Evaluation of Health Care Operating Rooms as Wet/Dry Locations

Final Report

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Bowie, Maryland
A key area of debate in the most recent revision cycle of NFPA 99, *Health Care Facilities* has been the topic of electrical environments in hospital operating rooms and whether they need to be classified as a wet location or dry location.

The present edition of NFPA 99 (2005) requires the governing body of the facility to determine if operating rooms are “wet locations” and therefore require special protection—usually either isolated power-supply systems or ground-fault circuit interrupters (GFCIs)—against electrical shock. However, there are two opposing schools of thought on establishing this designation requirement, with the debate attempting to balance the need to provide a safe environment for patients and operating room personnel while at the same time providing a risk based solution and not over-designing the electrical distribution system.

This study defines and analyzes the hazards associated with hospital operating rooms to clarify the classification type (i.e. wet location versus dry location) of their electrical environment. This includes a review of the existing literature on fluid spills and electrical hazards in the operating room, a gap analysis for missing information, and a proposed risk assessment method for hospitals to use to evaluate the proper classification of an operating room.

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The content, opinions and conclusions contained in this report are solely those of the authors.
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<tr>
<td>A</td>
<td>amperes</td>
</tr>
<tr>
<td>AAMI</td>
<td>Association for the Advancement of Medical Instrumentation</td>
</tr>
<tr>
<td>AHA</td>
<td>American Hospital Association</td>
</tr>
<tr>
<td>AIA</td>
<td>American Institute of Architects</td>
</tr>
<tr>
<td>AIMS</td>
<td>Advanced Incident Management System</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>APSF</td>
<td>Australian Patient Safety Foundation</td>
</tr>
<tr>
<td>ARF</td>
<td>Area Resource File</td>
</tr>
<tr>
<td>ASA</td>
<td>American Society of Anesthesiologists</td>
</tr>
<tr>
<td>ASHE</td>
<td>American Society for Healthcare Engineering</td>
</tr>
<tr>
<td>ASRS</td>
<td>Aviation Safety Reporting System</td>
</tr>
<tr>
<td>BLS</td>
<td>Bureau of Labor Statistics</td>
</tr>
<tr>
<td>BS</td>
<td>British Standard</td>
</tr>
<tr>
<td>CMS</td>
<td>Center for Medicare and Medicaid Services</td>
</tr>
<tr>
<td>CFOI</td>
<td>Census of Fatal Occupational Injuries</td>
</tr>
<tr>
<td>DOD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>ECRI</td>
<td>Emergency Care Research Institute</td>
</tr>
<tr>
<td>EKG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>EMC</td>
<td>electromagnetic compatibility</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GAO</td>
<td>Government Accountability Office</td>
</tr>
<tr>
<td>GFCI</td>
<td>Ground Fault Circuit Interrupter</td>
</tr>
<tr>
<td>HCUP</td>
<td>Healthcare Cost and Utilization Project</td>
</tr>
<tr>
<td>HEA-ELS</td>
<td>Technical Committee on Electrical Systems</td>
</tr>
<tr>
<td>HTM</td>
<td>Health Technical Memorandum</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>IEEE</td>
<td>Institute of Electrical and Electronics Engineers</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>IPS</td>
<td>Isolated Power System</td>
</tr>
<tr>
<td>IRIS</td>
<td>Incident Report Investigation Scheme</td>
</tr>
<tr>
<td>IT</td>
<td>Isolating Transformer</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
</tr>
<tr>
<td>L</td>
<td>liter</td>
</tr>
<tr>
<td>LIM</td>
<td>Line Isolation Monitor</td>
</tr>
<tr>
<td>m</td>
<td>meter</td>
</tr>
<tr>
<td>MAUDE</td>
<td>Manufacturer and User Facility Device Experience</td>
</tr>
<tr>
<td>MDSR</td>
<td>Medical Device Safety Report</td>
</tr>
<tr>
<td>MHSPSR</td>
<td>Military Health System Patient Safety Registry</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicines and HealthCare Products Regulatory Agency</td>
</tr>
<tr>
<td>NASA</td>
<td>National Aeronautics and Space Administration</td>
</tr>
<tr>
<td>NASHP</td>
<td>National Academy for State Health Policy</td>
</tr>
<tr>
<td>NEC</td>
<td>National Electrical Code</td>
</tr>
<tr>
<td>NEISS</td>
<td>National Electronic Injury Surveillance System</td>
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<tr>
<td>NFPA</td>
<td>National Fire Protection Association</td>
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<tr>
<td>NHIS</td>
<td>National Health Interview Survey</td>
</tr>
<tr>
<td>NIS</td>
<td>National Inpatient Sample</td>
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<tr>
<td>NPSD</td>
<td>Network of Patient Safety Databases</td>
</tr>
<tr>
<td>NPSA</td>
<td>National Patient Safety Agency</td>
</tr>
<tr>
<td>NQF</td>
<td>National Quality Forum</td>
</tr>
<tr>
<td>OR</td>
<td>Operating Room</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>PMA</td>
<td>Pre-Market Approval</td>
</tr>
<tr>
<td>psi</td>
<td>pounds per square inch</td>
</tr>
<tr>
<td>PSRS</td>
<td>Patient Safety Reporting System</td>
</tr>
<tr>
<td>RCD</td>
<td>Residual Current Device (European nomenclature for GFCI)</td>
</tr>
<tr>
<td>ROP</td>
<td>Report on Proposals</td>
</tr>
<tr>
<td>SFPE</td>
<td>Society of Fire Protection Engineers</td>
</tr>
<tr>
<td>SMDA</td>
<td>Safe Medical Devices Act</td>
</tr>
<tr>
<td>SOII</td>
<td>Survey of Occupational Injuries and Illnesses</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
</tr>
<tr>
<td>---------</td>
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<tr>
<td>SRE</td>
<td>Serious Reportable Event</td>
</tr>
<tr>
<td>STF</td>
<td>Slip, Trip, or Fall</td>
</tr>
<tr>
<td>TGA</td>
<td>Ageing Therapeutic Goods Adminstration</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>VAC</td>
<td>volts alternating current</td>
</tr>
<tr>
<td>VHA</td>
<td>Veterans Health Administration</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
Executive Summary

In the most recent round of code development for NFPA 99, *Standard for Health Care Facilities*, which was scheduled to be released in 2009, an area of debate emerged in the Report on Proposals and the Report on Comments. The debate involves areas of health care facilities, particularly operating rooms, and centers around two philosophies. Health care and occupational health professionals indicate that an operating room has the potential to be a wet location, because there is the possibility of standing fluids on the floor and/or other areas, such as an operating room table, and therefore, there are potential hazards and associated health risks to the doctors, nurses and patients within the facility room. Health care facility managers, however, indicate that there is not an established loss history, and therefore question why an electrical system should be installed to protect from a hazard, when it is not needed or wanted due to the extra installation and maintenance expenses. The debate was not settled during the 2009 revision cycle, and the 2009 edition was ultimately returned to the technical committee and NFPA 99 was placed in the annual 2011 revision cycle.

The motivation for this study is to provide a comprehensive view of the hospital operating room electrical environment in order to facilitate hazard analysis by an individual hospital, to establish whether a particular operating room should have a “wet procedure location” or “dry location” electrical classification. Conditions in the operating room can vary dramatically based on many factors, such as the type of surgery, collection methods for blood and fluids lost, and use of irrigation fluid. As a result, it is difficult to assign a single classification to all operating rooms. This report reviews the existing literature on fluid spills and electrical hazards in the operating room, and provides a gap analysis for missing information.

A risk assessment method is proposed for hospitals to use to evaluate the proper classification of an operating room. The recommended model is a risk ranking method based on the volume of a potential spill or liquid release and the subsequent liquid pool size. This method determines the annual probability of exposure to a liquid pool in an operating room.
1 Background and Introduction

During code development for National Fire Protection Association (NFPA) 99, Standard for Health Care Facilities, scheduled to be released in 2009, a key area of debate emerged in the Report on Proposals (ROP) and Report on Comments (ROC) documents. The debate involves areas of health care facilities, particularly operating rooms, and centers around two philosophies. Health care and occupational health professionals indicate that an operating room has the potential to be a wet location, because there is the possibility of standing fluids on the floor and/or other areas, such as an operating room table, and therefore potential hazards and associated health risks to staff and patients exist. Health care facility managers, however, indicate that there is not an established loss history, and therefore question why an electrical system should be installed to protect against such a hazard, when the system is not needed or wanted due to installation and maintenance expenses. The debate was not settled during the 2009 revision cycle, and the 2009 edition of NFPA 99 was returned to the technical committees and delayed to the 2011 revision cycle.

The current edition of NFPA 99 (2005) requires the governing body of the health care facility determine if operating rooms should be classified as a “wet procedure location.” NFPA 70, National Electrical Code (NEC), provides the following definitions:

- **Dry Location**: A location not normally subject to dampness or wetness. A location classified as dry may be temporarily subject to dampness or wetness, as in the case of a building under construction.

- **Wet Location**: Installations underground or in concrete slabs or masonry in direct contact with the earth; in locations subject to saturation with water or other liquids, such as vehicle washing areas; and in unprotected locations exposed to weather.

- **Wet Procedure Location**: Those spaces within patient care areas where a procedure is performed and that are normally subject to wet conditions while patients are present. These including standing fluids on the floor or drenching of the work area, either of
Areas classified as a wet procedure location require specific protection against electrical shock, such as isolated power supply systems or ground-fault circuit interrupters (GFCIs). Presently, it is not clear whether the procedures and situations probable in a hospital operating room should be performed in an area classified as a wet procedure location or in an area classified as a dry location. Considerations must be made to provide a safe environment for patients and staff, while providing a risk-based solution to prevent over design of the electrical distribution system within the operating room.

In the 2011 NFPA 99 ROP, the Technical Committee on Electrical Systems (HEA-ELS) is evaluating a proposal with the recommendation to require a risk assessment to classify an operating room as dry.

The objective of this research project is to define and analyze the hazards associated with hospital operating rooms, in order to clarify the wet procedure location or dry location classification of the electrical environment to assist HEA-ELS in the upcoming 2011 revision cycle with a recommended risk assessment methodology.

The following chapters investigate, compile and evaluate associated operating room hazards in an effort to provide a framework for developing a risk analysis methodology to be applied to hospital operating rooms with a broad range of usage. Specific hazards associated with situations that could occur during particular surgeries were considered.

Medical literature, manuals and texts are identified and information summarized to enable classification of typical surgical procedure and situational groups for use in an operating room risk assessment. Operating room usage across the United States (US) is summarized for the past 5 years. Several medical and health injury and incident databases were identified. Current electrical design practices used in the medical industry by the US and foreign countries are

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1 National Electrical Code, p. 28, 2008
summarized. A gap analysis of the available data provides recommendations for the types of data needed to develop a more robust risk analysis methodology. Following the gap analysis a recommended risk assessment methodology is outlines, followed by a project summary.
2 Literature Review

This study provides a comprehensive view of the hospital operating room electrical environment in order to facilitate hazard analysis by an individual hospital to establish whether a particular operating room should have a “wet procedure location” or “dry location” electrical classification. A literature review was conducted to collect and summarize applicable information relating to electrical safety in a hospital operating room. Hospital operating room usage was evaluated, including factors that may lead to a wet or dry environment, as well as typical failure mechanisms that could lead to increased risk of electric shock in a wet environment. Advantages and disadvantages of electrical systems recommended for use in both wet and dry environments were reviewed, as well as current design practices and policies in domestic and international operating rooms. Additionally, the literature review provides data to determine the prevalence of applicable injuries and deaths due to electric shock incidents.

2.1 Conditions in a Hospital Operating Room

The purpose of this section is to investigate the probability of the presence of an electric shock hazard associated with liquids in an operating room.

Documented incidents of electric shock and equipment malfunctions in a hospital operating room associated with the presence of liquids have occurred. For example:

- In the early 1970s, a urologist was burned on the eyebrow, using a scope while standing on a grounded floor and performing ground-referenced electrosurgery in a saline-soaked environment. The urologist was wearing conductive booties over bare feet at the time of the incident.²

• In 1997, a stopper detached from an urimeter collection bag, causing fluid to cascade over an extension cord power tap on the operating room floor, causing a power failure affecting the entire operating room.3

• In 1993, an accidental spill of a fluid container onto a blood pressure monitor caused a malfunction of the blood monitor. A replacement monitor was not available, causing harm to the patient.4

The presence of liquid on an operating room floor has been determined to be an important electrical safety factor, as liquid can reduce the resistance between the human body and the ground, presenting a danger of ground fault shock. Ground fault shock can occur when a live wire in a piece of electrical equipment makes contact with a conductive component of the exterior. Human contact with the electrified equipment while contacting a grounded surface can result in a ground fault shock, which can lead to serious injury or death.

2.1.1 Clinical Studies and Medical Literature

In order to quantify the probability of a wet condition existing in a hospital operating room, a search of the medical literature was conducted to gather information on relevant liquid spills. In addition to the limited published research on liquid spills and electrical safety in a hospital operating room, information was gathered from medical studies in various related areas. The information collected can be grouped into four categories:

• Patient blood and fluid loss;
• Irrigation fluid usage;
• Blood contamination of medical staff; and
• Blood and fluid spray and splatter.

Data in each category is directly related to electrical safety, but was collected for different reasons (i.e., patient health, hazardous material exposure and disposal, etc.). The data presented


in this section does not give a complete quantification of the amount of fluids present in the operating room or the probability of a spill, but represents a survey of the available literature. Information was also gathered on documented liquid spill events, which is presented in Section 2.1.2.

2.1.1.1 Patient Blood and Fluid Loss

The reviewed literature indicates that surgeons are familiar with typical blood loss associated with particular surgical operations. The evaluation of blood and fluid loss levels is critical to the life safety of the patient, therefore, effective monitoring and maintenance of fluid levels during surgery is required. In many surgical operations, significant amounts of blood can be lost. An average size adult body contains approximately 5L of blood.\(^5\) A 40% loss of blood (2L) can be life threatening. Blood loss can be characterized by defining several severity levels. A list of terms commonly used for characterizing blood loss is given in Table 1.

Table 1. Terms Used to Characterize Blood Loss

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0-500 mL</td>
<td>Shorn, 2010(^6)</td>
</tr>
<tr>
<td>Above Normal</td>
<td>500-1000 mL</td>
<td></td>
</tr>
<tr>
<td>Excessive</td>
<td>&gt;1000 mL</td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>&gt;500 mL</td>
<td>Shorn, 2010(^6)</td>
</tr>
<tr>
<td>Massive Blood Loss</td>
<td>1 Body Vol in 24 hours</td>
<td>Stainsby et al., 2006(^7)</td>
</tr>
<tr>
<td></td>
<td>50% Body Vol in 3 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>150 mL/min</td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>500-750 mL</td>
<td>Fortunato, 2000(^8)</td>
</tr>
<tr>
<td>Moderate</td>
<td>750-1500 mL</td>
<td></td>
</tr>
<tr>
<td>Major</td>
<td>1500-2250 mL</td>
<td></td>
</tr>
<tr>
<td>Catastrophic</td>
<td>&gt;2250 mL</td>
<td></td>
</tr>
</tbody>
</table>


The terms in Table 1 give an upper bound to the amount of blood reasonably expected to be lost on a frequent basis during common surgical operations. Attempts are frequently made to measure or estimate the actual amount of blood lost during surgery. The results of several studies for blood loss in surgical operations are shown in Table 2 and Table 3.

