PhEn-602
Pharmaceutical Facility Design

Week 2

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Construction Regulations

- Building and Zoning Codes
- Support Utilities:
  - Plant steam
  - Compressed air
  - Chilled water
  - Electrical Distribution
  - Air Handling and HVAC

International Code Council

- **International Code Council (ICC)** is a nonprofit membership association consisting of over 50,000 members dedicated to developing a single set of comprehensive model building codes. Most members are code officials.
  - http://www.iccsafe.org/
- **States adopt various codes from the ICC**

International Code Council

The mission of the International Code Council is to provide the highest quality codes, standards, products, and services for all concerned with the safety and performance of the built environment.

From International Code Council:

- **"The purpose of the Code is to establish the minimum requirements to safeguard the public health, safety and general welfare through structural strength, means of egress facilities, stability, sanitation, adequate light and ventilation, energy conservation, and safety to life and property from fire and other hazards attributed to the built environment".**

Construction Regulations - Building Codes

- Building Codes vs. Zoning Codes
  - Building Codes ensure the public health, safety and welfare within individual properties (i.e. the buildings themselves).
  - Zoning codes ensure the public health, safety and welfare of entire communities. Zoning codes are concerned about how multiple properties interact with each other and what impact they have on the overall community.

Construction Regulations - Building Codes

- Zoning Codes
  - Zoning codes are developed by local municipalities.
  - There is no national zoning code.
  - They can vary greatly by community.
  - Must be consulted for each project.
  - Typical zoning concerns:
    - Lot size, bldg. height, building coverage and impervious coverage, setbacks, parking, landscaping, signs, etc...

Construction Regulations - Building Codes

- **Building Codes are generally more extensive than zoning codes.**
- **ICC developed the IBC – International Building Code.**

International Building Code

The #1 design resource for designers and builders

The 2003 International Building Code addresses design and installation of building systems with requirements that emphasize performance. The IBC is coordinated with all the International Codes. This comprehensive building code establishes minimum regulations addressing the design and installation of building systems.Includes revamped structural provisions, reorganized occupancy classifications and the latest industry standards in material design.

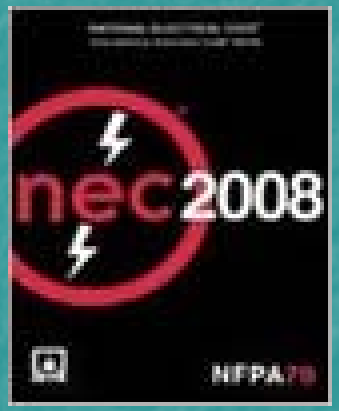
Table of Contents:

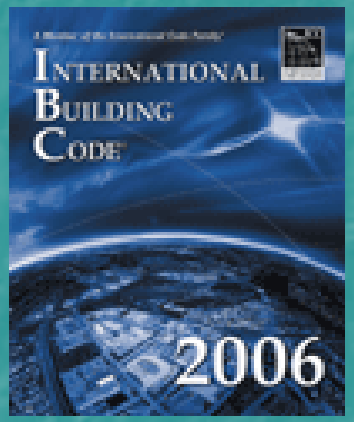
Construction Regulations - Building Codes

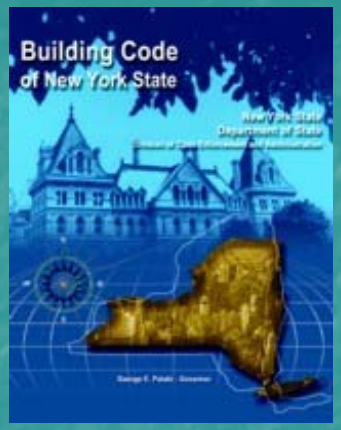
Sample of Codes adopted by New Jersey: Contained in the NJ Uniform Construction Code Code N.J.A.C. 5:23

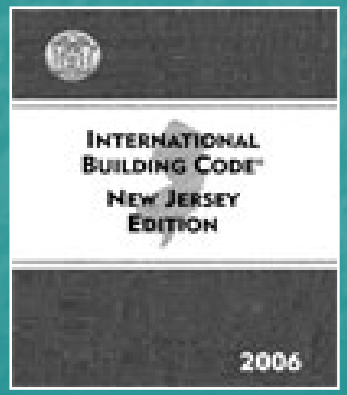
- ***2006 International Building Code® New Jersey Edition***
- ***2006 International Residential Code® New Jersey Edition***
- ***2006 International Mechanical Code® New Jersey Edition***
- ***2006 International Energy Conservation Code® New Jersey Edition***
- ***2006 International Fuel Gas Code® New Jersey Edition***
- **http://www.state.nj.us/dca/codes/forms/adopcode.shtml**
- **http://www2.iccsafe.org/states/newjersey/**

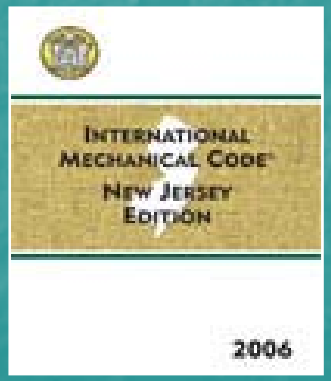
Building Codes











Construction Regulations - Building Codes

Construction Regulations - Building Codes establish “Use-Groups”

- Use Group A: Assembly uses
- Use Group B: Business uses
- Use Group E: Educational uses
- Use Group F: Factory and Industrial Uses
- Use Group H: High-hazard uses
- Use Group I: Institutional uses
- Use Group M: Mercantile uses
- Use Group R: Residential uses
- Use Group S: Storage
- Use Group U: Utility

Construction Regulations - Building Codes

- Most Pharmaceutical Facilities fall under Use Group F: *Factory and Industrial Uses*
- Under use group F there are two further classifications:
  - F-1: Moderate hazard
  - F-2: Light hazard

Construction Regulations - Building Codes

What kinds of things are covered under the national building codes?

- Structural loads (roof loads, wind loads, snow loads)
- Means of egress (e.g. exits, stairway's, doorways,etc..)
- Fire resistive construction, fire walls
- Fire protection systems (e.g. sprinkler systems and smoke detectors)
- Foundation systems and retaining walls
- Mechanical systems, plumbing code

ALL ARE IMPORTANT CONSIDERATIONS IN THE DESIGN OF A PHARMACEUTICAL FACILITY

Construction Regulations - Building Codes

- *NFPA – National Fire Protection Association*
  - *NFPA 101 - Life Safety Code*
  - *Means of Egress*

Construction Regulations - Building Codes

Other Important codes to consider:

- *NFPA 101: "Life Safety Code": Means of egress…must allow for prompt escape of occupants..*
- *NFPA 70: National Electric Code (NEC): Electrical requirements..wiring, power sources*

Construction Regulations - Building Codes

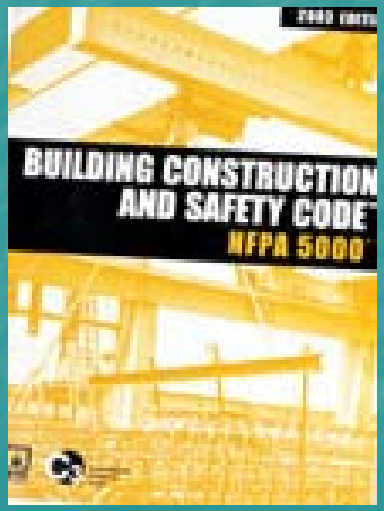
Other Important codes to consider:

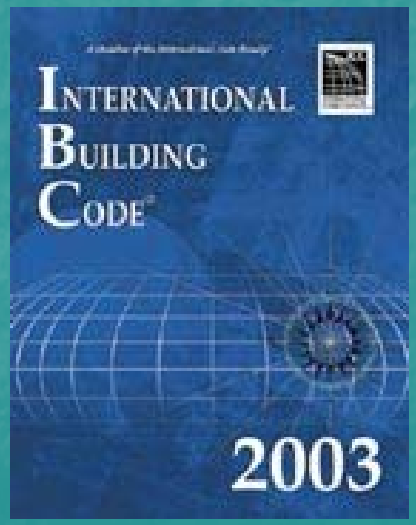
- *NFPA 13: Sprinkler System Design*
  - *Sprinkler systems are the predominant fire suppression system found in Pharmaceutical facilities*

Construction Regulations - Building Codes

NFPA has recently developed their own model building code – NFPA 5000, "Building Construction and Safety Code"

Competes with ICC's International Building Code (IBC)





Construction Regulations - Building Codes

- The shear number of codes that apply to facility design is overwhelming.
- The designer must be aware of which codes apply, and must understand how they are interpreted.
- The language of codes attempts to be precise, but often need interpretation to real-world situations.

There are a variety of codes and standards that the engineer must be aware of…it is daunting task…

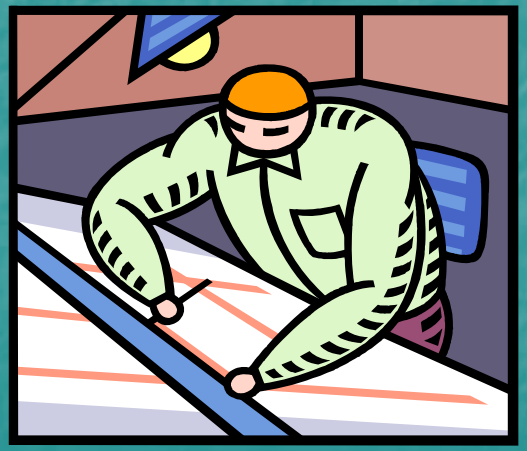
International Standards

Zoning Codes
(Local Town Ordinances)

Local and National
Building Codes
Plumbing Codes, Electrical Codes
Fire Codes

GMP's

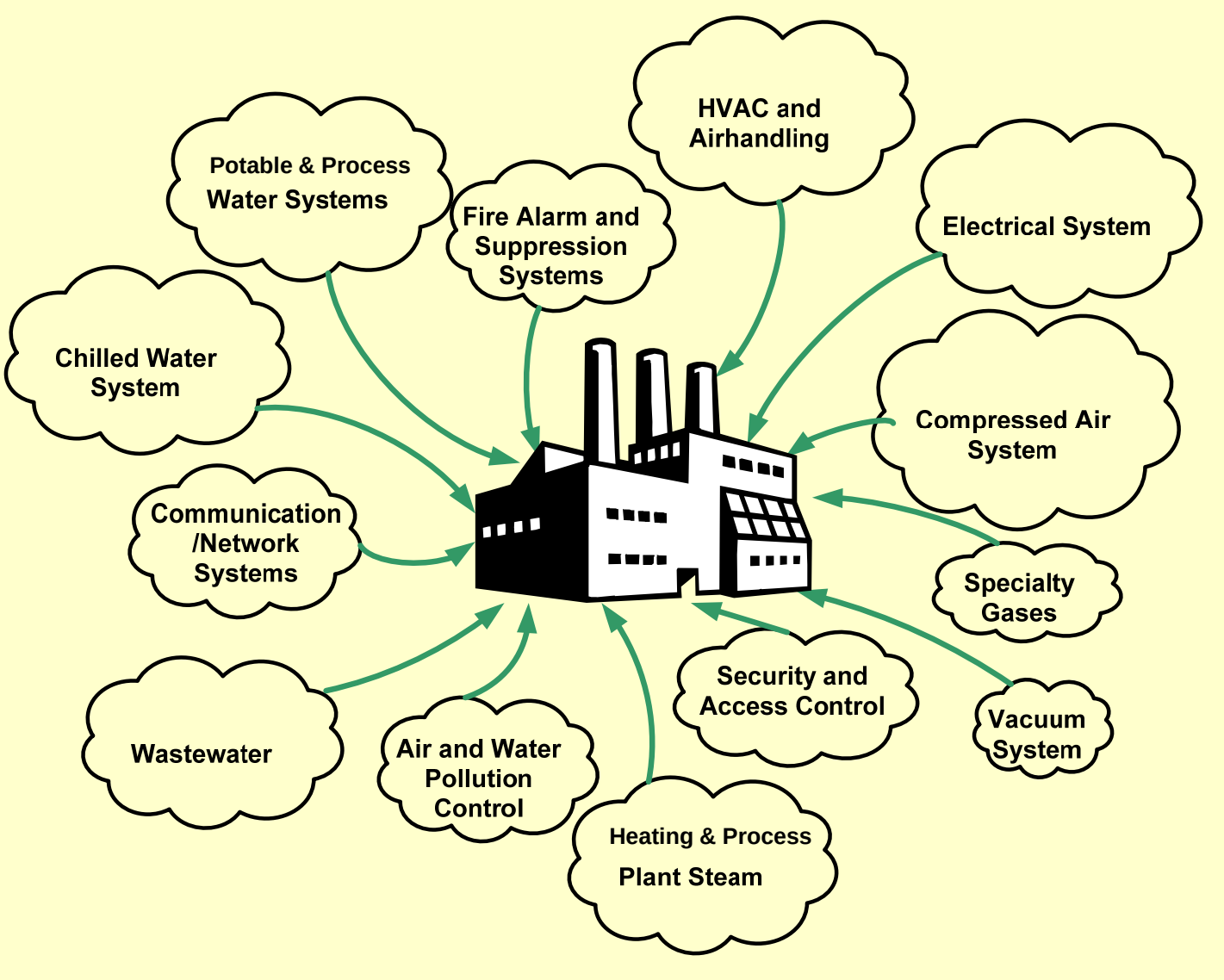
Environmental Regulations
Air, water, Waste



