

REGULATORY & ACCREDITING AGENCIES

OBJECTIVES

- ① Describe the differences between an accrediting agency and a regulatory agency
- ① Articulate the differences in standards, regulations, guidelines, and their impact on IC
- ① Discuss resources related to the different agencies' standards.

DEFINITIONS

◎REGULATORY:

A government organization that monitors compliance with rules, regulations, or standards. Non-compliance may result in fines or affect reimbursement.

◎ACCREDITING:

An external private sector organization which performs an evaluative process of a healthcare organization to ensure that it is meeting predetermined standards.

DEFINITIONS

◎ **STANDARDS** are performance expectations and/or structures or processes.

Examples: The Joint Commission, DNV

◎ **REGULATIONS** are official rules, and have to be followed.

Examples: CMS, OSHA, FDA, etc

◎ **GUIDELINES** are recommendations based on existing scientific data

Examples: CDC, HICPAC, etc.

ACCREDITING AGENCIES

- ① **The Joint Commission**
- ① **DNV- Det Norske Veritas**
- ① **American Osteopathic Association (AOA)**
- ① **College of American Pathologists (CAP)**
- ① **National Committee on Quality Assurance (NCQA)**
- ① **American Medical Accreditation Programs (AMAP)**
- ① **Commission on Accreditation of Rehabilitation Facilities (CARF)**

TJC STANDARDS

- ① **IC.01.01.01** The hospital identifies the individual(s) responsible for the infection prevention and control program.
- ① **IC.01.02.01** Hospital leaders allocate needed resources for infection prevention and control program.
- ① **IC.01.03.01** The hospital identifies risks for acquiring and transmitting infections.

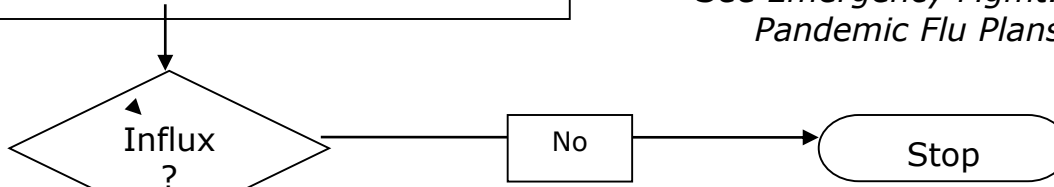
TJC STANDARDS

- ① **IC. 01.04.01** Based on the identified risks, the hospital sets goals to minimize the possibility of transmitting infections.
- ① **IC.01.05.01** The hospital has an infection prevention and control plan.
- ① **IC.01.06.01** The hospital prepares to respond to an influx of potentially infectious patients.

LMC INFLUX PLAN FLOWCHART

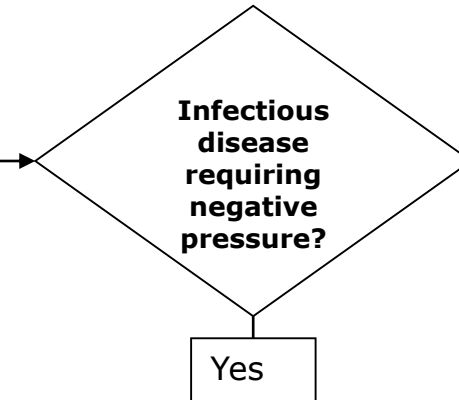
See Emergency Mgmt., Bioterrorism, &
Pandemic Flu Plans IC 7.105.1B

TRIAGE in ED: place mask on patient/provide tissues/decontaminate if necessary



Yes

Patient Placement:
ER – 37 beds
Intake Unit – 10 beds
Prep Hold – 22 beds
PACU – 9 beds
Community Center: 200
minor/ambulating patients