Table 2. Blood Loss in General Surgery

<table>
<thead>
<tr>
<th>Volume</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-600 mL</td>
<td>Ishihama et al., 2010(^9)</td>
</tr>
<tr>
<td>749-3670 mL</td>
<td>Boldt et al., 2006(^10)</td>
</tr>
<tr>
<td>0-5600 mL</td>
<td>Spence et al., 1990(^11)</td>
</tr>
</tbody>
</table>

Table 3. Blood Loss and Transfusion Data for Several Types of Surgery

<table>
<thead>
<tr>
<th>Volume of Blood</th>
<th>Type of Surgery</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2250 mL</td>
<td>Transfusion during vascular surgery</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>1479 mL</td>
<td>Transfusion during liver resection</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>1800 mL</td>
<td>Transfusion during hip arthroplasty</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>5490 mL</td>
<td>Transfusion during spinal fusion</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>1246 mL</td>
<td>Transfusion during prostate surgery (1)</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>1717 mL</td>
<td>Transfusion during prostate surgery (2)</td>
<td>Miller, 2005(^12)</td>
</tr>
<tr>
<td>10 mL/kg/hr</td>
<td>Abdominal surgery</td>
<td>Grocott et al., 2005(^13)</td>
</tr>
<tr>
<td>100-7000 mL</td>
<td>Spinal fusion surgery</td>
<td>Szpalski et al. 2004(^14)</td>
</tr>
<tr>
<td>400-1500 mL</td>
<td>Cardiovascular surgery</td>
<td>Friedel et al., 1991(^15)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>Procedure</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>75-2000</td>
<td>Laparoscopic splenectomy</td>
<td>Matteotti et al., 2006(^{16})</td>
</tr>
<tr>
<td>1102-2544</td>
<td>Liver surgery</td>
<td>Solomon, D. E., 1991(^{17})</td>
</tr>
<tr>
<td>465-1930</td>
<td>Spinal surgery</td>
<td>McNamara et al., 1991(^{18})</td>
</tr>
<tr>
<td>186-3317</td>
<td>Spinal surgery</td>
<td>Heller et al., 1991(^{19})</td>
</tr>
<tr>
<td>1386</td>
<td>Liver resection (1)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>685</td>
<td>Liver resection (2)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>18.4 mL/cm(^2)</td>
<td>Liver resection (3)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>569</td>
<td>Prostatectomy</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>637</td>
<td>Cystectomy</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>134</td>
<td>Mastectomy (1)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>352</td>
<td>Mastectomy (2)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>149</td>
<td>Mastectomy (3)</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>68</td>
<td>Vaginal hysterectomy</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
<tr>
<td>215</td>
<td>Hepatectomy</td>
<td>Seeber and Shandler, 2007(^{20})</td>
</tr>
</tbody>
</table>

Typically, blood lost is collected and does not reach the floor. If careful collection methods are not employed, however, pools of blood and bodily fluid could form from dripping or spilling of collection containers. As a result, these reported blood loss volumes are the quantity of fluid which could reasonably be involved in a spill accident.

### 2.1.1.2 Irrigation Usage

In many surgical operations, irrigation fluid is used to clean an incision or body cavity. Irrigation is also used to clean contaminated wounds,\(^{21}\) to achieve hemostasis and visualize a problem, and to reduce bacteria count, in various types of operations, such as neurosurgery, ear,

---


nose, and throat procedures, the treatment of wounds, and the treatment of burns. Typical volumes of irrigation fluid for several types of operations are provided in Table 4.

Table 4. Irrigation Usage in Several Types of Surgery

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>Type of Surgery</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,000-12,000</td>
<td>Joint arthroscopy</td>
<td>Fortunado, 2000(^{22})</td>
</tr>
<tr>
<td>1800-1900</td>
<td>Hip and knee replacement surgery</td>
<td>Singh and Kalairajah, 2009(^{23})</td>
</tr>
<tr>
<td>2,000-4,000</td>
<td>Cystoscopy during bladder surgery</td>
<td>Fortunado, 2000(^{22})</td>
</tr>
<tr>
<td>3,000-6,000</td>
<td>Transurethral prostatectomy</td>
<td>Fortunado, 2000(^{22})</td>
</tr>
</tbody>
</table>

High pressure irrigation systems can operate at up to 2 bar\(^{24}\) (28.9 psi), flow up to 2L/min\(^{25}\), and pose several risks. Irrigation fluid can splatter and drip, which poses contamination issues to staff, as well as electrical safety issues if fluids reach the floor. If large volumes of irrigation fluid are used, collection and containment is also an issue. Suction canisters are often used to collect irrigation fluid, and accidents can cause these canisters to spill their contents.\(^{26}\) Some hospitals use self-contained fluid waste management systems, which can hold up to 40L.\(^{26}\) In some cases, containment bags are used to collect irrigation fluid during jet lavage of foot and ankle wounds.\(^{27}\) If proper care is not exercised when handling suction containers, fluid waste management systems or containment bags, they all pose a significant spill hazard.

literature was surveyed for studies of the frequency of blood contamination of the operating room medical staff.

Quebbeman et al.\textsuperscript{28} performed a study that found most cases of blood exposure to be caused by finger pricks with needles. For orthopedic surgeries, they found that 20\% of all contaminations occurred on the face, mostly from splattering of blood from power tools. They also note that for orthopedic surgeries, “this group also had high rates of contamination of legs and feet due to the blood running down the side of the operating table.” Lynch and White\textsuperscript{29,30} found that of 8502 surgeries investigated, 864 (10\%) involved blood exposure to the skin of operating room staff. They also observed that surgical team members often had bodily fluid run under the drapes and onto their legs and feet. Fry et al.\textsuperscript{31} warn that operations involving power saws, drills, or irrigation fluid pose a risk of splattering from blood or irrigation fluid. Jagger et al.\textsuperscript{32} studied blood exposure to operating room staff and determined that blood splash, spray and spill is a common occurrence in the operating room. They observed that, “it is not unusual in the operating room environment for personnel to be exposed to blood even when they are located at a significant distance from the patient.” It should be noted that these five studies were all performed in 1990s, and common practices may have changed. A 2008 study by Meyers et al.\textsuperscript{33} examined 60,583 surgical procedures and found that 389 involved blood and fluid exposure by means of needle-stick, contact with non-intact skin or mucous membrane, and one instance of biting. These exposures represent a small fraction (0.64\%) of all surgeries surveyed and frequently do not involve significant amounts of blood.

2.1.1.4 Evidence of Blood and Fluid Spray and Splatter

Medical literature was surveyed for studies on blood and fluid spray and splash frequency during surgical operations. These studies were conducted by examining the eye shields, glasses, and gowns of operating room staff following surgeries and recording the presence of blood droplets. For the purpose of these studies, contact with skin or mucous membrane is not necessary for the splash to be counted. The results of the literature search are shown in Table 5.

Table 5. Observed Frequency of Blood Splash during Operating Room Surgical Procedures

<table>
<thead>
<tr>
<th>Splash Frequency (%)</th>
<th>Type of Surgery</th>
<th>Authors</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>65</td>
<td>Orthopedic Surgery</td>
<td>Bell and Clement, 1991&lt;sup&gt;34&lt;/sup&gt;</td>
<td>UK</td>
</tr>
<tr>
<td>100</td>
<td>Bone cutting, intramedullary reaming</td>
<td>Duthie et al., 1998&lt;sup&gt;35&lt;/sup&gt;</td>
<td>UK</td>
</tr>
<tr>
<td>62</td>
<td>C-Sections</td>
<td>Aisian et al., 2006&lt;sup&gt;36&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>51</td>
<td>Vascular procedures</td>
<td>Berrige et al., 1993&lt;sup&gt;37&lt;/sup&gt;</td>
<td>UK</td>
</tr>
<tr>
<td>33</td>
<td>Dermatological surgery</td>
<td>Birnie et al., 2007&lt;sup&gt;38&lt;/sup&gt;</td>
<td>UK</td>
</tr>
<tr>
<td>86</td>
<td>Orthopedic surgery</td>
<td>Collins et al., 2000&lt;sup&gt;39&lt;/sup&gt;</td>
<td>USA</td>
</tr>
<tr>
<td>50</td>
<td>C-Sections</td>
<td>Kouri et al., 1993&lt;sup&gt;40&lt;/sup&gt;</td>
<td>USA</td>
</tr>
<tr>
<td>32</td>
<td>Vaginal births</td>
<td>Kouri et al., 1993&lt;sup&gt;40&lt;/sup&gt;</td>
<td>USA</td>
</tr>
<tr>
<td>85</td>
<td>Surgical practitioners</td>
<td>Chong et al., 2007&lt;sup&gt;41&lt;/sup&gt;</td>
<td>NZ</td>
</tr>
<tr>
<td>26</td>
<td>General</td>
<td>Davies et al., 2007&lt;sup&gt;42&lt;/sup&gt;</td>
<td>UK</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th>Procedure</th>
<th>Reference</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>Vascular</td>
<td>Davies et al., 2007(^{42})</td>
<td>UK</td>
</tr>
<tr>
<td>30</td>
<td>Breast</td>
<td>Davies et al., 2007(^{42})</td>
<td>UK</td>
</tr>
<tr>
<td>6</td>
<td>Colorectal</td>
<td>Davies et al., 2007(^{15})</td>
<td>UK</td>
</tr>
<tr>
<td>12</td>
<td>Endocrine</td>
<td>Davies et al., 2007(^{42})</td>
<td>UK</td>
</tr>
<tr>
<td>9</td>
<td>Laproscopic</td>
<td>Davies et al., 2007(^{42})</td>
<td>UK</td>
</tr>
<tr>
<td>45</td>
<td>Overall</td>
<td>Davies et al., 2007(^{42})</td>
<td>UK</td>
</tr>
<tr>
<td>45</td>
<td>Overall</td>
<td>De Silva et al., 2009(^{43})</td>
<td>Cape Town</td>
</tr>
<tr>
<td>51</td>
<td>Overall</td>
<td>Endo et al., 2007(^{44})</td>
<td>Japan</td>
</tr>
<tr>
<td>75</td>
<td>Cardiovascular</td>
<td>Endo et al., 2007(^{44})</td>
<td>Japan</td>
</tr>
<tr>
<td>69</td>
<td>Neurosurgery</td>
<td>Endo et al., 2007(^{44})</td>
<td>Japan</td>
</tr>
<tr>
<td>60</td>
<td>Gastrointestinal</td>
<td>Endo et al., 2007(^{44})</td>
<td>Japan</td>
</tr>
<tr>
<td>60</td>
<td>Orthopaedic Surgery</td>
<td>Endo et al., 2007(^{44})</td>
<td>Japan</td>
</tr>
<tr>
<td>61</td>
<td>Tonsillectomy</td>
<td>Hanna et al., 2006(^{45})</td>
<td>UK</td>
</tr>
<tr>
<td>66</td>
<td>Procedural dermatology</td>
<td>Holzmann et al., 2008(^{46})</td>
<td>US</td>
</tr>
<tr>
<td>60</td>
<td>Gynecological surgeries</td>
<td>Sharma et al., 2003(^{47})</td>
<td>India</td>
</tr>
<tr>
<td>49</td>
<td>Endourology (urology)</td>
<td>Wines et al., 2008(^{48})</td>
<td>UK</td>
</tr>
<tr>
<td>84</td>
<td>Laproscopic nephrectomies</td>
<td>Wines et al., 2008(^{48})</td>
<td>UK</td>
</tr>
<tr>
<td>68</td>
<td>Pyeloplasties</td>
<td>Wines et al., 2008(^{48})</td>
<td>UK</td>
</tr>
<tr>
<td>58</td>
<td>Flexible ureteroscopies</td>
<td>Wines et al., 2008(^{48})</td>
<td>UK</td>
</tr>
</tbody>
</table>


2.1.2 Evidence of Fluid on the Floor during Surgical Operations

Some data is available on the frequency of fluid spills on the floor of an operating room. In one study, 5% of staff reported operating room procedures had pooling or ponding of fluids on the floor.\textsuperscript{49} While some operating rooms have floor drains, others employ drainage containers to collect fluids.\textsuperscript{50} If the level in these containers is not monitored, liquid can overflow and spill onto the floor. During some surgical operations, significant spills of blood and irrigation fluid can occur.\textsuperscript{51} Researchers estimate that the feet of surgeons become contaminated with blood in 13% of all operations, and with even greater frequency during higher blood loss procedures.\textsuperscript{52}

2.2 Study of the Volume of Surgery in the United States

2.2.1 Introduction

The National Inpatient Sample (NIS) database is part of the Healthcare Cost and Utilization Project (HCUP)\textsuperscript{53}, sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is the largest inpatient care database that is publicly available in the United States (US), containing data from 5 to 8 million hospital stays from approximately 1,000 hospitals sampled to approximate a 20% stratified sample of discharges from US community hospitals. Included among community hospitals are specialty hospitals, such as obstetrics-gynecology, ear-nose-throat, short-term rehabilitation, orthopedic, and pediatric institutions, as well as public hospitals and academic medical centers. Starting in 2005, the American Hospital Association (AHA) included long term acute care facilities in the definition of community hospitals; therefore, such facilities are included in the NIS sampling frame. Excluded from the NIS are short-term rehabilitation hospitals (beginning with 1998 data), long term non-acute care hospitals, psychiatric hospitals, and alcoholism/chemical dependency treatment facilities.

\textsuperscript{49} Kaiser Permanente NFPA 99 ROC, 2008.
\textsuperscript{53} Details about the NIS database and the HCUP program can be found at: \url{http://www.hcup-us.ahrq.gov/nisoverview.jsp}
NIS is the only national hospital database capturing information from all hospitalized patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured. In 2008, NIS derived its data from discharge records from 1,056 hospitals located in 42 states (which comprise 95% of the US population). Sampling weights are provided by HCUP to calculate national estimates. NIS data is available annually, dating back to 1988, allowing analysis of trends over time. The large sample size of the NIS program enables analyses of rare conditions, uncommon treatments, and hospital care associated with special patient populations, such as the uninsured. Inpatient stay records in the NIS include clinical (e.g., diagnosis and procedures) and resource use (e.g., hospital charges, length of stay) information typically available from discharge abstracts. NIS can be linked directly to hospital-level data from the AHA Annual Survey Database\textsuperscript{54} and to county-level data from the Health Resources and Services Administration Bureau of Health Professions Area Resource File (ARF), except in those states that do not allow the release of hospital identifiers.

\subsection*{2.2.2 Classification of Surgery}

For each discharge record in the NIS, up to 15 procedures performed during the patient’s hospital stay are recorded. It is often the case that more than one procedure was performed during a patient’s stay. Thus, in the present tabulation, each procedure within a discharge record is counted individually and used the same sampling weight for national projection. Procedures within the ICD-9-CM system are grouped broadly by body-system categories (e.g., respiratory system, digestive system) to facilitate summarization and tabulation. The same categories were used in the present exercise. These broad groupings are shown in Table 6.