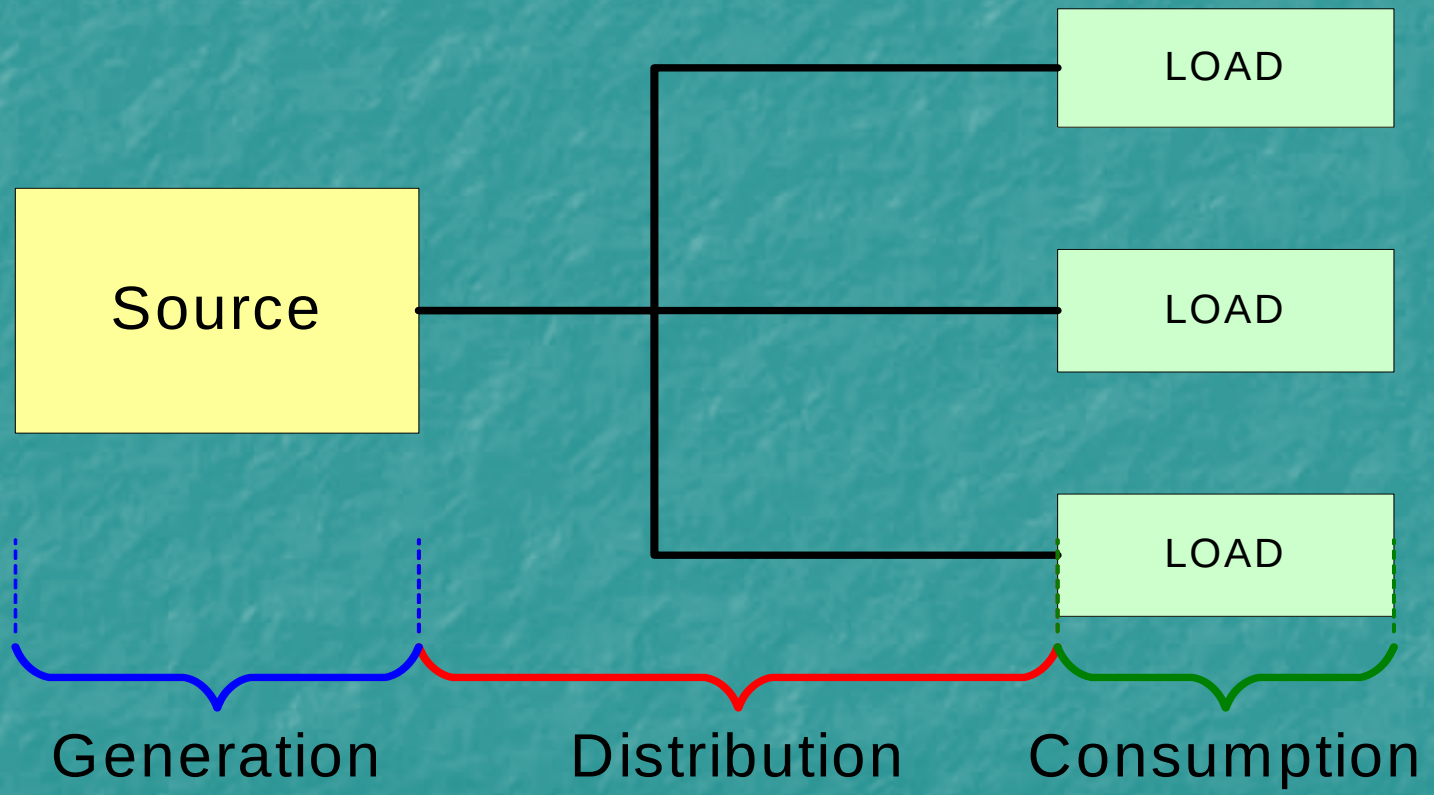
Construction Regulations - Building Codes

- Role of the Design Professional: Licensed by the individual state, has the legal responsibility to ensure that the designs meet the codes enforced within that state.
- Role of the Model Code Organizations (i.e. ICC and NFPA): To prepare, update and provide written interpretations of the building codes.
- Role of the Code Official: The public entity entrusted with enforcement of the code and has the legal authority to make code interpretations.

Support Utilities & Facility Systems



Utility Systems – General Profile

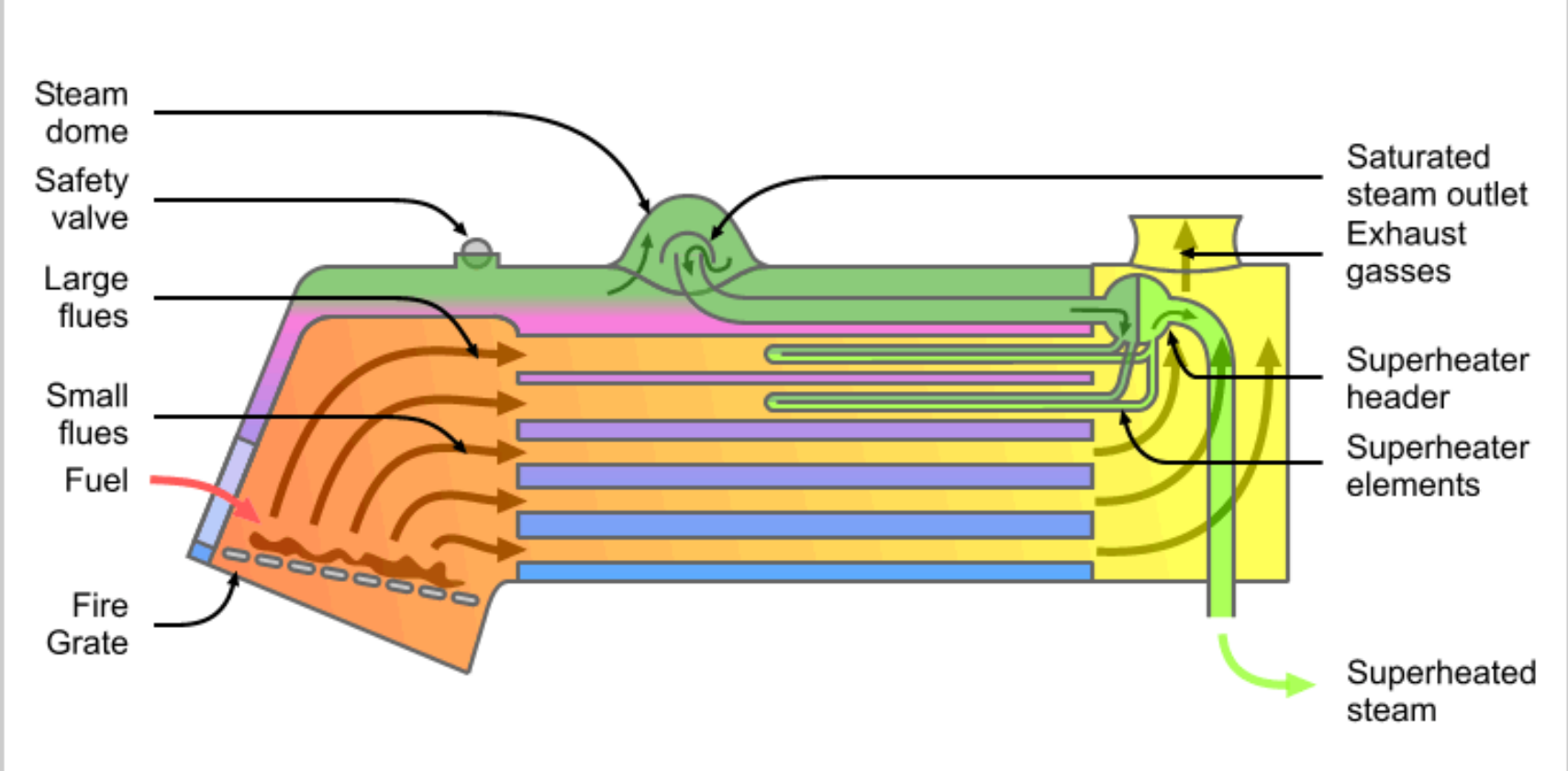


Support Utilities: Primary Steam for Heating

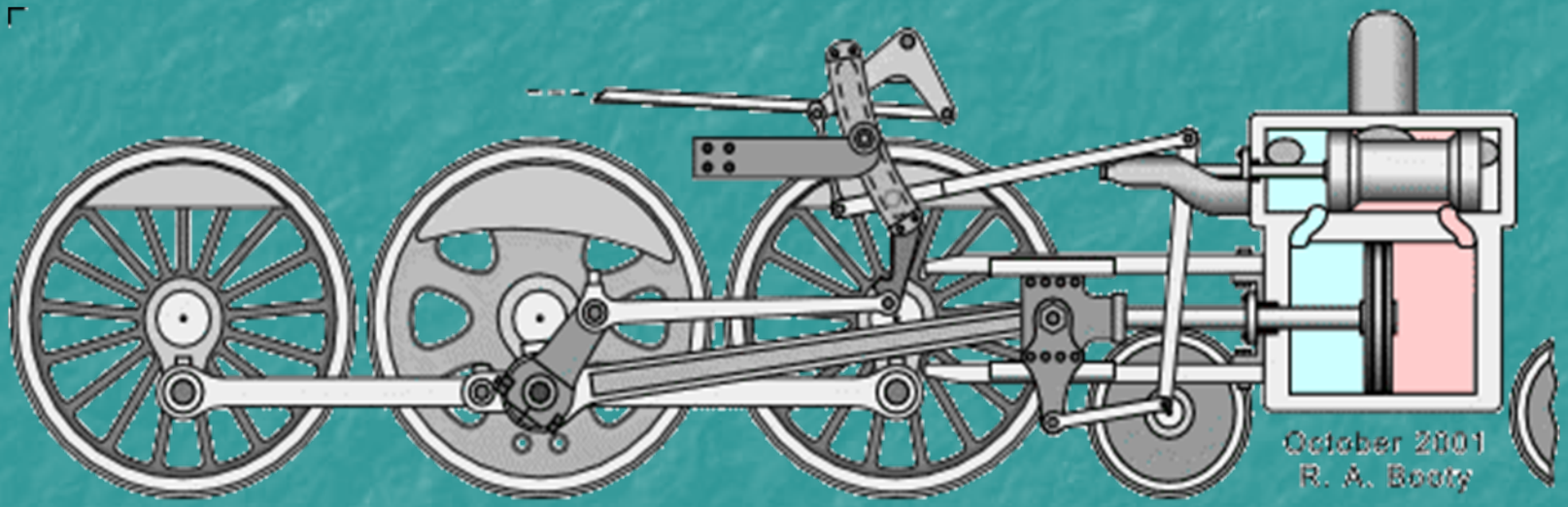
Heating Systems: Plant Steam

- High-pressure – typically 100 – 130 psig
- Low-pressure – typically 12 – 15 psig*
- Plays huge role in pharmaceutical facility systems
- Produced by boilers – many different types
- Boilers are rated in terms of boiler horsepower, convertible to lbs/hr of steam (1 BHP=34.5 Lbs/hr of steam)