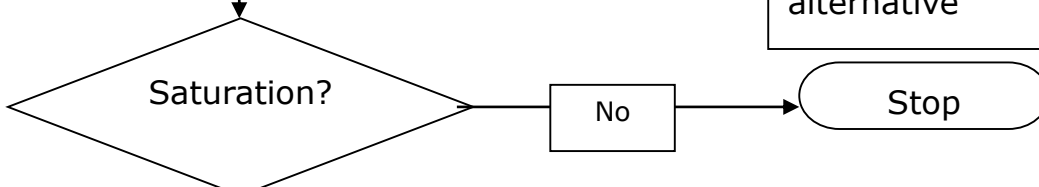


**Infectious
disease
requiring
negative
pressure?**

Yes

Place in Negative Pressure
Rooms: 31 beds (see list)
Nursing units for influx: ER,
ICU, Pediatrics, 2 C or
alternative

Activate Emergency
Operations Center – see
*Plans: EOC, Bioterrorism,
Pandemic Flu*



Saturation?

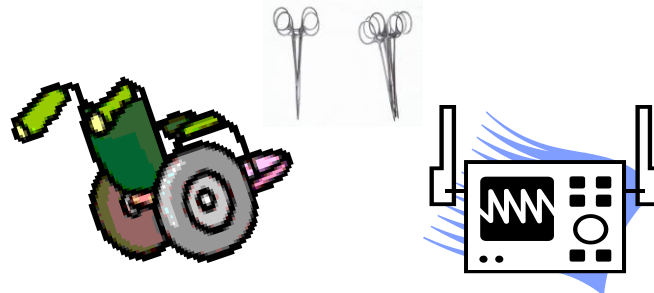
No

Stop

Notify:
City of Laredo Emergency Operation Center
Medical Operations Center (Health dept.)

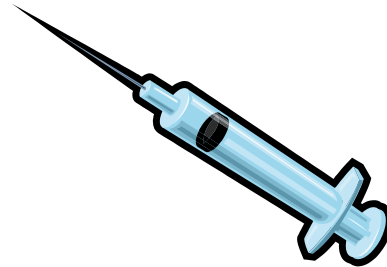
TJC STANDARDS

- **IC.02.01.01** The hospital implements its infection prevention and control plan.
- **IC.02.02.01** The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.



TJC STANDARDS

- **IC.02.03.01** The hospital works to prevent the transmission of infectious disease among patients, LIPs, and staff.
- **IC.02.04.01** The hospital offers vaccination against influenza to LIPs and staff.



TJC STANDARDS

- ① **IC.03.01.01 The hospital evaluates the effectiveness of its infection prevention and control plan.**

NATIONAL PATIENT SAFETY

GOAL (NPSG) -7



- ⦿ **NPSG.07.01.01** Comply with either the current CDC hand hygiene guidelines or the current WHO hand hygiene guidelines.
- ⦿ **NPSG.07.03.01** Implement evidence-based practices to prevent HAIs due to infections that are difficult to treat.
- ⦿ **NPSG.07.04.01** Implement evidence-based practices to prevent CLABSI.
- ⦿ **NPSG.07.05.01** Implement evidence-based practices for preventing SSI.
- ⦿ **NPSG.07.06.01** Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).

DNV

- IC.1
 - SR 1- The organization shall have a process in place, as required and/or recommended by CDC and related professional organizations, to maintain a sanitary environment for organization patients, staff and other. This process shall provide the means for avoiding and transmitting infections and communicable diseases

DNV

- IC.1
 - SR 2-The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization

DNV

- IC.1
 - SR 3- The Infection Prevention and Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight group.

DNV

- IC.1
 - SR 4- The documented process shall define the following:
 - SR 4a- A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The designated infection control officer or officers shall have the appropriate qualification and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases.

