



Regulatory Nightmares!!!!

(and how to avoid them)

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Who are the regulators ?

- DOH
- TJC
- OSHA
- DEA
- Licensing Boards

When and Why they visit.....



DOH	TJC	OSHA	All others
Complaint investigation Can last 1-5 days	Triennial Survey 3-5 days, 3-5 surveyors	Employee safety issues. Can be an employee complaint or an event we reported.	Investigation of concerns.
Licensure survey 3-5 days	Certification surveys Stroke, cardiac, transplant	Days to weeks	???
EMTALA Violation 3-5 days			



How do you know what to
expect???



No statutes or acts will be found at this website.

The Pennsylvania Code website reflects the Pennsylvania Code changes effective through 49 Pa.B. 3438 (June 29, 2019).

Information included at this site has been derived directly from the Pennsylvania Code, the Commonwealth's official publication of rules and regulations. Cite all material in the Pennsylvania Code by title number and section number.

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Chapter 28.....



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TJC Standards



Comprehensive Accreditation Manual

Standards
Elements of Performance
Scoring
Accreditation Policies

CAMH
for Hospitals
Effective January 2017

 The Joint Commission
Accreditation

An official publication of
The Joint Commission

<http://www.jointcommission.org>

Chapters = 18
Standards = 269
EP's = ?????!!!

The FGI Guidelines



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Guidelines

FOR DESIGN AND CONSTRUCTION OF

Hospitals

The Facility Guidelines Institute

2018 edition



Includes ANSI/ASH-PASHE
Standard 170-2017
Ventilation of
Health-Care Facilities



×

Guidelines

FOR DESIGN AND CONSTRUCTION OF

Outpatient Facilities

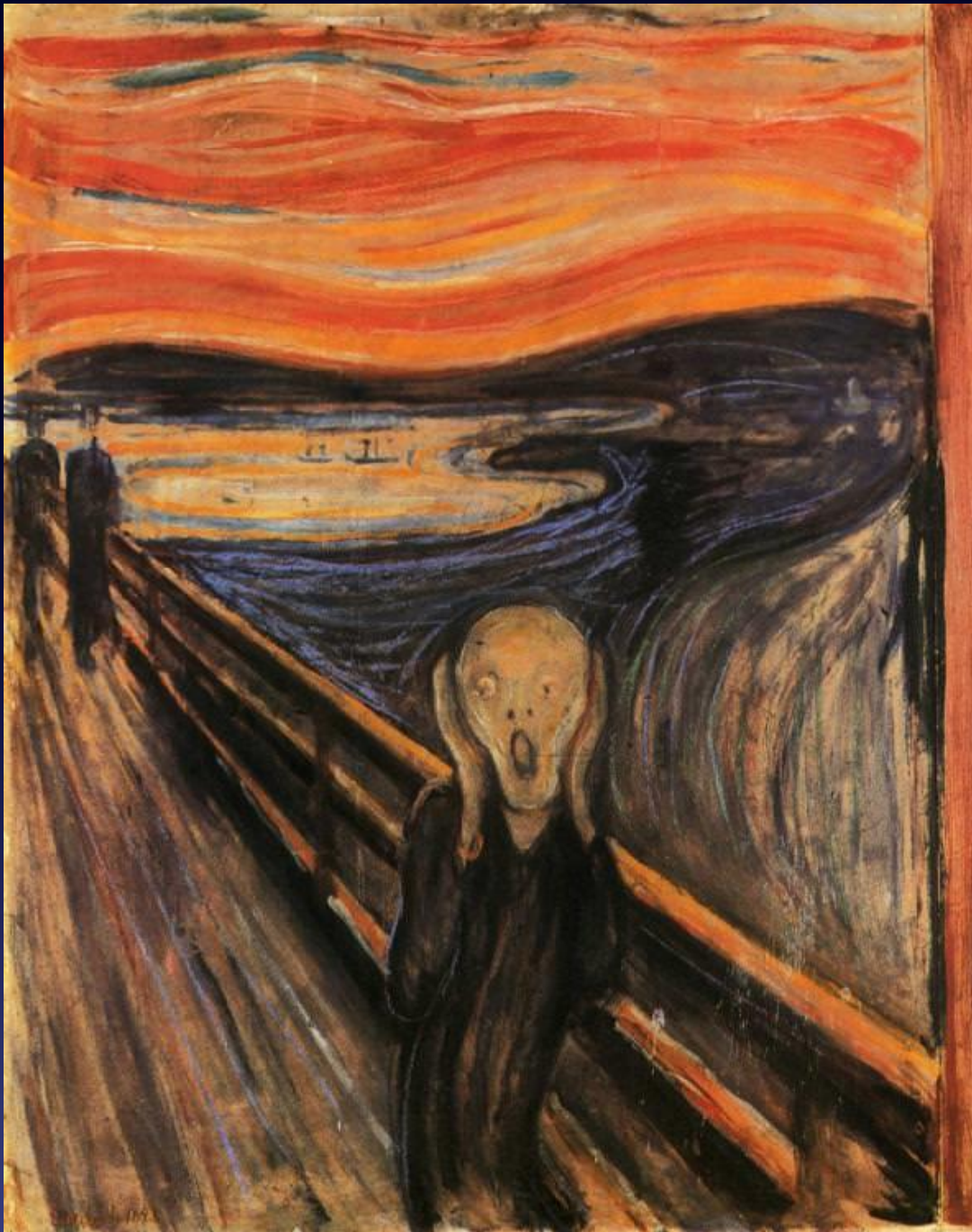
The Facility Guidelines Institute

2018 edition



Includes ANSI/ASH-PASHE
Standard 170-2017
Ventilation of
Health-Care Facilities





Basics.....



- Clear hallways
- Infection prevention practices
- Secure medication
- Working equipment
- Properly stored medical gases
- Privacy
- Then comes compliance with documentation standards and policies.



But first, how far have we come???

Instrument sterilization



Semi private rooms




Operating theatre



Current therapy



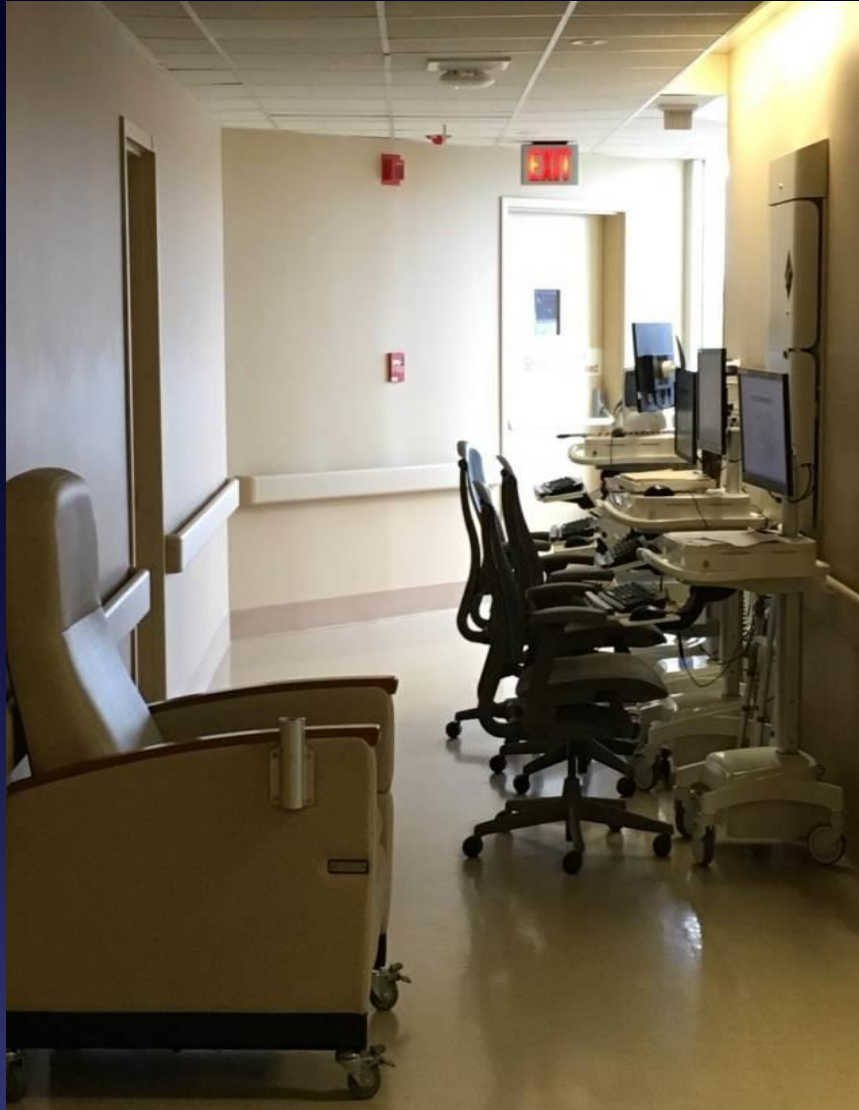
Over the counter medication



COCAINE
TOOTHACHE DROPS
Instantaneous Cure!
PRICE 15 CENTS.
Prepared by the
LLOYD MANUFACTURING CO.
219 HUDSON AVE., ALBANY, N. Y.
For sale by all Druggists.
(Registered March 1885.) See other side.