\textsuperscript{54} Health Forum, LLC © 2009
Table 6. Surgical Groups by ICD-9-CM Codes

<table>
<thead>
<tr>
<th>General Operation Type</th>
<th>ICD-9-CM Codes*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System</td>
<td>01 - 05</td>
</tr>
<tr>
<td>Endocrine System</td>
<td>06 - 07</td>
</tr>
<tr>
<td>Eye</td>
<td>08 - 16</td>
</tr>
<tr>
<td>Ear</td>
<td>18 - 20</td>
</tr>
<tr>
<td>Nose, Mouth, Pharynx</td>
<td>21 - 29</td>
</tr>
<tr>
<td>Respiratory System</td>
<td>30 - 34</td>
</tr>
<tr>
<td>Cardiovascular System</td>
<td>00.4 (adjunct vascular system procedures), 00.5 (other cardiovascular procedures), 00.6 (blood vessels), 35 - 39</td>
</tr>
<tr>
<td>Hemic and Lymphatic System</td>
<td>40 - 41</td>
</tr>
<tr>
<td>Digestive System</td>
<td>42 - 54</td>
</tr>
<tr>
<td>Urinary System</td>
<td>55 - 59</td>
</tr>
<tr>
<td>Male Genital Organs</td>
<td>60 - 64</td>
</tr>
<tr>
<td>Female Genital Organs</td>
<td>65 - 71</td>
</tr>
<tr>
<td>Obstetrical Procedures</td>
<td>72 - 75</td>
</tr>
<tr>
<td>Musculoskeletal (Orthopedic)</td>
<td>00.7 (hip), 00.8 (knee and hip), 76 - 84</td>
</tr>
<tr>
<td>Integumentary System (skin)</td>
<td>85 - 86</td>
</tr>
</tbody>
</table>

* These ICD-9-CM codes include all sub category numbers (e.g., code “08” includes 08.1, 08.2, etc.)

2.2.3 Volume of Procedures by Surgical Category

Exponent used the NIS data from 2004 to 2008 for the present study. Table 7 provides the estimated number of procedures performed each year in the US by the surgical categories listed in Table 6. The surgical category “other” captures all other procedures not specifically identified. These procedures primarily fall into the “diagnostic and therapeutic” category of operations (e.g., radiology, ultrasound, cardiac stress tests) and many are considered “non-operational.” Table 8 provides the estimated percentage of the total procedures performed each year in the US by surgical category; these percentages exclude the “other” procedures in the total, because these procedures do not necessarily occur in an operating room.
# Table 7. Procedure Volume by Surgical Category

<table>
<thead>
<tr>
<th>Category</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other</strong></td>
<td>18,724,723</td>
<td>19,112,759</td>
<td>19,644,035</td>
<td>21,541,455</td>
<td>21,404,916</td>
<td>100,427,889</td>
</tr>
<tr>
<td>Nervous</td>
<td>1,585,832</td>
<td>1,600,724</td>
<td>1,527,188</td>
<td>1,571,825</td>
<td>1,615,942</td>
<td>7,901,512</td>
</tr>
<tr>
<td>Endocrine</td>
<td>119,277</td>
<td>123,843</td>
<td>120,031</td>
<td>123,824</td>
<td>139,947</td>
<td>626,923</td>
</tr>
<tr>
<td>Eyes</td>
<td>84,728</td>
<td>91,688</td>
<td>75,152</td>
<td>62,681</td>
<td>66,124</td>
<td>380,374</td>
</tr>
<tr>
<td>Ear</td>
<td>40,548</td>
<td>54,317</td>
<td>40,098</td>
<td>40,032</td>
<td>43,096</td>
<td>218,092</td>
</tr>
<tr>
<td>Nose, Mouth, Pharynx</td>
<td>318,548</td>
<td>340,760</td>
<td>305,862</td>
<td>308,553</td>
<td>305,676</td>
<td>1,579,399</td>
</tr>
<tr>
<td>Respiratory</td>
<td>1,383,407</td>
<td>1,500,768</td>
<td>1,473,182</td>
<td>1,540,787</td>
<td>1,594,918</td>
<td>7,493,062</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>9,053,227</td>
<td>9,671,416</td>
<td>11,876,237</td>
<td>11,002,419</td>
<td>11,518,844</td>
<td>53,122,143</td>
</tr>
<tr>
<td>Lymphatic</td>
<td>419,794</td>
<td>453,690</td>
<td>425,866</td>
<td>481,861</td>
<td>490,140</td>
<td>2,271,352</td>
</tr>
<tr>
<td>Digestive</td>
<td>6,493,219</td>
<td>6,426,227</td>
<td>6,339,841</td>
<td>6,355,999</td>
<td>6,687,489</td>
<td>32,302,775</td>
</tr>
<tr>
<td>Urinary</td>
<td>1,155,112</td>
<td>1,143,079</td>
<td>1,182,217</td>
<td>1,227,371</td>
<td>1,334,942</td>
<td>6,042,721</td>
</tr>
<tr>
<td>Genital Organ (M)</td>
<td>1,430,375</td>
<td>1,454,294</td>
<td>1,442,856</td>
<td>1,533,926</td>
<td>1,463,496</td>
<td>7,324,947</td>
</tr>
<tr>
<td>Genital Organ (F)</td>
<td>2,072,939</td>
<td>2,033,611</td>
<td>1,943,275</td>
<td>1,917,398</td>
<td>1,812,658</td>
<td>9,779,880</td>
</tr>
<tr>
<td>Obstetrical</td>
<td>8,204,336</td>
<td>8,031,667</td>
<td>8,198,686</td>
<td>9,140,282</td>
<td>8,233,054</td>
<td>41,808,025</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>4,510,191</td>
<td>4,701,570</td>
<td>4,865,166</td>
<td>5,072,891</td>
<td>5,592,545</td>
<td>24,742,364</td>
</tr>
<tr>
<td>Integumentary</td>
<td>1,604,156</td>
<td>1,666,106</td>
<td>1,611,333</td>
<td>1,614,330</td>
<td>1,619,323</td>
<td>8,115,248</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>57,200,413</td>
<td>58,406,521</td>
<td>61,071,026</td>
<td>63,535,634</td>
<td>63,923,111</td>
<td>304,136,704</td>
</tr>
</tbody>
</table>

# Table 8. Procedure Percentage of Total Volume by Surgical Category*

<table>
<thead>
<tr>
<th>Category</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous</td>
<td>4.1%</td>
<td>4.1%</td>
<td>3.7%</td>
<td>3.7%</td>
<td>3.8%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Endocrine</td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Eyes</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.2%</td>
<td>0.1%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Ear</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Nose, Mouth, Pharynx</td>
<td>0.8%</td>
<td>0.9%</td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>3.6%</td>
<td>3.8%</td>
<td>3.6%</td>
<td>3.7%</td>
<td>3.8%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>23.5%</td>
<td>24.6%</td>
<td>28.7%</td>
<td>26.2%</td>
<td>27.1%</td>
<td>26.1%</td>
</tr>
<tr>
<td>Lymphatic</td>
<td>1.1%</td>
<td>1.2%</td>
<td>1.0%</td>
<td>1.1%</td>
<td>1.2%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Digestive</td>
<td>16.9%</td>
<td>16.4%</td>
<td>15.3%</td>
<td>15.1%</td>
<td>15.7%</td>
<td>15.9%</td>
</tr>
<tr>
<td>Urinary</td>
<td>3.0%</td>
<td>2.9%</td>
<td>2.9%</td>
<td>2.9%</td>
<td>3.1%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Genital Organ (M)</td>
<td>3.7%</td>
<td>3.7%</td>
<td>3.5%</td>
<td>3.7%</td>
<td>3.4%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Genital Organ (F)</td>
<td>5.4%</td>
<td>5.2%</td>
<td>4.7%</td>
<td>4.6%</td>
<td>4.3%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Obstetrical</td>
<td>21.3%</td>
<td>20.4%</td>
<td>19.8%</td>
<td>21.8%</td>
<td>19.4%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>11.7%</td>
<td>12.0%</td>
<td>11.7%</td>
<td>12.1%</td>
<td>13.2%</td>
<td>12.1%</td>
</tr>
<tr>
<td>Integumentary</td>
<td>4.2%</td>
<td>4.2%</td>
<td>3.9%</td>
<td>3.8%</td>
<td>3.8%</td>
<td>4.0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
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* The procedure percentages do not include the volume of the “Other” procedure category in the total.
2.3 Electrical Safety in the Operating Room

In the previous section, hospital operating room usage was evaluated to establish factors that may lead to a wet or dry environment. In this section, the electrical hazards associated with hospital operating rooms and safety practices cited in the literature are reviewed. Advantages and disadvantages of the electrical power systems currently recommended by the NEC and NFPA 99 for use in wet procedure locations and dry locations are summarized. A summary of the design practices and policies establishing electrical classification of the operating room environment in domestic and international settings is provided.

2.3.1 Electrical Hazards - Macroshock and Microshock

2.3.1.1 Macroshock

Macroshock is characterized as electric shock by greater than 5-1000 mA. Typically, current passes through extremities or limbs of the human body.\(^{55}\) Dry human skin is characterized with a resistance as great as 100,000 Ohms. Wet skin is characterized with a resistance on the order of 1000 Ohms. The reduction in resistance of conducting electrical current exposes a person with wet skin to risk of ventricular fibrillation from household voltages.\(^{56}\) This resistance to current can also be lowered by perspiration, skin abrasion, surgical incision, external pacemaker leads, and catheters that bypass the skin’s resistance. Patients who have an external conductor to the heart, such as pacemaker leads, are “electrically susceptible” and can be affected by microshock.\(^{56}\)

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2.3.1.2 **Microshock**

Microshock is characterized as electric shock by currents as low as 10-180 µA, concentrated in an area causing ventricular fibrillation, which is a severely abnormal heart rhythm.\(^5^7\)\(^5^8\)

Microshocks occur below the threshold of perception, which is approximately 1 mA.\(^5^8\)

Microshock currents can be attributed to one of three sources: 1) a cardiac lead as a current source (e.g., where current is transferred to the catheters when using ungrounded devices); 2) a cardiac lead as a current sink (e.g., where line current leaks from electrocardiograph to pacemaker leads); and 3) a ground loop (e.g., where a patient is connected to two grounded devices, one through a pacemaker lead, and then a third device not connected to the patient which has a fault, but connected to the same power outlet circuit, which sends a high leakage current through the ground connection, subsequently creating a resistance between the two instrument grounds, and consequently sending a lethal leakage to the patient’s catheter).\(^5^9\)

Electric shock could be caused by a difference in potential along the neutral lead, because all conductors have some resistance, which makes stray capacitive or inductive currents possible. Grounded electrodes attached to more than one part of the patient and from more than one piece of equipment supplied by different outlets also facilitate stray capacitive or inductive currents.\(^5^7\)

The two dominant mechanisms for leakage currents are capacitance associated with alternating current power systems and voltage division occurring by either the built-in design of a medical device or due to accidental insulation failure.\(^6^0\) Leakage current can also be attributed to imperfect insulation between the load and surrounding metal work, which creates an alternative pathway for current to return to the neutral line and stray or deliberate capacitance between live circuits, such as transformers and ground.\(^5^9\)

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Medical devices are required to have a ground current less than 100 µA. In the United Kingdom, all electrical equipment in the vicinity of the patient must conform to a leakage specification of less than 10 µA under normal working conditions. Wherever possible, such equipment should be battery operated and fully isolated from ground, however, all electrical circuits making contact with the patient must be electrically isolated from ground; all equipment susceptible to ground should be insulated. It is recommended that when using a grounded system, the ground connections on all outlets in a single clinical area be interconnected by a low resistance conductor to minimize voltage differences.

2.3.2 Electrical Safety Standard Origins

The origin for improving electrical safety in hospital operating rooms began with efforts to reduce the hazards associated with using flammable anesthesia. The focus of improving electrical safety practices was on the reduction of sources of static electricity and electric shock to improve fire safety. NFPA developed the first guideline on this topic in 1944, Safe Practices in Hospital Operating Rooms. In 1947, the NFPA guideline was generally adopted and in 1948 isolated power systems (IPS) with line isolation monitors (LIMs) were implemented in all anesthetizing locations. In 1949, the predecessor to NFPA 99 was codified.

Despite the focus on electrical safety in operating rooms to ultimately improve fire safety, a lack of standardization in wiring practices in operating rooms created electrical hazards. Specific hazards are cited in the literature, for example, the use of external ground wires in parallel to two-wire cords to ground medical equipment. In addition, it has been documented that 20% of

the electrical outlets in operating rooms in a hospital had improper socket wiring of the lead and neutral conductors, because of an absence of wiring practice requirements in the local building code.  

Electrocautery/electrosurgical unit devices were (and continue to be) a source of electrical incidents attributed to improper use of medical devices, especially related to the placement and contact of the associated grounding pad with the patient. User error and improper use of medical devices are two of the most often cited reasons for patient injury by the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. 

In the early 1960s, there was an increased focus on the prevalence of microshock in the medical industry. In 1967 a journal article reviewing the hazards of electrical apparatus in the medical industry, including the cause of at least 11 incidents of shock and ventricular fibrillation that occurred during surgical procedures from 1960 to 1967, was published. The author concluded that electric shock by medical devices is not rare, and improved electrical safety requires equipment to be properly grounded.

More recent reviews of medical literature alleg that unsubstantiated statistics were circulated in the medical industry, stating 1,200 incidents per year were due to misdiagnosed microshock electrocutions. Subsequently, these statistics were repeated and extrapolated.

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without justification to 5,000 incidents per year.\textsuperscript{74} The medical literature reviews\textsuperscript{71,72} indicate that these claims were the driving force for the NFPA Committee on Hospitals to advocate and implement requirements for the use of IPS as a safeguard against microshock.