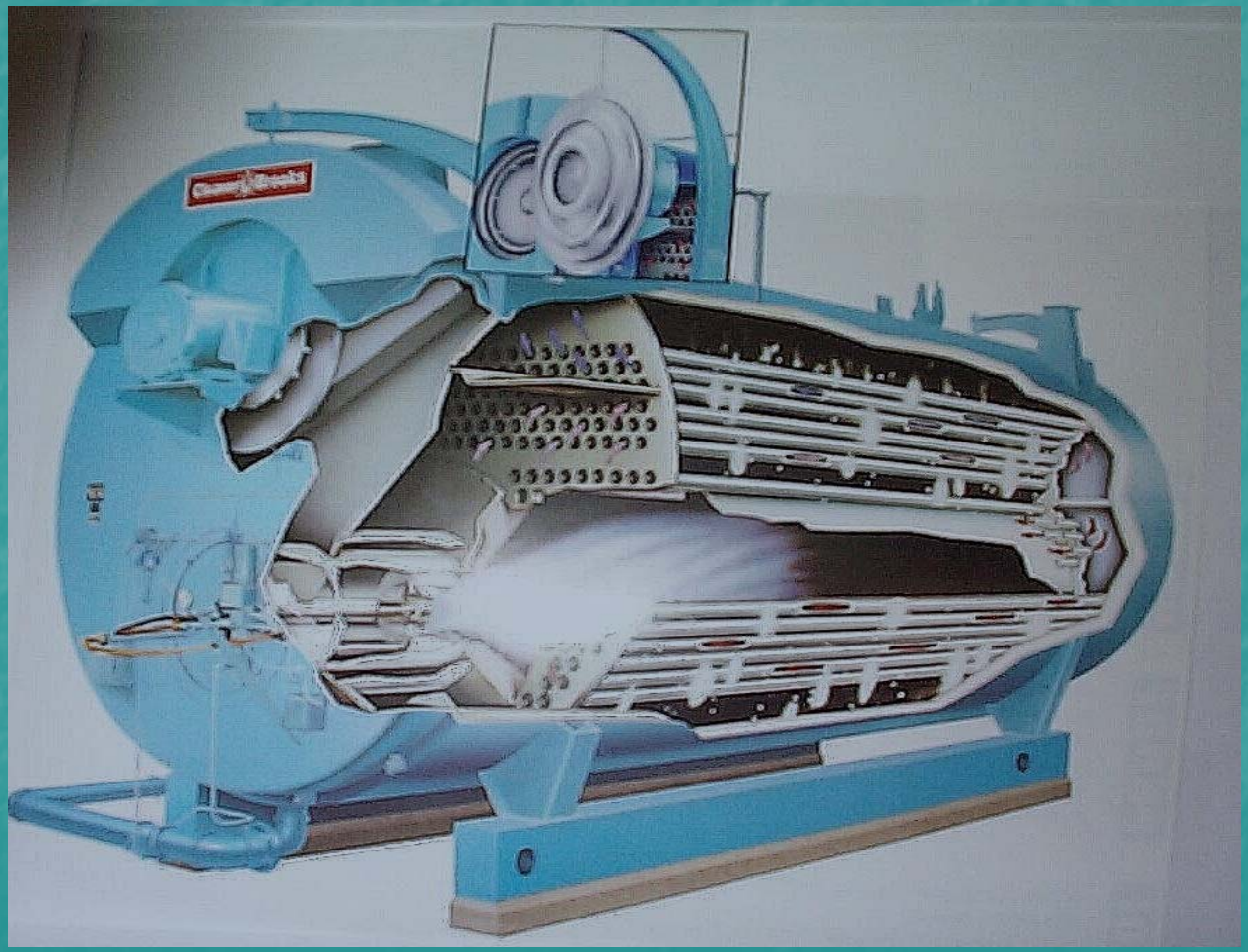
Fire-Tube Boiler

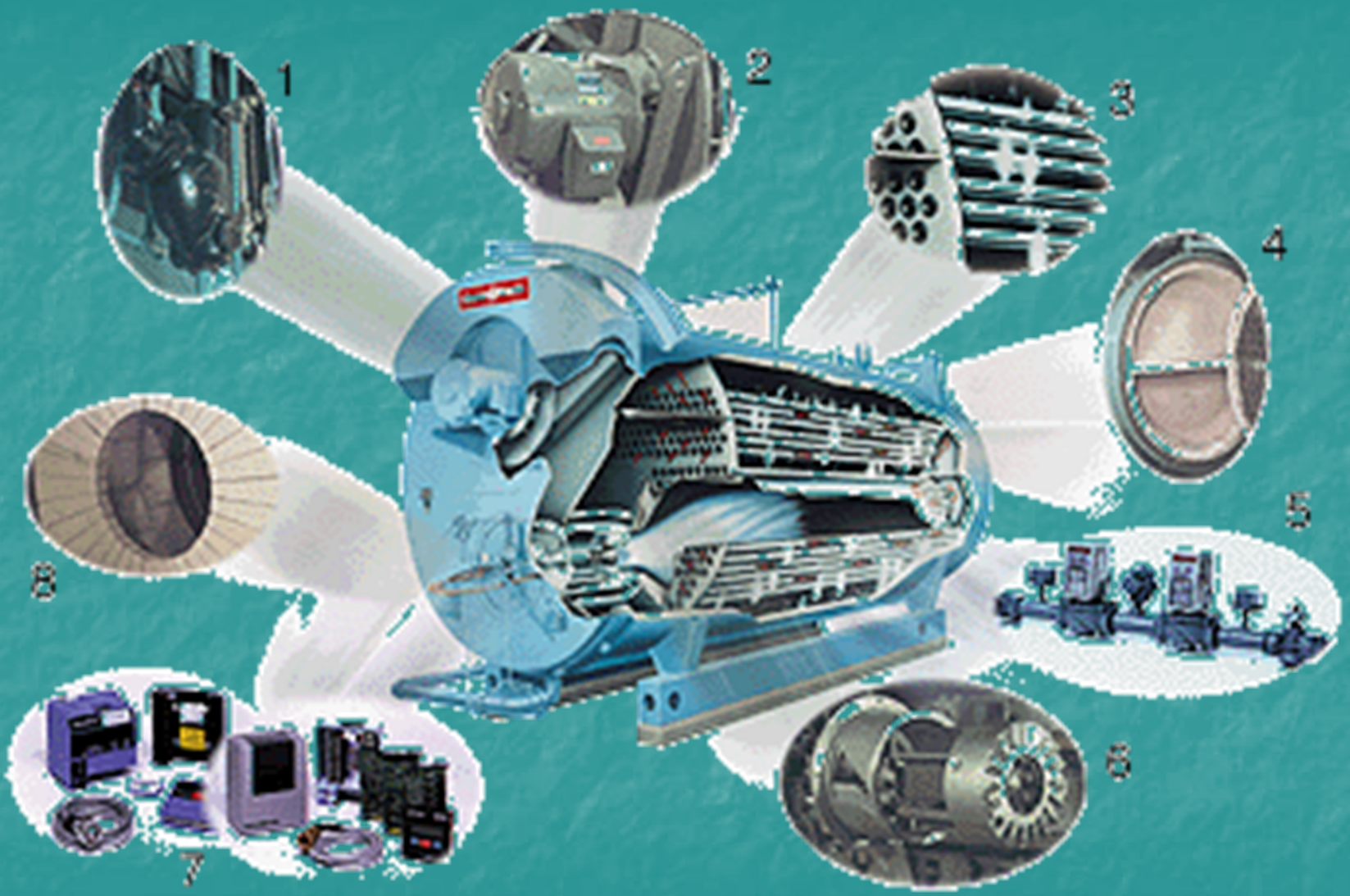


Steam Used to Drive Wheels



Commercial Fire - Tube Boiler

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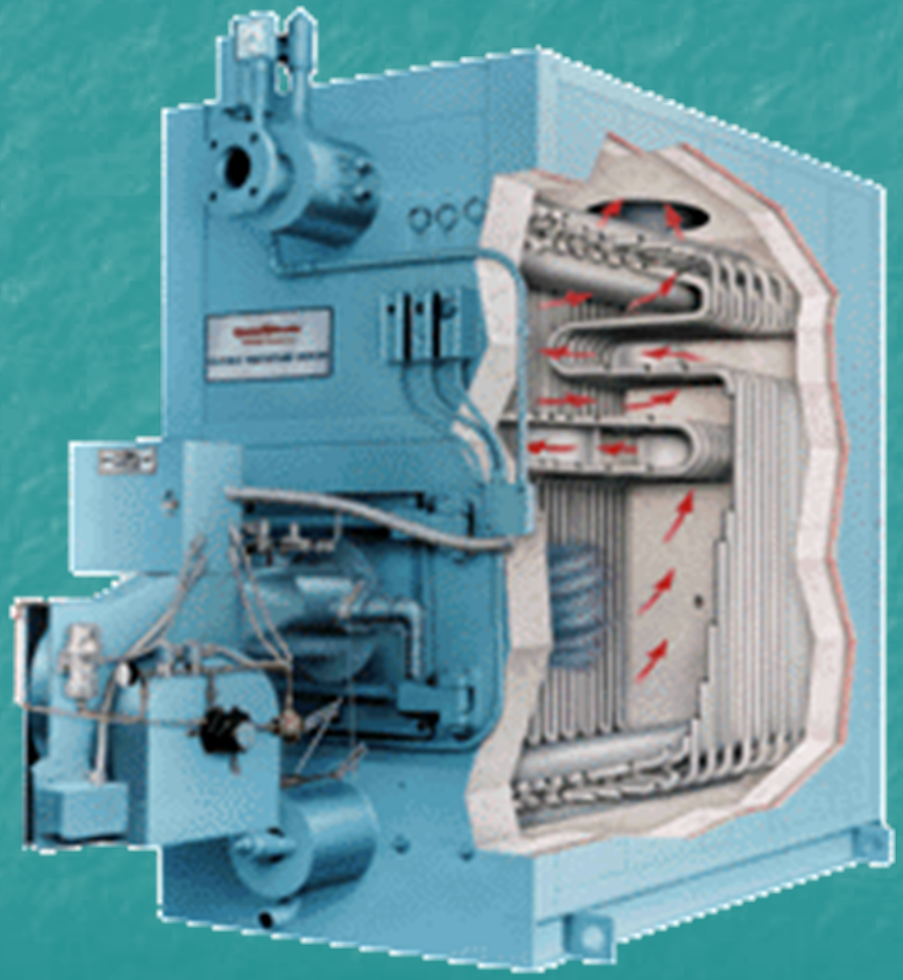
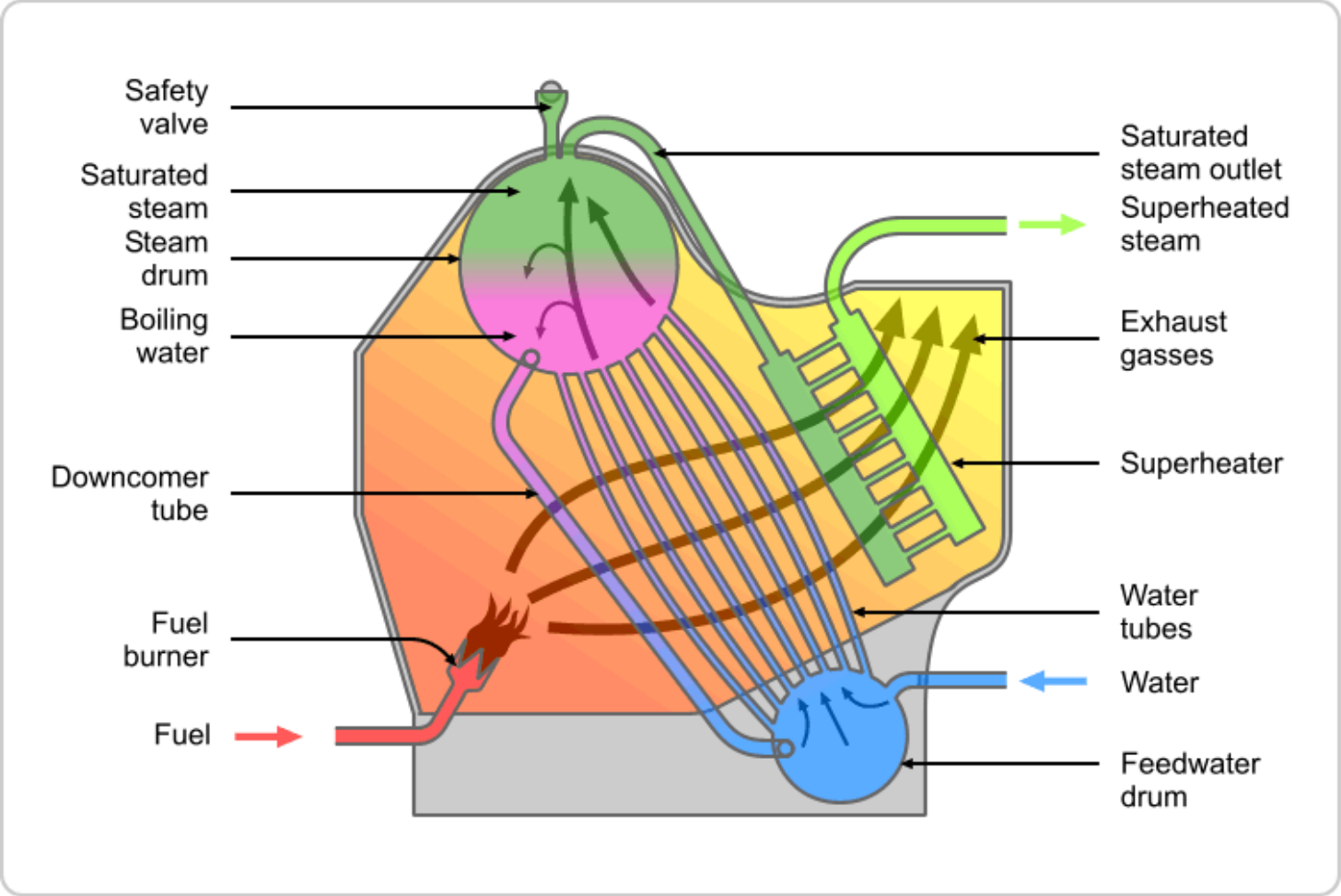
Commercial Firetube Boiler



Water-Tube Boiler



Support Utilities

Plant Steam

- Fuels typically used: Oil and Natural Gas
- Emissions are a huge issue
- Must be permitted through DEP
- Maintaining water level in the boiler is critical
- Steam is distributed throughout building in black steel pipe (welded, screwed or flanged)
- State requires constant monitoring by boiler operators*

Support Utilities - Facility Systems

Heating Systems: Plant Steam

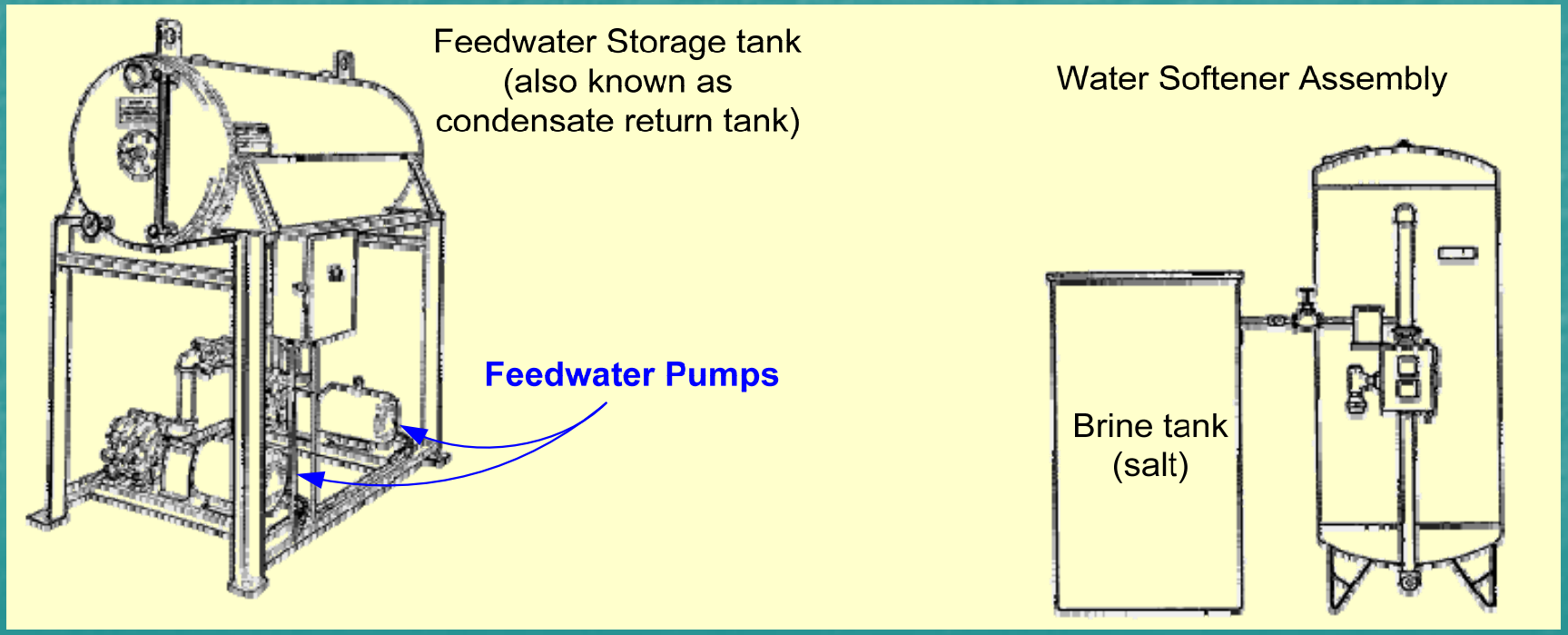
- High pressure steam often reduced to lower pressure for various applications
  - Reduction of high-pressure to lower pressure steam has two advantages:
    - **Easier to control at lower pressure**
    - **Higher latent heat than HP steam**

