ASHRAE Design Guide For Cleanrooms

Notes to Subcommittee Members:

1. The second draft of the "Table of Contents" shows a preliminary coverage of possible topics. The Contents and coverage will be subject to revising for continuous improvements by the authors, contributors and reviewers during the writing, editing, review and refinement processes.

2. A few modifications have been made from Draft 1 to reflect valuable suggestions from committee members: Each Section will have its own Bibliography List to allow readers in searching for related references only. Sustainability-related topics have been merged into a separate Chapter called "Cleanroom Design for Sustainability".

3. Book volume will be between 120,000-150,000 words, "Estimated Words" is tentatively assigned behind each Section title to allow authors to control the sizes of their respective Sections/Chapters to ensure the book properly structured and well balanced. Larger cleanroom market sectors will relatively have more coverage.

Table of Contents

(Second Draft by W. Sun. 8/30/2008)

Product Cleanliness Levels
Surface Cleaning

Chapter X Airborne Molecular Contamination
Typical Contaminants
Outgassed Organic Compounds from Cleanroom Materials and Components
Classification
Parameters for Consideration
Measurement, Testing and Compliance

Chapter X Liquidborne Contaminants
Particles in Process Liquids
Liquid-borne Particle Counters
Liquid Filtration

Chapter X Microbial Contaminations
Principles of Bio-contamination Control
Determine Airborne Bio-contamination Through Sampling
Sampling Devices
Evaluation and Expression of Sampling Data
Determine Surface Bio-contamination
Determine Bio-contamination in Liquids
Cleaning and Disinfection

Bibliography

SECTION 2 – CLEANROOM DESIGN AND ENVIRONMENTAL CONTROL SYSTEMS (30-36K words)

Chapter X Basic Requirements and Planning
Contamination Control and Cleanliness Requirements
Site Selection and Services Requirement
Building Configurations and Plans
Critical Flow Arrangements-Personnel, Material, Product and Waste
Architectural and Structural Considerations
Indoor Environmental Quality and Requirements
Outdoor Emission Requirement
Life Safety
Security and Access Control
Regulations
Project Size, Scope, Budget and Schedule

Chapter X Design Considerations
Architectural Layout
Airflow Patterns
- Unidirectional Flow
- Non-unidirectional Flow
- Mixed Flow

Air Patterns Effectiveness and Computer-Aided Flow Modeling
Indoor Design Conditions
Makeup Air
Process Exhaust
Filtration Systems
Cooling and Heating Loads
Determination of Required Room Air Change Rate and Air Velocity and Modeling
Basic Primary, Secondary and Tertiary HVAC System Configurations
- Single Makeup System without Return Air
- Single Makeup System with Return Air
- Single Makeup System with Recirculating Fan
- Single Makeup System with Recirculating AHU System
- Single Makeup System with Recirculating Fan and Recirculating AHU System

Primary, Secondary and Tertiary System Variations, Psychrometric Analysis and Selection
Airflow Direction Control Between Rooms
- Room Pressure Differential Criteria
- Pressurization Systems and Design Basics
- Single Room Pressurization Methods
- Multiple-Room (Suite) Pressurization
- Pressurization Controls

Airlock Selections and Utilizations
Application of Mini-Environments
- Contamination Control Concepts
- Filtration and Airflow Management
- Environmental Control and Monitoring
- External and Facility Support

Applications of Other Separative and Transfer Devices
Submicron Contamination and Design Practices
Microorganisms (Viables) and Control Considerations
Fire Safety
Electrostatic Charge and Grounding
Cleanroom Lighting
Electrical Systems
Communication Systems
Noise and Vibration Controls
Sizing and Redundancy

Chapter X Utility Services for Process
Environmental, Health and Safety (EHS) Considerations
Dry Clean Compressed Air
Fume Exhaust and Scrubber System
Solvent System
Drain Waste Neutralization System
House Vacuum System
Process Cooling Water
Ultra-Pure Water System
Clean Steam System
Production and Transmission of High Purity Gases
Waste Gas Abatement Systems
Control of Volatile Organic Compounds
Fire Protection

Chapter X Cleanroom Design for Sustainability
Considerations for Sustainability
Energy Conservation & Cost-Saving Concepts
Energy Utilizations, Balance and Modeling

Chapter X Cleanroom Construction
Layout and Approval of Installations
Construction Materials and Surface Finishes
Integration in Design and Construction

Bibliography

SECTION 3 – TESTING, CERTIFICATION, COMMISSIONING AND QUALIFICATION (12-16K words)

Chapter X Cleanroom Testing, Certification & Commissioning
Cleanroom Testing Standards
Testing Based on Occupancy States
- As-built
- At-rest
- Operational

