## **Operating Rooms as Wet/Dry Locations Risk Assessment Project**

**Final Report** 

Prepared by: Brenton Cox, Ph.D. *Exponent, Inc.* 



## FIRE RESEARCH

The Fire Protection Research Foundation One Batterymarch Park Quincy, MA, USA 02169-7471 Email: <u>foundation@nfpa.org</u> <u>http://www.nfpa.org/foundation</u>

© Copyright Fire Protection Research Foundation August 2012

#### FOREWORD

The recent movement toward using risk based approaches in assessing safety risks around the world has caused the NFPA Technical Committee on Health Care Facilities (responsible for NFPA 99) to incorporate requirements related to risk analysis in NFPA 99, *Health Care Facilities Code*. As the result of the Foundation project *Evaluation of Health Care Operating Rooms as Wet/Dry Locations*, NFPA 99 Section 6.3.2.2.8.4 states, "Operating rooms shall be considered to be a wet procedure location, unless a risk assessment conducted by the health care governing body determines otherwise." This means that operating rooms shall be provided with special protection against electric shock unless a risk assessment proves otherwise.

The previously mentioned Foundation study includes a methodology framework for this type of quantitative risk assessment. However, the current version of NFPA 99 does not incorporate any guidance on performing a risk analysis. This supplemental report provides user guidance including worked examples.

The content, opinions and conclusions contained in this report are solely those of the author.



## Operating Rooms as Wet/Dry Locations Risk Assessment Project

## **Technical Panel**

Ken Dungan, Performance Design Technologies Jan Ehrenwerth, Yale University Douglas Erickson, American Society for Healthcare Joseph Murnane, Underwriters Laboratories Inc. John Petre, Cleveland Clinic Sam Sampson, Minnesota Department of Labor & Industry Walter Vernon, Mazzetti & Associates Jonathan Hart, NFPA staff liaison

## **Principal Sponsor**

National Fire Protection Association

## **Project Contractor**

Exponent, Inc.

# Exponent®

Thermal Sciences

Operating Rooms as Wet/Dry Locations Risk Assessment Project

Project No. 1202311.000





## Operating Rooms as Wet/Dry Locations Risk Assessment Project

Prepared for

Kathleen Almand, P.E. Executive Director Fire Protection Research Foundation 1 Batterymarch Park Quincy, MA 02169

Prepared by

Brenton Cox, Ph.D. Exponent, Inc. 4580 Weaver Parkway Suite 100 Warrenville, IL 60555

August 6, 2012

© Exponent, Inc.

## Contents

List o	of Figur	es	3
List o	of Table	S	4
1	Risk A be Not	assessment to Determine When an Operating Room Can Be Considered to a Wet Procedure Location	5
1.1	Intro	oduction	5
	1.1.1	Wet Procedure Location	5
	1.1.2	Abnormal Release of Conductive Liquid	6
	1.1.3	Probability of a Release	7
	1.1.4	Probability of Intimate Contact with Patient or Staff	7
1.2	2 Gen	eral Quantitative Risk Assessment Methodology	8
	1.2.1	Step 1: Define the scope of the assessment	8
	1.2.2	Step 2: System Description	9
	1.2.3	Step 3: Hazard Identification	9
	1.2.4	Step 4: Incident Enumeration	9
	1.2.5	Step 5: Selection of Incidents, Outcomes, Cases	9
	1.2.6	Step 6: Estimation of Consequences	9
	1.2.7	Step 7: Estimation of Incident Frequencies	10
	1.2.8	Step 8: Estimation of Risk	10
1.3	3 QRA	A for Electric Shock Hazard in Operating Rooms	10
	1.3.1	Step 1: Define the scope of the assessment	11
	1.3.2	Step 2: System Description	11
	1.3.3	Step 3: Hazard Identification	11
	1.3.4	Step 4: Fault Tree Construction	11
	1.3.5	Step 5: Qualitative Examination of Structure	12
	1.3.6	Step 6: Quantitative Evaluation of Fault Tree	13
2	Examp	les of Quantitative Risk Analysis	14
2.1	Exa	mple 1	14
	2.1.1	Step 1: Define the scope of the assessment	14
	2.1.2	Step 2: System Description	14
	2.1.3	Step 3: Hazard Identification	14
	2.1.4	Step 4: Fault Tree Construction	14