DNV

- IC.1
 - SR 4
 - SR 4b- Any designated practitioner shall complete a course in basic surveillance by a recognized body or show evidence that they have supervision by a qualified infection control practitioner. If in the roll five years or longer there must be evidence of pertinent continuing education related to infection control, minimally every two years.
 - SR 4c- The infection control officer or officers must develop a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel

DNV

- IC.1
 - SR 4
 - SR 4d- The maintaining and control of records to account for incidents related to infections and communicable diseases

DNV

- IC.1
 - SR 5- Infection and communicable diseases shall be measured and analyzed to identify any patterns or trends.
 - SR6- The organization, through its CEO, Medical Staff and Nurse executive shall ensure that the Infection Control System and associated activities adequately address issues identified throughout the organization and there are prevention, correction, improvement and training programs to address these issues and provide adequate resources to accomplish the associated activities of the infection control program.

DNV

- IC.1
 - SR 7- Significant infection control data/information shall be disseminated no less than quarterly to the organization oversight group responsible for the infection control function
 - SR 8- Surveillance methodology shall be appropriated for the population served and approved no less than annually by the Infection Control Oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illness

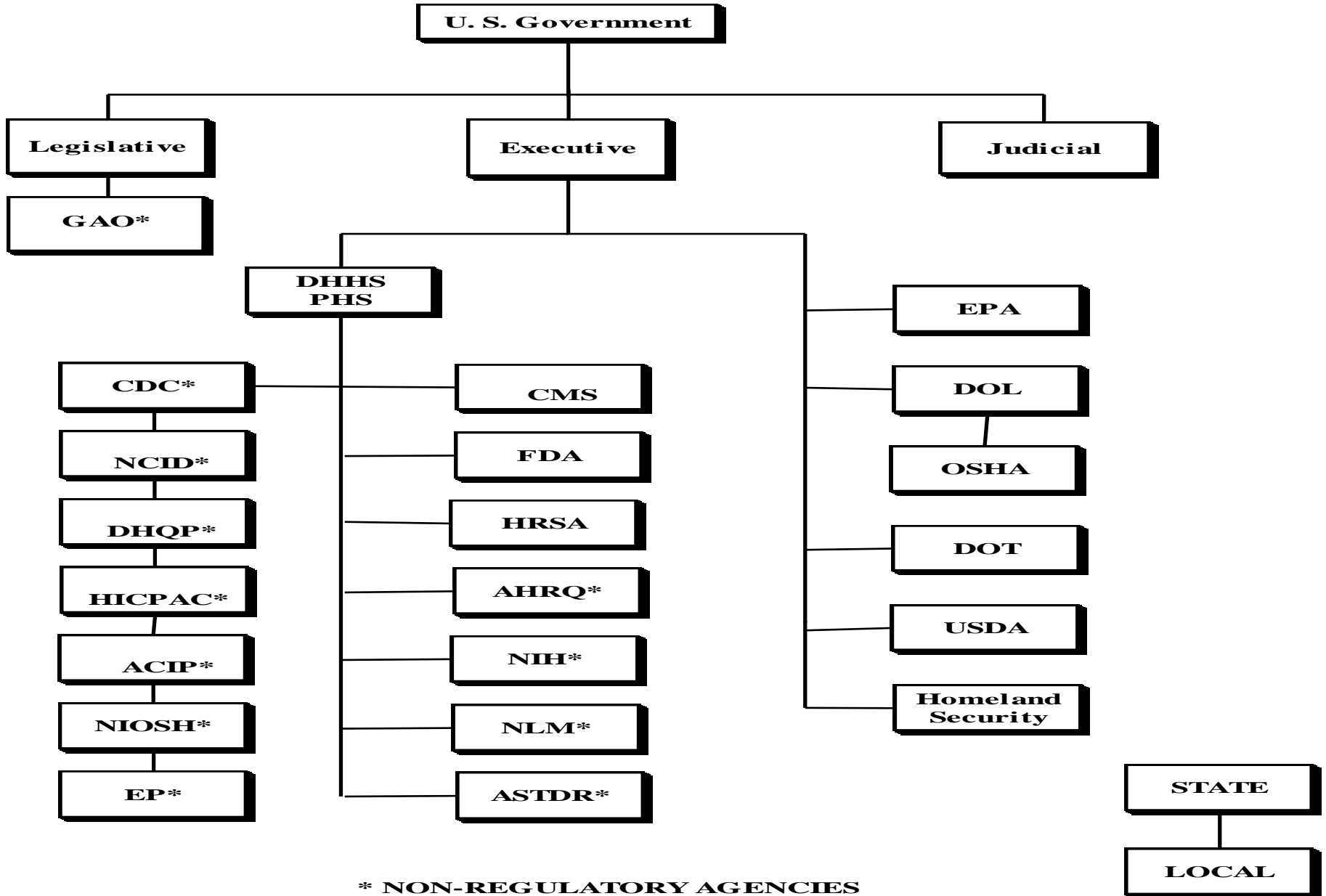
FEDERAL AGENCIES

- **Agencies are extensions of the legislative, executive, & judicial branches**
- **Most agencies impacting infection control programs emanate from the executive branch**



GOVERNMENT AGENCIES

Affecting Infection Control



* NON-REGULATORY AGENCIES

CENTERS FOR MEDICARE & MEDICAID

◎ CMS

- **Construction codes and standards for physical plant: *2010 Guidelines for Design & Construction of Hospital & Health Care Facilities***
 - American Institute of Architects & Academy of Architecture for Health/Facilities Guideline Institute
