RISK ASSESSMENT GUIDE

How to Identify and Analyze a Hospital Risk Assessment

CHT

Introduction

“Risk management is a structured approach to managing uncertainty related to a threat, through a sequence of human activities including risk assessment, strategy development to manage risk and mitigation of risk using managerial resources.

The strategies could include transferring the risk, to another party, avoiding the risk, reducing the negative effect and accepting some or all of the consequences of a particular risk.” Nadeem Baig, HSE

Several approval agencies are asking for or requiring Risk Assessment plans as part of their annual inspection routine. Other than the general principles outlined here, specific detailed guidelines for equipment, processes or buildings are still being formulated.

In general, risk assessment asks:

What can go wrong?
How bad could it be?
What action should be taken?
How often might it happen?
How do we avoid this problem in the future?

6 Steps to Provide a Remedy for an Identified Risk

1. Identify what failures or incidents can cause damage.
2. Identify who or what could be injured or displaced by such a failure or event: patients, staff or the public.
3. How critical would the damage be if the defect took place.
4. How likely is this problem to happen?
5. Create a remedy or procedure to work around the adverse event and identify the responsible parties.
6. Review the corrective action plan with staff to make sure they understand and can fulfill their responsibilities in the event of a defect occurring.

The events you identify should be filtered through a grid like the one on page 4 that clarifies the importance and urgency of action to remedy the problem and value the risk of a bad outcome.

Likelihood to Harm a Patient/Staff/Visitor

Immediate Threat to Life
(A threat that represents immediate risk or may potentially have serious adverse effects on the health or the patient, resident, or individual served)

HIGH
(Harm could happen at any time)

MEDIUM
(Harm could happen occasionally)

LOW
(Harm could happen, but would be rare)

LIMITED
(Unique occurance that is not representative of routine/regular practice)

PATTERN
(Multiple occurences with potential to impact few/some patients, visitors, staff and/or settings)

WIDESPREAD
(Multiple occurences with potential to impact most/all patients, visitors, staff and/or settings)