Page

4	Limita	23	
3	Refere	ences	22
	2.2.6	Step 6: Quantitative Evaluation of Fault Tree	20
	2.2.5	Step 5: Qualitative Examination of Structure	19
	2.2.4	Step 4: Fault Tree Construction	19
	2.2.3	Step 3: Hazard Identification	18
	2.2.2	Step 2: System Description	18
	2.2.1	Step 1: Define the scope of the assessment	18
	2.2 Exa	imple 2	18
	2.1.6	Step 6: Quantitative Evaluation of Fault Tree	15
	2.1.5	Step 5: Qualitative Examination of Structure	14

		Page
Figure 1.	Fault tree for electrical shock hazard in a generic operating room, without specific sources of liquids populated.	12
Figure 2.	Specific fault tree for scenario in Example 1.	15
Figure 3.	Specific fault tree for scenario in Example 2.	19

## List of Tables

Table 1.	Sample frequency table. A health care governing body might compile such a table from housekeeping logs or other records.	16
Table 2.	Probability of single-event exposure from release volumes of 75 mL, 750 mL and 3000 mL in areas of 10 $m^2$ and 50 $m^2$ .	16
Table 3.	Frequency of exposure per year categorized by liquid type and volume.	17
Table 4.	Annual frequency of exposure categorized by procedure.	18
Table 5.	Probability of single-event exposure from release volumes of 75 mL, 250 mL, 500 mL, 750 mL, and 1000 mL in an area of 50 $m^2$ .	20
Table 6.	Probability of exposure categorized by procedures per year and maximum volume of liquid stored.	21

Page

## 1 Risk Assessment to Determine When an Operating Room Can Be Considered to be Not a Wet Procedure Location

## **1.1 Introduction**

At the request of the Fire Protection Research Foundation, Exponent Failure Analysis Associates (Exponent) prepared this report to serve as guidance on performing quantitative risk analysis (QRA) as set forth in Section 6.3.2.2.8.4 of NFPA 99 Health Care Facilities Code (2012). This report serves as an addendum to a previous study, entitled "Evaluation of Health Care Operating Rooms as Wet/Dry Locations," and includes worked examples. <sup>1</sup> Additionally, it includes a recommended set of references for use in QRA.

#### 1.1.1 Wet Procedure Location

The default classification of an operating room is that it is a wet procedure location. Many procedures performed in operating rooms present the potential for the uncontrolled release of conductive liquids. This potential for uncontrolled drenching or pooling of liquid in the proximity to the variety of electrical equipment employed in a modern operating room exposes personnel and patients to a risk of electric shock. NFPA 99, 6.3.2.2.8.1, dictates that "wet procedure locations shall be provided with special protection against electric shock." NFPA 99, 6.3.2.2.8.7, requires that operating rooms classified as wet procedure locations "be protected by either isolated power or ground-fault circuit interrupters." NFPA 99, 3.3.184 defines a wet procedure location as follows:

"The area in a patient care room where a procedure is performed that is normally subject to wet conditions while patients are present, including standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff."  $^2$ 

<sup>&</sup>lt;sup>1</sup> Chernovsky, MK, et al. "Evaluation of Health Care Operating Rooms as Wet/Dry Locations," Fire Protection Research Foundation, October 2010.

<sup>&</sup>lt;sup>2</sup> NFPA 99, Health Care Facilities Code, 3.3.184.

However, some health care facilities may choose to limit the procedures and environmental factors in a specific operating room to reduce the likelihood of liquid being released. If it is determined that the procedures performed in an operating room might not warrant classification as a wet procedure location, the health care governing body (HCGB) may conduct a risk assessment to evaluate the risk of a release of conductive liquid that would result in electric shock. NFPA 99 Annex A, A.6.3.2.2.8.4, specifies that:

"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." <sup>3</sup>

If the risk analysis indicates that the risk level of electric shock is unacceptably high, then the operating room must be considered a wet procedure location. However, if the risk assessment concludes otherwise, the operating room might not require classification as a wet procedure location.<sup>4</sup> Note that the reliability of the analysis is dependent upon the accuracy of the probability estimates used in the risk assessment and the efficacy with which they are applied. If the HCGB is unable to perform a proper risk assessment, the operating room should be considered a wet procedure location.