Clear Hallways





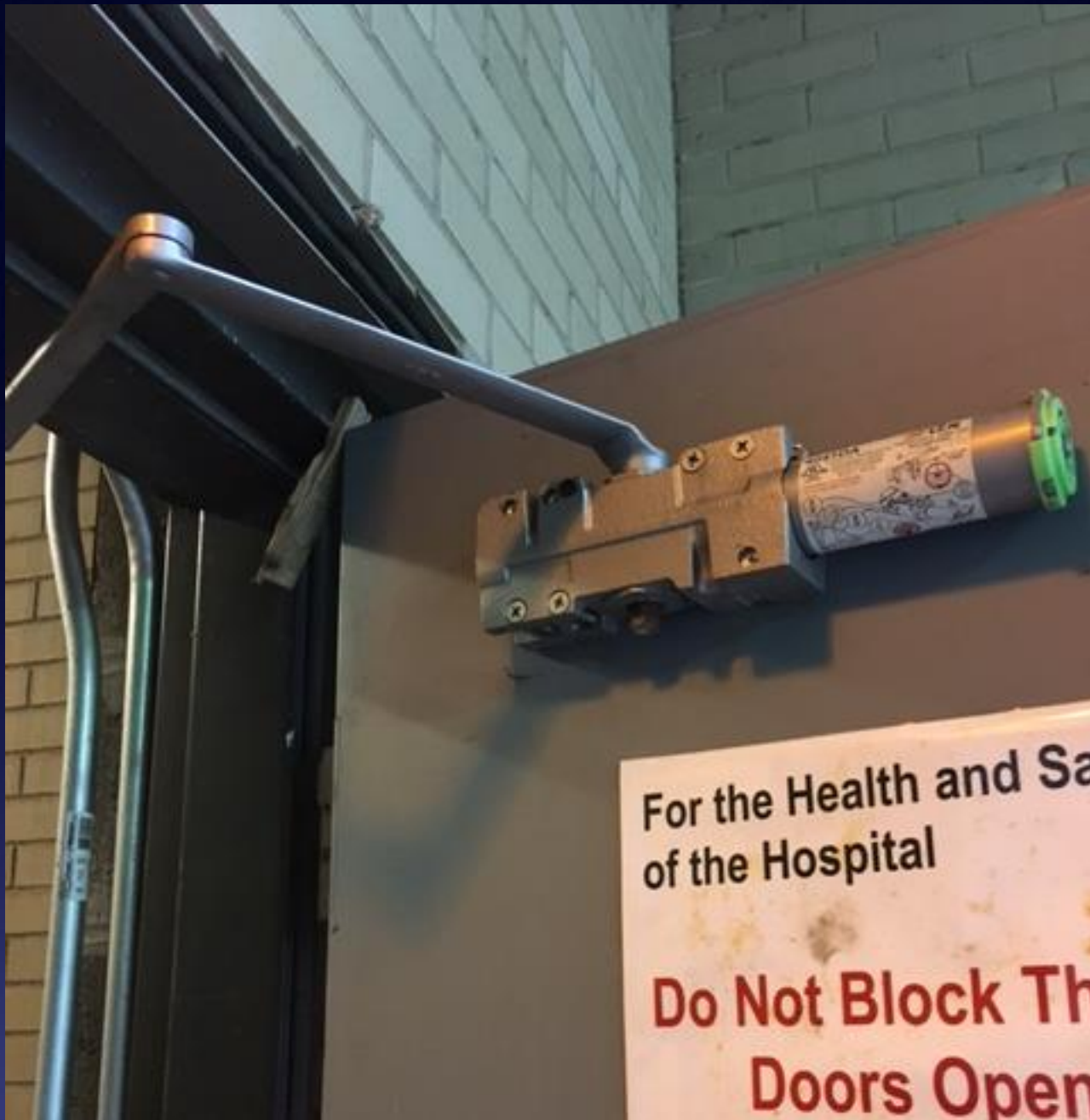




The Pepsi castle
Always there, never the same 2 days in
a row









Infection Prevention Practices

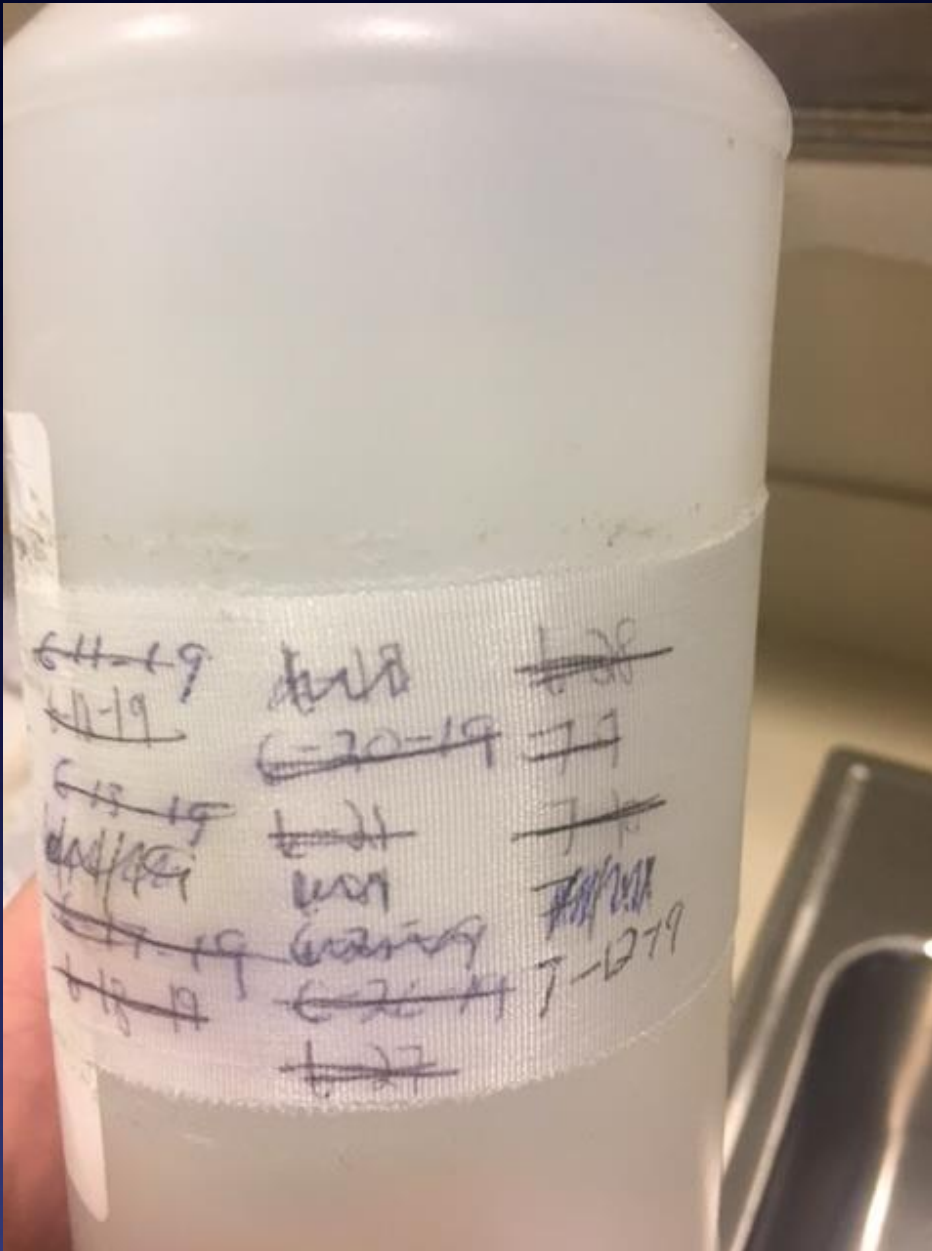




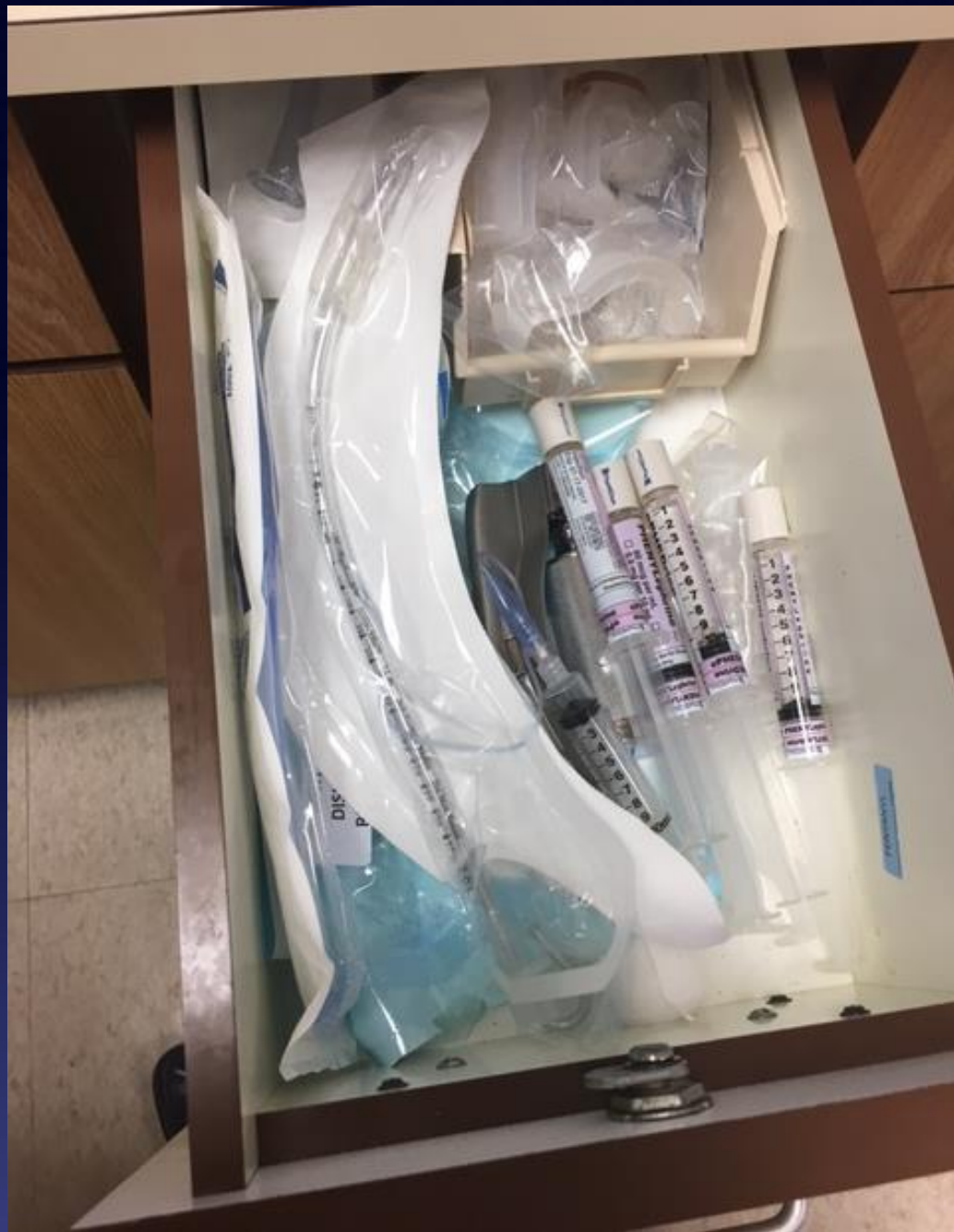
Shouldn't this
Have a tight
Closure?