- **Medicare Quality Improvement Organizations**
 - Services are medically necessary & appropriate
 - Meet recognized standards of care
- **Clinical Laboratory Improvement Act (CLIA 88, 42 CFR 493)**

CONDITIONS OF PARTICIPATION FOR IC

§482.42(a) Standard: Organization and Policies

A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

See the following websites:

- IC Interpretive Guidelines (pgs. 279-291)

http://www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf

- Assessing Hospital Compliance for Infection Control

https://www.cms.gov/Surveycertificationgeninfo/downloads/SCLetter12_01.pdf

CMS

§482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

§482.42(a)(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

FOOD & DRUG ADMINISTRATION

⊙ **FDA:** drugs, biologics, food, blood & blood products, medical & radiological devices, antimicrobial products, chemical germicides used in conjunction with medical devices.

- **Chemicals:**

- ⊙ **FDA, EPA, OSHA overlapping jurisdictions for chemicals**

- FDA regulates sterilants and high-level disinfectants used on medical devices which require 510 (k) process
 - Regulates chemical germicides formulated as antiseptics, preservatives or drugs used on or in the human body

- **Blood Safety standards**

- **Medical Device Act (1974)**

- **Safe Medical Device Act (SMDA) of 1990**

ENVIRONMENTAL PROTECTION AGENCY

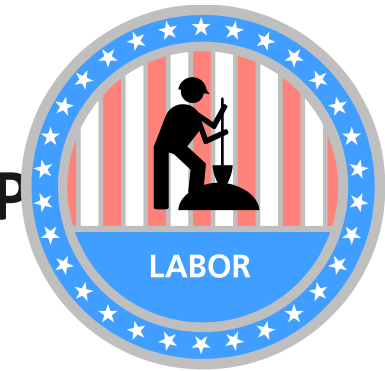
⊙ EPA independent regulatory agency

- Regulation & registration of chemical germicides part of the Federal Insecticide Fungicide & Rodenticide Act (FIFRA)
- EPA & FDA interagency agreement for testing
- Resource Conservation & Recovery Act (RCRA) 1976 – mgmt. of solid waste including regulated medical waste
- Incinerators & Medical Waste – emissions control & ash disposal



DEPARTMENT OF LABOR

- **Occupational Health & Safety (OSHA)**
- **1970 General Duty Clause**
- **Standards & compliance documents (CFR)**
 - Code of Federal Regulations (CFR)
- **Compliance Inspection**
- **Occupational illness/injury logs**



<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

OSHA contd.

