Institute has estimated. They noted that about 70% of fires involve electrosurgical equipment as the ignition source, and 10% involve lasers (ECRI Institute, 2009c). The present study found that 78 % of surgical fire reports in 2008 and 87% in 2009 were associated with electrosurgical device product codes (GEI and KNS). Additionally 3% of the surgical fire reports in 2008 and 6% of the 2009 reports were associated with lasers (product code GEX).

ECRI Institute has estimated that 75% of surgical fires involved oxygen, and 4% involved alcohol-based skin preparation agents (ECRI Institute, 2009c). The results of the present study note that oxygen was referenced in only ~30% of reports in 2008 or 2009 (29% and 30% respectively), which is vastly different. However, it is possible that oxygen was used in many more of the reported events, but that this information was not included in the report.

## ***Implications***

The results from this thesis compare relatively well to Bruley's 2004 MAUDE database search for surgical fire reports. Compared to state and national estimates, the number of surgical fire reports found in FDA's MAUDE database appears to relate more closely to counts in the state of Pennsylvania, and appear to grossly underestimate what is happening on a national scale (refer to Table 17 for a comparison).

Future searches conducted by FDA analysts may be conducted more efficiently by limiting the search criteria to the product codes listed in Tables 10 and 15, as these represent the actual product codes and devices associated with the surgical reports, out of the 200+ product codes that were included in the original search criteria.

Because FDA receives reports from both US and foreign sources, and because of the effects of underreporting, the number of surgical fire reports identified in this thesis does not make for a good estimate of the national frequency of surgical fires. However, publishing the results of FDA’s documented number of surgical fire reports in a public communication or campaign could help stimulate better reporting of surgical fires, and also give pause to clinicians to assess their risk of experiencing a surgical fire.

**Table 17: Comparison of MAUDE results to State data and National Estimates**

	<b>FDA MAUDE data 2008-2009 reports (excludes foreign reports)</b>	<b>Pennsylvania Patient Safety Authority (2007)</b>	<b>ECRI Institute (2009c)</b>
<b>Number of reports</b>	87	83	N/A
<b>Reporting period</b>	2 yrs	3 yrs	N/A
<b>Average reports/yr</b>	44	28	N/A
<b>National Estimate</b>	N/A	N/A	Estimated 550-650 surgical fires cases per year in the US.  <u>Note:</u> ECRI Institute’s data does not represent a tally of actual reports. Rather, it is an estimate created by scaling up Pennsylvania’s 28 reports per year using two models: - based on the percentage of the PA population out of the whole US population - based on the percentage of PA annual surgeries compared to the US total for annual surgeries

It should be noted that the most limiting factor to identifying and comparing surgical fire reports is the case definition used by the researcher. There is currently no published case definition of a surgical fire. This can make for an “apples to oranges” comparison among the different adverse event reporting databases that currently exist.

The reports of this thesis confirm that surgical fires, although relatively rare events, can have devastating consequences to the patient. These include permanent disability and disfigurement, and death. The results also confirm that oxygen and alcohol-based skin preparation agents, as well as electrosurgical devices are involved in a significant percentage of surgical fires. These findings support the continued efforts of the Preventing Surgical Fires initiative ([www.fda.gov/preventingsurgicalfires](http://www.fda.gov/preventingsurgicalfires)), to educate healthcare providers about the risks of fires, and encourage that best practices be adopted to mitigate the risk.

Per the constructs of the Health Belief Model, if FDA continues to lend its name and credibility to the Preventing Surgical Fires campaign, it may spur surgeons and other healthcare professionals reassess their risk of experiencing a surgical fire, and in doing so make them more likely to adopt best practices for prevention.

## ***Recommendations***

FDA and the other partners of the Preventing Surgical Fires initiative should continue their efforts, but also work on developing a detailed case definition for “surgical fire” and “operating room fire” so that all parties who review adverse event reports related to surgical fires may use the same definition. This will allow for better comparison of reports submitted to the various federal and state reporting databases.

Additionally, it would be a worthwhile endeavor to take a year of data (e.g. 2008) and through a memorandum of understanding or other contractual agreement, compare this data against the surgical fire reports submitted to the Pennsylvania Patient Safety Reporting Authority to determine whether or not reports being submitted at the state level are submitted to FDA's MAUDE database. Next steps from such an analysis would be the creation of a more formalized data sharing mechanism, or a program to enhance and encourage adverse event reporting, especially at the federal level.

Another action item to consider is to work with AHRQ and the National Quality Forum so that their "never event" for burns includes a more specific definition for surgical fires. By doing so, states such as Minnesota, which already report this information, will then have to report which of these burns are associated with surgical fires.

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## Appendix A: List of product codes used in search criteria

The list below represents device product codes that were used as part of the search criteria. The MAUDE database was queried for the key terms that follow to identify the related product codes listed below. These were then selected and used in the searches. Key terms: mask, sponge, gauze, endotracheal tube, tracheal, nasal cannula, gown, drape, degreaser, tincture, breathing circuit, electrosurg\* (to capture electrosurgical devices), cautery, electrocautery, laser, fiber optic, light source, drill, defibrillator (implanted defibrillator product codes were excluded), bur, burr.