Support Utilities

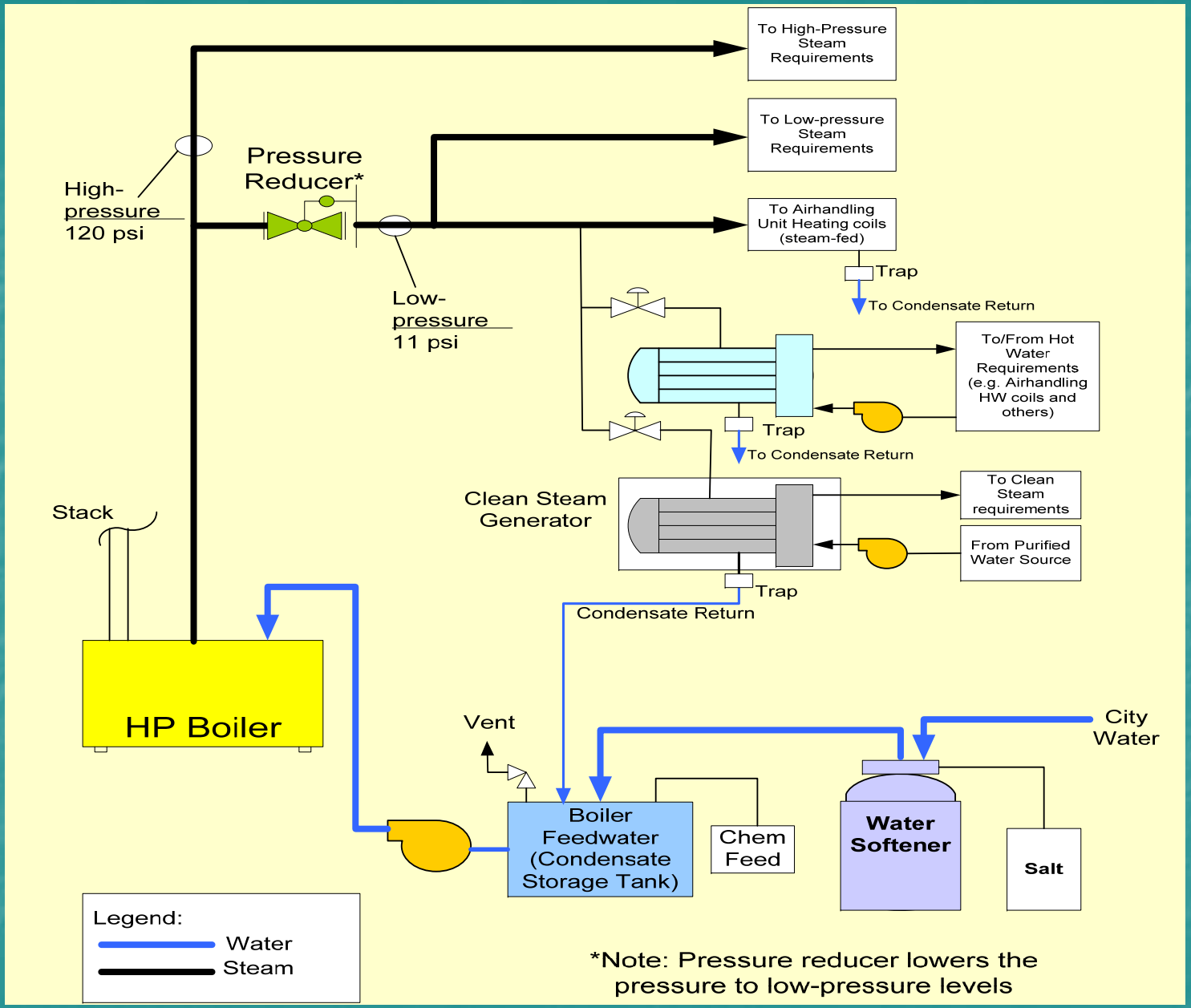
- **Uses of Plant Steam / Heating Systems:**
  - Provides for general heating
  - Can be fed directly to air handlers to provide heat for personnel comfort and environmental control
  - Often used to produce hot water, which is then directed to hot-water based heating coils in air handlers
  - Energy source for producing Water for Injection – steam is fed to Stills
  - Energy source for producing Clean Steam – steam is fed to Clean Steam Generators
  - Used in various heat exchangers throughout plant to support process loads (e.g. autoclaves, depyrogenation ovens)

Boiler Accessories

- **Condensate receiver - holds the feedwater that is pumped into the boiler**
- **Water Softener – Softens the water prior to entry into the boiler (removes hardness), in order to prevent scaling and premature failure of the boiler**

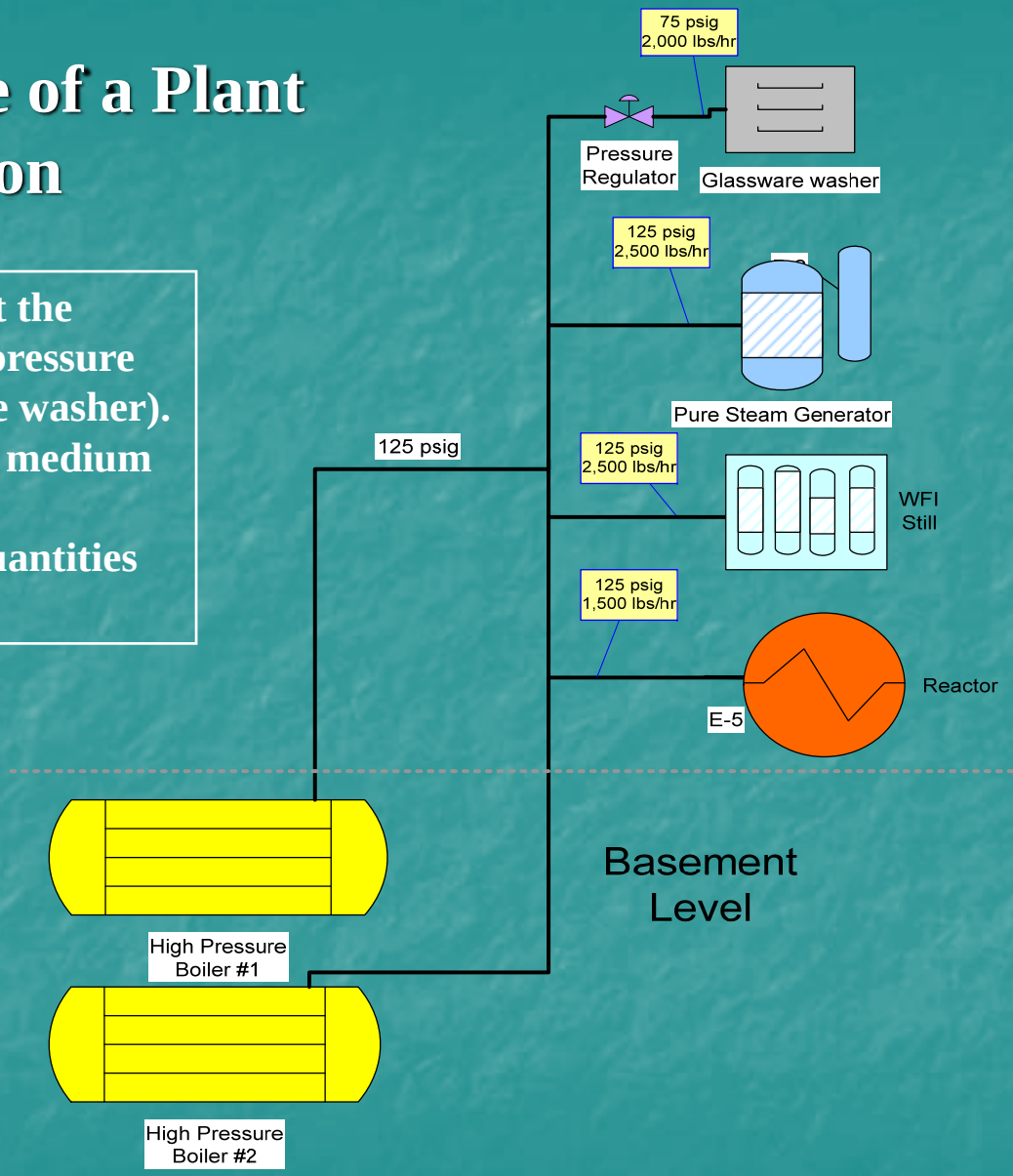


TYP. STEAM DiSTR.



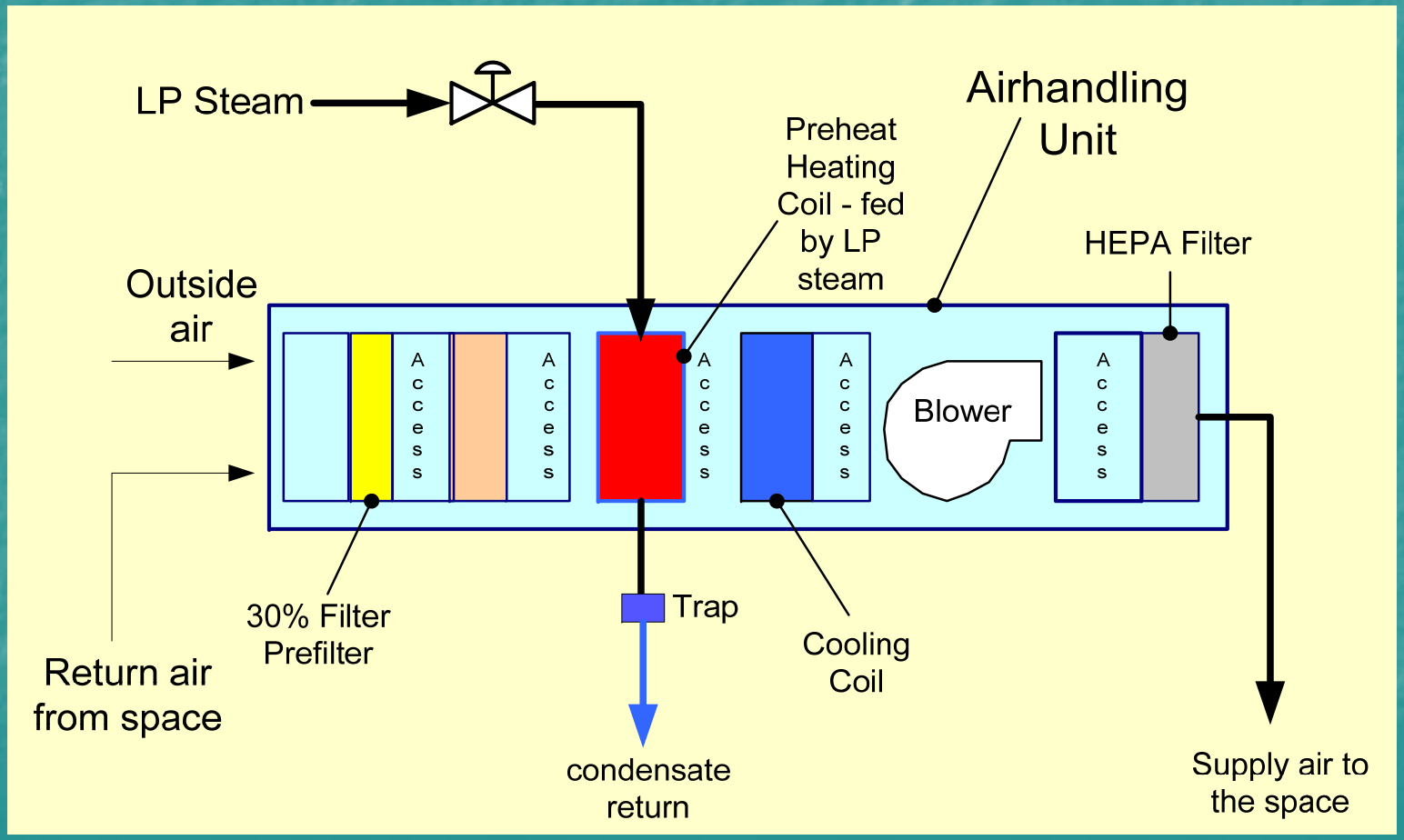
Another example of a Plant Steam Distribution

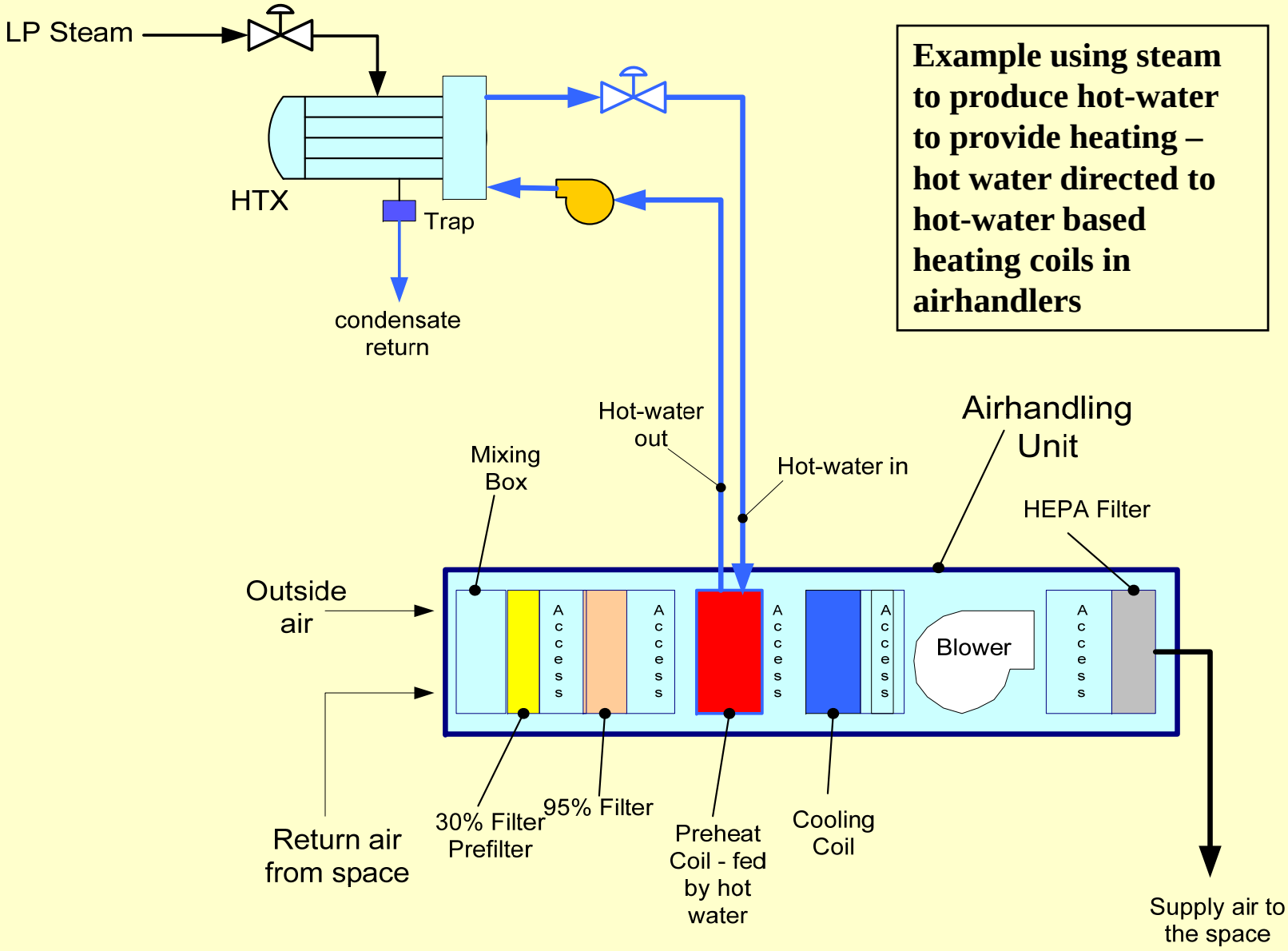
In this example we see that the pressure reducer reduces pressure for a single load (glassware washer). The pressure is reduced to medium pressure level (75 psig).
For this example, steam quantities are also shown.