#### 1.1.2 Abnormal Release of Conductive Liquid

If a procedure that might be performed in the operating room has an inherent possibility for the release of a conductive liquid, then this procedure must be considered when performing a risk analysis. Examples of procedures in which liquid release may not be expected are:

- 1. Local anesthesia.
- 2. Various minor outpatient cases.
- 3. Various other localized surgeries or procedures.

Some otherwise dry procedures may involve the use of intravenously administered liquid. Additionally, these procedures may have a small probability of patient-associated liquid release (e.g., urine, vomitus). When quantifying the risk of human contact to pooled liquid, typical

<sup>&</sup>lt;sup>3</sup> NFPA 99, Health Care Facilities Code, A.6.3.2.2.8.4

<sup>&</sup>lt;sup>4</sup> NFPA 99, Health Care Facilities Code, 6.3.2.2.8.4.

proximity to people contacting a source of electricity and typical liquid volumes involved should be considered.

Even if no procedures with an inherent possibility for release will be performed in the operating room, there may exist other environmental characteristics of the room that should be considered. An example is liquid storage in the room. If an unintended spill occurs, by means of human error or storage vessel failure, the liquid stored may be released in the form of a pool.

#### 1.1.3 Probability of a Release

The most important factor in quantitative risk assessment is the accuracy of the probabilities that are employed. Probabilities stated here are for demonstrative purposes only. A methodology for the establishment and normalization of comparative probabilities must be determined by the HCGB under guidance of qualified personnel performing the risk analysis. If sufficient data is available to quantify the probabilities of release events specific to the facility or type of facility in question, then this data should be used. If not, then conservative values should be taken from reliable sources or arrived at by use of good engineering judgment.

#### 1.1.4 Probability of Intimate Contact with Patient or Staff

Once the probability of a release resulting in pooled liquid have been established, it is necessary to establish the probability that human contact will be made with that pool. In general, this probability is the product of the frequency of the spill and the probability that the space affected by the spill is occupied during the spill.

The ability to perform this calculation and the accuracy of the result depend on the information known about the operating room practices and procedures. During many procedures, health care personnel and the patient will be localized around the operating table. However, other sources of liquid may exist away from typical procedural locations, such as scrub sinks or liquid storage containers. An assessment may require different treatment of these two types of spills.

### **1.2 General Quantitative Risk Assessment Methodology**

Here, a methodology is demonstrated for quantitative risk assessment of electric shock hazards in operating rooms. This methodology is consistent with the *American National Standard Z690.3-2011, Risk Assessment Techniques.* <sup>5</sup> Additionally, more detailed information has been drawn from the techniques of quantitative risk analysis in the chemical process industry, as presented in *Guidelines for Chemical Process Quantitative Risk Analysis* (henceforth abbreviated as *CPQRA*). <sup>6</sup>

Note the scope of this document is to provide examples of the application of quantitative risk assessment methodology, not to provide a reference for acceptable procedures or associated probabilities. The specific details associated with procedures and environmental factors in a patient care room should be evaluated by a qualified member of the risk assessment team.

#### 1.2.1 Step 1: Define the scope of the assessment

The scope of the assessment is to evaluate a specific hospital operating room as a wet procedure location or dry location by establishing the risk associated with an electrical shock hazard. Note that, since the purpose is to establish whether an operating room is a wet procedure location or a dry location, the scope of the risk assessment is to evaluate the likelihood that definition of "Wet Procedure Location" is fulfilled. I.e., the team should assess the likelihood that drenching or pooling of conductive liquid occurs in a location "intimate to the patient or staff."

If a patient care room is designated a wet procedure location, then the requirements of 6.3.2.2.8 must be fulfilled. If the patient care room is designated as not a wet procedure location, then administrative controls should be considered to limit or prevent wet conditions.

<sup>&</sup>lt;sup>5</sup> ANSI/ASSE/IEC/ISO 31010 (Z690.3-2011), Risk Assessment Techniques, American Society of Safety Engineers, 2011.

<sup>&</sup>lt;sup>6</sup> *Guidelines for Chemical Process Quantitative Risk Analysis*, 2<sup>nd</sup> Ed., American Institute of Chemical Engineers, 2000.

