



# 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, AAAHC*

◎ **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 (TJC)**
- ① **Accreditation Association for Ambulatory Health Care (AAAHC)**
- 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)**

# Joint Commission

- ① **IC.01.01.01** The organization identifies the individual(s) responsible for the infection prevention and control program.
- ① **IC.01.02.01** Organizational leaders allocate needed resources for infection prevention and control program.
- ① **IC.01.03.01** The organization identifies risks for acquiring and transmitting infections.
- ① **IC. 01.04.01** Based on the identified risks, the hospital sets goals to minimize the possibility of transmitting infections.

# Joint Commission

- ⦿ **IC.01.05.01** The organization has an infection prevention and control plan.
- ⦿ **IC.01.06.01** The organization prepares to respond to an influx of potentially infectious patients.
- ⦿ **IC.02.01.01** The organization implements its infection prevention and control plan.
- ⦿ **IC.02.02.01** The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

# Joint Commission

- ⦿ **IC.02.03.01** The organization works to prevent the transmission of infectious disease among patients, LIPs, and staff.
- ⦿ **IC.02.04.01** The organization offers vaccination against influenza to LIPs and staff.
- ⦿ **IC.03.01.01** The organization 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.07.05.01** Implement evidence-based practices for preventing SSI.



# AAAHC

## Chapter 7

- 7.1.A: Written program for infection prevention and control
- 7.1.B.1-3: Requirements for written infection prevention and control program
- 7.1.C.2: Documented evidence of the training and competence of the designated infection control and prevention
- 7.1.D.3: Written policy addressing the identification and processing of medical equipment and instruments that fail to meet high-level disinfection or sterilization parameters
- 7.1.D.5: Written process for monitoring and documenting cleaning, high-level disinfection, and sterilization
- 7.1.F: Written policies and procedures to protect against cross-infection

# AAAHC

- 7.I.G: Requirements for written policies addressing cleaning of patient treatment and care areas
- 7.I.H.3: Documented evidence of training and competencies of staff responsible for cleaning devices for use with multiple patients
- 7.II.G.2: Documentation that temperature monitoring occurs
- 7.II.H.1: Documentation that reprocessing single-use devices have been approved for reprocessing
- 7.II.H.2: Documentation that third-party reprocessor is FDA-registered
- 7.II.H.3: If reprocessing is done in-house, documentation that organization is FDA-registered
- 7.II.L.2: Written exposure control plan