Steam-Fed Heating Coil

Example using steam to provide heat. Low-pressure steam is fed directly to the heating coil in the airhandler




LP Steam
HTX
Trap
condensate return
Example using steam to produce hot-water to provide heating – hot water directed to hot-water based heating coils in airhandlers
Hot-water out
Hot-water in
Airhandling Unit
Mixing Box
HEPA Filter
Outside air
Access
Blower
Return air from space
30% Filter Prefilter
95% Filter
Preheat Coil - fed by hot water
Cooling Coil
Supply air to the space

Support Utilities

Other heating systems:

- **Hot-water: generated by plant steam or from hot-water boiler.**
- **Electric: Electric resistance heating also an option (rarely used due to operating expense)**

Air Handling & HVAC Systems

Air Handler/Air Handling Unit: A unit designed To deliver a certain amount of air, typically consisting of a fan, filter assembly, dampers, heating and cooling coils, and control instrumentation.

- Come in all sorts of sizes, and materials of construction.
- Rated in terms of capacity, measured in CFM of air delivered by the unit.

Typical Air Handling Unit

Air Handling & HVAC Systems

Different grades of air handling units:

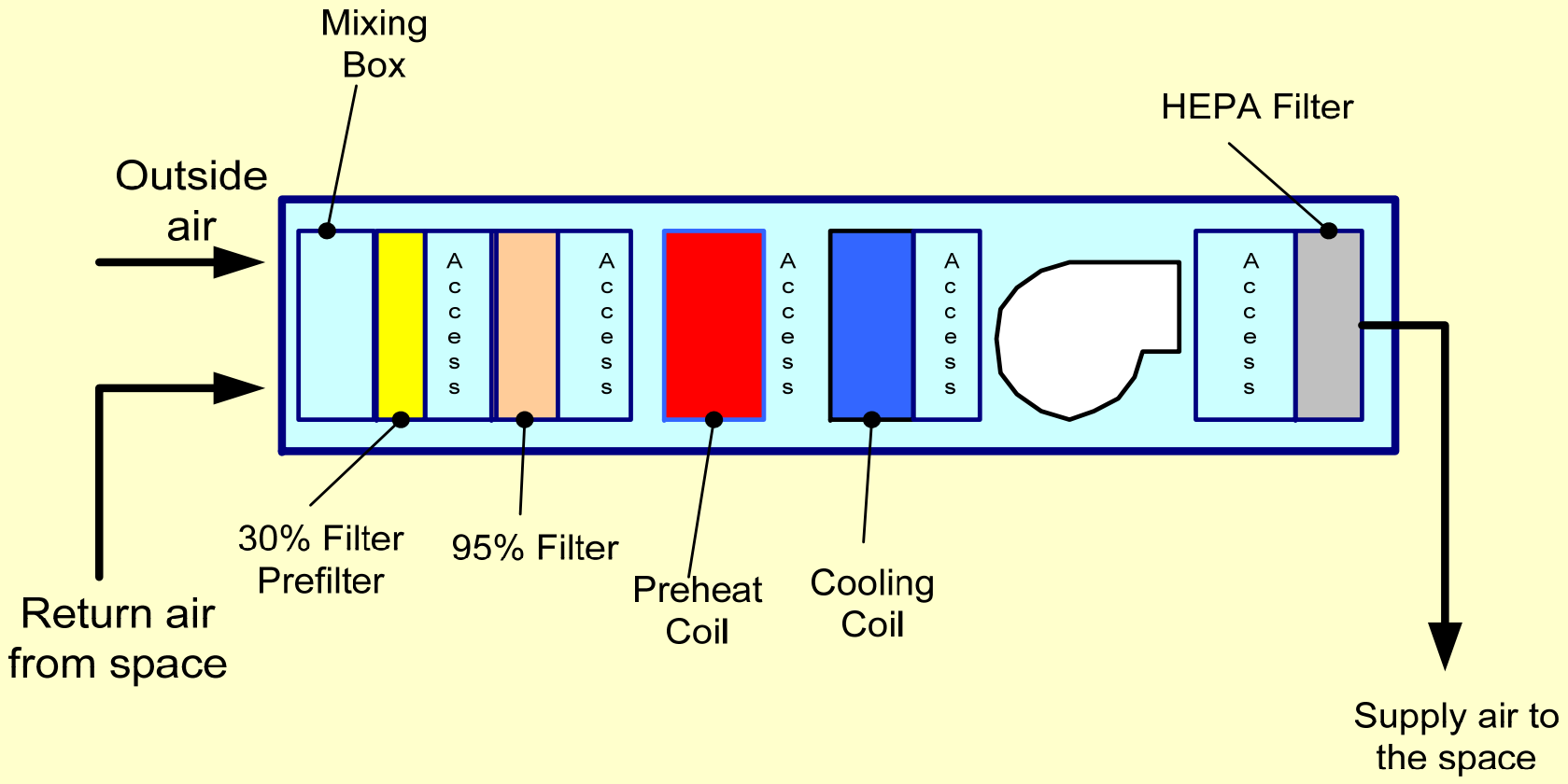
- Commercial grade – basic units serving commercial office buildings
- Industrial grade – more durable grade to serve manufacturing and other industrial areas
- Pharmaceutical grade – double wall construction, more stainless steel, lower leakage levels
- Some units are fitted with humidifiers and dehumidifiers

Air Handling & HVAC Systems

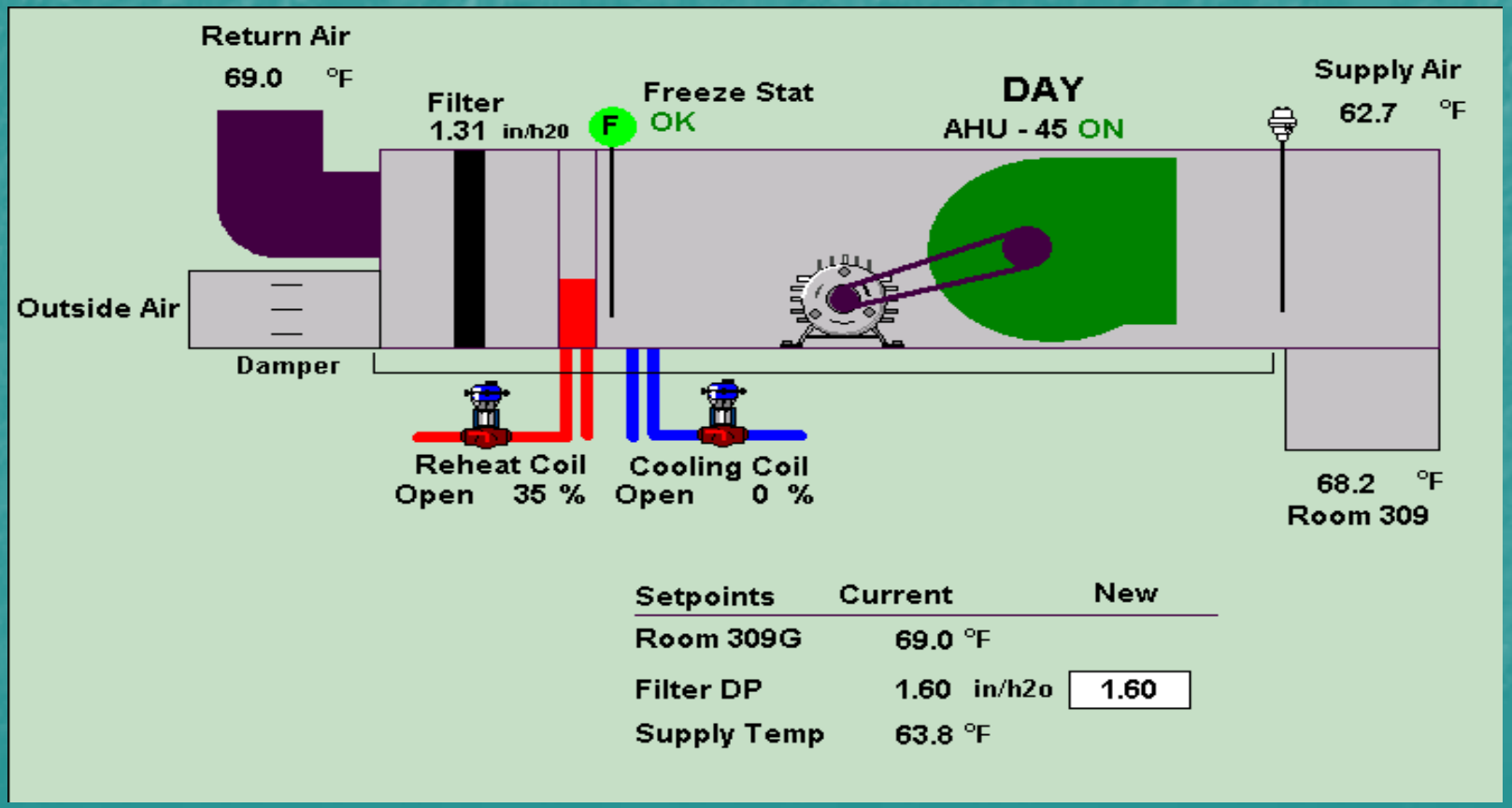
Air Handling units:

- Rated in terms of CFM
- Central station air handling unit – most common in commercial and industrial applications
- Consists of several modules
- Basic components of a central station air handling unit:
  - Filter section – to filter the air
  - Cooling coil section – to cool the air
  - Heating coil section – to heat the air
    - Sometimes have two – pre-heat and primary heat
  - Fan section – blowers that drive the air
  - Mixing box section – open plenum that allows outside air to mix with return air from the space

General Design Features
Typical Air Handling Unit



General Design Features
Typical Air Handling Unit



HVAC

Heating
Ventilating
Air Conditioning

In a broad sense, HVAC refers to the conditioning of a space typically for habitation, however it can also serve to support industrial requirements. HVAC can also refer to any and all of the systems and equipment used for these purposes*

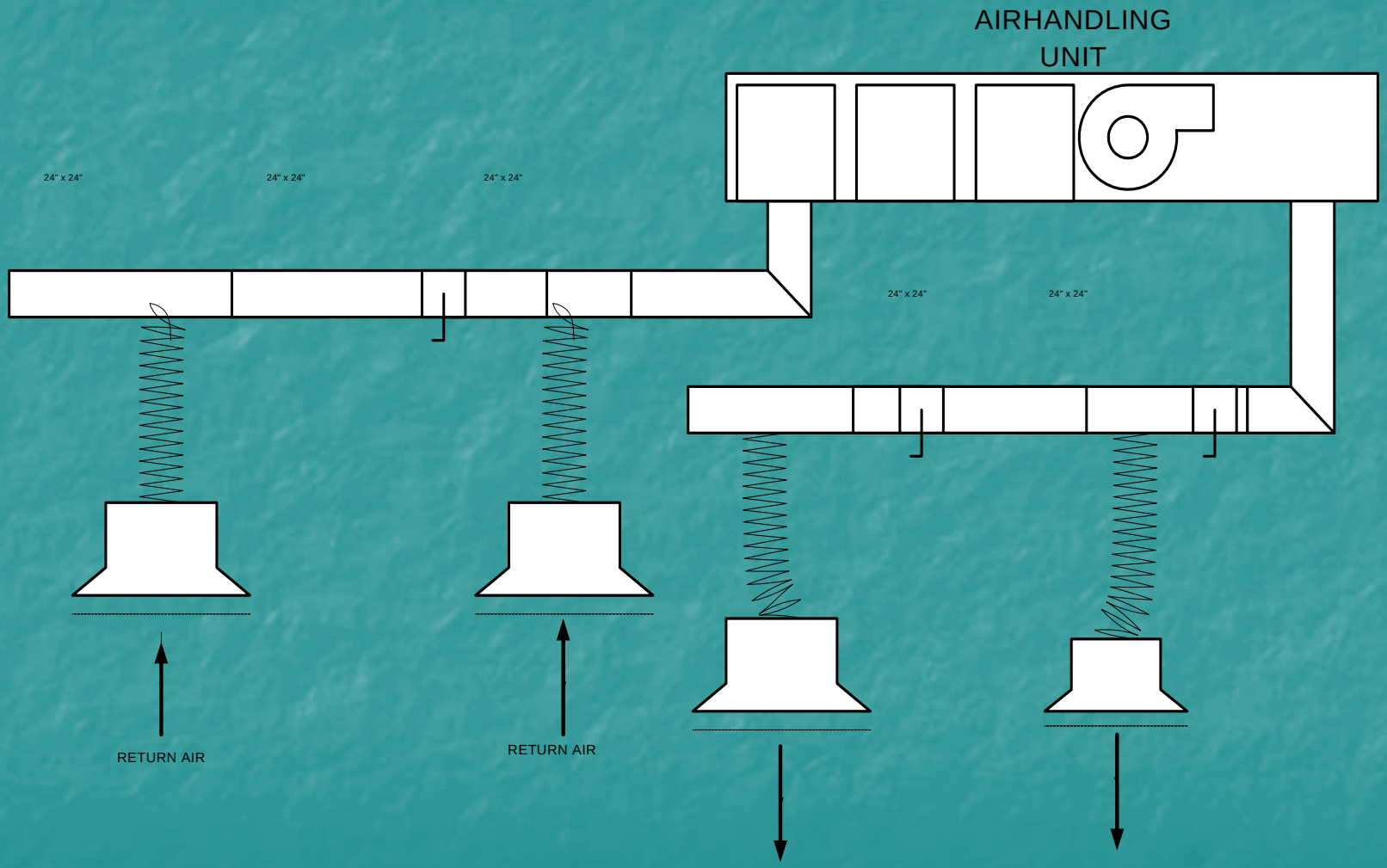
Air Handling & HVAC Systems

HVAC System*:

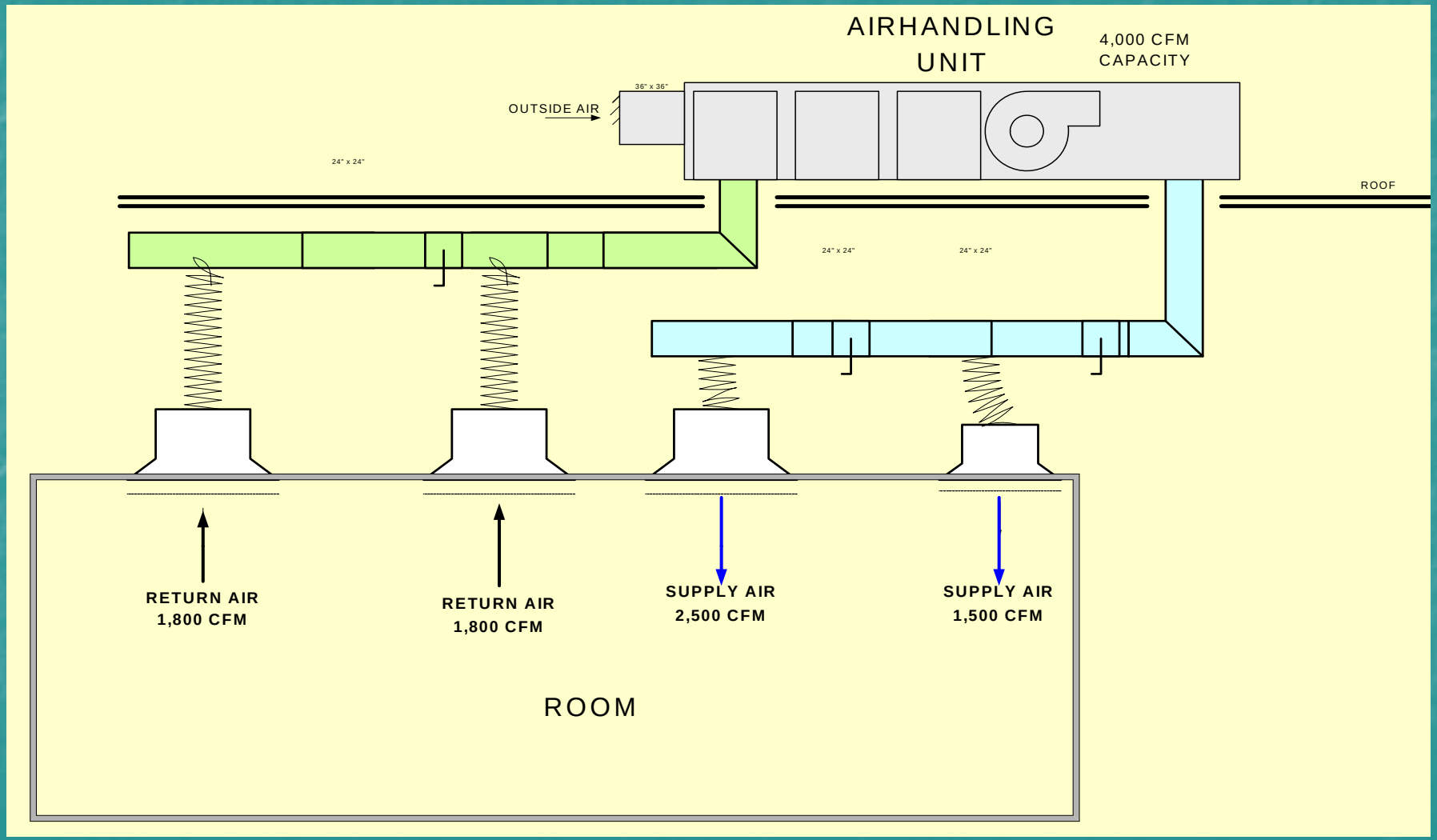
The Heating, Ventilation and Air Conditioning system, consisting of air handling unit (prime mover), ductwork (distributor) and associated dampers, valves, and instrumentation and controls.

- HVAC systems for industrial applications and Pharmaceutical and Chemical applications are more sophisticated than standard commercial HVAC systems

Air Handling & HVAC Systems



Air Handling & HVAC Systems



Air Handling & HVAC Systems

We will discuss HVAC systems and air handling units in greater detail later in the semester...

Support Utilities

Compressed-Air:

- Instrument Air
- Process Compressed Air
- Generated by air-compressors (Many Types)
- Distributed throughout the facility, typically in copper tubing.
- Measured in CFM (cubic feet per minute)
- Typically generated at 80 – 120 psig pressure

Support Utilities

Compressed-Air Uses

- Instrument air for all plant instruments and valves
- Fed to Process Air Dryers that feed oil-free, dry air to pharmaceutical equipment such as autoclaves, ovens, water for injection, etc.

Support Utilities

Compressed-Air Cooling:

All air compressors generate a significant amount of heat.

- Heat exchangers: inter-coolers and after-coolers cool the compressed air.
- Source of cooling:
  - Air cooled
  - Water cooled (city water, cooling-tower water sometimes used)

Typical Oil-free Air Compressor

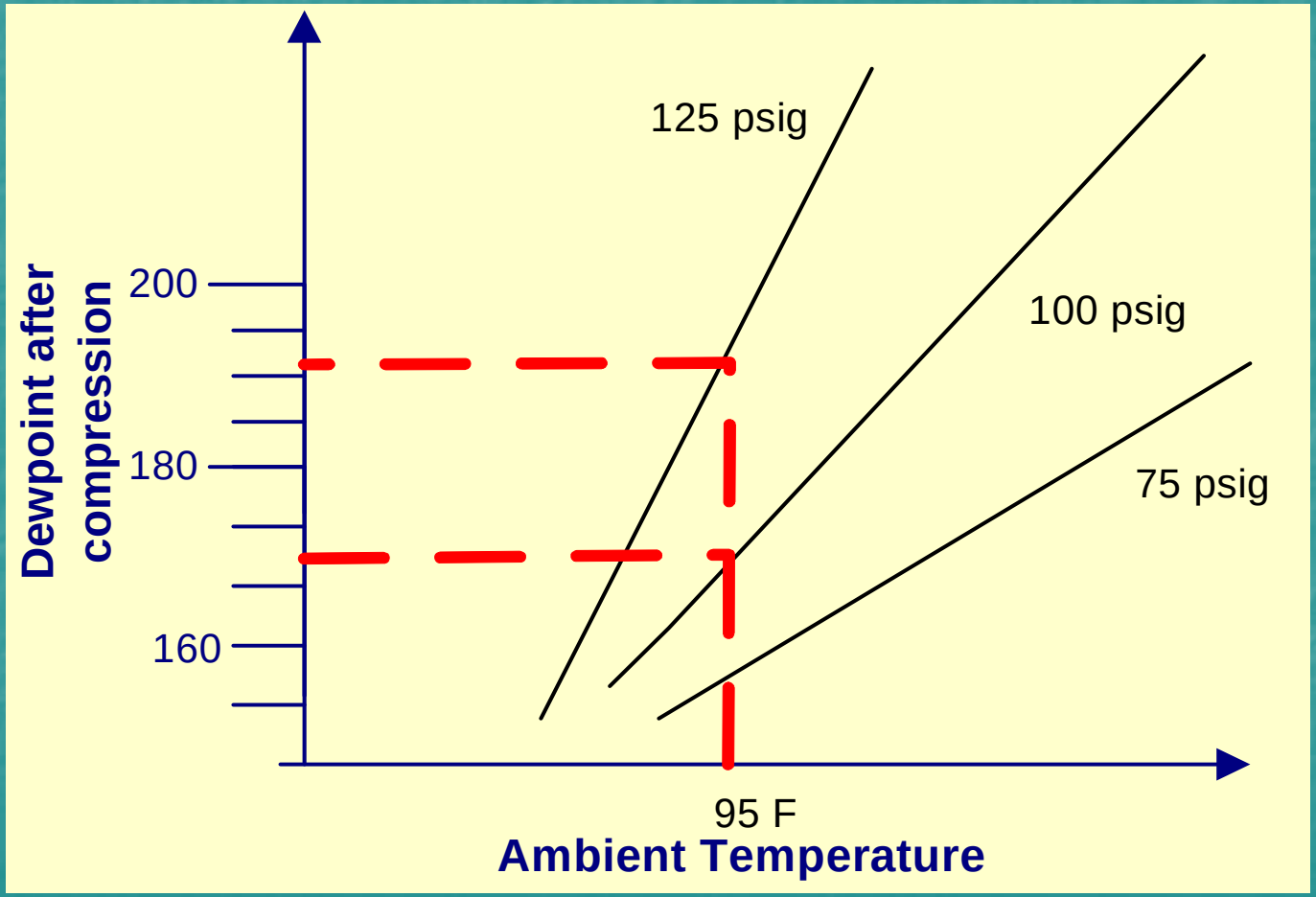
Support Utilities

Compressed-Air Drying

- Oil content (lack thereof), moisture content (dewpoint), and total particulates are important factors in pharmaceutical applications
- Dewpoint: the temperature at which moisture begins to condense as the temperature of the air-water mixture is reduced.
- Atmospheric air has a certain dewpoint, **during compression, the dewpoint of the air is raised.**

Compressed-Air Drying

During compression, air temperature and dewpoint rise



Support Utilities

Compressed-Air Drying

- Elevated dewpoints are not acceptable as condensation in distribution piping and equipment can occur – leads to corrosion
- Air Dryers are used to reduce the dewpoint/moisture content.

Support Utilities

Compressed-Air Drying

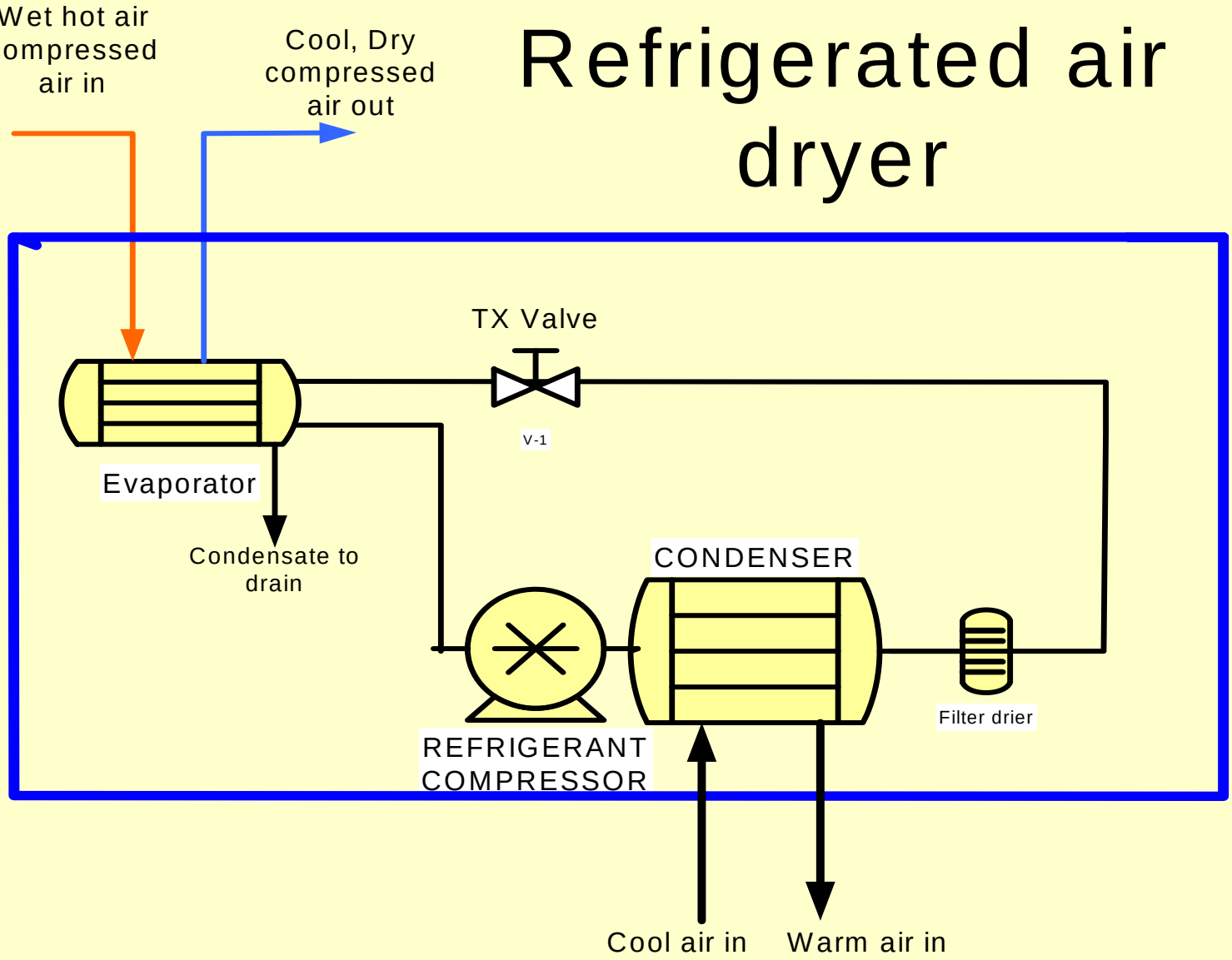
- Types of air dryers:
  - Refrigerated
  - Regenerative desiccant
- Can achieve lower dewpoints with the desiccant dryer
  - Refrigerated: 35°- 39°F dewpoint
  - Desiccant: typically – 40°F, but can go down to –100°F
  - We will discuss desiccants in more detail later in the semester……

Support Utilities

Compressed-Air Drying: refrigerated

- Warm compressed air is passed through evaporator, where it is cooled and dehumidified.
- Can achieve 35°- 39°F dewpoint.

Refrigerated air dryer



Refrigerated Air Dryer

Regenerative Compressed Air Drying

Regenerative air dryers use desiccant media to adsorb moisture and contaminants from compressed air. The desiccant media can be regenerated, or purged of the moisture it collects, and used again and again. Regenerative dryers use this process to allow compressed air to be dried to very low dew points of either 40˚F, -80˚F, or -100˚F. These low dew points are necessary for critical compressed air applications or for those in extremely cold ambient conditions where any moisture remaining in the air would freeze inside compressed air system piping and block flow.

Regenerative Compressed Air Drying

- Typically two tower design
- One tower is in operation, with wet air introduced into the desiccant chamber flows upward
- Desiccant is typically silica gel.
- The second tower gets regenerated – a small portion of the dry air from the first tower flows downward through the second tower, thus removing all the moisture it has collected.

Regenerative Desiccant Air Dryer

Support Utilities

Compressed-Air Distribution

- Typically in copper piping
- Where the air can come in contact with product or product contact surfaces, pre-cleaned, medical grade tubing is often used to reduce likelihood of contamination.
- Pressure regulators, and filters are often used at the use points, as required.
- Air receivers (storage tanks) are strategically placed in the system – especially needed at loads that require a large amount of compressed air over a short time period. These reduce sudden pressure drop in the system.