Typical Cleanroom Testing Equipment and Instrumentation

Required (Basic) Test - Airborne Particle Counts for Classifications
Optional (Additional) Tests
- Airborne Particle Counts for Ultrafine Particles
- Airborne Particle Counts for Macroparticles
- Airflow Volume, Velocity and Uniformity
- Air Pressure Differences
- Installed Filter System Leakage
- Airflow Direction and Visualization
- Temperature, Humidity and Uniformities
- Electrostatic and Ion Generator
- Particle Surface Deposition
- Recovery
- Containment Leak
- Conductivity
- Airborne Microbial Counts
- Surface Microbial Counts
- Lighting Level and Uniformity
- Noise and Vibration Levels

Cleanroom Commissioning

Chapter X Cleanroom Qualifications
Regulatory Validation Requirements
Various Qualification Protocols and Plans

Bibliography

SECTION 4 – CLEANROOM OPERATIONS (6-7K words)

Chapter X Operation General Requirements
Contamination (Particulate and Microbial) Control in Operation
Cleanroom Disciplines
Personnel Hygiene, Practices and Garments (Clothing, Masks, Gloves, and etc.)
Materials, Equipment and Machinery
Entry/Exit of Personnel, Material, Product and Waste
Cleaning and Decontamination

Chapter X Methods for Verifying Cleanliness
Ultraviolet Light
High Illuminance Oblique White Light
Continuous Flowing Duct Method
Reservoir Method
Contact Plate for Flat Surfaces
Swab for Non-Flat Surfaces

Bibliography

SECTION 5 - CLEANROOMS IN SEMICONDUCTOR & MICROELECTRONIC FACILITIES (15-18K words)

Chapter X General Considerations
Design Considerations for Semiconductor and Microelectronic Cleanrooms
Design Criteria and Indoor Air Quality
Filtration and Equipment
Environmental, Health and Safety & Risk Assessment

Chapter X Design for Fabrication, Process and Manufacturing
Semiconductor FAB Facilities
Microelectronic Product Manufacturing Facilities
Nanotech Facilities
Facility Planning and Architectural Plan

Typical Process Diagrams
Spaces Configurations
Airflow Arrangement in Semiconductor and Microelectronic Cleanrooms
Particle Emissions from Equipment and Process
Room Air Ionization
Treatment of Airborne Molecular Contamination
Design Considerations of Micro-vibration and Noise
ESD Controls in Cleanroom Environments
Off-Wafer Measurement of Contaminants
On-Wafer Measurement of Particles and Molecular Contaminants
Deposition of Molecular Contaminants in Gaseous Environments
Organic Contamination Removal
Gases and Chemicals

Bibliography

SECTION 6 - CLEANROOM IN PHARMACEUTICAL AND MEDICAL DEVICES FACILITIES (15-18K words)

Chapter X General Considerations
Design Considerations for Pharmaceutical Cleanrooms
Current Good Manufacturing Practices (cGMP)
Facility Planning and Architectural Plan
Building Code Compliance
Pharmaceutical Process Flow
Mechanical Utilities and High Purity Water and Steam
Containment/Isolation
Environmental, Health and Safety & Risk Assessment

Chapter X Design for Facilities
Oral Solid Dosage Facilities
Sterile Manufacturing Facilities
API Facilities
Lab Facilities
Packaging Facilities
Medical Devices Facilities
Controls, Monitoring and Alarms

Chapter X Qualifications
Validations
Qualification Plan and Acceptance Criteria
GMP-Compliant Qualification Protocols
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Bibliography

SECTION 7 – CLEANROOMS IN HEALTHCARE & BIO-TECH FACILITIES (10-12K words)

Chapter X General Requirements
Healthcare Facilities Design Guidelines and Standards
Major Airborne Pathogens
Infection Control Risk Assessment (ICRA)
Airborne and Surface Microbial Contaminations
Control of Particle and Microbiological Contaminations
- Sterilization
- Disinfection
- Radiation/UV Treatment
- Filtration

Architectural and Design Considerations
Ventilation, Room Pressure and Filtration Requirements
Certification and Qualifications

Chapter X Cleanroom Technologies in Airborne Infection Control Spaces
Operating Room
Infection Isolation Room
Protective Environment
Critical-Care Room
Pharmacy
Bio-safety Labs
Bio-tech Facilities

Bibliography

SECTION 8 – CLEANROOMS IN AEROSPACE, OPTICAL, AUTOMOTIVE, FOOD PROCESSING & OTHER INDUSTRIES (10-14K words)

Chapter X Cleanrooms in Aerospace Industries

Chapter X Cleanrooms in Optical Devices Industries

Chapter X Cleanrooms in Automotive Industries

Chapter X Cleanrooms in Food Processing Industries

Chapter X Other Cleanroom Applications

Bibliography

TERMINOLOGY (3-4K words)