6-11-19	6-11-19	5-28
6-11-19	6-20-19	7-7
6-15-19	6-21	7-7
6-15-19	6-21	7-7
6-17-19	6-21	7-7
6-18-19	6-26-19	7-12-19
	6-27	

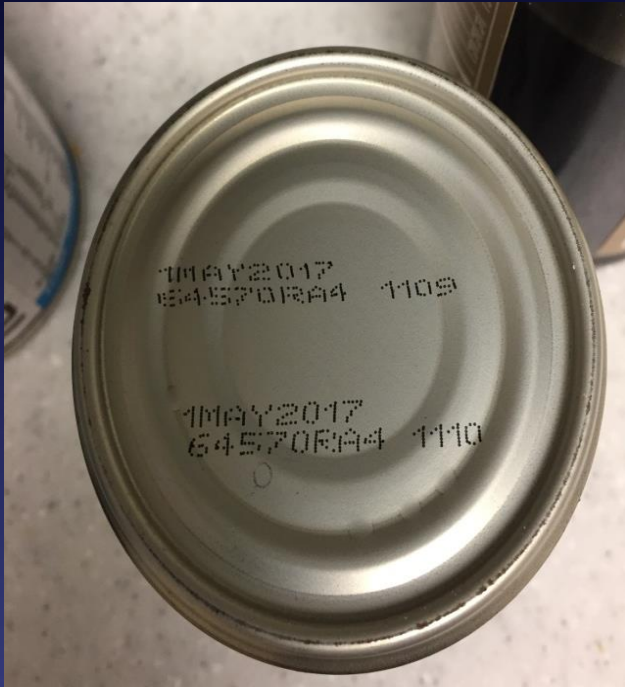
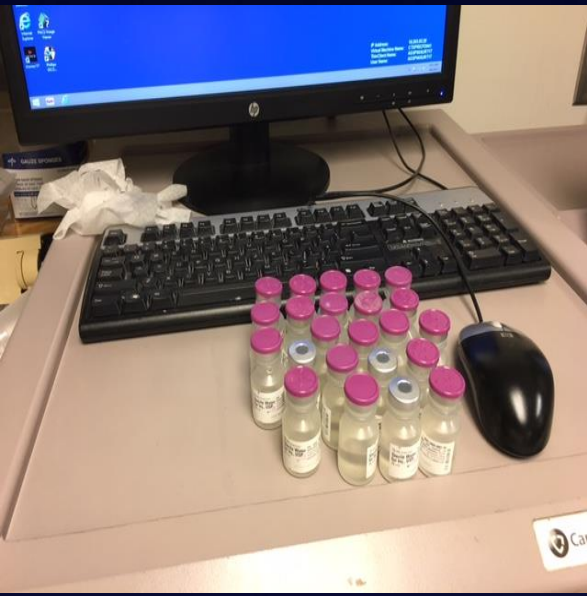


I never thought that
Stethoscopes and
Water went well
Together. Apparently
I was mistaken!





Expired supplies found April 2018





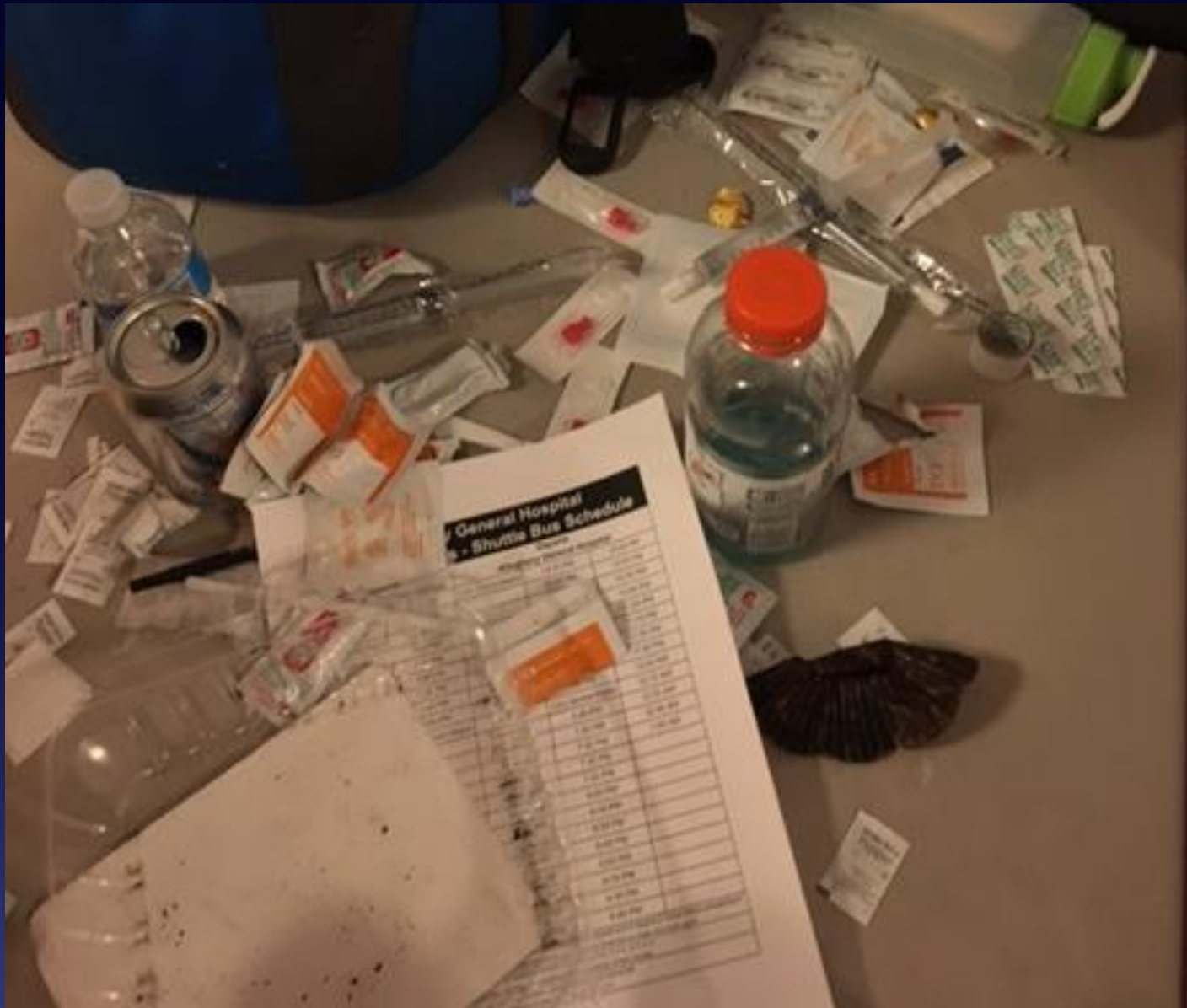
Secure Medication















...dies will significantly improve patient safety in
...ringes are not equipped with safety needles.