Support Utilities

Compressed-Air Distribution

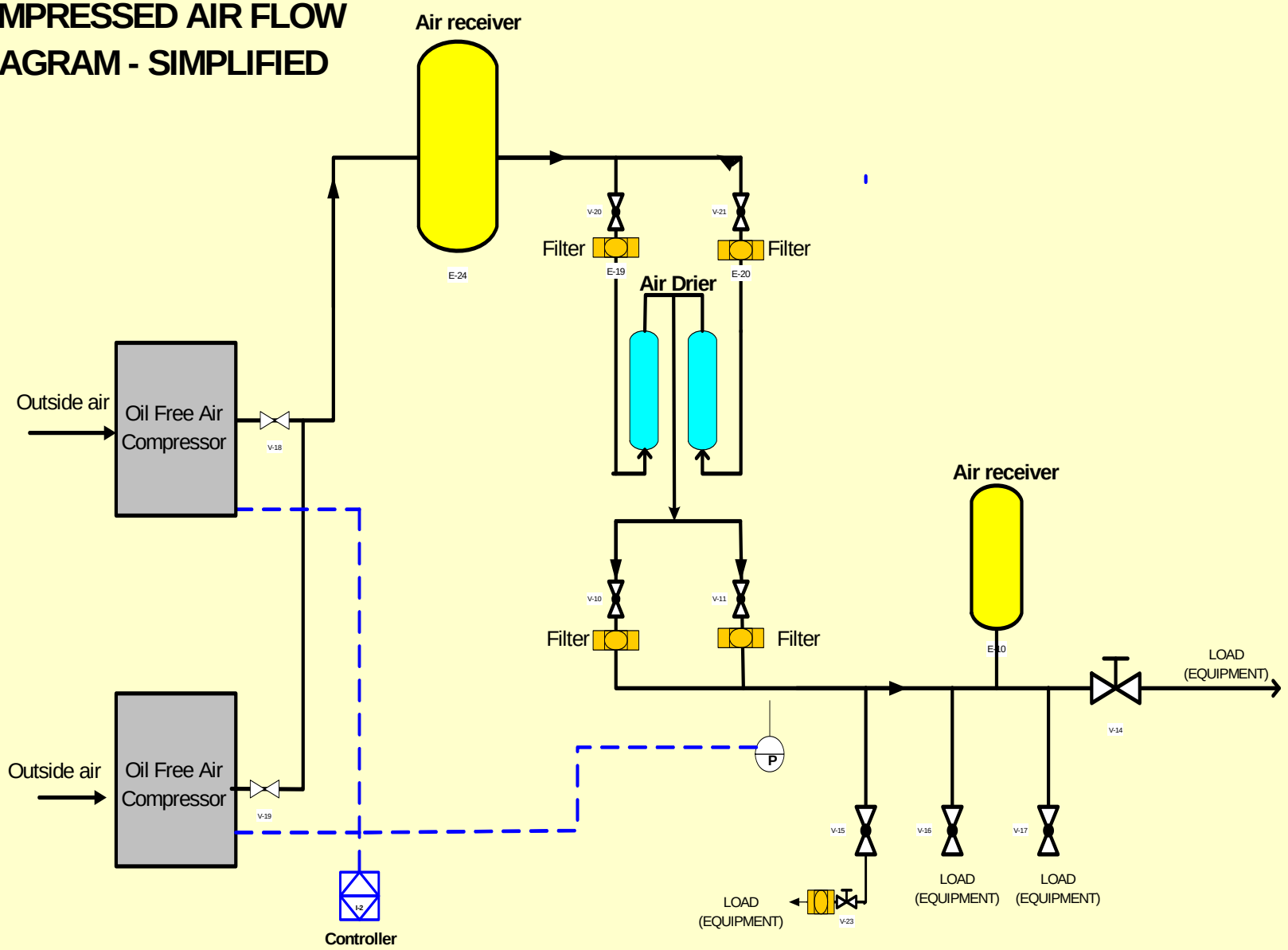
- Filters to remove particulate and any remaining oil droplets typically at inlet and outlet of air dryers
- Compressors cycle on and off based on pressure level in the system
- Achieved thru pressure sensing in the distribution main – input fed to controller (typically PLC).
- PLC in turn cycles compressors on and off.

Support Utilities

Compressed-Air Distribution

- Typically have redundant compressors connected in parallel
- Start and stop based on pressure in system

COMPRESSED AIR FLOW DIAGRAM - SIMPLIFIED



Support Utilities

Central Chilled Water Systems

- A distributed system that provides “chilled” water to air handlers and equipment
- Chilled water is created by chillers – many different types – based on refrigeration cycle
- Distributed throughout plant by pumps
- Temperature typically runs between 42° and 50° deg F.
- Fed to air handlers that provide air-conditioning for the building, for personnel comfort and environmental control
- In some cases, used directly by process equipment to provide cooling for the process

Support Utilities

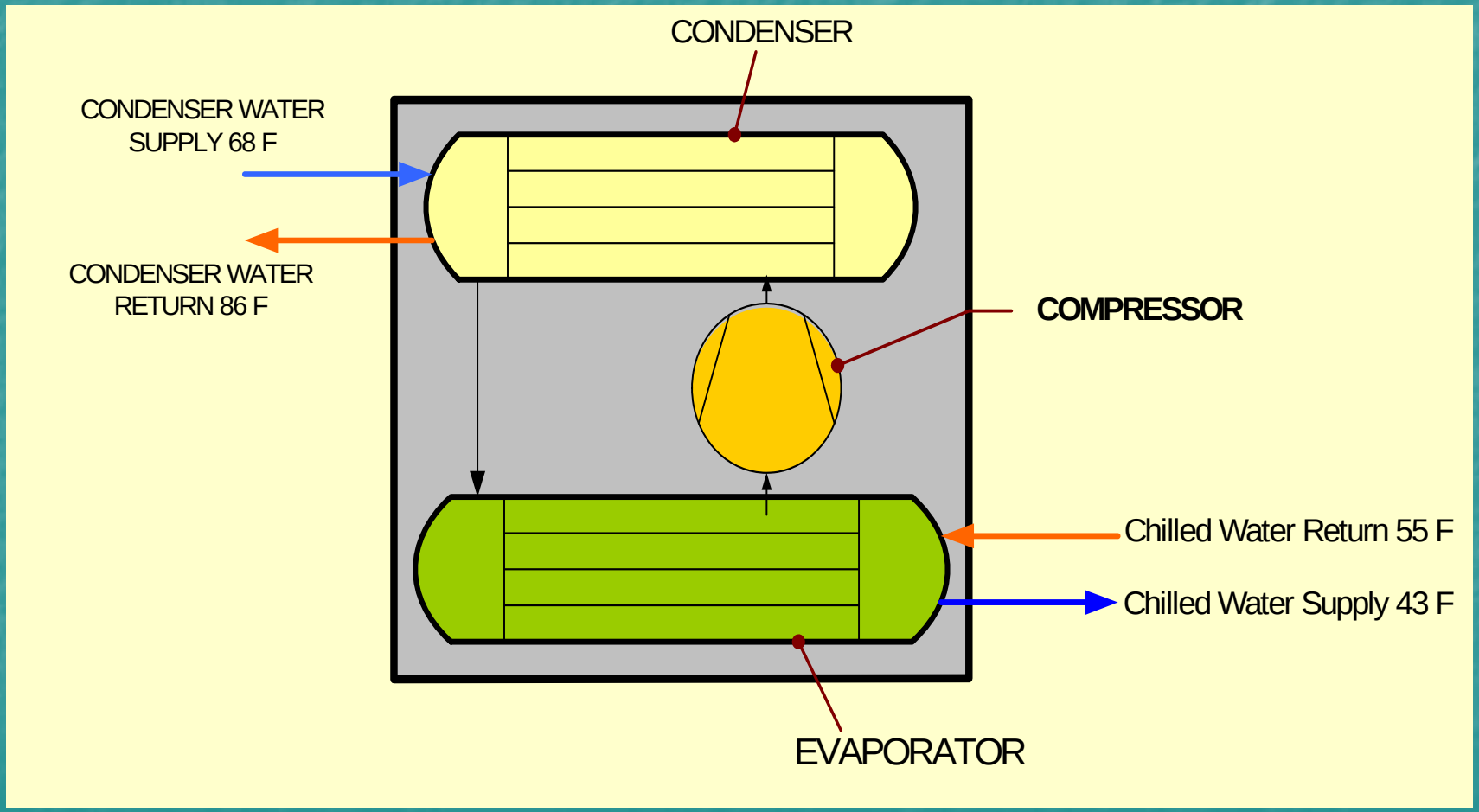
Central Chilled Water Systems

Centrifugal Chillers

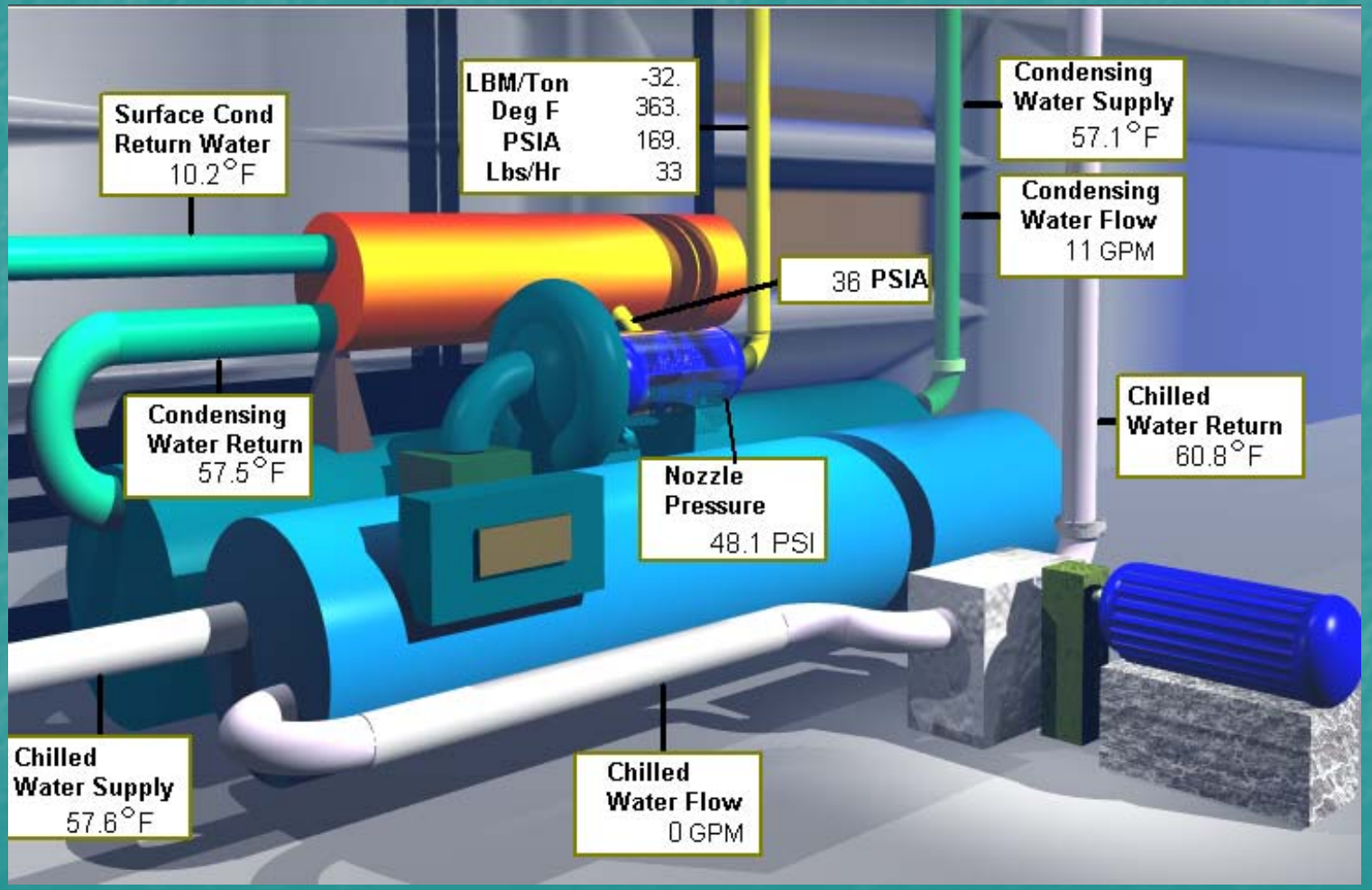
- Primary components: evaporator, condenser and compressor
- Refrigerant gas is pumped by the compressor into the condenser.
- Condenser water flows through the condenser and cools the refrigerant
- Condenser water is cooled in the cooling tower
- Liquid refrigerant flows through the evaporator, where it then cools the water to produce chilled water.