#### 1.2.2 Step 2: System Description

Compile the information necessary for the risk analysis. This includes the size of the patient treatment area, the size of the operating room, the types and volumes of liquids used in the rooms, and the types of procedures performed in the room.

#### 1.2.3 Step 3: Hazard Identification

Using the experience and operational knowledge of the risk assessment team, identify the pooling and drenching hazards associated with each procedural or environmental source of liquid, as well as the electric shock hazards associated with each piece of electrical equipment. In the recommended method of fault tree analysis, each hazard possibly leading to electric shock occupies a position on a fault tree.

#### 1.2.4 Step 4: Incident Enumeration

Enumerate each possible hazardous incident identified in Step 3 without regard for importance or initiating event.

#### 1.2.5 Step 5: Selection of Incidents, Outcomes, Cases

In this step, the list of all possible incidents is reduced to the minimum number of representative examples. The goal of this step, as stated in *CPQRA*, is to "*limit the total number of incident outcome cases to be studied to a manageable size, without introducing bias or losing resolution through overlooking significant incidents or incident outcomes.*" <sup>7</sup> For example, all procedures that require the use of a hanging intravenous fluid bag with the same volume of liquid in the same way share the same probability of that bag leaking and that volume of liquid spilling. These events would all be collapsed onto one incident and outcome case.

#### 1.2.6 Step 6: Estimation of Consequences

Here, the consequences of all selected incidents are considered. For the purposes of this analysis, the ultimate consequence of the fault tree is electric shock, but the likelihood of this consequence depends on the likelihood of the container failure and the volume of liquid spilled, as well as the likelihood of human contact. The volume of liquid spilled is the consequence of

<sup>&</sup>lt;sup>7</sup> Guidelines for Chemical Process Quantitative Risk Analysis, 2<sup>nd</sup> Ed., American Institute of Chemical Engineers, 2000, Page 24.

container failure. The extent of liquid pooling or drenching is a consequence of the volume of liquid spilled. The immediate consequence of each incident must be considered to quantify the probability of the ultimate consequence that represents the hazard.

Uncertainties are inherent to most consequence analyses. In these cases, a conservative estimate of the uncertainties leads to a conservative estimate of the consequence. While conservative estimates are important to ensure that the system is overdesigned, these estimates should be as realistic as possible to avoid excessive overdesign. It is for this reason the *CPQRA* states that "consequence analysis should be approached with intelligence tempered with a good dose of reality and common sense."

#### 1.2.7 Step 7: Estimation of Incident Frequencies

The likelihood an incident will occur can be quantified by calculating the frequency with which the incident will occur in circumstances similar to those being considered. Quantifying the frequency may be easier than identifying probability of failure by other means, especially if record keeping provides sufficient historical data.

In the absence of directly applicable data, good judgment must be used in selecting representative data or model results.

#### 1.2.8 Step 8: Estimation of Risk

The risk of electric shock is the product of the probabilities associated with each coinciding fault leading to the electric shock.

## **1.3 QRA for Electric Shock Hazard in Operating Rooms**

Here, the general methodology is applied specifically to the electric shock hazard in operating rooms. Fault tree analysis (FTA) is employed, which combines several of the steps enumerated in the general methodology. These steps should be performed by a knowledgeable team of hospital staff. This team should consist of at least one individual familiar with the procedures performed or intended to be performed in the operating room, and at least one qualified risk assessment professional.

#### 1.3.1 Step 1: Define the scope of the assessment

To assess the likelihood that drenching or pooling of conductive liquid occurs in a location intimate to the patient or staff, who is also in a location intimate to electrical equipment.

#### 1.3.2 Step 2: System Description

Examine the specific operating room being considered. Identify the functional purpose of this operating room and list the potential liquids allowed into the room. Identify the potential liquids associated with the patient and surgical procedure type.

#### 1.3.3 Step 3: Hazard Identification

For the purposes of this assessment, the hazard is predetermined to be electric shock. In FTA, electric shock is called the "top event", and serves as the trunk of our fault tree.