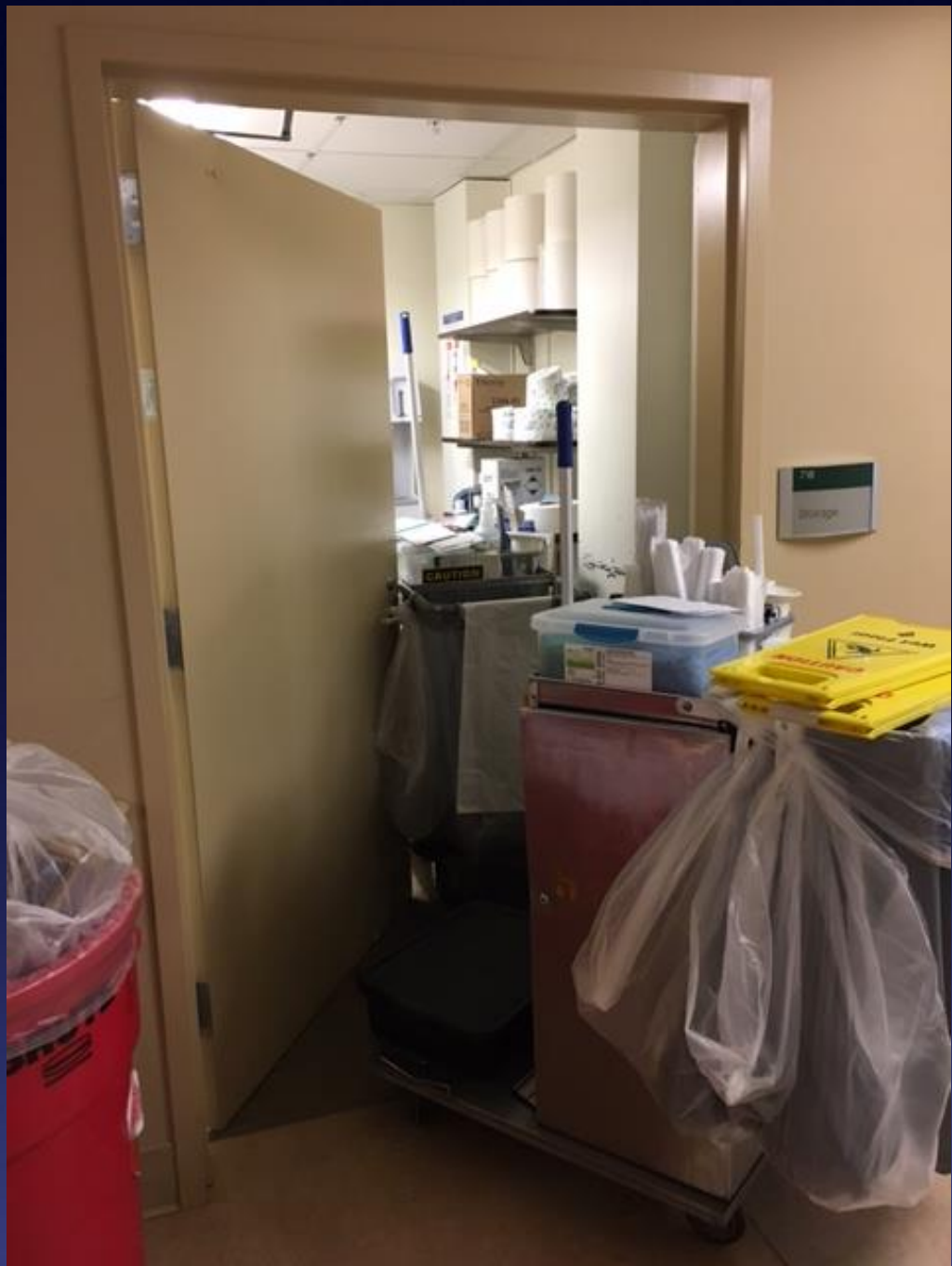
25

MED ROOM



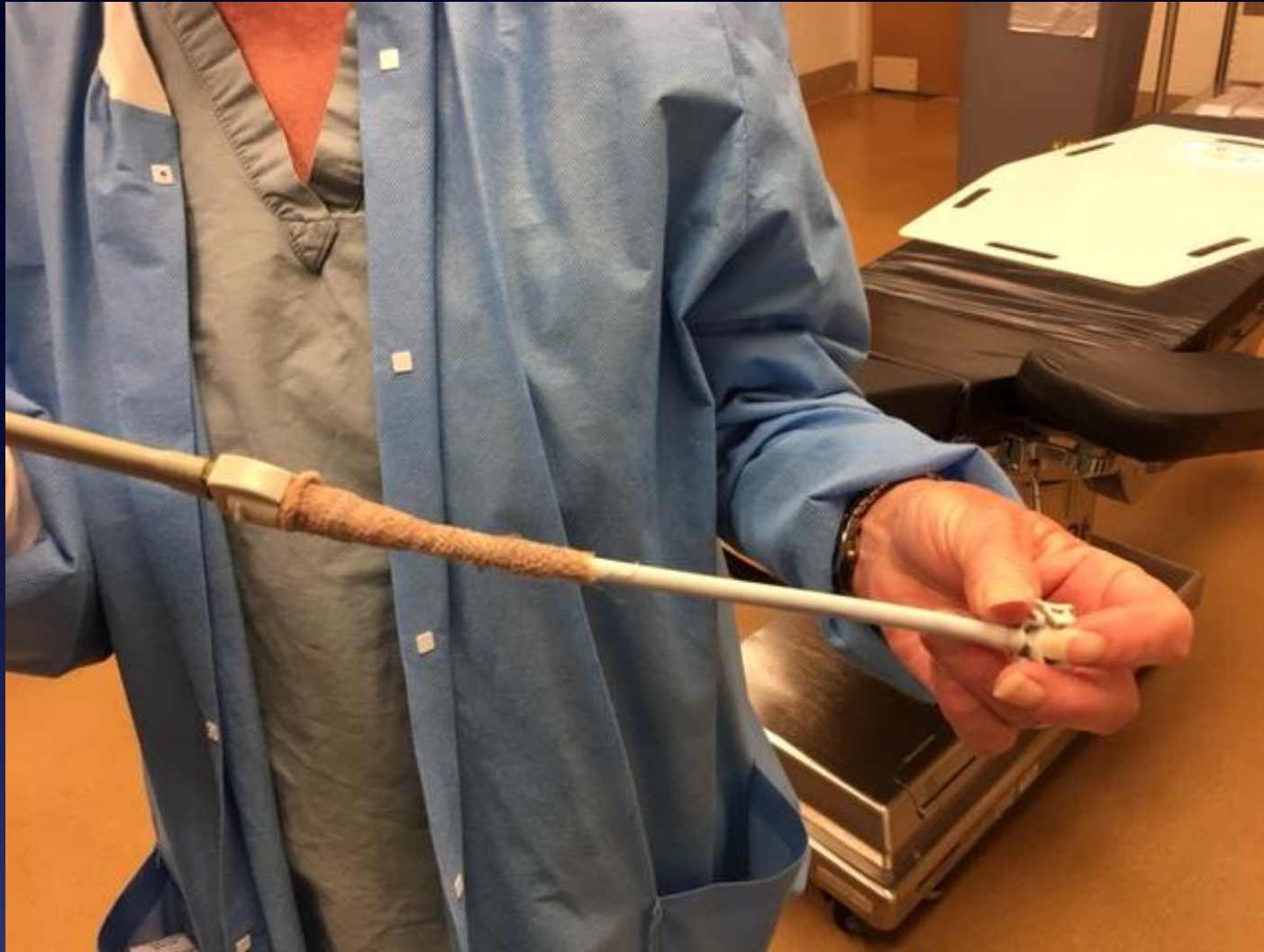
Working Equipment











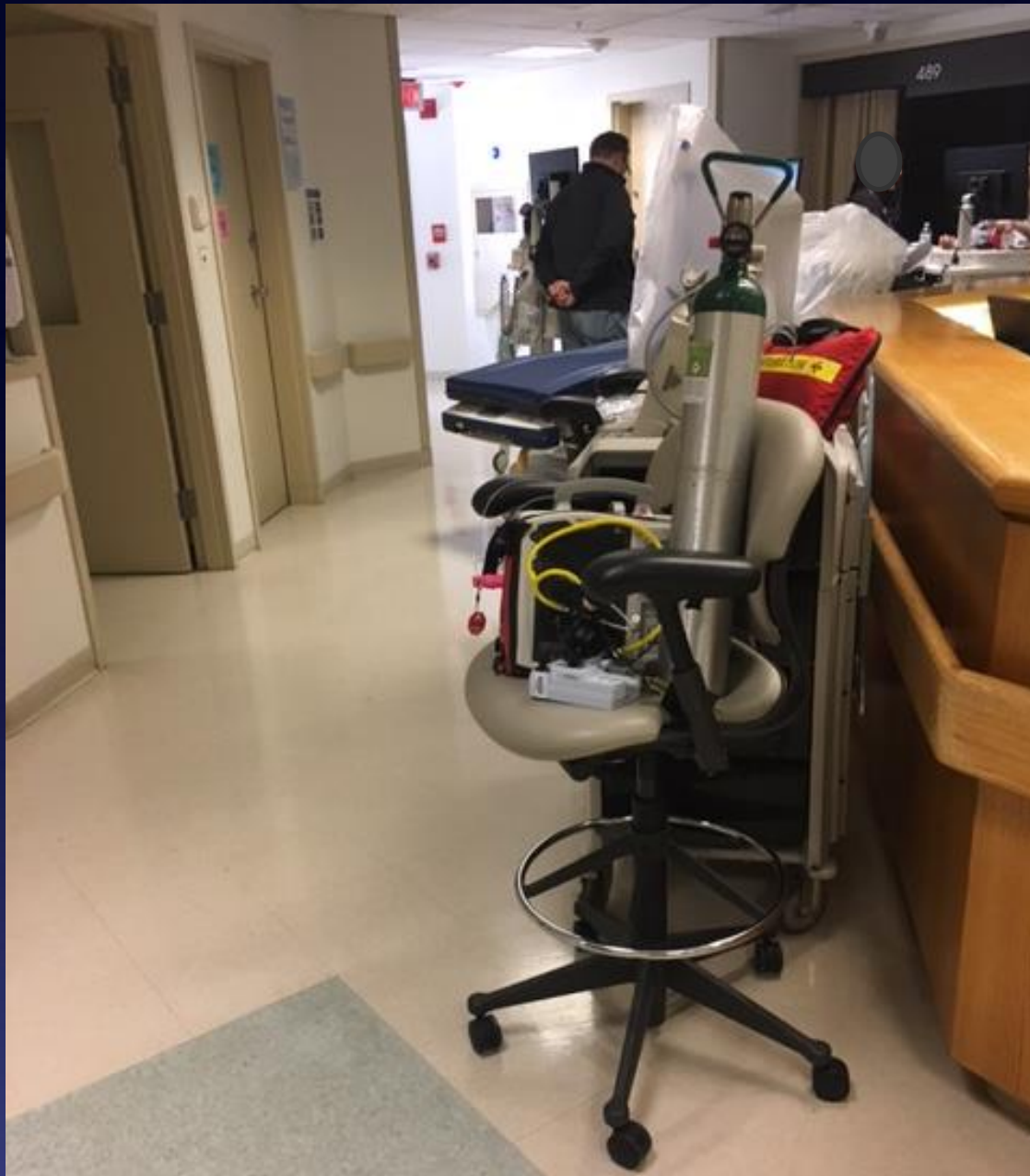


The suction catheter is too small to fit into the suction tubing.