### 2.3.3 Electrical Safety Practices

Throughout the literature reviewed, a number of electrical safety practices for the operating room are recommended. Electrical cords that extend down walls or those that cross the floor are considered hazardous, because they create a tripping hazard.\textsuperscript{75} Power cables should not be stretched across traffic lanes.\textsuperscript{75} Straight or curved ceiling mounted tracks and articulating booms should be used to bring electrical outlets close to the operating room table.\textsuperscript{75} Multiple-plug extension boxes (i.e. power taps) should not be left on the floor where they can come in contact with fluids and electrolyte solutions.\textsuperscript{76} When power taps are employed in the operating room, outlets should include watertight covers that flip into place when unused.\textsuperscript{77} Extension cords with power taps should not be used in operating rooms, because they are a tripping hazard and, “any saline-based (therefore conductive) irrigation that ends up on the floor can soak the sockets and allow electricity to flow from the extension via the shortest route to earth.”\textsuperscript{78}

A number of additional safeguards to electrical shock are recommended.\textsuperscript{75} Liquids should not be placed on an electrical device. Machines should be turned off when plugging in cords to power outlets. Electrosurgical and laser units may interfere with operation of other equipment, therefore, these units should be located on the operators’ side of the table and far from monitoring equipment. Additionally, the units should be plugged into separate circuits, with no extension cords. Care should be taken when operating any electrical equipment. The units should be regularly checked for frayed or broken power cords, functioning power switches, and

\textsuperscript{74} In June 1970, a report was distributed by the UPI wire service that Ralph Nader alleged in a speech that 5000 deaths attributed to microshock occurred each year in the nation's hospitals.


proper grounding. All electrical equipment should be inspected by the biomedical engineering department before initial use and routinely, preferably monthly, but at least quarterly.\footnote{Fortunato Nancymarie, ed. Berry and Kohn’s Operation Room Technique, 9th edition, Mosby, Missouri, USA, 2000.}

In addition to general electrical safety, there are several safety recommendations in the literature for working around electrically sensitive patients. When pacemaker leads or catheters are handled, gloves should be used.\footnote{Ehrenwerth Jan, Seifert Harry A, “Electrical and Fire Safety” in Barash Paul G, Cullen Bruce F, Stoelting Robert K, eds. Clinical Anesthesia, 5\textsuperscript{th} edition. Lippincott Williams & Wilkins, Philadelphia, PA, 2006.} Additionally, a pacemaker lead or catheter should not be handled while also in contact with an oscilloscope, monitor, or other electrically powered equipment.\footnote{Magee Patrick, Tooley Mark, The Physics, Clinical Measurement, and Equipment of Anaesthetic Practice, Oxford University Press Inc., New York, USA, 2005.}

\subsection*{2.3.4 Electrical Power Systems in the US Medical Industry}

\subsubsection*{2.3.4.1 Grounded Systems}

In the event of a short circuit in an electrical device that has a three-prong plug, where the
ground wire is connected to the chassis of the unit, the ground wire will conduct the majority of
the fault current away from the person in contact with the unit. Electronic devices without a
ground wire should not be used in the operating room, as a person touching a medical device
chassis with a ground fault will receive a shock.

2.3.4.2 IPS

IPSs are used when a location is classified as a wet procedure location. This type of system
significantly reduces the potential for macroshock to occur. The voltage from either of the two
line conductors (analogous to the hot and neutral of a ground-based system) is approximately 60
VAC, and connecting a low impedance pathway from either of the lines to ground will produce
some current flow, typically on the order of a few mA, depending on the level of isolation. The
LIM detects degraded isolation of the system, which creates a potential low impedance pathway
to ground and provides alarm notification. If a fault occurs, the power is not automatically
tripped to other devices on the same circuit, instead, an alarm will sound by the LIM to notify
personnel to investigate the alarm source.

An IPS may supply power to the entire operating room, however, a hospital can elect to power
equipment directly involved with the surgical operations and required to maintain life support
with an IPS, and implement a conventional grounded power system for lighting circuits and
equipment not required to maintain life support.

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An IPS does not prevent microshock, because currents of 2 to 5 mA potentially flow undetected, below the threshold of the LIM.\textsuperscript{91,92,93} The allowable leakage current alarm level of the LIM is currently 5 mA.\textsuperscript{97}

The sum of several appliances in use on an individual circuit, each having degraded isolation with a small leakage current potential can trip the LIM alarm.\textsuperscript{94,95} Frequent LIM alarms due to multiple devices and/or aging wiring can lead to desensitization of “nuisance alarms”, causing personnel to ignore the LIM.\textsuperscript{96,97} In 1981, the allowable leakage current permitted by the NEC and NFPA 99 was increased from 2 mA to 5 mA to reduce nuisance alarms.\textsuperscript{97} Another disadvantage of the LIM is that it is susceptible to newly developed artifactual causes of alarm (e.g., devices that emit electrical radiation, such as instruments that generate ultrasonic sound waves for tumor disintegration and aspiration and stereotaxic monitors that use radio waves to track sensors attached to patients).\textsuperscript{92} If a LIM alarm is ignored, a hazard could occur if a second fault is present in which the other supply wire is grounded.\textsuperscript{98}

The safety of an isolated circuit can be defeated by an unrecognized unintentional connection to ground (i.e. a defective device with an internal fault to the grounded chassis).\textsuperscript{99,100}

Manufacturers of electrical equipment often place separate isolation transformers within the

power supply of their products,\textsuperscript{95,97} causing the LIM to be insensitive to ground faults distal to the second level of isolation.\textsuperscript{100}

2.3.4.3\hspace{1em}GFCIs

GFCIs are used on particular circuits in conjunction with a grounded power system, when an area is classified as a wet procedure location. GFCI outlets eliminate the potential for macroshock to occur.\textsuperscript{101} The GFCI circuit is designed to sense a specified difference or imbalance in the current flow in the range of 4 to 6 mA between the hot conductor and either the ground or the neutral conductor of the same circuit. This diversion of current is usually associated with unintended leakage current or an unintentional low impedance pathway to ground, such as human contact.\textsuperscript{102} When the current difference is sensed, the circuit is tripped in milliseconds. The GFCI can be manually reset and is equipped with a test button.

A single fault trips the GFCI and disconnects the power to all devices on the circuit. Therefore, it is widely recognized in the literature that GFCIs are not for use with life support or other critical operation equipment. GFCIs also have similar problems to isolating transformers, when the sum of several appliances in use on an individual circuit each has degraded isolation with a small leakage current potential.\textsuperscript{103} GFCIs do not prevent microshock, because currents below 4 to 6 mA potentially flow without alarm or power shutoff.\textsuperscript{101}

2.3.5\hspace{1em}Electrical System Design Practices and Commentary in the Medical Industry

In the current edition of NFPA 99, the governing body of the hospital facility is responsible for designating their operating rooms as a critical care areas and classifying whether the areas are a wet procedure location. A number of groups in the healthcare industry have made statements and policies relating to environmental classification, including:

• Governmental agencies;
• Professional associations and societies;
• Authorities having jurisdiction, including individual states; and
• Other stakeholders, including hospital staff.

2.3.5.1 **Governmental Agencies**

Department of Defense (DOD) policy specifies (post 2002) that operating rooms, delivery rooms, cystoscopy rooms, oral surgery, cardiac catheterization rooms and other such rooms are not wet areas.\(^{104}\) The prior DOD policy (1991) classified operating rooms, delivery rooms, hydrotherapy, and therapeutic pool areas as wet use areas corresponding to NFPA 99.\(^ {105}\)

The 2008 directive of the Veterans Health Administration (VHA) declares that operating rooms and cardiac catheterization rooms are not wet locations for electrical safety purposes.\(^ {106}\) Historically, these rooms within VHA facilities were designated as wet locations and required IPSs. A previous (2002) VHA directive declared areas used for cystoscopy, arthroscopy, and birthing rooms labor/delivery as wet areas.\(^ {107}\)

2.3.5.2 **Professional Associations and Societies**

The Emergency Care Research Institute (ECRI) maintains that hospital operating rooms are not designated as wet locations.\(^ {108}\) They have stated that investing in isolated power and equipotential grounding systems are both unreasonable and unnecessary.\(^ {109}\)

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\(^ {107} \) Department of Veterans Affairs, Veterans Health Administration, Electrical Safety Policy for Patient Care Equipment, VHA Directive 2002-030, 2002.


During the 2008 American Society for Healthcare Engineering (ASHE) 45th Annual Conference and Technical Exhibition, 120 member participants unanimously voted to have ASHE oppose that all operating rooms be considered wet locations.  

The American Society of Anesthesiologists (ASA) in 2008 approved a “Statement on Non-operating Room Anesthetizing Locations”, which issued guidelines for any anesthetizing location and provided examples of wet locations: cystoscopy, arthroscopy, birthing room in labor and delivery.

The Association for the Advancement of Medical Instrumentation (AAMI) 2004 Electrical Safety Manual states that operating rooms are not necessarily wet locations. Currently, a 2008 document has been released with recommendations based on ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance and the latest editions of NFPA 72 and NFPA 99.

The Institute of Electrical and Electronics Engineers (IEEE) publishes a recommended practice for electrical systems in health care facilities, which summarizes the debate of opinions on whether operating rooms should be considered wet or dry locations and refers to the current edition of the NEC and NFPA 99 for guidance on the classification.

The 2010 Hospital Accreditation Standards released by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) refers to current applicable standards regarding the classification of operating rooms as wet or dry environments.

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2.3.5.3 **Individual State – Authority Having Jurisdiction**

The authority having jurisdiction governing a health care facility has the ability to supersede the minimal requirements of NFPA 99 with regard to requiring IPSs in operating rooms. Local and state jurisdictions can have different requirements, and the governing bodies should be consulted.

2.3.5.4 **Literature**

In the literature, a number of stakeholders, including hospital groups and healthcare professionals, have contributed opinions to the debate of whether operating rooms should be classified as wet procedure locations or dry locations. The following citations are the result of a literature review of publically available journal articles, healthcare studies, and health care textbooks. The contributors typically speak from experience; however, there is limited documentation of specific operating room procedures, surgeries, clinical studies, or incident statistics.

Kaiser Permanente, a national health care provider undertook an empirical study of the effectiveness of IPSs in comparison to grounded power systems in their hospital operating rooms. In approximately 1992, Kaiser Permanente chose to discontinue installing IPSs in their operating rooms.\(^{115}\) An assessment of the study data of safety records and interviews with hospital staff revealed that electrical problems were rare in operating rooms with grounded power systems, and that IPSs do not provide the promised benefit of improving electrical safety. Kaiser Permanente also concluded that IPSs potentially have harmful side effects, specifically nuisance alarms to LIM alarms and desensitization.\(^{115}\) Kaiser Permanente conducted another survey of their hospitals with both grounded power systems and IPSs in response to the 2009 NFPA 99 public comment cycle.\(^{116}\) The study found no history of injury due to electric shock, with rare instances of minor electrical shock. Kaiser Permanente determined that by spending capital funds on IPSs, the opportunity is lost to upgrade operating rooms with new medical equipment, wiring, and better maintenance procedures.\(^{116}\)


Jan Ehrenwerth, a professor of anesthesiology at Yale University, John Wills and Dan Rogers, both professors of anesthesiology and critical care medicine at the University of New Mexico, describe an incident involving saline irrigation fluid from a cystoscopy procedure on the floor of an operating room. Ehrenwerth et al. also allege that prior to the procedure, the operating room had been cleaned by throwing buckets of water on the floor. The authors indicate that blood spillage onto the floor occurs in many major surgical operations and irrigation fluid spillage onto the floor during arthroscopies and cystoscopies frequently occurs. They conclude that operating rooms should be designated as wet procedure locations.\textsuperscript{117}

Steven Barker, a professor of anesthesiology from the University of Arizona, and D. John Doyle a medical professor at Case Western Reserve University, describe that an operating room has an almost universal presence of liquids, including water, blood, gastrointestinal contents, urine, etc., on the floor. They concede that there may be operating rooms that can usually be kept dry. They conclude from their experience that operating rooms are never dry locations.\textsuperscript{118}

Other literature review findings are as follows:

- Dennis Fung, a professor of anesthesiology at the University of California, states that operating rooms are wet environments and therefore electrically hazardous.\textsuperscript{119}

- Lawrence Litt, a professor of anesthesia and perioperative care at the University of California in San Francisco, references common wet events in operating rooms as dripping of saline, blood or other conducting liquid on the floor.\textsuperscript{120}

- Franklin Day, a doctor in the Department of Anesthesiology in the Oakland, California Naval Hospital, indicates that while not all anesthetizing locations qualify as wet procedure locations, general purpose operating rooms and obstetric delivery rooms

\textsuperscript{117} Wills John H, Ehrenwerth Jan, Rogers Dan, “Electrical Injury to a Nurse Due to Conductive Fluid in an Operating Room Designated as a Dry Location,” Anesthesia & Analgesia, V110:6:1647-1649, 2010.


appear to meet the definition of a wet procedure location and should be designated as such.\textsuperscript{121}

- Lawrence Litt and Jan Ehrenwerth further characterize numerous types of surgeries as a wet environment\textsuperscript{122} and cite three other references that characterize operating rooms as wet procedure locations.\textsuperscript{123}

### 2.3.6 Comparable Foreign Electrical System Standards in the Medical Industry

The comparable international electrical system standard to NFPA 99 is International Electrotechnical Commission (IEC) 60364-7-710:2002, \textit{Electrical Installations of Buildings, Requirements for Special Installations or Locations – Medical Locations}. The standard does not designate operating rooms as wet procedure locations, however, the standard requires hospital operating rooms have Group 2 protection\textsuperscript{124}, which requires IPSs (designated as isolating transformers [IT]) for life support equipment.\textsuperscript{124} The LIM detection requirement is less than or equal to 1 mA peak current under a fault condition.\textsuperscript{125} There are also power requirements for non-life supporting equipment. Operating rooms with Group 2 protection require GFCIs (called residual current devices [RCDs]) with 30 mA operating current on the following equipment: circuits for the supply of operating tables (for mechanical controls), circuits for X-ray units, circuits for large equipment with a rated power greater than 5 kVA, and circuits for non-critical electrical equipment (non life-support).\textsuperscript{126} In addition, in Group 2 operating rooms where

\begin{flushleft}
\textsuperscript{124} IEC 60364-7-710: 2002, section 710.3.7
\textsuperscript{125} IEC 60364-7-710: 2002, section 710.413.1.5
\textsuperscript{126} IEC 60364-7-710: 2002, section 710.413.1.3
\end{flushleft}
intracardiac procedures take place, supplementary equipotential bonding conductors are required (connected to earth reference bar).\textsuperscript{127}

In the United Kingdom, the comparable medical industry electrical system standard is Health Technical Memorandum HTM 2007:1993 \textit{Electrical Services Supply and Distribution}, which has technical recommendations in-line with British Standard BS 7671 \textit{Requirements for Electrical Installations}, and IEE Guidance Note 7:2004, \textit{Special Locations}, 2\textsuperscript{nd} edition, Chapter 10 – Medical Locations, which is based on IEC 60364-7-710 requirements.