#### 1.3.4 Step 4: Fault Tree Construction

Constructing the fault tree is the FTA-specific equivalent of the more general Incident Enumeration and Selection of Incidents, Outcomes and Cases (Steps 4 and 5 from above). Here, we enumerate the incidents that can lead to our top event, electric shock by manual fault tree construction. <sup>8</sup> A general fault tree for electric shock hazard in the operating room is shown in Figure 1.

Each level in the fault tree is the result of iteratively asking "How can this happen?" and relating the answers with appropriate "and" and "or" logical connectors. For example, a patient or staff member comes in contact with a piece of electrical equipment, and a grounding medium (e.g., conductive liquid). This is an example of an "and" logical connector between the top event and the second level of events. The elimination of any of the three lower-level incidents prevents fulfillment of the higher-level incident. The grounding medium in this example could emanate from the patient or procedure, or it could be a source associated with the room. This is an example of an "or" logical connector between the second and third levels.

<sup>&</sup>lt;sup>8</sup> Guidelines for Chemical Process Quantitative Risk Analysis, 2<sup>nd</sup> Ed., American Institute of Chemical Engineers, 2000, Page 309.

Note that the fault tree, as presented, is missing the lowest-level, or "basic" events. For instance, blood is identified as a contributing factor to the probability of liquid associated with patient or procedure. The probability of blood loss or spillage is determined by lower-level factors such as the procedure-specific probabilities and storage-related probabilities.



Figure 1. Fault tree for electrical shock hazard in a generic operating room, without specific sources of liquids populated.

#### 1.3.5 Step 5: Qualitative Examination of Structure

Once the fault tree has been constructed, it can provide insight into the relationship between faults. In the case of electrical shock in operating rooms, this step may reveal avoidable pathways to a shock hazard. Administrative controls and standardization of procedures may reduce the risk of shock in these cases.

#### 1.3.6 Step 6: Quantitative Evaluation of Fault Tree

This step combines Steps 5, 6 and 7 from the general QRA methodology presented in the previous section. The probability of each incident is calculated in terms of frequency. The fault tree can then be used to construct an event tree for an electric shock hazard. From the event tree, probability is propagated for each selected branch until the probability is quantified for the top event.

## 2 Examples of Quantitative Risk Analysis

## 2.1 Example 1

#### 2.1.1 Step 1: Define the scope of the assessment

To assess the likelihood that drenching or pooling of conductive liquid occurs in a location intimate to the patient or staff.

#### 2.1.2 Step 2: System Description

The operating room floor is approximately 5 m by 10 m, with four operating tables measuring 2 meters by half a meter, spaced evenly through the room. In this room, only normally dry procedures will be performed. However, a hanging bag might be used for intravenous fluid delivery. No other fluid is stored in this room.

#### 2.1.3 Step 3: Hazard Identification

Electric shock is the hazard of interest.

#### 2.1.4 Step 4: Fault Tree Construction

Figure 2 demonstrates a modified form of the general fault tree in Figure 1. Here, the room of interest has no associated liquids, so that branch is eliminated. No irrigation will be performed in this room, so that branch is also eliminated. The initiating incidents, or "basic events" associated with each remaining liquid release are populated from knowledge of allowed procedures. Each basic event has some associated probability. In this example, it is assumed that any release occurs in the presence of electrical equipment and coincides with the failure of the electrical safeguards. These assumed conditions are called "house events" and assigned a probability of one. The other basic events have some probability per procedure between zero and one.

#### 2.1.5 Step 5: Qualitative Examination of Structure

The structure of the fault tree reveals that loss of containment of liquid associated with the patient accounts for the majority of the risk pathways. Where it is possible, the HCGB may consider secondary containment to reduce these frequencies.



Figure 2. Specific fault tree for scenario in Example 1.

#### 2.1.6 Step 6: Quantitative Evaluation of Fault Tree

This step combines Steps VI and VII from the general QRA methodology presented in the previous section. The probability of each incident is calculated in terms of frequency, and those frequencies are used to calculate the risk. A hypothetical historical record is used to develop frequencies, shown in Table 1. Note that these figures are for demonstrative purposes and not intended to represent real frequencies. In this record is the number of occurrences for each category of liquid release during the allowed procedures. Occurrences are further categorized by volume of the release. Greater volumes of release will have a lower frequency of occurrence but a higher probability of exposure.

