



Overview of Voluntary Standards for Laboratory Improvement

SAFER • HEALTHIER • PEOPLE™



Voluntary and Regulatory Standards

- Voluntary

- ❖ Driven by technical need
- ❖ Scientific process
- ❖ Professional sector input
- ❖ Content = Specifics
- ❖ Technical and consensus review process
- ❖ Impact - outcomes
- ❖ Accountability more professional than legal
- ❖ Flexible process, amenable to change

- Regulatory

- ❖ Driven by political attention
- ❖ Legal process
- ❖ Multi sector input
- ❖ Content = Principles
- ❖ Political and technical review process
- ❖ Impact - costs
- ❖ Clear consequences for non compliance
- ❖ Not a nimble process, updates take time



Examples of Voluntary Standards Development

- NCCLS
- Centers for Disease Control & Prevention
- American Society for Microbiology
- College of American Pathologists
- COLA
- Joint Commission on Accreditation of Healthcare Organizations



Framework for Discussion

- Are critical needs met by voluntary standards?
- Who are the customers, e.g., laboratory scientists and end-users of laboratory test results?
- What drives priority for development, e.g., professional interest and gaps identified from needs assessments?
- How are benefits and outcomes measured?
- What drives “compliance?”



CDC Experience with a Voluntary Standard



Dr. Fred Tenover, Implementation of NCCLS
Antimicrobial Susceptibility Testing Standards



Thank you

SAFER • HEALTHIER • PEOPLE™