New Zealand and Australia follow AS/NZS 2500:2004, \textit{Guide to the safe use of electricity in patient care}, and AS/NZS 3003:2003, \textit{Electrical installations - patient treatment areas of hospitals and medical, dental practices and dialyzing locations}. The Australian and New Zealand standards require that cardiac and body protected areas incorporate either GFCIs (RCDs) or an IT and LIM (IPS with an LIM).\textsuperscript{128} For cardiac protected areas, both systems also require a ground connection to any conductive object either directly or indirectly in contact with the patient. This is to protect against microshock causing ventricular fibrillation induced by small currents flowing to the heart via pace maker wires and pulmonary artery catheters.\textsuperscript{128}

In Canada, the comparable medical industry electrical system standard is the Canadian Electric Code: 2009. Rule 24-116 has requirements similar to NFPA 99, where IPSs are optional in operating rooms and required in wet procedure locations. However, there is an exception in New Brunswick, where regulations state that IPSs should not be installed.\textsuperscript{129} A document issued by the Institute of Biomedical Engineering at the University of New Brunswick to supplement the Canadian Electric Code states that isolated electrical systems are not effective in reducing the hazard of microshock. The restrictions on electromedical equipment and other safety precautions that are necessary to protect patients from microshock hazards serve also to protect

\textsuperscript{127} IEC 60364-7-710: 2002, section 710.413.1.6
against higher current shock and are effective with grounded, as well as isolated electrical systems.\footnote{Institute of Biomedical Engineering, University of New Brunswick, “Wiring Guidelines – for patient service areas in New Brunswick Hospitals,” October 2006.}

\section*{2.3.7 Electrical Equipment Design Practices}

In recent years, there has been an improvement in medical device regulation and more stringent standards for the design of medical electrical equipment. The current international standard is IEC 60601-1:2006, \textit{Medical electrical equipment - General requirements for basic safety and essential performance}. Other countries have adopted this standard, for example, the US has adopted the standard with deviations, as well as Canada, Brazil, Japan, Korea, and Australia/New Zealand. In the IEC 60601 code family there are collateral standards governing medical systems, electromagnetic compatibility (EMC), radiation protection, and medical device software. There are also standards for specific types of devices (e.g. electrosurgical equipment, hospital beds). The underlying philosophy of IEC 60601-1 is that equipment must be safe in normal and single fault conditions. The device design requires two layers of protection against excessive unintentional current, defined as leakage current, passing through the patient or operator.\footnote{Biersach Brian R, Marcus Michael L, “Designing Medical Electrical Equipment to Meet Safety Certification and Regulatory Requirements” Medical Equipment Compliance Associates, LLC, accessed August 2010, www.mecaassociates.com/info_01.pdf} Electric shock risk is reduced by either grounding the chassis or preventing the operator from being able to touch the chassis.\footnote{Graham Stephen, “Electrical safety in the operating theatre,” Current Anaesthesia & Critical Care, V15:350-354. 2004.} The design is also required to be evaluated to demonstrate that it is safe in normal and single fault conditions.\footnote{Magee Patrick T, “Electrical Hazards and their Prevention,” Chapter 25 in Davey Andrew J, Diba Ali. eds. Ward’s Anaesthetic Equipment, 5th edition. Elsevier Saunders, 2005.}

\subsection*{2.3.7.1 Medical Device Design as an Alternative Electrical Safety Practice}

A number of citations in the literature recommend that medical device design can improve electrical safety as an alternative to the electrical power system design. A better alternative to an IPS with a LIM is to include a small isolating transformer in the circuitry of each individual item of electrically powered medical equipment, which can be connected to the patient.\footnote{Institute of Biomedical Engineering, University of New Brunswick, “Wiring Guidelines – for patient service areas in New Brunswick Hospitals,” October 2006.} The patient...
circuit is not connected to ground (fully floating), but the equipment enclosure may be earthed/grounded.\textsuperscript{134} Most electrical equipment used in an operating room already has built-in electrical isolation of output power.\textsuperscript{135} The necessity of installation of IPSs and LIMs in operating rooms is questioned, and it is concluded that the decision depends on the type of electrical equipment that is used and on the surgical situation.\textsuperscript{135}

The reliability of medical devices as an expectation of a clinical user’s needs is also discussed. The authors describe the typical product life-cycle environment of a medical electronic device through an example scenario, where an emergency room physician moves monitors around in the emergency room, bumping them into stationary objects, dropping them on the floor, and spraying them with liquids. The authors express the importance of defining the product life-cycle environment as a step in the suggested Design for Reliability Paradigm used by the authors to reduce the ambiguity of the FDA direction for medical device design.\textsuperscript{136} FDA regulation §860.7 (b) identifies four relevant factors that should be considered when assessing safety and effectiveness, the second of which is “the conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use.”


2.4 Incident Reporting of Electrical Related Injuries in an Operating Room

In this section, criteria and classifications for reporting adverse events in the medical industry are reviewed. A selection of databases of medical adverse event and incident reporting are reviewed and summarized. Data relating to electrical incidents in hospital operating rooms or the general health care industry are presented when available. In the literature, a number of trends in adverse event reporting were identified that have effects on the electric shock incidence rate in hospital operating rooms. The medical literature was searched for electric shock incidents occurring in hospital operating rooms. Case studies summarizing electric shock events occurring in a hospital operating room are organized by decade.\textsuperscript{137}

2.4.1 Medical Incident Reporting

In the US, it is estimated that up to 99,000 hospitalized patients die annually due to medical errors, in combination with errors of omission, hospital acquired infections, and adverse events in nursing home and ambulatory care settings.\textsuperscript{138,139} In 1999, the Institute of Medicine (IOM) called for a nationwide, mandatory reporting system of standardized information about adverse events to be provided for state government collection.\textsuperscript{138} State governments are currently in the process of forming, developing and refining their adverse reporting systems in response to this IOM report.

There are a number of regulatory imperatives in the medical industry for reporting incidents and adverse events:

- The Safe Medical Devices Act (SMDA) requires that a hospital report any incident in which the manufacturer’s medical device may have contributed to injury to the

\textsuperscript{137} It should be noted that some of the citations were only found through examination of the reference lists of other relevant documents. Therefore, it should not be expected that the reviewed list of incidents in the published literature is complete.


manufacturer within 10 business days. If the manufacturer is unknown, the occurrence must be reported to the FDA.\textsuperscript{140}

- JCAHO requires hospitals have a mechanism to analyze and reduce sentinel events through corrective action.\textsuperscript{140} Sentinel events are an unexpected occurrence involving death or serious physical or psychological injury.

- The Occupational Safety and Health Administration (OSHA) must be alerted when an employee’s health has been compromised by an injury in the workplace.

- Additionally, the state health department and local, regional, and national authorities have reporting requirements for accidents that result in injuries.\textsuperscript{140}

In the following sections, a selection of databases related to medical adverse event and incident reporting are reviewed and summarized. Data relating to electrical incidents in hospital operating rooms or the general health care industry are presented when available.

2.4.1.1 Groups Monitoring Medical Incident Databases

After the 1999 IOM report, the National Academy for State Health Policy (NASHP) tracked state adverse event reporting systems that were formed with the intent to improve patient safety. In 2007, NASHP issued a survey report summarizing the progress of state efforts to implement adverse event reporting systems.\textsuperscript{141} The NASHP website also provides links to the adverse event reporting tools by state, allowing access to publically available reports of the compiled state findings.\textsuperscript{142}

AHRQ also maintains a comprehensive list of event reporting systems, including state, government, foreign government, independent, and health care agency reporting programs.\textsuperscript{143} AHRQ is in the process of developing a Network of Patient Safety Databases (NPSD) that will receive, analyze and report on nationally aggregated patient safety event information. Currently,


\textsuperscript{142} http://www.nashp.org/pst-state-list

\textsuperscript{143} http://www.pso.ahrq.gov/formats/psersys.htm
there is no centralized adverse event reporting system for hospitals to submit adverse event data, which would disseminate adverse event information to a national audience. Instead, there are separate federal, state and nongovernmental entities that receive and disclose adverse event information. Depending on the entity, reporting by hospitals is either voluntary or mandatory, and the entities have different data collection procedures, privacy protections, and dissemination practices. AHRQ officials have estimated that initial NPSD data will be available for analysis and disclosure in early 2011.\textsuperscript{144}

AHRQ has also developed a reporting framework to assist hospitals with reporting complete descriptions of event records\textsuperscript{145}, including eight event-specific common formats pertaining to frequently occurring and/or serious patient safety events:\textsuperscript{146}

- Blood or blood product;
- Device or medical/surgical supply;
- Fall;
- Healthcare associated infection;
- Medication or other substance;
- Perinatal;
- Pressure ulcer; and
- Surgery or anesthesia.

None of the AHRQ common formats relate specifically to electric shock incidents.

The National Quality Forum (NQF), with support from the US Department of Health and Human Services, also aims to improve the quality of healthcare in the US by monitoring state adverse event reporting activities. In 2002, NQF published a report summarizing a consensus-based list

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{145}] http://www.pso.ahrq.gov/formats/eventdesc.htm
\item[\textsuperscript{146}] http://www.pso.ahrq.gov/formats/commonfmt.htm
\end{itemize}
\end{footnotesize}
of Serious Reportable Events (SREs) to assist states with implementing and improving patient safety reporting systems. This list of SREs was updated in 2006, identifying 28 adverse events that are serious, largely preventable, and of concern to healthcare providers, consumers, and other stakeholders.\textsuperscript{147} There are six categories of SREs, including:

- Surgical events;
- Product or device events;
- Patient protection events;
- Care management events;
- Environmental events; and
- Criminal events.

“Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility” is specifically included as one of the environmental SREs.

In order to assist hospitals with the development of their reporting systems, JCAHO published a document in 2007, \textit{Sentinel Event Policy and Procedures},\textsuperscript{148} which defines occurrences that are subject to review and considered sentinel events:

- Any unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition;
- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge;
- Unanticipated death of a full-term infant;
- Abduction of any patient receiving care, treatment and services;
- Discharge of an infant to the wrong family;
- Rape;

\textsuperscript{148} http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/
• Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;
• Surgery on the wrong patient or wrong body part;
• Unintended retention of a foreign object in a patient after surgery or other procedure;
• Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter); and
• Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

The Center for Medicare and Medicaid Services (CMS) developed of list of hospital-acquired conditions, which is divided into ten categories. CMS uses the list to determine reimbursement rates, which are affected by hospitalizations complicated by these categories of conditions not present on admission. “Electric shock” is a condition included in the subset of events for the category “falls”. The ten categories of hospital-acquired conditions are as follows:

• Foreign object retained after surgery;
• Air embolism;
• Blood incompatibility;
• Pressure ulcers (stages III and IV);
• Falls;
• Manifestations of poor glycemic control;
• Catheter-associated urinary tract infection;
• Vascular catheter-associated infection;
• Deep vein thrombosis/pulmonary embolism; and
• Surgical site infection.

149 Fiscal Year 2009 Final Inpatient Prospective Payment System Rule, 73 Fed. Reg. 48434, 48471 (August 19, 2008)
The NQF, JCAHO, CMS and AHRQ serious event lists are nationally recognized lists used in the development of adverse event reporting systems.\textsuperscript{150} It should be noted that these lists differ in the types of adverse events to be reported.

2.4.1.2 **Federal Databases**

2.4.1.2.1 **FDA MAUDE Database**

FDA receives reports of adverse events involving medical devices through the Manufacturer and User Facility Device Experience (MAUDE) database. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. The data is web searchable; however, there are limited keyword and search capabilities.\textsuperscript{151} The data is also publically available for download to create a searchable database. However, “MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.”

A 2004 review of the MAUDE database found that “user error” and “improper use” are the two most often cited reasons for patient injury. The review concluded that since most of the entries in these databases are manufacturer-generated, it is not surprising that their reports appear to shift responsibility and risk to the clinician and health care organization.\textsuperscript{152}

The MAUDE database files of incident reports ranging from the start of data collection in 1996 through August 2010 were downloaded and searched in Microsoft Excel. Each incident report contains an entry which specifies the location where the incident occurred. Many incident reports left this entry blank, so it is difficult, if not impossible, to determine the incident location. Therefore, only incident reports which contained valid location entries were included in the search. There were 518,384 incident entries with a specified location. Of these, only 92 incidents occurred in an operating room, and none of these 92 incidents involved electric shocks.


\textsuperscript{151} http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

2.4.1.2.2 US Department of Defense

In response to the IOM 1999 report, the DOD established the Military Health System Patient Safety Registry (MHSPSR) in 2001. The registry accepts monthly reports via an electronic system from all military treatment facilities. The database incorporates event codes based on JCAHO reportable event categories. The reports of adverse events, close calls, and root cause analyses are reviewed and analyzed by the Patient Safety Center. They, in turn, execute action plans to address patterns of patient care errors, produce quarterly patient safety newsletters, hot topic articles, quarterly reports, and patient safety training sessions. However, all information is protected from general release.

2.4.1.3 State Databases

Medical event reporting systems have been adopted by 26 states plus the District of Columbia. Of these, 25 states and the District of Columbia have adopted mandatory reporting systems, and one state (Oregon) has adopted a voluntary reporting system. Twelve states and the District of Columbia use the list of SREs compiled by NQF, and the other 14 states use their own lists of events to be reported. States using the NQF SREs are: California, Connecticut, District of Columbia, Illinois, Indiana, Minnesota, Nevada, Oregon, Maryland, New Jersey, Vermont, Washington, and Wyoming. States using state defined lists are: Colorado, Florida, Georgia, Kansas, Maine, Massachusetts, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, and Utah. Table 9 lists the states with adverse medical event reporting systems.

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Table 9. List of States using Adverse Medical Event Reporting Systems

<table>
<thead>
<tr>
<th>State</th>
<th>Start date(^{155})</th>
<th>Publicly available annual reports or event summaries</th>
<th>Electric shock category included in reports or event summaries</th>
<th>Reported shock incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO</td>
<td>1988, revised 4/1997, 2005</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>DC</td>
<td>7/2007</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>FL</td>
<td>1985, revised 1998, 2003, and 2008</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>GA</td>
<td>2003</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL</td>
<td>1/2008</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IN</td>
<td>2006</td>
<td>Yes</td>
<td>Yes</td>
<td>0 (2006-2009)</td>
</tr>
<tr>
<td>KS</td>
<td>1988</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>MA</td>
<td>1980’s, revised 1995</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>MD</td>
<td>3/2004</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>ME</td>
<td>2004</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>MN</td>
<td>enacted 4/2003, revised 2007</td>
<td>Yes</td>
<td>Yes</td>
<td>0 (2003-2009)</td>
</tr>
<tr>
<td>NJ</td>
<td>1990, updated system operational 2/2005</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>NV</td>
<td>enacted 2003, revised 1/2005</td>
<td>Yes</td>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td>NY</td>
<td>10/1985, electronic reporting added in 1998</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>OH</td>
<td>1995, new law enacted 4/2007</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>OR</td>
<td>5/2006</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>PA</td>
<td>1998, revised for 4/2004</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>RI</td>
<td>1994</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>SC</td>
<td>1976, amended 2006</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SD</td>
<td>Regulated in 1987, updated in 1995 and 2000, statute created 1/2006</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>TN</td>
<td>Prior to 1999, revised 2002</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>UT</td>
<td>10/2001, revised 4/2007</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>VT</td>
<td>Statute 7/2006, rule adopted for 1/2008</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>WA</td>
<td>Regulation 1995, statute 2006</td>
<td>Yes</td>
<td>Yes</td>
<td>0 (2004-2009)</td>
</tr>
<tr>
<td>WY</td>
<td>7/2005</td>
<td>Yes</td>
<td>Yes</td>
<td>0 (2005-2008)</td>
</tr>
</tbody>
</table>
Table 9 shows that this literature search discovered only a single electrical incident included in the state annual reports. Some state annual reports do not explicitly list electric shock data, but may include it in categories such as “other” or “miscellaneous.” The NQF list specifies an event that is classified as “environmental” and specifically called “patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.” States that use the NQF list collect data on electric shock incidents under this event classification, but do not necessarily include this data in annual reports or event summaries. For example, the District of Columbia, Illinois, Maryland, New Jersey, Oregon, and Vermont use the NQF list, but do not include electric shock data in their annual reports or event summaries.