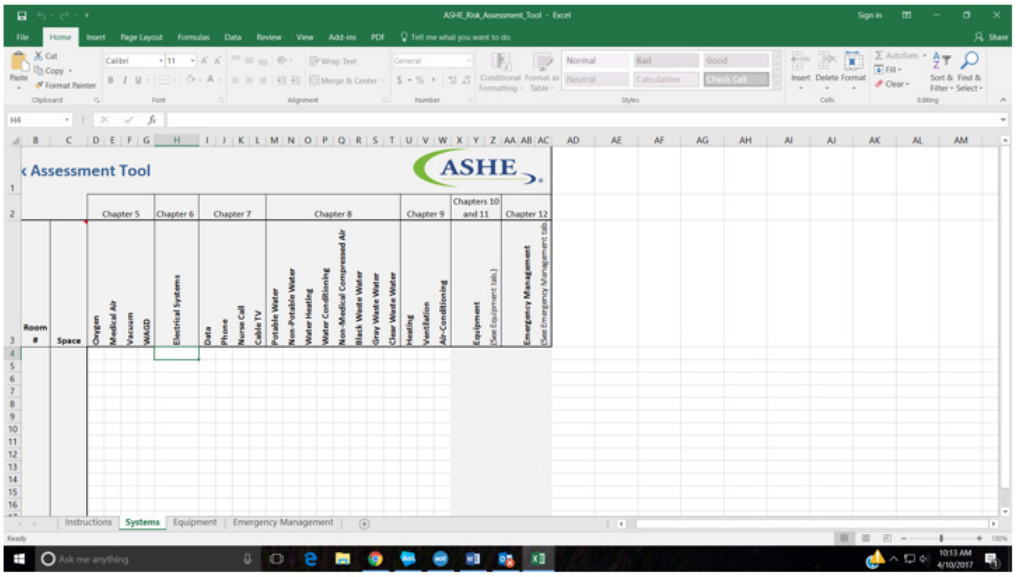
Scope

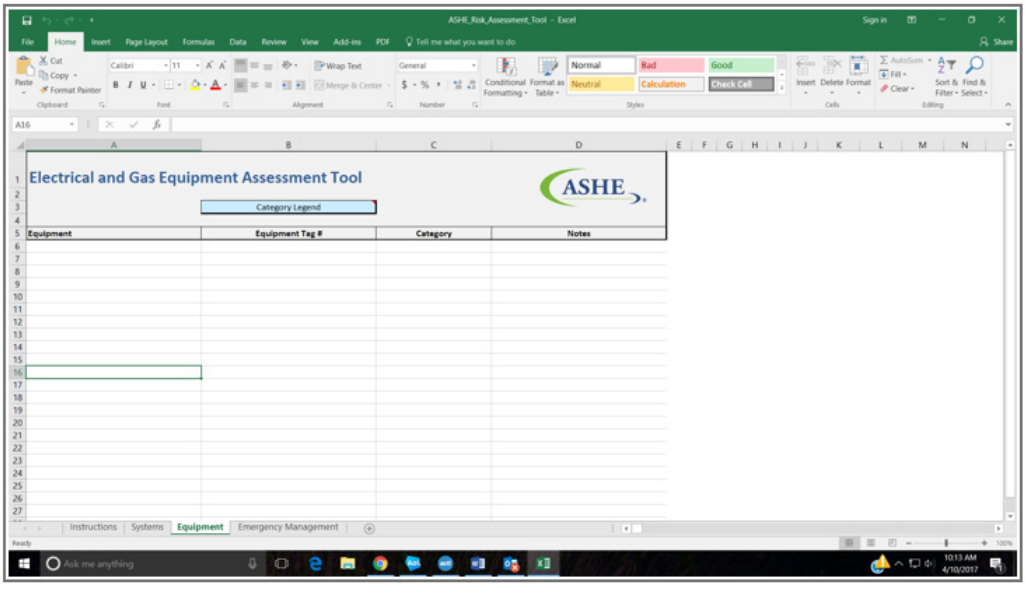
List Equipment to Prepare for Remedies

ASHE provides a spread sheet to list equipment and areas of the hospital that are important to patient care and from there you can individually plan the remedies for failures that may occur at these sites.

NFPA, CMS and TJC require an inventory of equipment to be available during inspection and for medical gas purposes that would be the starting point of filling out the equipment grid from ASHE below.

Risk Assessment Form





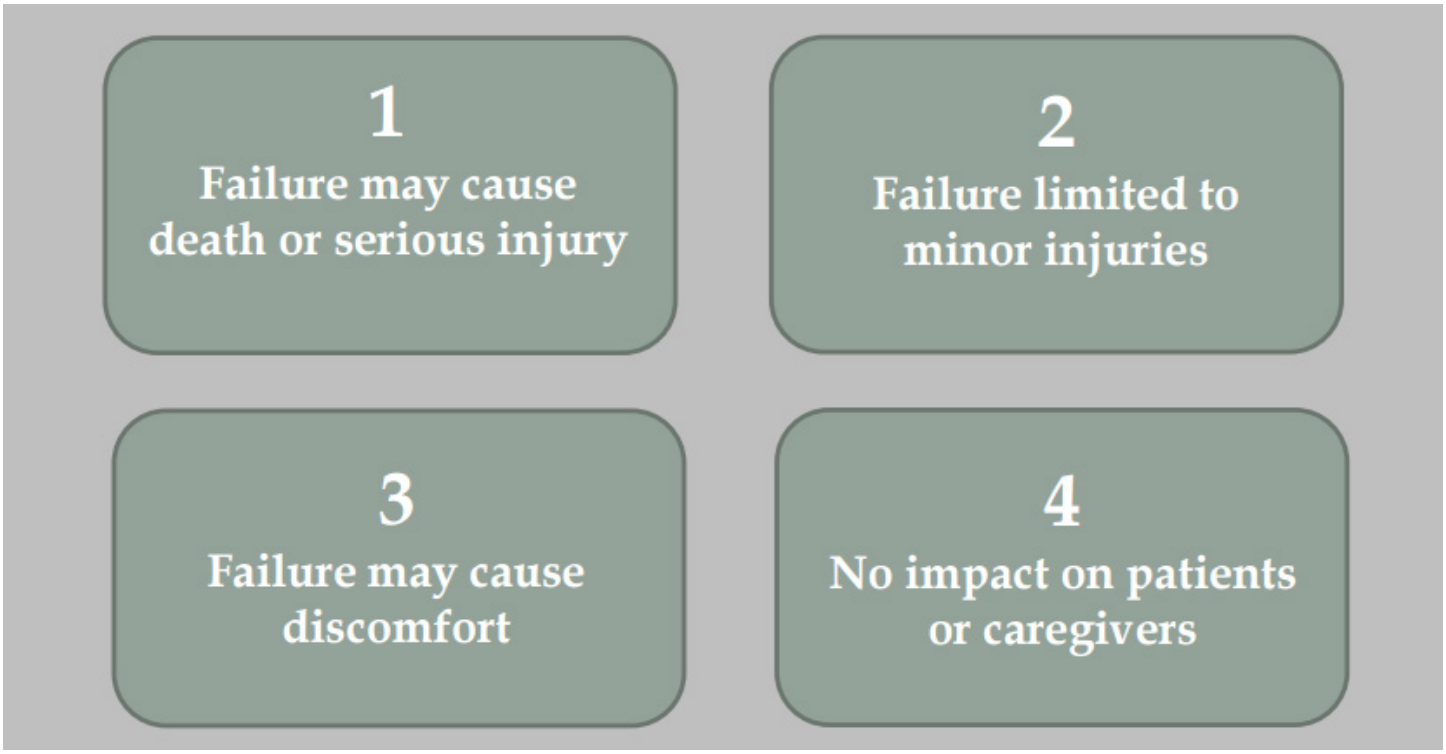
Hospital Risk Assessment Defined by Risk to Patient

Risk based assessment assigns a value to each asset by their use and their potential to be harmful to the patients or staff. For example, an oxygen outlet in an emergency room would have the highest urgency while the outlet in the storeroom would have the lowest priority.