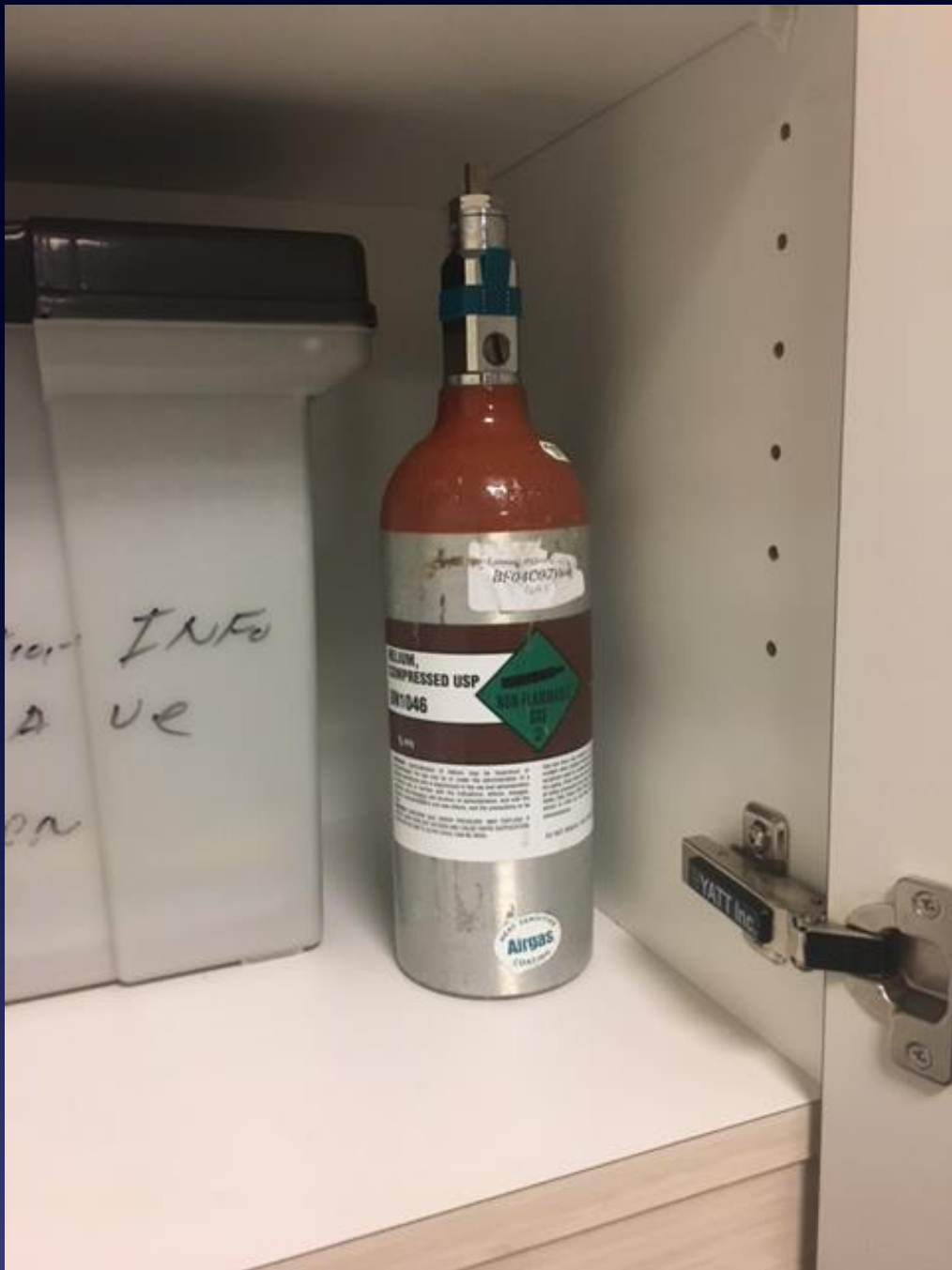








Properly stored medical gases



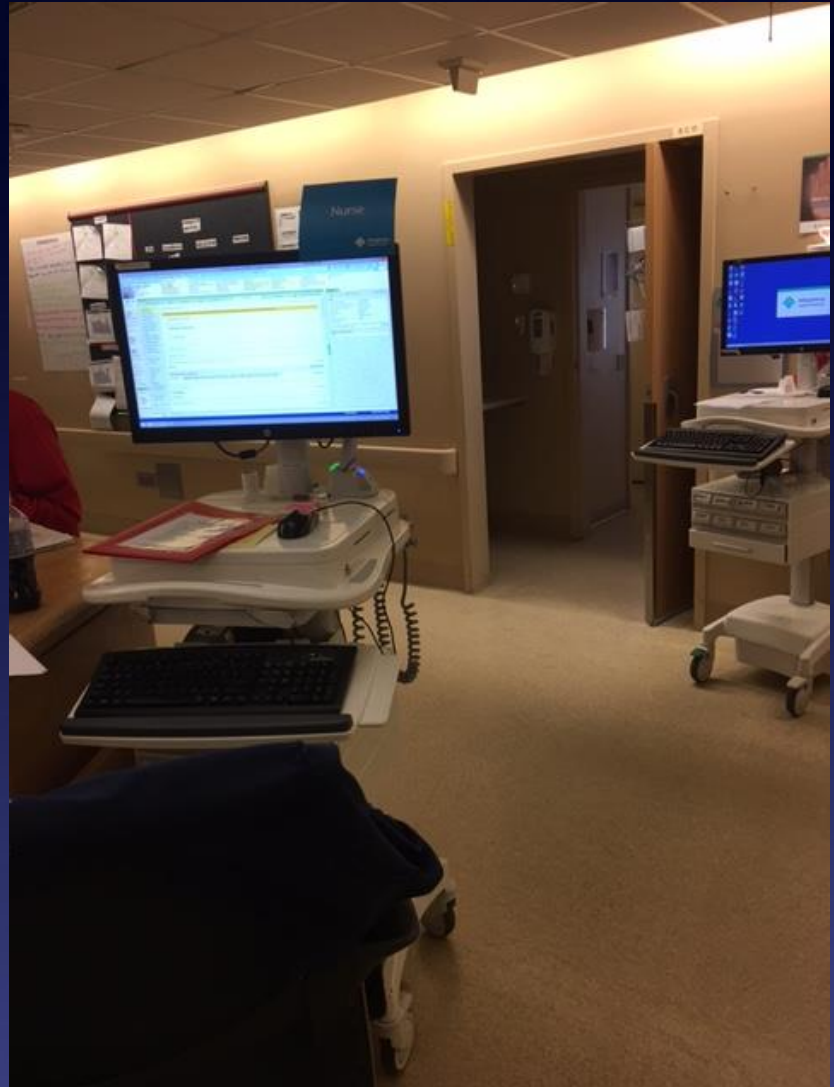
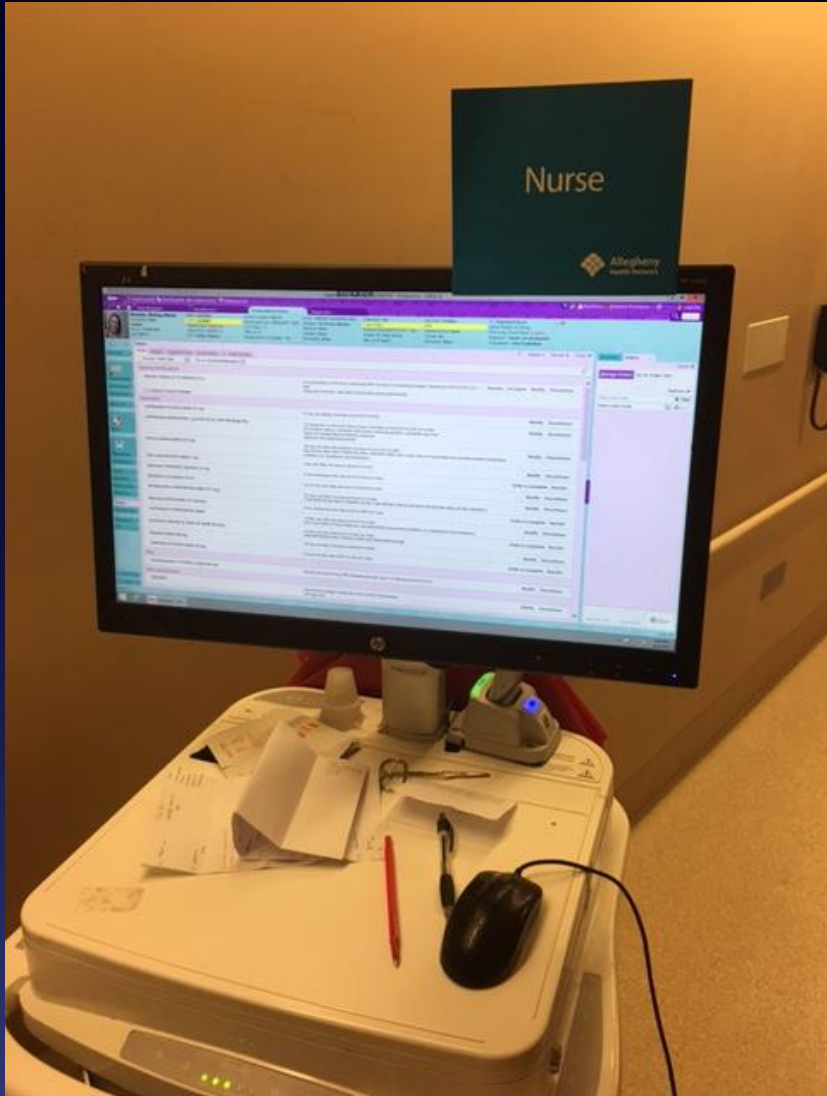