	Probability Per Procedure of Release Categorized by Liquid Type and Volume				
Liquid Type	< 75 mL	75-750 mL	750-3000 mL	>3 L	
Blood	1E-01	1E-03	1E-04	1E-06	
Urine	1E-02	1E-04	1E-06	1E-08	
IV Liquid	1E-02	1E-03	1E-05	-	
Vomitus	1E-04	1E-06	1E-08	-	
Meds	1E-04	1E-06	-	_	

## Table 1.Sample frequency table. A health care governing body might compile such a<br/>table from housekeeping logs or other records.

For each patient or procedure associated release, it is assumed that the release occurs within 1 meter of the operating table. As operating table is 2 meters by 0.5 meters, the pooling occurs randomly somewhere in a region of 4 meters by 2.5 meters, or an area of  $10 \text{ m}^2$ .

A previous report on the subject of operating rooms as wet/dry locations reported a correlation for thickness of a pool, *T*, in mm, as a function of volume of spill, *V*, in liters, at a spill-height of 1 m, from data presented in the SFPE Handbook 4<sup>th</sup> Ed. <sup>9</sup> This correlation, T[mm] = -0.0028 $V[L]^2 + 0.14 V[L] + 1.0167$ , is utilized here to compute the pool area, *A*, in meters, associated with various volumes of spilled liquid, where A[m] = V[L]/T[mm](note that this is an approximation arrived upon by extrapolating experimental data collected in a range of 5 to 30 L). Pool area is then divided by the area of interest to compute a probability of exposure to pooling or drenching. For volumes greater than 3 L, it is assumed that contact with the puddle will occur. The results are tabulated in Table 2 for areas of interest of 10 m<sup>2</sup> and 50 m<sup>2</sup>. In this example, 10 m<sup>2</sup> is the area of interest.

Volume of Release (mL)	Pool Thickness (mm)	Area (m2)	Diameter (m)	% of 10 m2
75	1.03	0.0730	0.305	0.730%
750	1.12	0.670	0.923	6.70%
3000	1.41	2.13	1.65	21.3%

Table 2.Probability of single-event exposure from release volumes<br/>of 75 mL, 750 mL and 3000 mL in areas of 10 m² and 50 m².

<sup>&</sup>lt;sup>9</sup> Chernovsky, MK, et al. "Evaluation of Health Care Operating Rooms as Wet/Dry Locations," Fire Protection Research Foundation, October 2010.

Once the frequency of release and the area affected by the release have been established, the missing piece is the utilization of the room. For instance, if an operating room is host to 4 procedures a day, 100 days per year, and the average procedure involves 4 people (patient plus 3 staff), then the probability of exposure per procedure is multiplied by 4000 exposure opportunities per year to compute a frequency per year. For the procedure-associated releases, an area of 10 m<sup>2</sup> is considered, and so the frequency of a person occupying the space associated with a 75 mL spill is 4 [people per procedure] \* 1000 [procedures per year] \* 0.730% [75 mL pooling area in 10 m<sup>2</sup> utilized area] / 100% = 29.2 [people in 75 mL pooling area in 10 m<sup>2</sup> utilized area].

To compute the probability of exposure, the frequency of a person occupying the space associated with a release of a given volume is multiplied by the frequency of release of a given liquid associated with that volume. E.g., annual frequency of exposure to a blood release of < 75 mL is given by 29.2 [people in 75 mL pooling area in 10 m<sup>2</sup> utilized area per year] \* 1.0E-1 [75 mL releases of blood per year] = 2.9 [people exposed per year]. The results are shown in Table 3. These values are summed for volume category to yield the probability of exposure due to each particular liquid type, shown in Table 4.

	Frequency of Exposure Per Year Categorized by Liquid Type and Volume					
Liquid Type	< 75 mL	75-750 mL	750-3000 mL	>3 L		
Blood	< 2.9E+00	< 2.7E-01	< 8.5E-02	< 4.0E-03		
Urine	< 2.9E-01	< 2.7E-02	< 8.5E-04	< 4.0E-05		
IV Liquid	< 2.9E-01	< 2.7E-01	< 8.5E-03	-		
Vomitus	< 2.9E-03	< 2.7E-04	< 8.5E-06	-		
Meds	< 2.9E-03	< 2.7E-04	-			

Table 3. Frequency of exposure per year categorized by liquid type and volume.