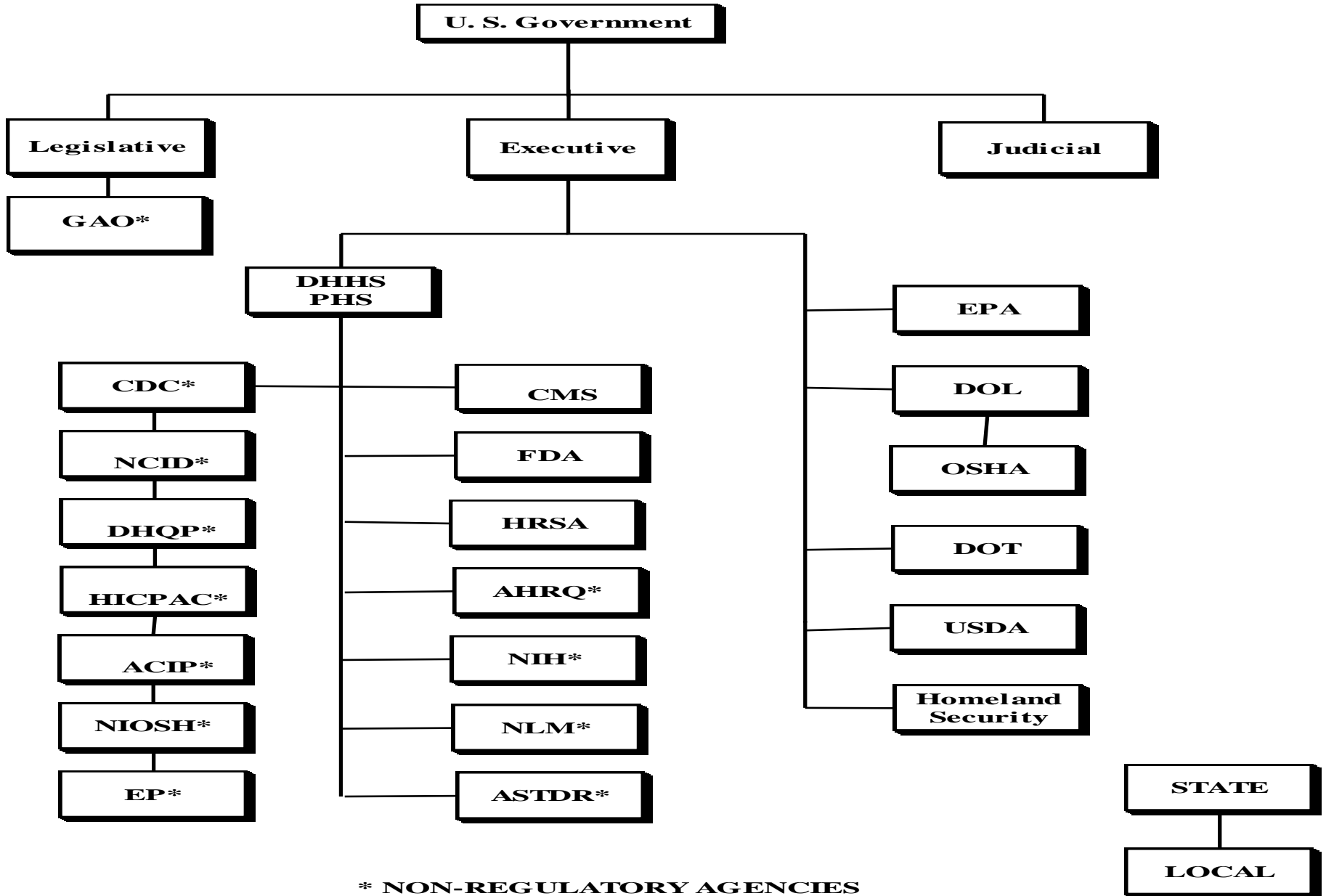
# FEDERAL AGENCIES

- **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



# Centers for Medicare & Medicaid Services (CMS) Condition for Coverage

**§416.51 – Infection Control:** The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases

Must contain:

- ✓ Provide a functional and sanitary environment for surgical services
- ✓ Be based on national recognized infection control guidelines
- ✓ Be directed by a designated health care professional with training in infection control
- ✓ Be integrated into the ASC's QAPI program
- ✓ Be ongoing
- ✓ Includes actions to prevent, identify and manage infections and communicable diseases
- ✓ Include mechanisms to immediately implement corrective actions and preventive measures that improve the control of infections within the ASC

# 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

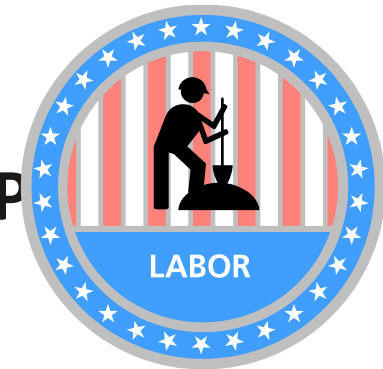
- Regulation & registration of chemical germicides part of the Federal Insecticide Fungicide & Rodenticide Act (FIFRA)
- EPA & FDA interagency agreement for testing
- Resource Conservation & Recovery Act (RCRA) 1976 – mgmt. of solid waste including regulated medical waste
- Incinerators & Medical Waste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



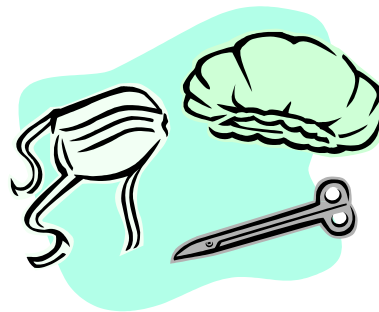
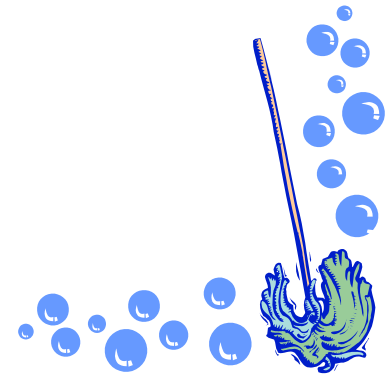
<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

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 1910.1030. 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***