The state reporting systems differ on the criteria used to define adverse events, the amount and type of information submitted about patients, and whether hospitals’ submissions include information about the causes of events. This affects how information about adverse events is reported and the types of events that are reported, which in turn makes it difficult to interpret the findings.

2.4.1.4 Foreign Databases

In the United Kingdom, the Medicines and HealthCare Products Regulatory Agency (MHRA)\textsuperscript{156}, formed in 2003, regulates the use of all healthcare devices and medicines within the United Kingdom. Problems with medical devices are reported to MHRA from other authorities in the United Kingdom, voluntary reporting by users, voluntary reporting by manufacturers, and obligatory post marketing surveillance by the manufacturers.\textsuperscript{157} Healthcare workers are encouraged to self-report any device failure. MHRA analyzes and disseminates the incident data and provides Medical Device Alerts and publically available annual reports. In the annual reports, however, specific category events, such as electric shock are not reported; only device group statistics are available, for example “surgical equipment.”\textsuperscript{158}

\textsuperscript{156} www.mhra.gov.uk


The United Kingdom also has formed the National Patient Safety Agency (NPSA), which receives medical device-related adverse incidents anonymously. This data is analyzed to detect trends and identify areas to improve medical practices.\textsuperscript{157}

The Australian Government Department of Health and Ageing Therapeutic Goods Administration (TGA) has also developed a medical device incident database.\textsuperscript{159} Since 2001, TGA has published general statistics on the adverse events submitted to its medical device Incident Report Investigation Scheme (IRIS). The IRIS system is used to record and track reports of adverse events or problems associated with medical devices submitted to TGA. TGA also releases safety alert articles to provide important information about medical device incidents.\textsuperscript{160}

The Australian Patient Safety Foundation (APSF) a non-profit independent organization dedicated to the advancement of patient safety has developed the Advanced Incident Management System (AIMS)\textsuperscript{161}, a software to collect, classify, and manage incident reports from near misses to sentinel events.

The APSF has contributed to the World Health Organization (WHO) patient safety project to develop an international classification for patient safety.\textsuperscript{162} In the WHO final report, a framework for classifying incident types for reporting is diagramed, and “exposure to electricity” is a subset of incident type “Patient Accidents.” It is unknown at this time if this newly developed international classification is used by any adverse reporting databases.

2.4.1.5 \textbf{Independent Database}

The National Aeronautics and Space Administration (NASA) developed the Patient Safety Reporting System (PSRS)\textsuperscript{163} jointly with the VHA.\textsuperscript{164} The PSRS is designed to be

\textsuperscript{159} http://www.tga.gov.au/problem/iris/iris-index.htm
\textsuperscript{160} http://www.apsf.net.au/products.php
\textsuperscript{162} http://www.psrs.arc.nasa.gov, accessed September 2010.
complementary to a medical facility's internal system, or a primary system responsible for capturing close calls, events, patient safety concerns, and suggestions. This is a confidential and non-punitive program, as NASA is an independent research organization without regulatory or enforcement interest. Prior to development of the PSRS, NASA administered a similar program, the Aviation Safety Reporting System (ASRS) for more than 30 years with over 850,000 reports. An agreement is necessary between a healthcare organization and NASA to have access to publications, such as a quarterly or monthly newsletter.

2.4.1.6 **Case Histories – Sentinel Alerts**

ECRI is a nonprofit health research agency that periodically reviews problems that have occurred with medical devices and lessons learned. ECRI has a web-based Problem Reporting Network\textsuperscript{165} for healthcare providers, patients, and manufacturers to voluntarily report medical device related incidents and deficiencies. ECRI analyzes the data it receives for specific hazards and publishes Medical Device Safety Reports (MDSR)\textsuperscript{166} which are medical device incident and hazard information independently investigated by ECRI. ECRI focuses on prevention or reduction of medical device risks to patient care and healthcare worker safety. In ECRI’s Health Alerts Database, there are eleven MDSRs related to electric shock and or electrocution, excluding those MDSRs associated with emergency defibrillation:

- Electrical Safety Requirements: Patient Care Areas versus Non-Patient-Care Areas, 1998
- Lesions and Shocks during Iontophoresis, 1997
- Extension Cords and Multiple Outlet Strips, 1996
- Leakage Current Limits for Electronic Equipment Used in Non-Patient-Care Areas, 1996
- Electronic Equipment Mounted on IV Poles, (spills on electrical equipment), 1993
- Risk of Electric Shock from Patient Monitoring Cables and Electrode Lead Wires, 1993
- Q&A Regarding Leakage Current Measurements, Powering Lasers, Electrical Outlets and Extension Cords, 1993

\textsuperscript{164} http://www.patientsafety.gov/faq.html#OnlyPSRS, accessed September 2010.

\textsuperscript{165} https://www.ecri.org/Pages/ReportAdeviceProblem.aspx

\textsuperscript{166} http://www.mdsr.ecri.org/default.aspx
- OR Renovations and the Use of Isolated Power and Explosion-Proof Plugs, 1992
- Connection of Electrode Lead Wires to Line Power, 1987
- Sterilization of Medical Devices (caused electrical plug degradation) 1979
- Electrical Plugs: A Compendium of Problems, 1979

JCAHO maintains a Sentinel Event Database, where they collect data from the review of sentinel events, root cause analyses, action plans, and follow-up activities related to self-reported incidents. They analyze the data for significant frequency and trends to identify specific sentinel events that form the basis of Sentinel Event Alerts published when appropriate, describing common underlying causes and suggested steps to prevent occurrences in the future. JCAHO has identified 45 issues from February 1998 through June 2010. However, only one issue is related to electricity: #37 Preventing adverse events caused by emergency electrical power system failures, September 2006.

In summary, development of the medical industry adverse event reporting database structure has been relatively recent, occurring over the past 10 years. A consistent standard of event reporting and presentation of the resulting data is not available, making it challenging to specify an electric shock incidence rate in hospital operating rooms.

### 2.4.2 Workplace Injury and Fatality Databases

Bureau of Labor Statistics (BLS) produces two widely used sources of data on occupational fatalities and injuries in the United States. The annual Survey of Occupational Injuries and Illnesses (SOII) produces national injury estimates and rates from a sample survey of business establishments. The SOII data provides case counts by industry, occupation, source of injury, nature of injury, part of body affected, and type of event. This database contains neither case narratives for individual injury incidents nor information about risk factors. The Census of Fatal Occupational Injuries (CFOI) identifies high-risk demographic and industry/occupation groups and includes a case narrative. However, since both of these databases were designed to accommodate all types of occupational fatalities, they do not contain sufficient detail to

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specifically identify electric shock incidents in a hospital operating room, and can only identify contact with electric current in the general healthcare industry and occupation.

The SOII data on non-fatal cases involving days away from work was reviewed for contact with electric current each year from 2003 to 2008. The occupational industry sector, Health Care and Social Assistance, records show that 210, 140, 260, 200, 120, and 90 cases occurred per year from 2003 to 2008, respectively. It is probable that most, if not all of these cases involved non-operating room work, however, this is impossible to determine, as case narratives are not recorded. A similar check of CFOI data revealed no reportable deaths from contact with electric current in healthcare industries or occupations.

Other general workplace injury databases, including general electrical incidents are identified; however, these databases were not reviewed:

- IEEE Electrical Safety Resource Center Website, standards.ieee.org/esrc/case_histories.html
- Occupational Hazards Website, http://www.occupationalhazards.com
- http://www.safteng.net/Incident_Alert_Archives/Electrical%20Accidents.htm
- National Electronic Injury Surveillance System (NEISS)
- National Health Interview Survey (NHIS)
- State-based Trauma Registries

2.4.3 Trends in Adverse Event Reporting

In the literature, a number of trends in adverse event reporting were identified that would have effects on the electric shock incidence rate in hospital operating rooms. The following subsections summarize these trends and their possible effects.
2.4.3.1  **Trends in Medical Device Adverse Events**

In 2008, the US Government Accountability Office (GAO) reported that the number of adverse event reports associated with medical devices increased substantially from 2000 to 2006.\(^{168}\) Upon further review of possible causes of the increase in adverse event reports several shortcomings were identified. In 2008, the FDA reported that they were unable to review all of the adverse event reports received which affected their ability to understand the risks related to the use of medical devices. In addition, the FDA efforts to review class III devices to a more stringent standard were not complete. In 2009 GAO determined that the FDA has not met a statutory requirement to inspect certain domestic medical device manufacturers every two years.\(^{168}\) The shortcomings of the FDA in premarket and postmarket activities would tend to increase the electric shock incidence rate in hospital operating rooms.

2.4.3.2  **Underreporting of General Workplace Incidents**

Underreporting of electrical injuries in the general workplace occurs due to a number of reasons:\(^{169}\)

- Classifying workplace incidents varies depending on the available event information;
- Employers vary in their effort or ability to report incidents;
- Workplace cultures exert peer pressure that favors not recording electrical incidents;
- Management is not rewarded for reporting and a track record of difficulties can affect promotion and pay opportunities; and
- Employees vary in their effort to report incidents, because drawing attention to an unsafe act is not appreciated or in an employee’s best interest, as they are expected to conduct themselves safely.

There have been a number of reporting studies regarding general workplace injuries. In 1986, OSHA confirmed that employers underreport occupational injuries and illnesses.\(^{170}\) A 1987 BLS

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study of 192 employers in Michigan and Missouri found that injuries were underreported by 10% and injuries involving lost workdays were underreported by 25%. In 1990, a report by GAO identified three major reasons for underreporting:

1) intentional under recording in response to OSHA inspection policies or employer safety competitions
2) lack of understanding of the recording and reporting system
3) lack of priority placed on recordkeeping by employers, lack of supervision of recordkeeping.

In studies published between 2004 and 2006, researchers demonstrated that the BLS SOII database captures only 33 to 67% of all occupational injuries and illnesses. It is recommended that the SOII database not rely solely on employer based data sources. The SOII surveillance system should include basic changes to address the reasons that lead to underreporting. The following conceptual filters lead to underreporting:

- The worker needs to report the injury/illness or medical care to supervisor;
- Healthcare providers need to recognize work-relatedness;
- Treatment needs to be charged to workers’ compensation;
- Healthcare providers need to participate in an occupational disease reporting system; and
- The injury/illness needs to be recorded by the employer.

Underreporting of workplace injuries artificially decreases the electric shock incidence rate in hospital operating rooms.

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2.4.3.3 Underreporting of Medical Incidents

There are several examples of underreporting workplace injuries in the medical industry. Underreporting of percutaneous injuries is common, with rates of up to 96% published. In 2010, a survey of 30 surgeons was performed to document their experiences using two medical devices, a cat’s paw retractor and Gillies’ forceps. Twenty-eight respondents had an incident with the cat’s paw retractor, with only one reporting an injury to the hospital occupational health department, for a total of 96.4% underreporting. Twenty-two respondents had an incident with the Gilles’ forceps, with none reporting an injury to the hospital occupational health department, for a total of 100% underreporting.

More serious is the trend in underreporting of adverse events involving patients in the medical industry. The tendency is to under-report adverse events, especially when a practitioner perceives an element of personal responsibility.

Additional reasons for underreporting adverse events are documented. Those responsible for investigating and reporting are not privileged to all patient safety incidents, because of the litigious nature of the health care industry. Physicians, nurses, healthcare workers and hospitals treat all medical adverse events as confidential. As a result of this increased pressure to reduce risk, disciplinary action is often the first recourse for a mistake. This leads to further medical mistakes, as root causes are not identified through failure investigations after an adverse event has occurred. Eliminating an individual from a position seems to be normal to solve problems.

NQF, who assists the healthcare industry with the development of adverse event reporting databases, comments in their 2010 report, “the fear of retaliation against facilities or individuals

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fuels efforts to resist reporting and can shift the focus away from care, hamper morale, and foster distrust, all of which undermine efforts to establish a culture of safety.”176

Underreporting of adverse medical events artificially decreases the electric shock incidence rate in hospital operating rooms.

2.4.4 Literature Citations of Electrical Incidents

The medical literature was searched for electric shock incidents occurring in hospital operating rooms. The following sections summarize electric shock events and case studies that were found during the literature review. Some of the citations were only found through examination of the reference lists of other relevant documents. Therefore, it should not be expected that the following list of incidents is complete.

2.4.4.1 1960s

At least eleven incidents of shock and ventricular fibrillation during surgical procedures in the literature were identified from 1960-1967.177 Five of these incidents were attributed to line current leakage of devices and implanted cardiac pacemakers, three of the incidents were attributed to ungrounded and/or defective medical equipment (i.e. cardiac monitor, soldering iron, and injection pump) and three were of undetermined or uncited cause.

Two incidents occurred from 1962-1963 not already referenced above, involving ventricular fibrillation by currents less than physical perception leading directly to the heart via pacemaker electrodes and catheters.178

2.4.4.2 1970s

In the early 1970s an incident occurred involving a urologist that was burned on the eyebrow, using a scope while standing on a grounded floor and performing ground-referenced

electrosurgery in a saline-soaked environment. The urologist was wearing conductive booties over bare feet at the time of the incident.\textsuperscript{179}

An incident occurred where a patient connected to an electrosurgical return plate was intensely shocked when an electrocardiogram (EKG) device was powered by an incorrectly wired outlet with the ground and neutral leads transposed.\textsuperscript{180} The physician also experienced a minor shock. The building code for the city had no requirement for standardized wiring polarity, and it was found that 20\% of the outlets in the hospitals operating rooms had reversed polarity.

2.4.4.3 \textbf{1980s}

In retrospect to failed attempts to modify the 1973 edition of NFPA 56A with respect to permitting the use of grounded electrical power instead of isolated power, an attempt was made to quantify the risk of electric shock in hospitals. Arguments indicate that electrical safety precautions usually control a larger share of the hospital’s biomedical equipment safety budget than is justified by the actual hazard levels.\textsuperscript{181}

2.4.4.4 \textbf{1990s}

An incident involving a bipolar electrosurgical device with an internal IT with damaged ceramic insulator mounts occurred, because it had been dropped. The damage caused the IT to become connected to ground.\textsuperscript{182} The medical device was powered by an isolated power supply in conjunction with a LIM. A resident was severely shocked while gripping a patient’s hand while simultaneously in contact with the operating room table frame when the electrosurgical device was activated.

\textsuperscript{179} Hyndman Bruce H., “A Thirty-Two Year Perspective on a Clinical Engineer’s Contributions to Patient Safety,” IEEE 2004.