The frequencies of exposure from each liquid type are then summed to yield the frequency of exposure due to any liquid type. The resulting value is < 4.2 [exposures per year]. For the purposes of this example, our cutoff criteria is 1 [exposure per year], and thus this room would be classified as a "Wet Procedure Location." Note that the method of application of the volume of release correlation leads to a bounding of probability by the likelihood associated with the largest release that would still be in that volume category. More refined categories would most likely lower the probability of exposure.

Liquid Type	Frequency of Exposure Per Year		
Eiquia Type	Categorized by Liquid Type		
Blood	< 3.3E+00		
Urine	< 3.2E-01		
IV Liquid	< 5.7E-01		
Vomitus	< 3.2E-03		
Meds	< 3.2E-03		

 Table 4. Annual frequency of exposure categorized by procedure.

#### 2.2 Example 2

#### 2.2.1 Step 1: Define the scope of the assessment

To assess the likelihood that drenching or pooling of conductive liquid occurs in a location intimate to the patient or staff.

#### 2.2.2 Step 2: System Description

The operating room floor is approximately 5 m by 10 m, without a traditional operating table. No procedures with any possibility of liquid release will be performed here. However, the cabinets are used to store liquid, and there is a scrub sink in the room.

#### 2.2.3 Step 3: Hazard Identification

Electric shock is the hazard of interest.

#### 2.2.4 Step 4: Fault Tree Construction

Figure 3 demonstrates a modified form of the general fault tree in Figure 1. Here, the room of interest has no associated liquids, so that branch is eliminated. No foreseeable liquids are associated with patient or procedure. However, this part-time operating room also serves as a liquid storage location. Again, it is assumed that each basic event has some associated probability. It is assumed that any release occurs in the presence of electrical equipment and coincides with the failure of the electrical safeguards. These incidents are called "house events" and assigned a probability of one. The other basic events have some probability per procedure between zero and one.



Figure 3. Specific fault tree for scenario in Example 2.

#### 2.2.5 Step 5: Qualitative Examination of Structure

Here, the sole source of liquid release is loss of containment. Where it is possible, the HCGB may consider secondary containment to reduce the frequency of loss of containment.

#### 2.2.6 Step 6: Quantitative Evaluation of Fault Tree

The probability of each incident is estimated in terms of frequency, and those frequencies are used to estimate the risk. Here, little detail is known about storage locations for the room. Thus, it is assumed that the liquid could spill anywhere in the 50 m<sup>2</sup> of open space in the room. The container type and liquid type is unknown. The existence of a spill is assumed as a house event (*Probability* = 1).

Note that this number is very conservative. In actuality, the probability of a spill may depend on such factors as the type of liquid stored, the height at which the liquid is stored, the frequency with which the liquid is handled, the container type, the container material, and the average temperature and temperature changes to which the container is exposed. A generic probability for loss-of-containment is  $10^{-5}$  failures per handling of packaging unit. <sup>10</sup>

Again, the correlation,  $T[mm] = -0.0028 V[L]^2 + 0.14 V[L] + 1.0167$  is used to compute the pool area, *A*, in meters, associated with various volumes of spilled liquid, where A[m] = V[L]/T[mm]. Pool area is then divided by the area of interest to compute a probability of exposure to pooling or drenching. In Table 5, results are plotted over a range of volumes time for an open space of 50 m<sup>2</sup>. As both the conductive fluid and the electrical equipment are now assumed to exist, the probability of electric shock becomes the probability that someone is exposed to the release. The data from Table 5 is used, along with the frequency of utilization, to determine the volume of liquid that can be stored without leading to a probable electric shock hazard.

Volume of Release (mL)	Pool Thickness (mm)	Area (m <sup>2</sup> )	Diameter (m)	% of 50 m2
75	1.03	0.0730	0.305	0.146%
250	1.05	0.2377	0.550	0.475%
500	1.09	0.4604	0.766	0.921%
750	1.12	0.670	0.923	1.34%
1000	1.15	0.867	1.050	1.73%

Table 5.Probability of single-event exposure from release volumes of 75 mL, 250 mL,500 mL, 750 mL, and 1000 mL in an area of 50 m².