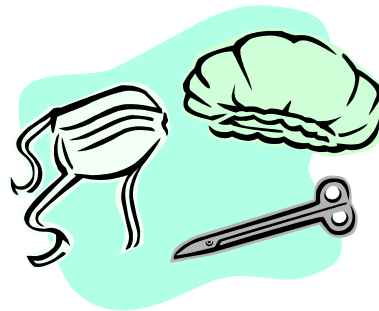
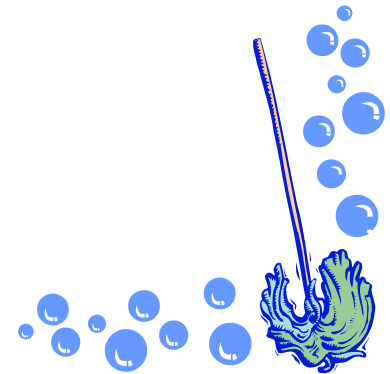
- **29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Final Rule; effective March 6, 1992.**
- **CPL 2-2.44D. Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens; effective November 5, 1999.**
- **29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Needle stick and Other Sharps Injuries; Final Rule. Amended and effective April 18, 2001. * *Includes additional definitions & examples on engineering controls (safety devices)* 29 CFR Part 1910.1035.**
- **Occupational Exposure to Tuberculosis; Proposed Rule; October 17, 1997. * *OSHA withdrew proposal, but see CDC 2005 TB guidelines***

1. **Definitions**
2. **Exposure Control Plan (ECP)**
3. **Engineering & Work Practice Controls
- Personal Protective Equipment (PPE)**
4. **HIV & HBV Research Labs**
5. **Vaccination, Post-Exposure Follow-up**
6. **Labeling & Training**
7. **Record Keeping**
8. **Education**



METHODS OF COMPLIANCE

- **Universal Precautions**
- **Engineering Controls**
 - Sharps with engineered sharp injury protection
 - Needleless systems
- **Work Practice Controls**
 - No-hands procedures for handling sharps
 - Eliminating hand-to-hand instrument passing
- **Personal Protective Equipment**
 - <http://www.cdc.gov/ncidod/dhqp/pdf/ppe/PPEslides6-29-04.ppt>
- **Housekeeping**



NEEDLESTICK SAFETY & PREVENTION ACT

⊙ **29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; Needle stick and Other Sharps Injuries; Final Rule. Amended and effective April 18, 2001.**

- *Includes additional definitions & examples on engineering controls (safety devices)*

REQUIREMENTS

⦿ Implement safer medical devices

- Evaluate annually with input from front line HCWs
 - Listing of employees involved in the evaluations requested; or
 - Minutes of meetings, documents used to request employee participation, or records of responses received from employees

⦿ Engineering Controls - control measures that isolate or remove a hazard from the workplace

- sharps disposal containers
- sharps with engineered sharps injury protections
- needleless systems

NOTE: CHECK YOUR RESPECTIVE STATE'S REQUIREMENTS

List of Registered Needleless Systems and Sharps Devices with Engineered Sharps Injury Protection in Texas

<http://www.tdh.state.tx.us>

OSHA and TB Compliance

- **29 CFR Part 1910.134 Respiratory Protection Standard: July 2, 2004**
 - **Approved respirators**
 - **NIOSH approved N-95 or higher particulate respirators**
 - **Half- or full-face elastomeric respirators**
 - **Powered air purifying respirators (PAPR)**
 - **Medical Evaluation before fit test**
 - **Fit test on hire and annually**