# OSHA contd.

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

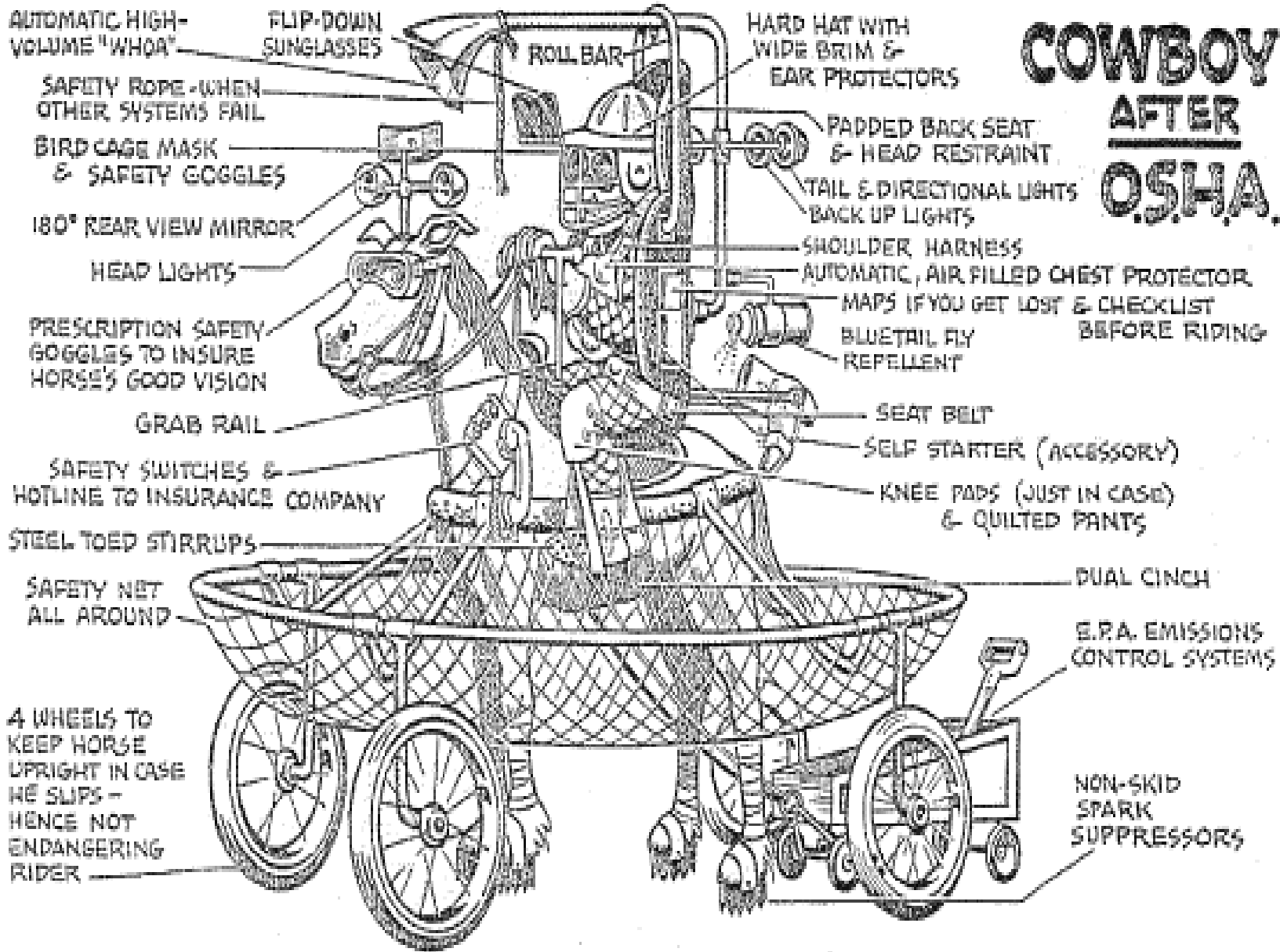


# OSHA ANNUAL REQUIREMENTS

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

AUTOMATIC, AIR FILLED CHEST PROTECTOR

PRESCRIPTION SAFETY GOGGLES TO INSURE HORSE'S GOOD VISION

MAPS IF YOU GET LOST & CHECKLIST BEFORE RIDING

BLUETAIL FLY REPELLENT

GRAB RAIL

SEAT BELT

SELF STARTER (ACCESSORY)

SAFETY SWITCHES & HOTLINE TO INSURANCE COMPANY

KNEE PADS (JUST IN CASE) & QUILTED PANTS

STEEL TOED STIRRUPS

DUAL CINCH

SAFETY NET ALL AROUND

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

