



▶ **Written Policies and Procedures**
Key Elements to a Comprehensive and Effective Clinical Compliance Program



▶ **Disclaimer:**

Employee of Midwest Dental who is supporting this presentation.



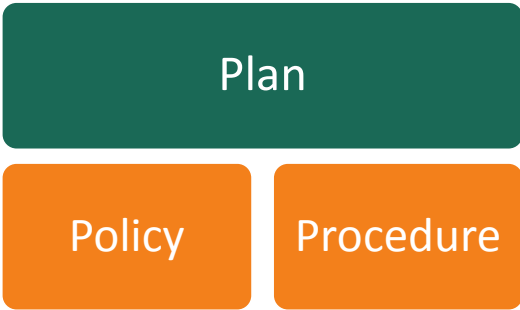
▶ **Objectives:**

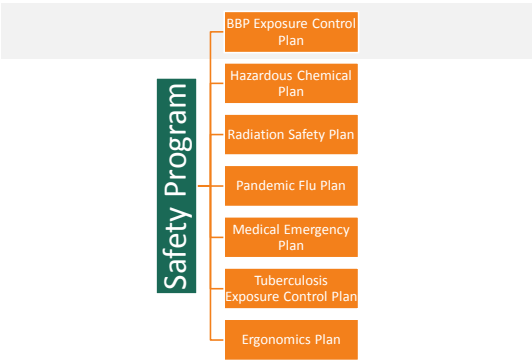
- Understand the key elements for developing a clinical compliance program
- Understand the importance of Standard Operating Procedures
- Recognize the essential components of a Standard Operating Procedure
- Recognize organizations and agencies that provide resources and guidance for clinical compliance



Plan vs. Policy vs Procedure

	Plans/Programs: overall strategy to achieve a specific result
	Policies: rules and regulations, guiding principal of an organization; a component of the plan
	Procedures: guide for action; a reflection of policy; a component of the plan





► Why have written plans, policies and procedures?

They provide

- Consistency
- Clarity
- Accountability



► Plans: Where do they come from?



State and local regulatory agencies



► OSHA®

Occupational Safety Health and Administration

- Employee focused
- Provides employee rights and responsibilities

- General Industry
 - Bloodborne Pathogens
 - Hazard Communications





Centers for Disease Control and Prevention

- Provides guidelines for the control and prevention of disease
- Guidelines and Guidance
 - Guidelines for Infection Control in Dental Health Care Settings – 2003
 - Guideline for Hand Hygiene in Health Care Settings
 - Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management
 - US Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis





Association for the Advancement of Medical Instrumentation

- Safe and effective healthcare technologies
 - Development
 - Management
 - Use
- ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities





Environmental Protection Agency

- Waste disposal
- Radiation protection





American National Standards Institute

- Dentistry Materials
- Rotary Dental Tools
- Dental Implants
- Dental Tools
 - Sterilizers
 - Sterilization of instruments

- Eye wash stations
- Protective eyewear



Food and Drug Administration

- Medical Devices
 - Instructions for use
 - Reprocessing instructions

- Products



▶ State and Local Regulatory Agencies

- State Dental Board
 - Infection control
 - Recordkeeping
 - Delegation
 - Sedation
- Health Department
 - Infectious disease guidance
- Environmental Protection/Natural Resources Dept
 - Waste disposal
 - Radiation protection
- State OSHA plan



▶ The Alphabet Soup of Clinical Compliance



State and local regulatory agencies



Horizontal lines for notes

▶ Policies

01 • Guide for thinking and action

04 • Provide a general approach

02 • Set by upper management

05 • Do not provide methods of doing work

03 • Directly related to goals

06 • Are the basis for procedures



Horizontal lines for notes

▶ Sample Policy

(Company Name) is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this goal, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."



Horizontal lines for notes

▶ Procedures

- 01 • Guide for action
- 02 • Follow policies
- 03 • Emphasis step-by-step details
- 04 • Rigid and allow no freedom
- 05 • Set a standard method for performing a task
- 06 • Indirectly related to goals

▶ Standard Operating Procedure

- A. # & Title
- B. Date of development/implementation
- C. Revision date
- D. Purpose
- E. Scope
- F. Affected Employees
- G. Equipment
- H. Definitions/Abbreviations
- I. Resources

▶ Sample SOP Template

Standard Operating Procedures

Clinical Safety Procedure #	
Date Implemented:	Revision Date:

- A. Purpose
- B. Scope
- C. Responsibility/Affected Employees
- D. Personal Protective Equipment
- E. Definitions & Abbreviations
- F. Resources

Sample SOP

Standard Operating Procedures

Clinical Safety Procedure #15: Use of Personal Protective Equipment (PPE) Clinical	
Order Implemented:	3/1/2015
Revision Order:	02/2016

A. Purpose
 Protection clothing (ie. gowns, lab coats) is worn to prevent contamination of street clothing and to protect the skin from exposures to blood and body fluids.

B. Scope
 Clinic gowns will be worn using the following guidelines:

1. Sleeves must be long enough to protect the forearms.
2. Consistently belted, wrapped or closed.
3. Dipping patient care activities likely to generate splashes or sprays of blood or body fluids.
4. During procedures likely to generate splashes or sprays of blood or body fluids, including operator disinfection and handling of contaminated instruments ready preparation for sterilization.
5. Changed daily.
6. Changed when becoming visibly soiled.
7. Removed before leaving the clinical area.
8. Laundered in a controlled laundry service or in-office following In-Office Laundry Instructions. In-office laundering is only done using laundry equipment located and fully installed at the office. Clinic gowns should never be taken home and laundered.
9. Do not cut door pockets.

C. Responsibility/Assigned Employees
 Dentists, Dental Hygienists, Dental Assistants, Lab Technicians

D. Personal Protective Equipment
 Clinic gown

E. Definitions & Abbreviations

F. Resources
 Bloodborne Pathogen, Standard 1910.1030
 CDC Guidelines for Infection Control in Dental Health Care Settings, 2003
 CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care, March 2011

► Development

- Upper management commitment
- Create your list of needed plans
- Recruit assistance as needed
- Choose a template
- Write it out
- Review and finalize
- Implement

► Implementation

- Existing employees
- New hires
- On going



Employee compliance vs. employee commitment



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Resources

- Government agencies
 - Federal
 - State – including state dental board
 - Local
- National and state dental associations
- Organization for Safety, Asepsis and Prevention (OSAP)



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Summary



Policies are the compass that points us in a direction



Procedures are the map that gets us to our destination

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► Questions



► Contact info

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