A 1993 study of the first 2,000 incidents reported to the Australian Incident Monitoring System.\textsuperscript{183} There were six cases in which an electrical hazard was identified. There were two incidents involving electric shock, where anesthetists received shocks after touching a faulty device and the chassis of another device simultaneously. Class I equipment has ground conductors capable of conveying leakage currents from faulty devices via the operator, especially if they have wet skin, which is very common with anesthetists.\textsuperscript{184} Another reported incident involved an accidental spill of a fluid container onto a blood pressure monitor, which caused a malfunction of the blood monitor. This incident caused harm to the patient, as another replacement monitor was not available.\textsuperscript{183}

Four electrical shock incidents that took place in the operating rooms at the Naval Hospital Oakland in Oakland, California, which had grounded power supply systems installed, were reported:\textsuperscript{185}

- Case 1 involved an intermittent problem in a neurosurgical video recorder and television. When a technician unlocked the cabinet containing the power supply, he was shocked by an arc jumping from the cabinet to his key. There may have been a possible ground problem, but no specific fault was identified.
- Case 2 involved a housekeeping staff member who was shocked while using a hydro-vac with a frayed power cord to clean a wet floor.
- Case 3 involved an operating room technician who received a shock while plugging an electrosurgery device into a wall outlet with loose wire.
- Case 4 involved an operating room technician who was shocked adjusting the dimmer switch of surgical field lights, which had recently been replaced, however, no abnormality was found.


Two incidents of cardiac microshock were reported, where capacitive coupling occurred between a unipolar electrosurgical pen tip and the reference EKG electrode disconnected from the patient, but connected to the pulmonary artery catheter.\textsuperscript{186}

Two incidents of microshock were reported in 1992, where capacitive coupling occurred between a unipolar electrosurgical pen tip and numerous metallic trocars in close contact in the abdomen.\textsuperscript{187} Trocars for laparoscopic surgery are now made of plastic.

An incident involving a stopper becoming detached from an urimeter collection bag occurred, causing fluid to cascade over an extension cord power tap on the operating room floor. This caused the power to fail in the entire operating room.\textsuperscript{188}

\textbf{2.4.4.5 2000s}

Two incidents were reported where power to the operating room was lost during open heart surgery, with the cause determined to be humidity in the outlet powering the fluid and blood heater.\textsuperscript{189} It is recommended that sealed plugs be used and anesthesia equipment not be used as an electrical supply for other apparatus.

An incident occurred in Australia where an ungrounded operating table and placement of a (damaged) power cord under the operating room table support leg led to leakage current provided by another device (firstly an image intensifier and secondly an electrosurgical device) through the “live” table to earth, causing arc flashing and tripping of the GFCI into which the severed cord was plugged.\textsuperscript{190}

\begin{flushleft}
\textsuperscript{190} Courtney NM, McCoy EP, Scolaro RJ, Watt PA, “A Serious and Repeatable Electrical Hazard – Compressed Electrical Cord and an Operating Table,” Anaesthesia & Intensive Care, V34:3:392-396. 2006.
\end{flushleft}
An electric shock incident occurred during a cystoscopy procedure, where an operating room nurse was shocked while plugging in an argon beam coagulation unit into an extension cord with a four-receptacle metal junction box with rubber and plastic casing in a wet environment (i.e. floor cleaned by “throwing buckets of water on the floor” before the operation and additionally there was normal cystoscopy irrigation fluids on the floor).\textsuperscript{191}

In 2008, a search was conducted on more than 800,000 reports submitted since 2004 to the Pennsylvania Patient Safety Advisory.\textsuperscript{192} The keywords “shock” and/or the phrase “line isolation monitor” in reports with operating room as the location resulted in the five reports summarized here:

- A staff member reported receiving a shock while touching the patient and anesthesia machine during the same time that the surgeon touched the patient with a Bovie pencil.

- While performing cystoscopy and a transurethral resection of the prostate using an Erbe Bovie CE 7090 on a patient under spinal anesthesia, the patient jumped and felt something go up the back. The surgeon also felt a shock in the finger twice. At the same time, the Bovie stopped working. The Bovie cord and electrode were both changed, and the Bovie started to work.

- While using a Trivex light source machine, the light appeared to not be as bright as normal. A staff member was shocked while trying to reposition the light cord in the machine. The machine sparked a few times at the light source and began to smell hot. The machine was turned off, unplugged, and taken out of service.

- An employee conveying a metal cart pushed the auto-open button on the outside of the operating room doors and received a large shock that could be felt from arm to feet. Another employee holding onto the other end of the metal cart also received a shock.

- A KCI Air Bed (SN.BKOK 01612) was wired incorrectly and set off the LIM alarm. The air bed was rewired, correcting the problem.


3 Gap Analysis

In the previous section, a literature survey was summarized to provide a comprehensive view of the hospital operating room electrical environment in order to facilitate hazard analysis by an individual hospital, to evaluate whether a particular operating room should have a “wet procedure location” or “dry location” electrical classification. An analysis of the available literature with a particular focus on utilization of the data to support a hazard assessment methodology revealed gaps in the data that are necessary to support a detailed quantitative hazard assessment methodology for evaluating operating rooms as a wet or dry location. The following sections identify relevant gaps in the data and provide suggested means for obtaining the data in the future.

3.1 Operating Rooms as Wet Procedure Locations or Dry Locations

In the medical literature, surgeons, anesthesiologists and nursing staff identify that common knowledge about blood and fluid loss and irrigation practices for specific surgeries is gained by experienced practitioners. However, while evaluation of blood and fluid loss during surgery is identified as a critical step to monitoring a patient’s health, medical literature has cited the difficulty of operating room staff to quantify these losses accurately during operating room procedures.\(^\text{193,194}\)

There is a plethora of clinical study information on many types of surgical operations available in the literature, too many to review for the scope of this study. However, the data can be hospital and even surgeon specific, which contributes to higher data uncertainty.

While health care professionals have provided opinions of the nature of the operating rooms and examples of types of events that lead to wet environments, clinical studies of the frequency at


which these events (such as spills) occur have either not been performed or are not available in the general medical literature.

Kaiser Permanente performed a survey of staff working in their group of hospitals, but the scope of the study was not clear from the condensed presentation of the results.\textsuperscript{195} A well vetted clinical study and/or questionnaire-based survey with a carefully focused scope to identify the frequency and quantity of liquid releases for a statically based selection of hospitals would be valuable.

\section*{3.2 Adverse Event and Incident Reporting}

\subsection*{3.2.1 Database Information}

Analysis of the available databases and presentation of the resulting statistics often revealed that there was not enough specific information to determine cause, or at least verify that the event occurred in an operating room during a surgical procedure.

For an electrical incident case history to be meaningful, it should include the following information:\textsuperscript{196}

\begin{itemize}
  \item Summary of the incident describing the scenario including who, what and where;
  \item Resulting or potential injury, including the extent of the injury;
  \item Background information describing clarifying elements, such as the environment, procedure compliance, contributing factors, and other circumstances; and
  \item Lessons learned, summarizing conclusions and corrective actions taken.
\end{itemize}

NQF reports that significant incongruities remain among the state adverse event reporting systems, relating to differing implementation approaches and differing perspectives toward


reporting patient safety events. This has led to inconsistent results for improving the adverse outcome rate of events.

The fact that AHRQ is implementing and will maintain a national based NPSD that incorporate common formats for standardized data collection is promising. However, it is unclear from the description of the AHRQ common formats if electric shock adverse events will be tracked. It is also undetermined as to how AHRQ plans to analyze the statistics and to what extent they will disclose their findings. For example, some states require reporting of adverse events classified using the NQF list of 28 SREs, however, the types of events and how they are reported differ.

The use of quality control criteria to assess data quality of incident reports, placing emphasis on missing data for key variables, timeliness of reporting, and unresolved duplication is encouraged. Using the North American Association of Central Cancer Registries quality control criteria to assess the data quality is recommended. The adverse event database reporting systems should implement a means of assessing the quality of the adverse event reports received from the hospitals and convey that information in their reports.

Until a more consistent standard of adverse event reporting and presentation of the resulting data is available, evaluating or even estimating an electric shock incidence rate in hospital operating rooms is challenging. State adverse event databases should provide incident statistics in all categories and all sub-categories of adverse event classifications in the analysis reports. For the purposes of evaluating an operating room as a wet or dry environment, the NQF list of 28 SREs, which specifically includes electric shock as a reportable event, is the most useful event list. A database using an adverse event list based on the CMS hospital acquired conditions should

breakout the categories into the various tracked conditions. Details should be provided on the types of events included in “other” categories.

In addition, having the ability to search an adverse event database for specific incident report summaries (e.g. the MAUDE database) based on the adverse event classification lists which have been vetted to remove personal data and other identifying is ideal. Identifying the root cause of electric shock, the electrical equipment and safety systems involved, and the environmental factors are important elements in a quantitative risk assessment.

### 3.3 Electrical System

#### 3.3.1 Prevalence of Grounded vs. Isolated Electrical Systems across the US

One aspect of evaluating an electric shock incidence rate is to consider the cause of the adverse event, so as to provide a one to one comparison. When reviewing the adverse event database, background information about the electrical system and other safety systems in place at the time of the event is important to evaluating the event cause. The current ratio of isolated power in comparison to grounded electrical systems utilized by hospitals in their operating rooms is currently unknown. This ratio has an effect on interpretation of the incident data.

There is limited data on the number of grounded electrical systems in comparison to the number of IPSs currently in use. A 2000 survey of the Kaiser Permanente group of hospitals indicated that half of their operating rooms used IPSs and the other half used grounded systems.\(^{201}\) Due to continuing hospital policy where all of their operating rooms are defined as dry locations, in 2008, out of 48 medical centers with 396 operating rooms, 22% had IPSs currently installed.\(^{202}\)

Medical associations who monitor operating room usage or have access to hospital design records do not track type of electrical systems installed in US hospitals:


• AHA does not track power systems installed in their annual survey of hospitals.\textsuperscript{203}
• ASHE does not track power systems installed.\textsuperscript{204}
• JCAHO does not track power systems installed.\textsuperscript{205}

Another source of useful data regarding IPSs is how often the LIMs alarm or when IPSs trip. It was discussed in the literature that a disadvantage of the IPS and LIM systems are “nuisance alarms.” These records should be a part of hospital clinical and biomedical engineering department maintenance and service request records. Starting in the 1980s, clinical engineering departments analyzed data from service requests, including equipment, accessories and users.\textsuperscript{206} Quarterly reports of these statistics chosen as measures of performance were submitted to the hospital’s safety and risk management committee. A field survey of hospital records to acquire statistical data on maintenance is recommended.

### 3.3.2 Electrical System Costs

Another important aspect in the debate regarding evaluation of hospital operating rooms as wet or dry locations is the cost difference of IPSs in comparison to grounded systems. In order to perform a cost-benefit analysis, the following costs and benefits are applicable:\textsuperscript{207}

• Design fees;
• Construction/installation;
• Commissioning and staff training;
• Routine maintenance;
• Reduced damages due to cost to address health effects of injuries;

\textsuperscript{204} Personal communication with John Collins at ASHE.
\textsuperscript{205} Personal communication with Jerry Gevais an electrical engineer in the standards department at JCAHO.
\textsuperscript{206} Hyndman Bruce H., “A Thirty-Two Year Perspective on a Clinical Engineer’s Contributions to Patient Safety,” IEEE 2004.
\textsuperscript{207} Meacham Brian J, Charters David, Johnson Peter, Salisbury Matthew, “Building Fire Risk Analysis,” Section 5 Chapter 12 in DiNennon et al, eds. SFPE Handbook of Fire Protection Engineering, 4\textsuperscript{th} edition. NFPA, Quincy, Massachusetts, 2008.
• Reduced medical liability suits; and
• Reduced insurance premiums.

Upon review, the literature did not provide a balanced outlook on the construction and maintenance costs given the significant variations in cost of living, materials, and labor wages across the US. The following two sections summarize the electrical system cost information obtained; further study is warranted.

3.3.2.1 Construction/Installation Costs

• In 2007, an IPS panel may cost twice as much in comparison to a grounded panel with GFCI breakers, and the estimated extra labor and material to install an IPS was approximately 15% more.  

• In 2000, the difference in cost for installing an IPS in comparison with a grounded system was approximately $30,000 per operating room.  

In 2008, the cost to install an IPS per operating room was $71,500 for a retrofit and $42,900 for new construction. These figures describe the total cost of the system, not the incremental cost of an IPS.

3.3.2.2 Maintenance Costs

It is reported in the literature that maintenance of an IPS includes regular testing to confirm that the actual level of isolation meets appropriate standards and that LIMs are functioning correctly. It is important for clinical personnel (such as operating room staff) and technical personnel (such as clinical engineering staff) to understand the function of IPSs. In particular, it is important to establish policies and procedures for staff response to LIM alarms.


Over the 30 year life of an IPS, it is estimated that there is an additional $197,000 in operating costs (using 2008 dollars).\textsuperscript{212}

\textsuperscript{212} Kaiser Permanente, comment submitted to NFPA 99-2009 ROC, 2008.
The study presented in this report is intended for use by the NFPA Fire Protection Research Foundation to assist with their decision making related to NFPA 99, *Standard for Health Care Facilities*. Proper application of this report requires recognition and understanding of the limitations of both the scope and methodology of the study.

The scope of the study was to gather information to assist the HEA-ELS in addressing the issue of whether hospital operating rooms should be classified as wet procedure locations. This study does not specifically address every possible electrical hazard. The end-user of this study is expected to be knowledgeable of the operating room in question and exercise good engineering judgment.

The risk assessment methodology forming the basis of the results presented in this report is based on mathematical and statistical modeling of physical systems and processes, as well as data from third parties. Given the nature of these evaluations, significant uncertainties are associated with the various hazard and loss computations, some of which are accounted for in the methodology, while other uncertainties (i.e., as-built construction details, modifications, current conditions, material characteristics, etc.) cannot be readily incorporated into the analyses. These uncertainties are inherent in the methodology and subsequently in the generated hazard and loss results. These results are not facts or predictions of the risk that may occur as a result of future events or any specific event; as such, the actual risk in a specific operating room may be materially different from those presented in this study. Furthermore, the assumptions adopted in determining these loss estimates do not constitute the exclusive set of reasonable assumptions, and use of a different set of assumptions or methodology could produce materially different results.

The basis of a hazard analysis is to identify incident scenarios in order to evaluate risk by defining the probability of failure, the probability of various consequences, and the potential impact of those consequences. Risk is a function of the probability or frequency and
consequence of a particular accident scenario. In a risk assessment, there are several steps in order to evaluate, prioritize, and manage hazards and their associated risk:

1) Define the scope of the assessment;

2) System Description, compiling information needed for the risk analysis;

3) Hazard Identification, using aids such as experience, operations knowledge, what-if analysis, fault tree analysis, failure modes and effects analysis, and event tree analysis;

4) Incident Enumeration, without regard to importance or initiating event;

5) Selection of Incidents, Outcomes, Cases, where one or more significant incidents are chosen to represent all identified incidents;

6) Estimate Consequences, if consequences of an incident are acceptable at any frequency the analysis of the incident is complete, if not acceptable then continue analysis;

7) Modify System to Reduce Consequences, if no feasible and economically viable modifications available, continue analysis;

8) Estimate Frequencies, if frequency of an incident is acceptably low the analysis is complete, otherwise continue analysis;

9) Modify System to Reduce Frequency, if no feasible and economically viable modifications available, continue analysis;

10) Combine Frequency and Consequences to Estimate Risk, if risk estimate is below the target or the strategy offers acceptable risk reduction, the analysis is complete;

11) Modify System to Reduce Risk, if no modifications are found than fundamental changes to the system are necessary.

