# Section I

## ESTABLISHING THE NEED

1. **Introduction**  
   - What Manuals?  
   - Application  
   - A Manual by Any Other Name  
   - Manual Categories  
     - Operational Manuals  
     - Technical Manuals  
   - Manual Components  
     - Policy  
     - Procedure  
     - Supporting and Static Documents  
       - Forms  
   - Who Writes the Manuals?

2. **Overview of Quality Assurance**
   - What Is Quality Assurance?  
   - Documentation  
   - Accuracy and Reliability  
   - Dynamic System  
   - QA Is Not Optional  
   - Quality Assurance Program Components  
     - Quality Assurance Manual  
     - Staff Qualifications and Training (Initial and In-Service)  
     - Proficiency Testing (Internal or External)  
     - Sample Control (Collection, Handling, and Storage)  
     - Documented, Standardized, and Validated Protocols  
     - Reagent and Instrument Reliability  
     - Authenticated Reference Material  
   - Responsibilities  
     - Senior Management Responsibilities  
     - Define Goals and Objectives  
     - Facilitate Deficiencies with Corrective Action
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Personal Protective Equipment 
Blood-Borne Pathogens 
Chemical Hygiene Plan 
Hazardous Waste Disposal 
Spill Control and Containment 
Laboratory Fume Hoods 
Ergonomics and Office Safety 
Forms and Static Documents 

Health and Safety Manual Templates 
Safety Responsibility and Authority 
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