



Technical Regulations – U.S. Procedures and Practices

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Outline

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- Regulatory Agencies
- Applicable U.S. Law and Policy
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- Conclusions



What is a technical regulation?

- A governmental order having the force of law

You will find U.S. federal regulations in:

- Federal Register: proposed and final texts
- Code of Federal Regulations: all regulations in force (www.gpoaccess.gov)



U.S. Regulatory Approach

- There is no single approach to regulation in the United States
- Regulatory agencies follow their implementing legislation and direction from Congress to create, administer and enforce regulations
- Regulatory agencies must comply with laws and Executive Orders regarding the process for creating regulations



Examples of U.S. Regulatory Agencies

- Consumer Products Safety Commission
- Department of Agriculture
- Department of Transportation
- Environmental Protection Agency
- Federal Communications Commission
- Food and Drug Administration
- Occupational Safety and Health Administration
- Mine Safety and Health Administration

Responsible for oversight of products, processes and systems that affect consumer and worker health and safety, and the environment



Applicable U.S. Law and Policy

- Administrative Procedures Act
- Executive Order 12866 (1993)
- National Technology Transfer and Advancement Act (1996)
- Trade Agreements Act of 1979, as amended in 1994 and 1996



Administrative Procedures Act

- Ensures transparency and open rule-making
 - Requires publication of a notice of proposed rulemaking
 - Opportunity for comment
 - Agency consideration of comments
 - Publication of final rule with effective date



Executive Order 12866

- Procedures for regulatory planning and review
- Agencies must consider:
 - Regulatory alternatives (including not to regulate)
 - Potential benefits
 - Costs
 - Impacts
- Each agency must submit to OMB a regulatory plan semi-annually; including regulatory objectives and priorities
- Each agency must also submit proposed regulations to OMB for review



National Technology Transfer and Advancement Act

- U.S. law and policy* require federal agencies to:
 - Use voluntary standards to the extent practicable in regulation, procurement and policy activities
 - Report development of agency-unique standards
 - Participate in the development of voluntary consensus standards relevant to their needs

*Public Law 103-114 and OMB Circular A-119



Goals of the Government in Using Voluntary Consensus Standards

- Eliminate the cost to the government of developing its own standards
- Decrease the cost of goods purchased and the burden of complying with regulations
- Promote efficiency and economic competition through harmonization of standards
- Further the policy of reliance on the private sector to supply government needs for good and services



What Does “Use” Mean?

- Incorporation of a standard in whole, or in part, or by reference in regulation
 - In particular, agencies use voluntary standards for test methods, sampling procedures, or protocols
- Reference to standards in agency guidance documents
- “Use” may be determined in part by agencies’ enabling legislation, and by availability of relevant standards



Title IV of the Trade Agreements Act of 1979

- Implements the WTO TBT Agreement



Summary

- Regulatory agencies develop regulations in the United States
- Both law – the Administrative Procedures Act – and policy (Executive Order 12866) establish procedures for regulatory agencies to develop regulations in an open, transparent and practical manner
- Regulatory agencies are directed by the Trade Act and the NTTAA to use voluntary consensus standards where applicable



Conclusions

- Regulatory planning and review guidance directs agencies to consider whether regulation is needed and to conduct cost-benefit analyses of various approaches
- When agencies make a determination that regulation is needed and that standards are an appropriate tool to support regulation; they may “use” standards in many different ways
- At last count, more than 6,000 private sector standards were incorporated by reference into federal regulations
- Agencies continue to introduce new procedures to improve compliance with law and policy



Useful Websites

- www.gpoaccess.gov
- www.regulations.gov
- standards.gov



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