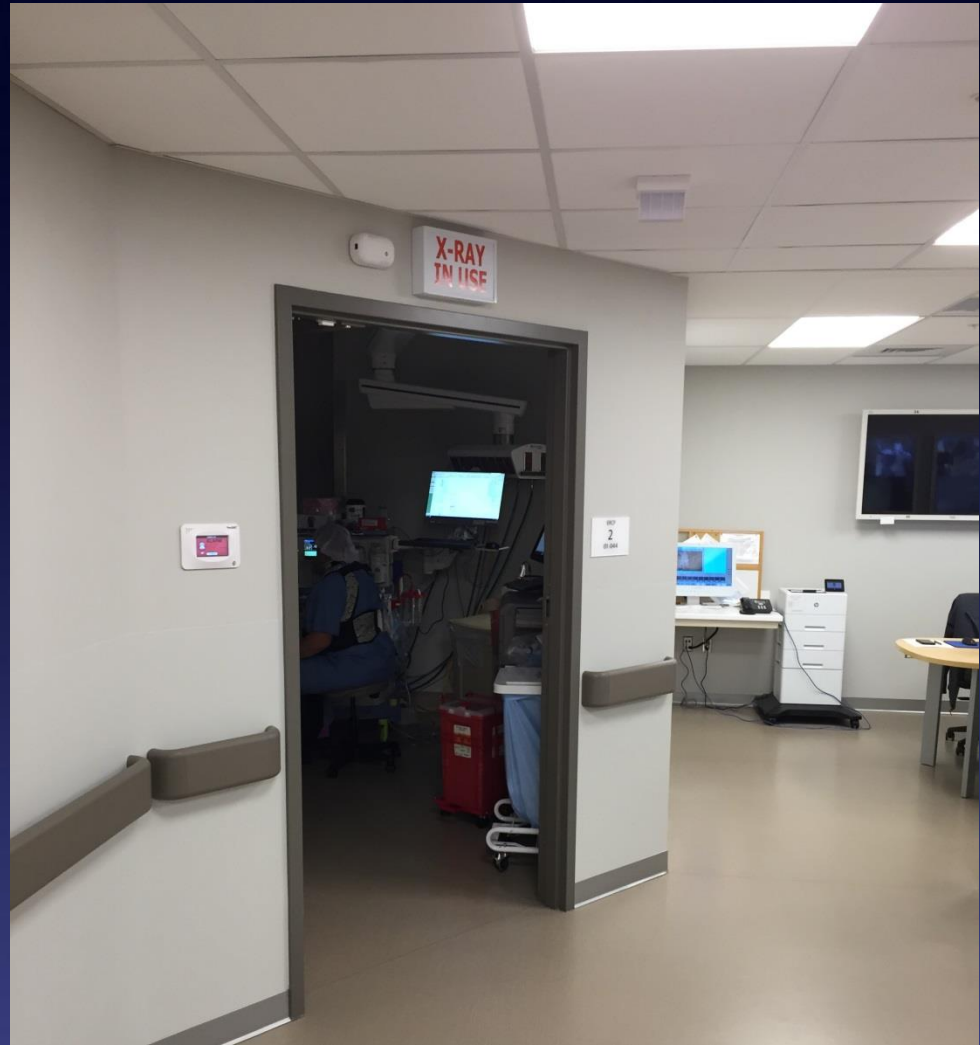






Privacy



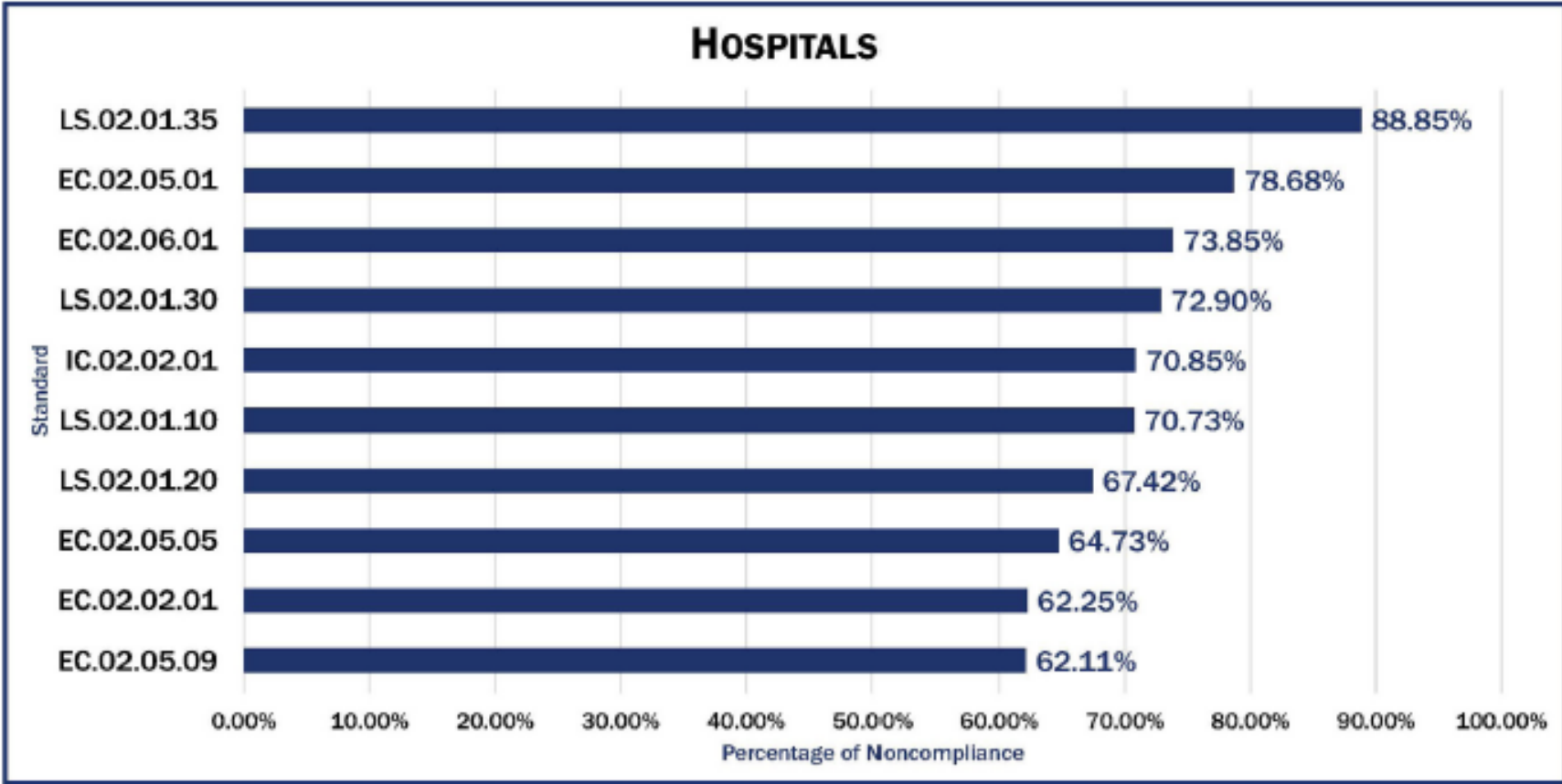




Survey Analysis for Evaluating Risk (SAFER) Matrix

		<i>IMMEDIATE THREAT TO LIFE</i>		
		LIMITED	PATTERN	WIDESPREAD
Likelihood to Harm a Patient/Visitor/Staff	HIGH	Red	Red	Red
	MODERATE	Yellow-Orange	Orange	Orange
	LOW	Yellow	Orange	Orange

Most Common TJC Findings 2018



Note: The data included for the hospital program were derived from an average of 1,460 applicable surveys.