The hospital in conjunction with the inspecting company following NFPA guidelines would establish an urgency level to each device and then set an inspection and repair schedule for the assets based on the risk rating to patients rather than the date on the calendar.

Building System Categories Defined by Threat

The categories are broken down into harm to patients, staff and visitors.



4 Categories by Threat

Category 1

The system **must always be highly functional**. An example in this category would be a medical gas system in an ICU.

Category 2

A system failure **would not involve risk to life**. High dependability is expected in this category.

Category 3

Failure would **cause discomfort** but not likely to cause injury.

Category 4

Patients are **not adversely affected.**

Critical Factors to Consider When Evaluating Risks Associated With Equipment

Whether equipment is critical (TJC high-risk) equipment is one of the tests. It may even be the most important factor to consider, but it is not the only factor.

Within The State Operations Manual, Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, A-0724 (Rev.); Interpretive Guidelines §482.41(c)(2), CMS states "Factors for a hospital to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- "How the equipment is used and the likely consequences of equipment failure or malfunction – would failure or malfunction of the equipment hospital-wide or in a particular setting be likely to cause harm to a patient or a staff person?"
- "How serious is the harm likely to be?"
- "How widespread is the harm likely to be?"
- "Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;"

Maintenance requirements of the equipment:

- Are they simple or complex?
- Are the manufacturer's instructions and procedures available in the hospital, and if so can the hospital explain how and why it is modifying the manufacturer's instructions?
- If the manufacturer's instructions are not available in the hospital, how does the hospital assess whether the AEM uses appropriate maintenance strategies?
- How readily can the hospital validate the effectiveness of AEM methods for particular equipment? For example, can the hospital explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?"
- "The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction"
- "Incident history of identical or very similar equipment"

CMS also stated “Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.”

“Legacy computerized maintenance management systems (CMMS) generally do not adequately address these AEM inclusion risk assessment requirements with their original risk assessment programming. This situation appears to be because the newly required risk assessment factors are generally not the same as the more commonly-used factors that hospitals have used in past utility system risk assessments. A new risk assessment framework appears to be required to support AEM-inclusion decisions.”

Suggested CMS Checklist to Identify Risks and Their Protections and Remedies

1.1 SYSTEM RISKS AND SAFEGUARDS

Enter the system risk and safeguard determined for each system risk identified.

Table 15 - System Risk and Safeguard

Risk and Safeguard	Response Data
Item No.	<Item No.>
Business Function	<Business Function>
Risk Level	<Risk Level>
Threat Name	<Threat Name>
Vulnerability Name	<Vulnerability Name>
Risk Description	<Risk Description>
Business Impact	<Business Impact>
Existing Controls	<Existing Controls>
Likelihood of Occurrence	<Likelihood of Occurrence>
Impact Severity of Occurrence	<Impact Severity of Occurrence>
Risk Level of Occurrence	<Risk Level of Occurrence>
Recommended Safeguard Description	<Recommended Safeguard Description>
Residual Likelihood of Occurrence	<Residual Likelihood of Occurrence>
Residual Impact Severity	<Residual Impact Severity>
Residual Risk Level	<Residual Risk Level>
Implementation Priority	<Implementation Priority>
Implementation Rationale	<Implementation Rationale>

Source: CMS.gov

For general hospitals performing anesthesia the risk level for medical gas equipment is always high as they sustain life and their interruption would likely mean death or serious harm to patients and perhaps other equipment;. except in priority 3 sites.

The default inspection and testing regime for medical gas equipment has been the Manufacturer's suggested cycle. This usually means: annually for passive equipment: Outlets, valves and alarms and quarterly for active source equipment like pumps and compressors and monthly for power changeover systems.

In Summary

As the various agencies collaborate on their reporting standards and regimens the responsibility of the hospital to identify and maintain equipment is paramount.

The surveyors may well ask for an inventory of any or all equipment in the hospital including its maintenance history for at least the past two years. Any equipment failures that lead to serious harm to patients or staff are likely to be scrutinized as the process evolves. Detailed records of defective parts and adjustments need to be recorded as well.

An exhaustive study by John Collins, FASHE, HFDP done for ASHE determined the most frequently failing devices leading to patient injury were circuit boards. Assuming this holds true for your hospital, the medical gas system should be very reliable as the only circuit boards are in the alarm systems.

This could mean more scrutiny on the activation and calibration of alarm systems for medical gas. Motors and wear parts were far behind in terms of creating failures, but many of these potential failures can be anticipated with a regular preventive maintenance program.

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