Risk analysis can range from simple screening studies to a detailed risk analysis involving large numbers of incidents while using highly sophisticated frequency and consequence models. In the cases where quantification of the frequency of an incident is less well understood and historical data is not available, semi-quantitative risk analysis utilizing tools, such as risk matrices, fault tree analysis, and event tree analysis methods to evaluate consequences are used.
A risk assessment can be performed in order to assist the evaluation of particular hospital operating room and associated expected procedures for electrical classification of the environment as a wet or dry procedure location. One of the proposals currently being considered by the NFPA 99 HEA-ELS committee during the 2011 ROP/ROC cycle, is the recommendation to add a new code section as follows:213

4.3.2.8.3* Operating rooms shall be considered to be a wet procedure location unless a risk assessment conducted by the health care governing body determines otherwise.

A.4.3.2.8.3 In conducting a risk assessment, the health care governing body should consult with all relevant parties, including, but not limited to, clinicians, biomedical engineering staff, and facility safety engineering staff.

In order to define the scope of the risk assessment, it is important to consider the current definitions. The NEC provides the following definitions:

Dry Location: A location not normally subject to dampness or wetness. A location classified as dry may be temporarily subject to dampness or wetness, as in the case of a building under construction.

Wet Location: Installations underground or in concrete slabs or masonry in direct contact with the earth; in locations subject to saturation with water or other liquids, such as vehicle washing areas; and in unprotected locations exposed to weather.

Wet Procedure Location: Those spaces within patient care areas where a procedure is performed and that are normally subject to wet conditions while patients are present. These include standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff. Routine housekeeping procedures and incidental spillage of liquids do not define a wet location.214

From these definitions, quantities of liquids that pool upon release are indicated as important.

Additionally, Appendix B of NFPA 99 provides explanatory material on the nature of electrical hazards. The fundamental electrical hazard in a wet procedure location is an electric shock. NFPA 99 Figure B.1.2.2.1(b)215 indicates the primary interrelated systems involved with the

fundamental hazard. There are three primary components in this hazard system: people, equipment and the environment. The people involved are the patient and operating room staff, such as surgeons, anesthesiologists, nursing staff, and other assistants. The equipment involved includes the medical devices, electrical power supply, and electrical safeguards. The environment includes conductive surfaces, such as the floor, plumbing, and any area made more conductive by the additional presence of conductive liquids. The presence of liquids in the environment can be intimately associated with the patient or with the room. The chance of a person sustaining an electric shock is dependent on a combination of all three components.

The hazard system to best evaluate the hospital operating room as a wet or dry location can be represented by the fault tree schematic in Figure 1. In the figure, in order to focus on the possibility of a wet environment contributing to an electric shock hazard, the people are necessary participants and the equipment is a contributing hazard. The equipment and associated safeguards have multiple potential methods of malfunction that depend on the type of equipment and the failure modes, such as aging and wear and tear. These failure modes are outside the scope of the hazard assessment to evaluate the operating room environment. The environmental component of the fault tree is the focus of the hazard assessment.
The following describes a risk assessment method to assist a healthcare governing body to determine if their operating rooms (on an individual basis depending on expected usage) should be considered a wet procedure location.

### 4.1 Risk Ranking Based on Spill Size

The hazard scenario model of NFPA 99 Annex B (Figure B.1.2.2.1 (b)) identifies the key elements necessary to lead to an electric shock hazard in the operating room. Figure 2 summarizes some example causal factors for electric shock in a fault tree format. The risk ranking method proposed here assumes that the hazard of interest (electric shock) is fixed and constant at a state designated as “severe.” The likelihood of electric shock is assumed to be a function of liquid pool size only. This assumption focuses attention of the wet or dry nature of the floor or work area surfaces. Other factors, such as the timing of the liquid release (i.e. frequency of spills), the probability that an electrical medical device, including any safeguards, is in a fault condition, and the probability of contact with electrical equipment are either not available or not well defined. Therefore, these probabilities are assumed to be automatically present and equal to one, so as to create an opportunity for an electric shock. Furthermore, it is
assumed that a liquid release will occur. Thus, the only variable considered is the probability of the human subject contacting the wet surface. Figure 3 summarizes this concept in the form of an event tree. This is a conservative approach (i.e., this approach will tend to overestimate the probability of exposure especially, because it is unlikely that a liquid release resulting in a liquid pool will occur with every use of the operating room).

The probability of exposure is based on the volume of the liquid released. The probability of personnel exposure to a subsequent liquid pool is calculated as the ratio of two areas: the pool area divided by the unoccupied area of the operating room floor. The recommended algorithm is given below:

- Form a knowledgeable team of hospital staff (i.e., medical clinicians, operating room manager, biomedical engineering staff, and facility safety engineering staff).
- Choose the specific operating room under consideration. The objective is to determine if this room should be designated as a wet or dry procedure location under NFPA 99.
- Identify the functional purpose of the chosen operating room and list the potential liquids allowed into the room, as well as the potential liquids associated with the patient and surgical procedure type(s) (e.g., in order of increasing volume, an anesthetic ampoule, a bag of saline solution, or a container of irrigation fluid).
- Select the largest single source of liquid in the operating room. Calculate the pool size of this volume of liquid (procedure described below):
- Calculate the total area (wall-to-wall) of the operating room. Subtract the footprint areas of fixed or portable equipment in the room, not including the operating room table surface area or other work area. The net open area is the unoccupied area of the operating room.

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216 Typical surgical procedures to be performed in the hospital operating room can be reviewed for estimated blood loss volumes, estimated body fluids (e.g., IV fluids, urine output), and the use of liquid medications, sterilizers, and irrigation fluids to support surgical procedures. Medical literature referenced in Section 2.1 can be used as guidance and/or individual medical personnel experience. Liquid containment vessels for suction and blood recycling should also be included.
• Calculate the ratio of the liquid pool area to the unoccupied area of the operating room. This ratio is defined as the probability of personnel exposure to the liquid release or simply the probability of exposure.

Note that this algorithm considers only a single-event exposure. This does not contemplate the multiple exposures an individual may be exposed on an annual basis.
Figure 2. Fault tree for an electric shock hazard in a hospital operating room including example liquids and possible modes of liquid release for consideration in the risk ranking analysis based on spill size.
Figure 3. Event tree for an electric shock hazard in a hospital operating room for the risk ranking analysis based on spill size.
The fourth edition of the Society of Fire Protection Engineering (SFPE) Handbook includes data from applicable studies relating pool size to a fixed-quantity, unconfined liquid spill.\textsuperscript{217} The intent of the data is to relate a fuel spill volume to the potential pool fire diameter. However, in addition to various fuels, data for spills of water on concrete and tile floor are provided in Table 2-15.1 and Figure 2-15.4 of the SFPE Handbook 4\textsuperscript{th} Edition; see Figure 4 for a reproduction of this data. This data is a first order approximation of potential liquids found in a hospital operating room, which are often water based. Higher order approximations would involve correlations developed that base pool thickness on physical liquid properties, such as surface tension and viscosity.\textsuperscript{218} A higher order correlation was not available at the time this report was created.

A polynomial trend line was fit to the SFPE Handbook data from water spilled on a concrete surface from one meter height to determine a first order approximation and correlate the empirical data to other spilled water volumes. The equation for the polynomial trend line is as follows:

\[
\text{Thickness} = -0.0028V^2 + 0.14V + 1.0167
\]

Equation 1

where \textit{Thickness} is the pool thickness [mm] and \textit{V} is the volume of liquid released [L]. This data set of a fixed volume water spilled from one meter height provides a conservative estimate of pool diameter as a function of spill volume, as a thinner pool will result in a larger pool diameter for a given spill volume. The pool diameter as a function of liquid release volume is shown in Figure 5. The pool diameter assumes a circular pool determined from the pool area, both of which are calculated as follows:

\[
\text{Pool Area} = \frac{V}{\text{Thickness}}
\]

Equation 2


\textsuperscript{218} Further experimental data has been performed by Dan Gottuk with publication of a new data set and higher order correlation anticipated in 2010: Mealy CL, Benfer M, Gottuk DT, “Fire Dynamics and Forensic Analysis of Liquid Fuel Spill Fires,” Grant No. 2008-DN-BX-K168, Office of Justice Programs, National Institute of Justice, Department of Justice, 2010 (in preparation).
$D = \frac{4}{\sqrt{\pi}} \text{Pool Area}$

Equation 3

where $\text{Pool Area}$ is in $[\text{m}^2]$ and $D$ is the pool diameter [m]. This data set provides a pragmatic measure to develop liquid release severity categories.

Figure 4. Data presented in the SFPE Handbook 4th Ed., pool thickness as a function of an unconfined, fixed quantity of water spilled on tile or concrete floor from a discrete height: (purple circles) water on concrete from 0.5 m height (blue diamonds) water on concrete from 1 m height, (green triangles) water on tile from 0.15m, (red squares) water on tile from 0.9 m
Figure 5. Pool diameter as a function of liquid volume assuming a circular pool as estimated from the polynomial fit trend line of the SFPE empirical spill data for a spill of water on concrete from 1 m presented in Figure 4; The blue squares represent sample volumes of liquid selected in the sample calculation (Table 10) of probability of exposure.

Considering an operating room with an unoccupied area of 50 m$^2$, Table 10 illustrates a sample calculation on how to evaluate the risk of an unconfined release of a fixed volume of liquid using the algorithm described above for a single-event exposure.
An overall risk assessment is needed to be able to classify the operating room environment as wet or dry. Risk is defined as the chance per year that an unprotected person (i.e., the operating room staff or patient) located at a specific position (i.e., in an operating room in contact with a faulty electrical device) relative to the risk source (i.e., exposure to a wet environment). The maximum risk that an individual may be subjected to can be expressed in terms of the greatest probability that any individual in the operating room may be exposed to a life or health threatening event (i.e., contact with a conductive liquid leading to electric shock). Using the above described algorithm, the worst case single-event probability of exposure to a liquid pool in an operating room can be determined. From this calculation demonstrated in Table 10, the annual probability of exposure for the operating room can be calculated. The annual probability of exposure factors in the effect of occupancy (i.e., the utilization of the operating room).

The recommended algorithm to determine annual risk is to multiply the probability of exposure for a single event (i.e., one surgical procedure in a specific operating room) by the projected number of procedures that occur in a year in that specific operating room. Table 11 illustrates a sample calculation comparing a 50 m² operating room with high utilization to an operating room of the same size with low utilization for the liquid volumes in the sample calculation presented in Table 10. An operating room with high utilization was estimated to be four procedures per day, 250 days per year, and an operating room with low utilization was estimated to be one procedure per day, 25 days per year, for example purposes only.

Table 10. Sample Calculation for a Single-Event Exposure in a 50 m² room

<table>
<thead>
<tr>
<th>Severity Category of Potential Liquid Release</th>
<th>Volume of Liquid</th>
<th>Estimated Pool Diameter</th>
<th>Probability of Exposure (Single Event)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-existent</td>
<td>&lt; 75 mL</td>
<td>&lt; 0.30 m (1.0 ft)</td>
<td>&lt; 1.5 E-3</td>
</tr>
<tr>
<td>Small</td>
<td>75 mL to 750 mL</td>
<td>0.30 m (1.0 ft) to 0.92 m (3.0 ft)</td>
<td>1.5 E-3 to 1.3 E-2</td>
</tr>
<tr>
<td>Medium</td>
<td>750 mL to 3000 mL</td>
<td>0.92 m (3.0 ft) to 1.64 m (5.4 ft)</td>
<td>1.3 E-2 to 4.3 E-2</td>
</tr>
<tr>
<td>Large</td>
<td>&gt; 3000 mL</td>
<td>&gt; 1.64 m (5.4 ft)</td>
<td>&gt; 4.3 E-2</td>
</tr>
</tbody>
</table>
Table 11. Sample Calculation to Determine Annual Risk based on the Probability of Exposure to a Liquid Pool

<table>
<thead>
<tr>
<th>Severity Category of Potential Liquid Release</th>
<th>Volume of Liquid</th>
<th>Probability of Exposure (Annual Utilization)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>High Utilization OR</td>
</tr>
<tr>
<td>Non-existent</td>
<td>&lt; 75 mL</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>Small</td>
<td>75 mL to 750 mL</td>
<td>1.5 to 13.4</td>
</tr>
<tr>
<td>Medium</td>
<td>750 mL to 3000 mL</td>
<td>13.4 to 42.5</td>
</tr>
<tr>
<td>Large</td>
<td>&gt; 3000 mL</td>
<td>&gt; 42.5</td>
</tr>
</tbody>
</table>

An annual probability of exposure of greater than or equal to one means that exposure to a liquid pool is certain. To interpret the results of the Table 11 sample calculation for the operating room with high utilization, the annual risk of exposure to a liquid pool is more likely than not if there are any volumes of liquids present that are on the order of 75 mL.\(^{219}\) With this sample scenario, there are many opportunities for exposure, and therefore the operating room should be classified as a wet procedure location. For the operating room with low utilization, volumes of liquid up to 750 mL can be regularly present and the operating room classified as a dry location.

The High/Low Utilization OR classification used in Table 11 is one possible way to quantify the utilization of an operating room, but other methods can be used. For example, if there is sufficient data available, the number of procedures per day can be modified to reflect the number of long time duration procedures that occur in the operating room in question.

\(^{219}\) For the high utilization sample scenario, the volume of liquid should be less than 50 mL in order to not lead to certain exposure.
**Summary**

The motivation for this study is to provide a comprehensive view of the hospital operating room electrical environment in order to facilitate a risk analysis by an individual hospital, to establish whether a particular operating room should have a “wet procedure location” or “dry location” electrical classification.

A literature review was performed to address the electrical classification of hospital operating rooms, which focused on hazards resulting in electric shock to occupants. Environmental conditions in the operating room were found to vary based on operational factors, such as the type of surgery or procedure being performed, and use of irrigation fluid. The data presented does not give a complete quantification of the amounts of fluids present in the operating room or the probability of a liquid release, but represents a survey of the available literature.

A review of adverse event reporting in the medical industry reveals that reporting systems have been under development in the US for only the past 10 years, with only slightly more than half of the states with reporting systems in place to track adverse events. It has also been identified that practitioners in the healthcare industry resist reporting adverse events due to a fear of disciplinary action, which shifts the focus away from utilizing the databases to establish a culture of safety by calling attention to root causes and improving training in certain areas to improve patient safety.

A gap analysis of the literature addresses data to evaluate an operating room as a wet or dry location, adverse event and incident reporting, and information about the current electrical systems used in the medical industry. Consistent standards of adverse event classification, analysis, and reporting are not implemented, however, the AHRQ is in the process of implementing and maintaining a national network of databases, with the first results anticipated in 2011.

A risk assessment method is proposed for hospitals to use in order to evaluate the proper classification of an operating room. The recommended model is a risk ranking method based on
the volume of a potential spill or liquid release and the subsequent liquid pool size as determined from empirical liquid spill data onto hard surfaces published in the SFPE Handbook, 4th edition. This method determines the annual probability of exposure to a liquid pool in an operating room. A sample calculation is demonstrated for a range of liquid volumes in an average size hospital operating room with both high and low utilization.