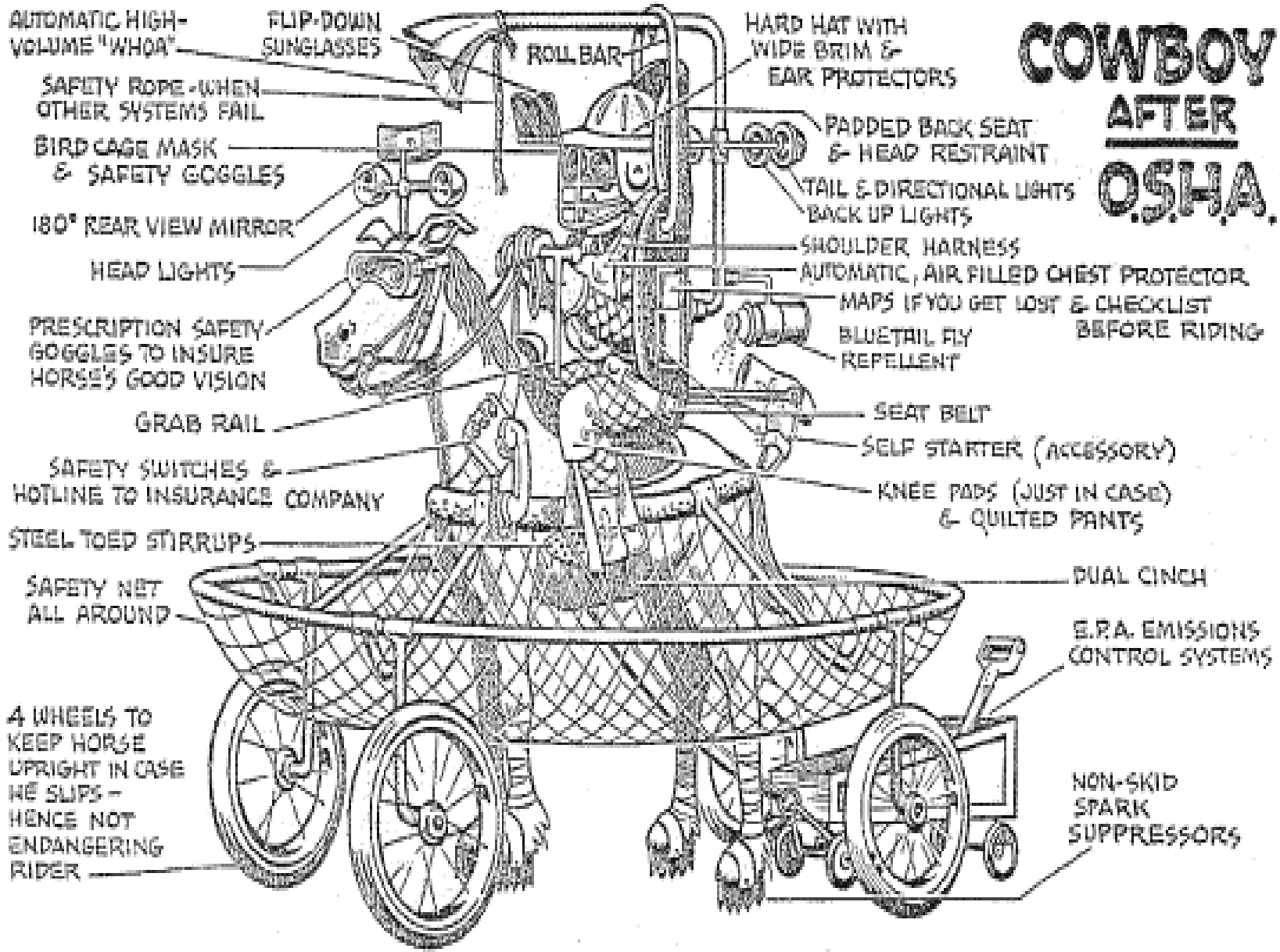
OSHA contd.

- ⦿ **29 CFR Part 1910.132 Personal Protective Equipment**
- ⦿ **29 CFR Part 1910.1200 Hazard Communication**
- ⦿ **29 CFR Part 1910.148 Formaldehyde**
- ⦿ **29 CFR Part 1910.19 Indoor Air Quality**

OSHA ANNUAL REQUIREMENTS

- ⦿ Review your Bloodborne Pathogen Plan
- ⦿ Review/Revise your Exposure Determination List
- ⦿ Safer medical devices
- ⦿ Education on TB & Bloodborne Pathogens
- ⦿ Respiratory program
- ⦿ Sharps safety program





COWBOY AFTER OSHA.