The Joint Commission

Standard	EP	SAFER™ Placement	EP Text	Observation
LS.02.01.35	14	Moderate Limited	The hospital meets all other Life Safety Code automatic extinguishing requirements related to NFPA 101-2012: 18/19.3.5.	<div data-bbox="1226 207 1555 349" style="border: 1px solid black; width: 170px; height: 100px;"></div> <div data-bbox="1555 207 1864 321" style="border: 1px solid black; width: 160px; height: 80px;"></div> <p>as observed that the lead apron rack obstructed access to the fire hose. This was validated by the manager. This finding was observed during survey activity, but corrected onsite prior to the surveyor's departure. The corrective action taken needs to be included in the organization's Evidence of Standards Compliance submission</p>

EC.02.05.01	15	Moderate Limited	<p>In critical care areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, temperature and humidity.</p> <p>Note: For more information about areas designed for control of airborne contaminants, the basis for design compliance is the Guidelines for Design and Construction of Health Care Facilities, based on the edition used at the time of design (if available).</p>	<div data-bbox="1255 771 1584 921" style="border: 1px solid black; width: 170px; height: 105px;"></div> <div data-bbox="1584 771 1864 892" style="border: 1px solid black; width: 145px; height: 85px;"></div> <p>... the air in a sterile storage room area, adjacent to an elevator machine room, in Central Sterile Processing was negatively pressurized with respect to the adjacent machine room.</p>
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IC.02.01.01	1	Moderate Limited	The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.	<p>in electrophysiology lab, six blankets were observed on top of linen cart uncovered and exposed. The Director of Cardiac Cath validated this observation.</p>
				<p>in the SICU, the ice machine tray was visibly dirty. Staff confirmed the drain was blocked and was scheduled for repair.</p>
				<p>with the Ultrasound Technician, she stated that once the transvaginal ultrasound's completed, the plastic covering which may have body fluids or blood is</p>
				<p>removed from the probe and discarded in the trash can in the room. The discarding of the plastic covering in the trash can continues to the end of the day when all transvaginal procedures have been performed. At the end of the day, the contents in the trash can are transported/placed in the red biohazard trash can. At the time of the survey, there was not a biohazard receptacle in the Ultrasound Procedure Room for the disposal of items with body fluids or blood. The Manager and Vice President of Operations confirmed the observation.</p>
				<p>accumulated at two locations on horizontal gantry surfaces in an operating room.</p>
				<p>dispenser port in the GI lab was unclean. This deficiency was corrected immediately.</p>

<p>IC.02.02.01</p>	<p>2</p>	<p>High Widespread</p>	<p>The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 4) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/#r3 (Sterilization and Disinfection in Healthcare Settings).</p>	<p>...by observing... Endoscopy reprocessing area, it was observed that several errors were made in the use of the Acecide test strips, as follows: 1)the strips are good for 90 days after opening, but the expiration day was marked on the vial of strips as 10/3, 3 months, rather than 10/1. 2) the dilution to make the negative controls was to be a 1:1 dilution. The acecide and water to make this dilution was "eyeballed" in a dixie cup with no gradations, not measured. 3) the test strip IFU states that 3 strips each were to be tested for both positive and negative controls. Per the Endo tech, and as documented, only one test strip each was tested for the positive and negative control when a new vial was opened.</p>
				<p>...by observing... Center, it was observed that the chemical indicators in use for the Tropon machine expired 9/9/17, which is over 2 years ago.</p>
				<p>...site. A sterilized tray of surgical instruments was found in storage in Central Sterile Processing in the Ambulatory Surgery Center weighed more than 28 pounds. The manufacturer's instructions for use for the wrap indicated the maximum recommended weight for wrapped instrument tray was 25 pounds. The department did not have a scale to measure the weight of instrument trays.</p>
				<p>...site. The Central Sterile Processing Department in the Ambulatory Surgery Center used metricide OPA for high level disinfection. The personnel did not perform quality control on the test strips used for quality control on the disinfectant as outlined in the manufacturer's instructions for use for the test strips.</p>

High Likelihood to harm Patient/Staff/Visitor



MOCK SURVEY: 5/18-5/19/2017

- Pressure not maintained in the procedure rooms in the GI Lab (doors open during procedures)
- 2 OR doors in ASC does not close; performed cardiac cath with door open
- Excessive/improper storage in the OR; corridors/OR doors blocked
- ED Fast Track: only 1 point of egress
- Waste water leak in EP Lab 4; stained ceiling tile in EP Lab 1

- Anesthesia syringes not labeled, labels not complete, empty syringe labeled

- Unsecured high risk medications, esp Anesthesia
- Medical gas storage: not secure; excessive #'s; industrial grade
- T&H not controlled in the OR rooms
- Process for cleaning surgical instruments

Limited

Pattern

Widespread

Moderate Likelihood to harm Patient/Staff/Visitor



- High risk fall prevention interventions not in place
- No hand hygiene (physicians)
- Multi-use of single-use pill cutters
- Duplicate therapy, narcotics

- Family interpreting
- Mixed O2: full and empty
- Noncompliance with rag/bag/tag
- Staff unable to describe fire evacuation process
- Exposed hair/dangling earrings in the OR
- From pt room to soiled room: not transporting instruments in rigid container, no biohazard label
- Not following MD pain med orders

- Smoke wall penetrations
- Storage in exit corridors
- Procedural sedation orders include ranges
- Crash carts not locked, missing checks

Limited

Pattern

Widespread

Low Likelihood to harm Patient/Staff/Visitor



- Lock broken (anesthesia cupboard)
- WOW drawers not secure
- Med fridges not checked/secure, temps out of range
- Med room messy
- IV fluid in warmer w/o date & temp high
- Stretcher blocking fire pull station
- Blanket warmers: logs incomplete
- Supply carts w/o solid bottoms
- MD's in GI Lab w/o face shields, food mixed with patient care supplies
- Storage w/in 18" of sprinkler head
- Contrast not stored per MIU
- Using white out on logs
- Horizontal storage of lead aprons
- INA not complete
- Furniture with torn covers
- Not documenting review of allergies pre-procedure (non-invasive); incomplete allergy history on an inpatient
- Molasses in unlabeled containers
- Laundry on the floor
- Suction machine w/o PM
- Stat lab not meeting TATs
- Using wrong indication for non-violent restraint .
Selecting avoid self harm instead of interference with medical treatment
- Soiled utility room with neutral pressure
- No SAFE HAVEN signage

- Outside shipping containers
- Food not labeled/dated, missing fridge temps
- IV bags spiked in advance & other issues with IV fluid (OR)
- Missing initial pain assessment; pain not reassessed
- E/C issues in the OR
- Beverages in NS, on WOWs
- Staff using tape and ace wraps to repair equipment
- Delayed egress doors w/o signage
- Trash on the floor
- Cork boards
- Disinfectant wipes lids open
- Rusty equipment (IV poles)

- EOC: cleanliness issues/ dust, walls dinged and marred
- Door issues, broken
- Paper sings and tape
- BR cords too short/long
- Nourishment rooms dirty
- Exposed PHI
- Uncovered linen
- NCPs: goals w/o dates, not individualized, not updated, not applied to patient care, task list not used
- Supplies on the floor
- Clean supply rooms messy
- Computer drop downs do not automatically retract
- Expired supplies & meds
- Soiled rooms not secure
- Sharps not secure
- Storage under sinks

Limited

Pattern

Widespread



sample joint commission tracers



All



Images



News



Shopping



Videos



More

Settings

Tools

About 1,430,000 results (0.40 seconds)

[PDF] Tracer Methodology - The Joint Commission

[https://www.jointcommission.org › assets › Joint_Commission_Mock_Trac...](https://www.jointcommission.org/assets/Joint_Commission_Mock_Trac...) ▼

-Samples from all programs/services operated by organization. -Surveyors attempt to minimize disruptions to the organization. Tracer Methodology ...

[PDF] Conducting a Mock Tracer in your Health Center - The Joint ...

[https://www.jointcommission.org › assets › Mock_Survey_Presentation](https://www.jointcommission.org/assets/Mock_Survey_Presentation) ▼

Lynette Munday, MD, Joint Commission. Clinical Surveyor ... improvement. Understanding the Tracer Methodology ... Patient Care Tracer Activity ... **Example.** Your mock “surveyor” meets with staff who manage the infection control program ...



Images for sample joint commission tracers



→ More images for sample joint commission tracers

Report images

Environmental Assess



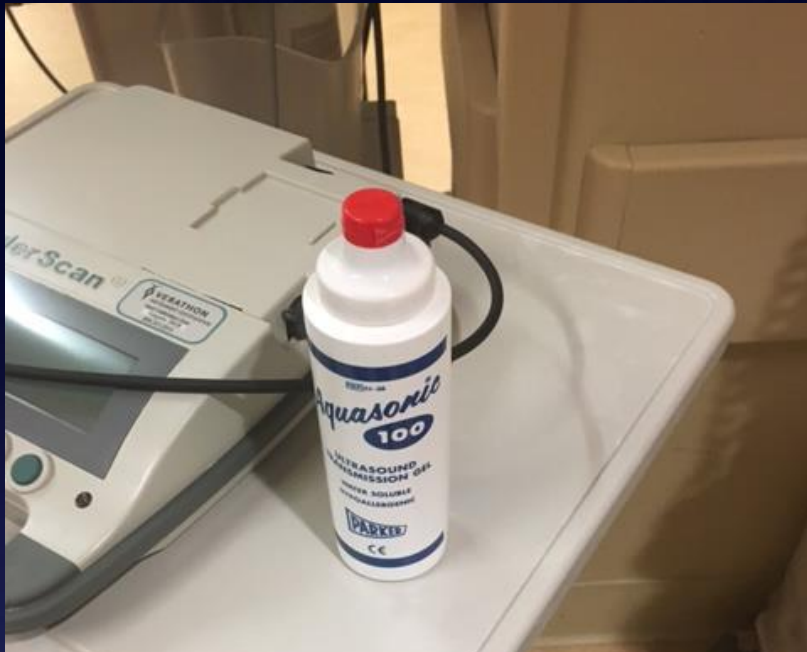
1						
2						
3	Y=yes, N=no, N/A=Not applicable					
4	Assessment Area/Unit					
5	Crash cart checks complete / Defib plugged in	n	y	y	y	n
6	No pill residue in crusher	y	y	y	n	n
7	No Obstructed Fire hose, electrical /medical gas panels, doors blocked, codes on doors	n	n	y	n	n
8	Eyewash logs up to date			y	n	
9	RMW process adhered to; soiled Utility Rooms clean	n	y	y	y	n
10	Open electrodes dated with the date opened	n	n	n	n	n
11	O2 storage correct	y	y	n	n	y
12	Hallways Free from storage	n	n	n	n	n
13	Med fridge in range or appropriate action noted	n	n	n	y	y
14	Nutrition fridge in range as above	y	n	n	y	y
15	Patient food dated and ingested within 24 hours of date	n	y	y	y	y
16	Total Yes	30.0%	50.0%	54.5%	45.5%	40.0%

Next steps:



- Findings broken down into groupings:
 - Facilities
 - Procedural
 - Patient Care
 - EVS/IP
 - HR/Credentialing
 - Life Safety
- Weekly meetings with senior leadership
- Tracers by units and Safety/Regulatory teams
- EOC tracers
- Data back to the owners.....