1. ODR
2. OAP
3. OAN
4. NXF
5. NWI
6. NVK
7. NUJ
8. NTK
9. NLW
10. NLV
11. NLU
12. NLT
13. NLR
14. NHN
15. NEF
16. NCR
17. KNF
18. JOT
19. NBL
20. MYC
21. MXO
22. MWD
23. MVQ
24. MVG
25. MVF
26. MUL
27. MUK
28. MRX
29. MNO
30. MGC
31. MBZ
32. LZS
33. LYB
34. LXU

35. LXS  
36. LXR  
37. LWX  
38. LQJ  
39. LPC  
40. LOI  
41. LNK  
42. LMS  
43. LLW  
44. LLP  
45. LLO  
46. LLF  
47. LKW  
48. KNS  
49. JOS  
50. HQQ  
51. HQP  
52. HQO  
53. HQF  
54. HQB  
55. HPJ  
56. HIN  
57. HIM  
58. HHR  
59. HGI  
60. MPC  
61. MKJ  
62. LDD  
63. DRL  
64. DRK  
65. OAY  
66. NTN  
67. MPU  
68. HET  
69. GCT  
70. FEM  
71. FCQ  
72. HIC  
73. HDG  
74. HBI  
75. FST  
76. FFS  
77. FDG  
78. FCW  
79. FCT  
80. FCS

- 81. FCR
- 82. EQH
- 83. DQE
- 84. OXS
- 85. OWH
- 86. OTL
- 87. ORK
- 88. OPT
- 89. OOE
- 90. ONQ
- 91. ONO
- 92. ONH
- 93. ONG
- 94. ONF
- 95. ONE
- 96. OLP
- 97. OLI
- 98. OHT
- 99. OFI
- 100. OEL
- 101. OEJ
- 102. HFI
- 103. HFG
- 104. HAM
- 105. GEX
- 106. GEI
- 107. FFI
- 108. FEH
- 109. FAS
- 110. FAR
- 111. EWG
- 112. EKZ
- 113. DWG
- 114. BWA
- 115. OFP
- 116. CAI
- 117. CAH
- 118. CAG
- 119. IAL
- 120. KOY
- 121. OEA
- 122. FYE
- 123. FYC
- 124. FYB
- 125. FYA
- 126. FME

127. FXO  
128. LRQ  
129. ECO  
130. ETL  
131. CAT  
132. BZB  
133. BTQ  
134. OST  
135. OGI  
136. OFS  
137. NYT  
138. NWA  
139. NMA  
140. NLB  
141. LNZ  
142. KCI  
143. KCH  
144. KCG  
145. KCC  
146. JCT  
147. EPE  
148. CCT  
149. CBI  
150. CBH  
151. BTR  
152. BSR  
153. BSK  
154. NAB  
155. MXY  
156. GER  
157. MRL  
158. LWH  
159. LLR  
160. HQR  
161. HOZ  
162. GEQ  
163. GEL  
164. GDY  
165. FRO  
166. FRL  
167. FQA  
168. FGS  
169. EFQ  
170. OXZ  
171. OUK  
172. OBN

173. NMC  
174. MUP  
175. KLW  
176. KHA  
177. KGB  
178. HOY  
179. FXX  
180. BSJ  
181. BYG  
182. BYF  
183. BTK  
184. ORT  
185. OJJ  
186. OJI  
187. OHX  
188. OHW  
189. OBG  
190. NME  
191. MSA  
192. MGR  
193. MGQ  
194. MGP  
195. MDN  
196. HQS  
197. HOG  
198. HOF  
199. GXR  
200. FPY  
201. EKJ  
202. CGO  
203. OIS  
204. NWF  
205. NLZ  
206. NLY  
207. NLP  
208. NLO  
209. NLN  
210. LXI  
211. HXY  
212. HTW  
213. HTT  
214. HBG  
215. HBF  
216. HBE  
217. HBD  
218. HBC



219. HBB  
220. GFF  
221. ERL  
222. EQJ  
223. EJJ  
224. DZJ  
225. DZI  
226. DZA  
227. NVY  
228. NSA  
229. NPN

## Appendix B: Detailed Breakdown of Report Counts by Report Source and Event Date

<b>Surgical Fire Reports</b>	<b>2008</b>	<b>2009</b>
<b>Total # Reports</b>	<b>65 *, ** +4 from 2009</b>	<b>47</b>
# Foreign Reports	16 + 2/4 from 2009 foreign	8
# country unknown reports	1	0
<b>Total # Reports from US sources</b>	<b>48 +2 from 2009</b>	<b>39</b>
# Reports with Event Date < Year of Interest	7 (2/7 - already identified in foreign reports event dates 2007)	6 2/6 - 2007, both US 4/6 - 2008, but 2/4 already identified in foreign
# Reports Event Date Blank/Unknown	5	3
<b>Total # Reports with YEAR Event Dates from US Sources</b>	<b>38 (+ 2 from 2009)</b>	<b>32</b>
<b>Operating Room Fire Reports</b>	<b>2008</b>	<b>2009</b>
<b>Total # Reports</b>	<b>22 +1 from 2009</b>	<b>21</b>
# Foreign Reports	2 +1 from 2009	1
# country unknown reports	0	0
<b>Total # Reports from US</b>	<b>20</b>	<b>20</b>
# Reports with Event Date < Year of Interest	1	1 (report has 2008 event date, but is also Foreign)
# Reports Event Date Blank/Unknown	0	4
<b>Total # Reports with 2008 Event Dates from US Sources</b>	<b>19</b>	<b>16</b>

\* one report of an apparent airway fire, that does not contain the word fire or flame, but notes significant soot present in airway (tonsillectomy, oxygen in use)

\*\* one report of surgical fire is that of a paramedic providing care, and fire occurring outside of hospital with oxygen in use