AUTOMATIC HIGH-VOLUME "WHOA"

FLIP-DOWN SUNGLASSES

ROLL BAR

HARD HAT WITH WIDE BRIM & EAR PROTECTORS

SAFETY ROPE - WHEN OTHER SYSTEMS FAIL

PADDED BACK SEAT & HEAD RESTRAINT

BIRD CAGE MASK & SAFETY GOGGLES

TAIL & DIRECTIONAL LIGHTS
BACK UP LIGHTS

180° REAR VIEW MIRROR

HEAD LIGHTS

SHOULDER HARNESS

PRESCRIPTION SAFETY GOGGLES TO INSURE HORSE'S GOOD VISION

AUTOMATIC, AIR FILLED CHEST PROTECTOR

MAPS IF YOU GET LOST & CHECKLIST BEFORE RIDING

GRAB RAIL

BLUETAIL FLY REPELLENT

SAFETY SWITCHES & HOTLINE TO INSURANCE COMPANY

SEAT BELT

SELF STARTER (ACCESSORY)

STEEL TOED STIRRUPS

KNEE PADS (JUST IN CASE) & QUILTED PANTS

SAFETY NET ALL AROUND

DUAL CINCH

E.P.A. EMISSIONS CONTROL SYSTEMS

4 WHEELS TO KEEP HORSE UPRIGHT IN CASE HE SLIPS - HENCE NOT ENDANGERING RIDER

NON-SKID SPARK SUPPRESSORS

STATE & LOCAL

STATES

- ⊙ **Dept. of Public or Community Health**
- ⊙ **Agencies for Health Care Facility Enforcement**
- ⊙ **Agencies for Enforcement of Medical Waste Programs**
- ⊙ **State Plans for OSHA & Labor Dept.**

LOCAL

- ⊙ **Local Health Departments**
- ⊙ **Fire Marshall; Water Jurisdiction**

PUBLIC HEALTH SERVICES

- ◎ **Centers for Disease Control & Prevention (CDC)***
- ◎ **National Center for Infectious Diseases (NCID) ***
- ◎ **Division of Healthcare Quality Promotion (DHQP) ***
- ◎ **Healthcare Infection Control Practices Advisory Committee (HICPAC) – 1991 ***

PUBLIC HEALTH SERVICES

- ◎ **Advisory Committee On
immunization Practices (ACIP) – 1974

- ◎ **National Institute for Occupational
Safety and Health (NIOSH) – 1970 ***
- ◎ **Public Health Emergency
Preparedness and Response ***
- ◎ **Health Resources and Services
Administration (HRSA)**

PUBLIC HEALTH SERVICES

- ◎ **Agency for Healthcare Research & Quality (AHRQ)***
- ◎ **National Institutes of Health (NIH)***
- ◎ **National Library of Medicine (NLM)***
- ◎ **Agency for Toxic Substances and Disease Registry (ATSDR)***
- ◎ **Dept. of Transportation (DOT)**
- ◎ **Department of Agriculture**

OTHER AGENCIES

- ⦿ **Institute for Healthcare Improvement (IHI)**
- ⦿ **American Institute of Architects/Academy of Architecture for Health/Facility Guidelines Institute (AIA/FGI)**
- ⦿ **American Nat'l Standards Institute (ANSI)**
- ⦿ **American Society of Heating, Refrigerating, & Air Conditioning Engineers (ASHRAE)**
- ⦿ **American Society of Healthcare Engineers (ASHE)**
- ⦿ **American Society of Hospital Pharmacists (ASHP)**
- ⦿ **Association for the Advancement of Medical Instrumentation (AAMI)**
- ⦿ **National Fire Protection Association (NFPA)**
- ⦿ **American Conference of Governmental Industrial Hygienists (ACGIH)**

QUESTIONS?

COUNTERTHINK