TJC TIPS



Make sure to date any multi-patient use items when you open them! This includes:

- Aquasonic gel
- Surgilube
- Rubbing alcohol
- Hydrogen Peroxide



TJC TIPS



**Remember to
keep exit
hallways clear!**

TJC Tips



No original packing boxes in unit or department storerooms!



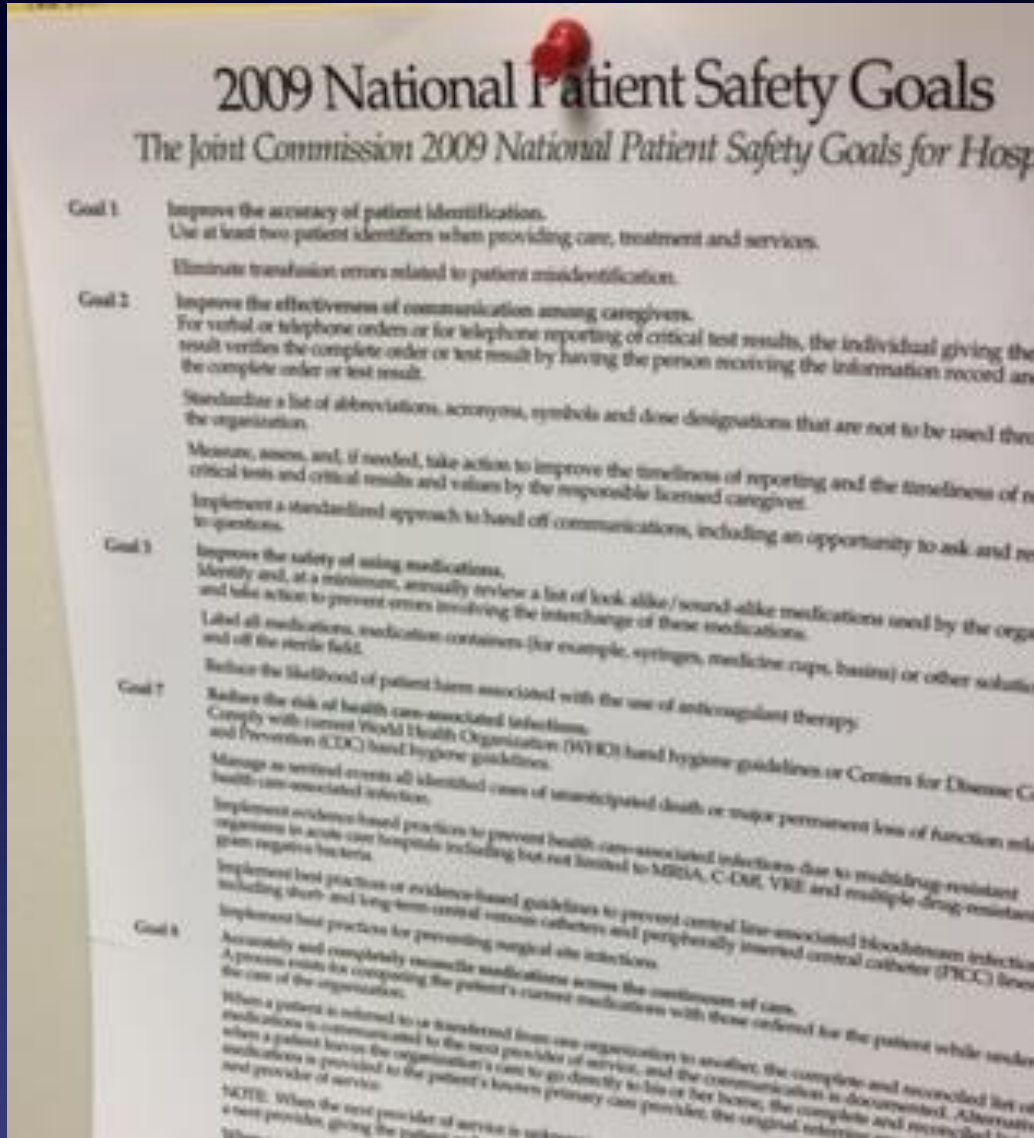
TJC Tips



**Don't block
oxygen shut off
valves or fire
extinguishers!**



TJC Tips



Make sure
your
references
are current!!

TJC Tips



Year: Oct. 2017

24		25		26		27		28		29	
3	7	3	7	3	7	3	7	3	7	3	7
pm	am	pm	am	pm	am	pm	am	pm	am	pm	am
IF TEMPERATURE IS IN WHITE SECTION*											
X	X	X			X	X					
			X	X							
TEMPERATURE IS IN WHITE SECTIC											

**Make sure
temperature
logs are
accurate!**

TJC Tips



Red bin
trash or
Regular
waste?



Environment of Care

The Environment of Care standards are intended to promote a safe, functional and supportive environment within the hospital so that quality and safety are preserved. Environment of Care includes three basic elements: the building or space, equipment used, and people. This chapter stresses the importance of managing risks in the environment: safety and security, fire, hazardous material and waste, medical equipment, and utility systems.

Key Provisions

- **Safety and Security:** Product recalls, access to security-sensitive areas, smoking, risks in the physical environment
- **Hazardous Material and Waste:** Hazardous chemicals, radioactive materials, gases and vapors, energy sources
- **Fire Safety:** Risks from fire and smoking, other products of combustion, fire response plans and drills, fire detection alarms and suppression equipment
- **Medical Equipment:** Selection, testing, maintenance, contingency when equipment fails
- **Utilities:** Inspection and testing of operating components, control of airborne contaminants, management of disruptions



Best Practices

- All dirty instruments must be transported in covered, red containers labeled **BIOHAZARD**
- Electrical panels, fire extinguishers, fire pull stations must be accessible and not blocked with equipment
- NO items are ever to be stored in or obstructing stairwell exits
- Only full, unopened oxygen tanks are to be stored in the tank labeled **FULL**
- Oxygen cylinders and tanks must be secured at all times
- Aseptic control, clean in patient care areas, cleaning agents, barriers of reusable critical supports, connected devices, barriers, nursing equipment, nursing units, etc.
- Freely accessible, daily use and maintenance must be completed
- The fire exit route must be clear of all equipment

Allegheny Health Services

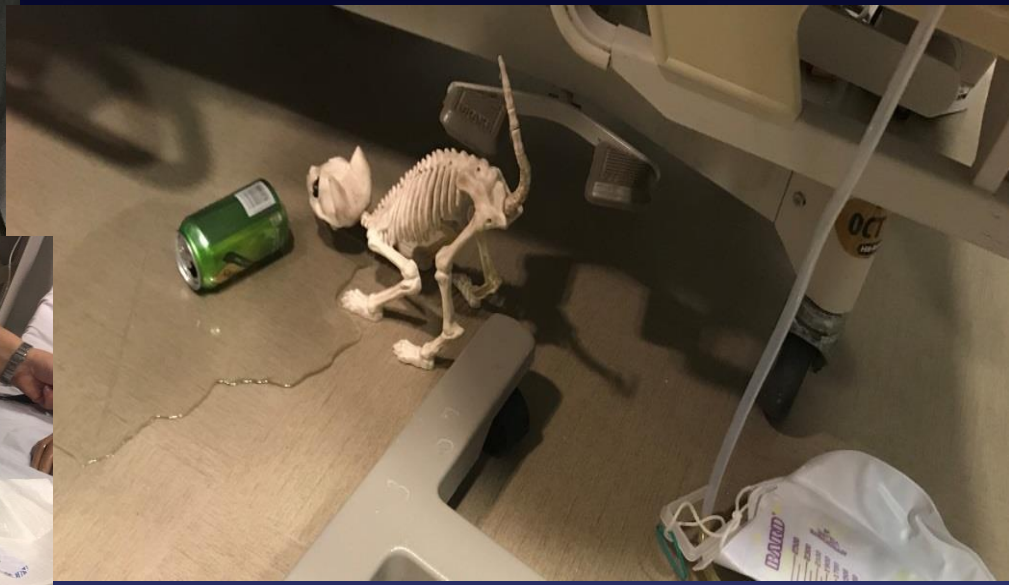


The Regulatory Fair





The Room of Horrors







???