<sup>0</sup> Guidelines for Quantitative Risk Assessment, CPR 18E, Publication Series on Dangerous Goods (PGS), 2005.

The last column in Table 5 is multiplied by the number of people per year that are at risk of exposure. For example, if 500 procedures are performed with 2 people present (patient and personnel), then 1000 possible exposure events occur. These results are shown in Table 6 for various combinations of maximum liquid volume and utilization.

Procedures	People Per	Probability of Exposure Per Year Categorized by Liquid Volume				Volume
Per Year	Procedure	< 75 mL	< 250 mL	< 500 mL	< 750 mL	< 1000 mL
500	2	1.460	4.755	9.208	13.391	17.333
250	2	0.7302	2.377	4.604	6.696	8.666
100	2	0.2921	0.9510	1.842	2.678	3.467
50	2	0.1460	0.4755	0.9208	1.339	1.733

 Table 6.
 Probability of exposure categorized by procedures per year and maximum volume of liquid stored.

Again, a cutoff criterion of *1 exposure per year* is employed. Thus, the maximum volume of liquid that can be stored is 75 mL for 250 2-person procedures per year utilization, 250 mL for 100 2-person procedures per year, and 500 mL for 50 2-person procedures per year.

## 3 References

Below is a list of recommended references for use in quantitative risk analysis.

- 1. ANSI/ASSE/ISO Guide 73 (Z690.1-2011), Vocabulary for Risk Management, American Society of Safety Engineers, 2011.
- 2. ANSI/ASSE/ISO 31000 (Z690.2-2011), Risk Management Principles and Guidelines, American Society of Safety Engineers, 2011.
- 3. ANSI/ASSE/IEC/ISO 31010 (Z690.3-2011), Risk Assessment Techniques, American Society of Safety Engineers, 2011.
- 4. Society of Fire Protection Engineering Handbook, 4<sup>th</sup> Ed., NFPA, 2008. reference for spill volume versus diameter.
- 5. *Guidelines for Chemical Process Quantitative Risk Analysis*, 2<sup>nd</sup> Ed., American Institute of Chemical Engineers (AIChE)/Center for Chemical Process Safety (CCPS), 2000. – reference for risk analysis methodologies and techniques applied to the chemical industry.
- 6. *Guidelines for Quantitative Risk Assessment, CPR 18E, 2005.* A guideline originally published by the Dutch governmental Committee for the Prevention of Disasters (CPR), now part of the Publication Series on Dangerous Substances.
- 7. National Electrical Code (NFPA 70), NFPA, 2011. reference for electrical
- 8. *Guidelines for Hazard Evaluation Procedures*, 2<sup>nd</sup> Ed., CCPS, 1992. Guide for qualitative hazard analysis, primarily targeted to the chemical industry.
- PRA Procedures Guide: A Guide to the Performance of Probabilistic Risk Assessment for Nuclear Power Plants, 2 volumes, NUREG/CR-2300, US NRC, 1983. – Thorough guide for probabilistic (quantitative) risk assessment; generally useful, although targeted to individuals performing probabilistic risk assessments of light-water-reactor (LWR) nuclear power plants.
- 10. Performance of Plastic Packaging for Hazardous Materials Transportation: Part I Mechanical Properties (Report No. DOT/MTB/OHMO-76/4) – This reference contains information regarding the performance of plastic packaging. It was compiled for the Department of Transportation for purposes related to the transport of hazardous materials, but may be relevant for the prediction of failure of liquid storage containers. It is made available through the National Technical Information Service.

## 4 Limitations

The study presented in this report is intended for use by the Fire Protection Research Foundation to assist with their decision making related to evaluation of health care operating rooms as wet/dry locations. 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 illustrate methods for performing quantitative risk assessment methods for the evaluation of health care operating rooms as wet/dry procedure locations as defined in the NFPA 99, the Health Care Facilities Code (2012). This study is intended to supplement considerations for compliance with Section 6.3.2.2.8.4 of NFPA 99 Health Care Facilities Code (2012). This study specifically does not address any other aspect of electrical, fire, or life safety.

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. However, other uncertainties such as for example, as-built construction details, modifications, current conditions, material characteristics, among others 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 loss that may occur as a result of future events or any specific event; as such, the actual losses 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.