Central Chilled Water Systems

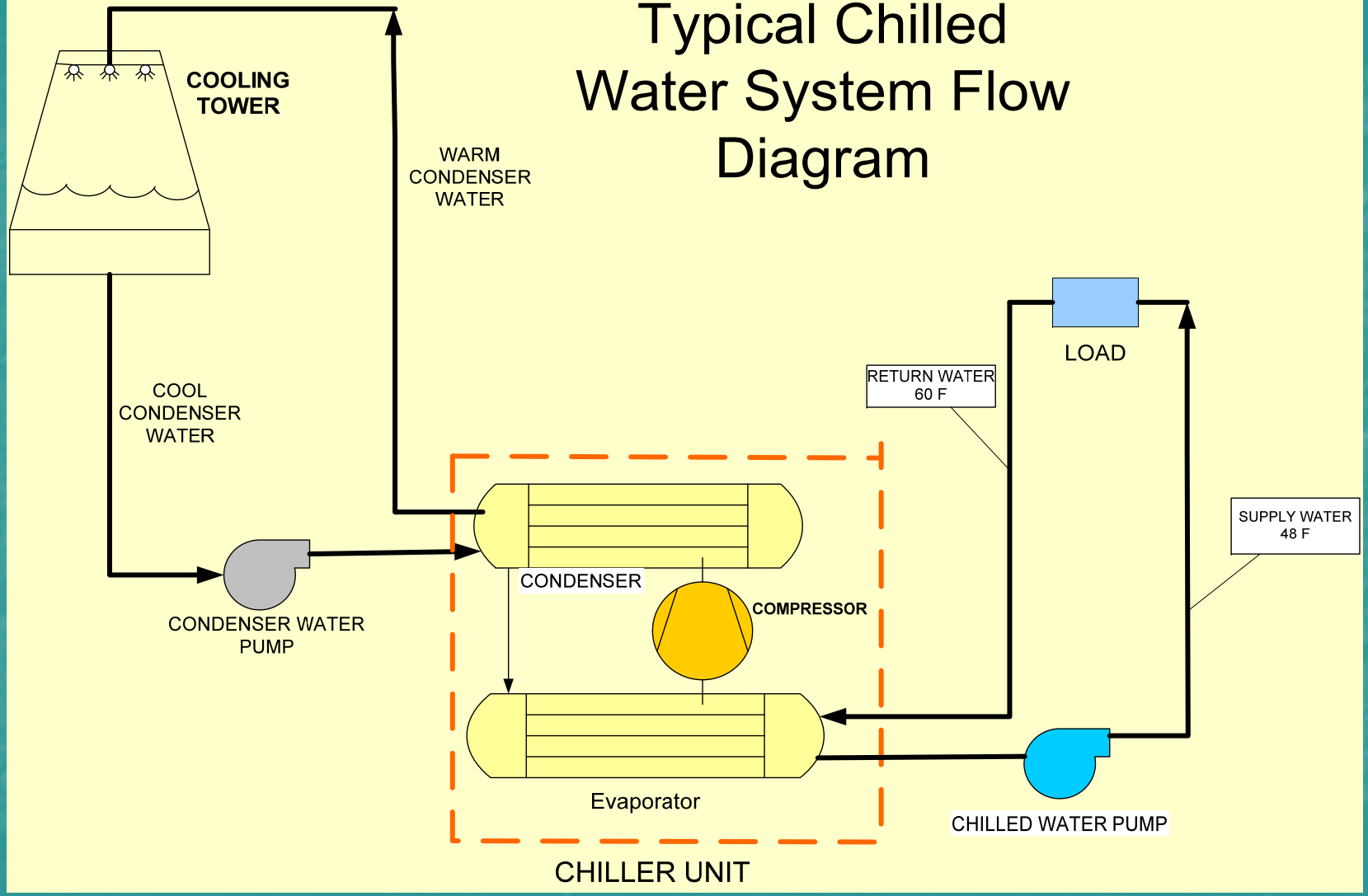
Centrifugal Chiller

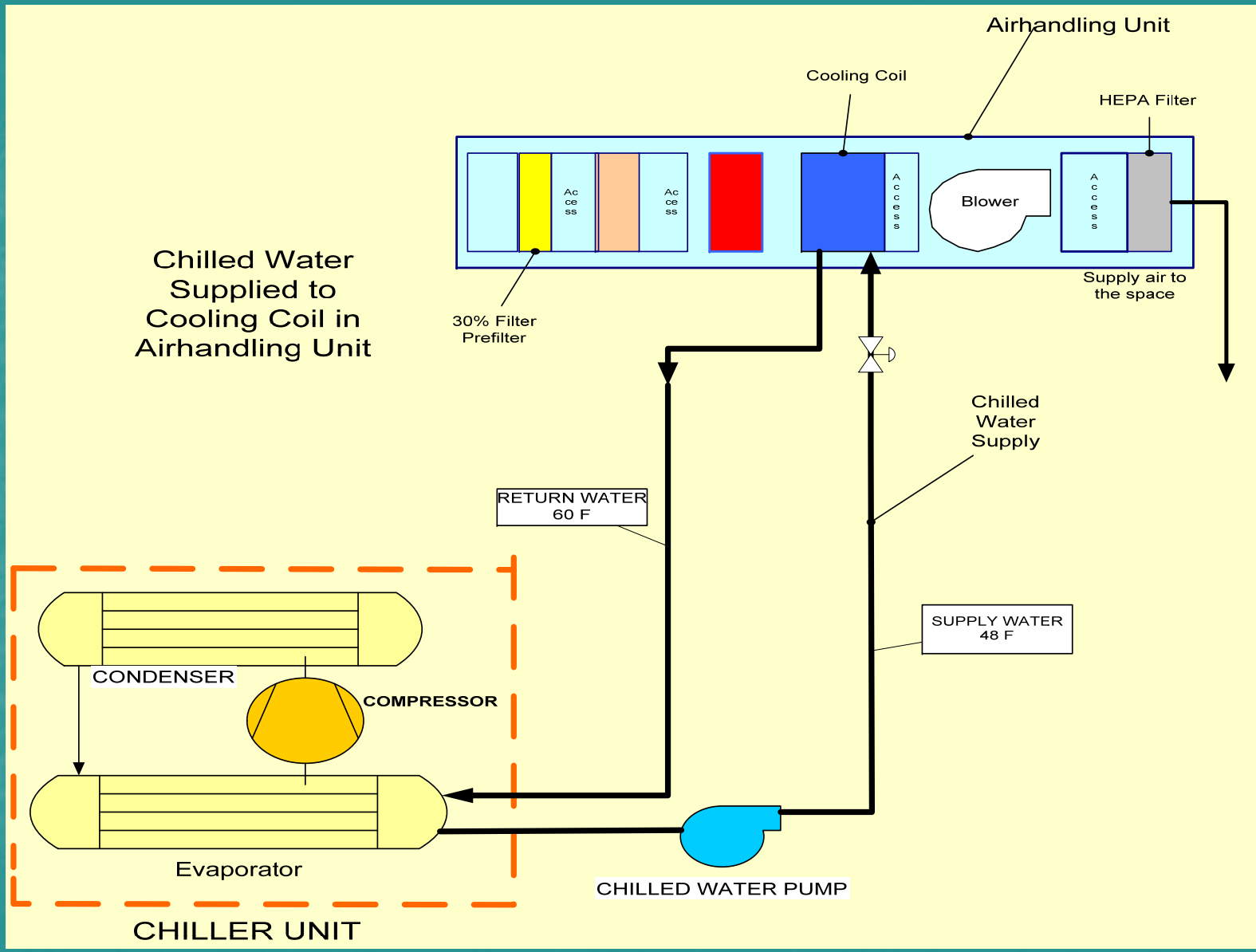


Central Chilled Water Systems



Typical Chilled Water System Flow Diagram



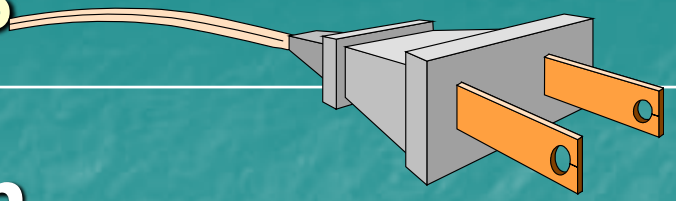

Airhandling Unit
Cooling Coil
HEPA Filter
Blower
Supply air to the space
30% Filter Prefilter
Chilled Water Supplied to Cooling Coil in Airhandling Unit
Chilled Water Supply
RETURN WATER 60 F
SUPPLY WATER 48 F
CONDENSER
COMPRESSOR
Evaporator
CHILLED WATER PUMP
CHILLER UNIT

Support Utilities

Electrical Distribution

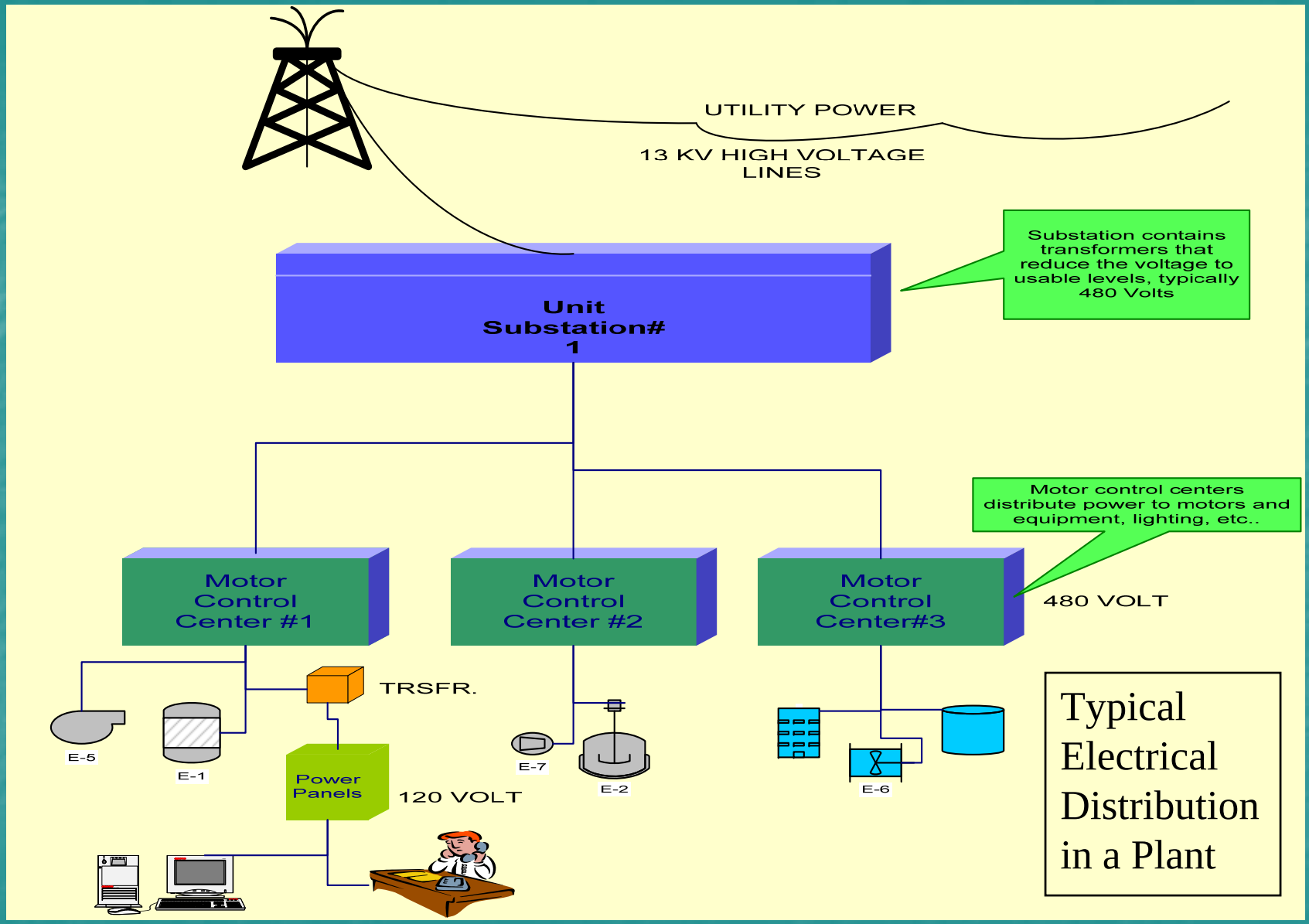
- Must consider size and location of substation.
- Size and location of local motor control centers
- Must ensure design is consistent with all applicable codes (NEC)
- Consider if client desires on-site back-up generation

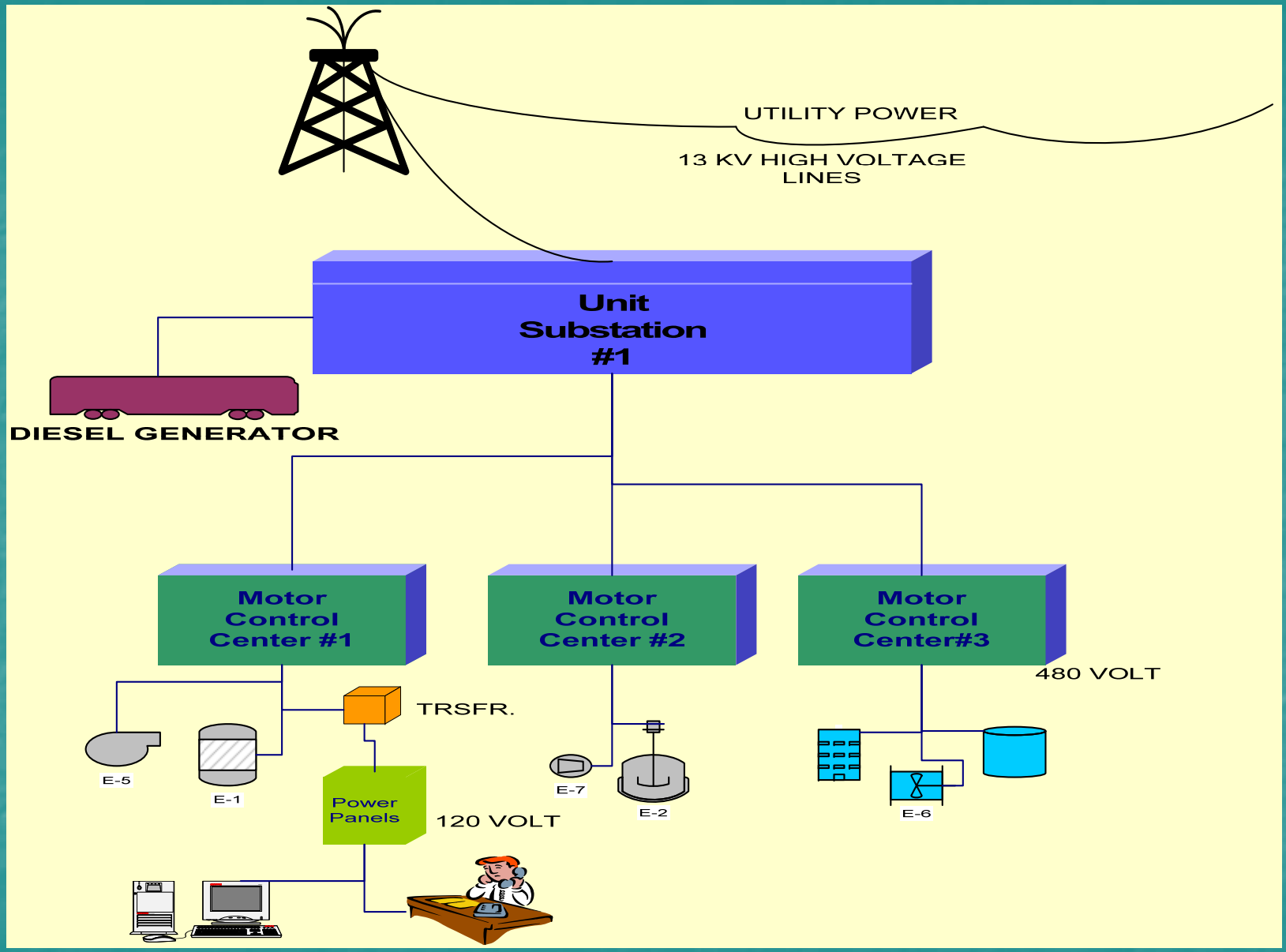
Support Utilities

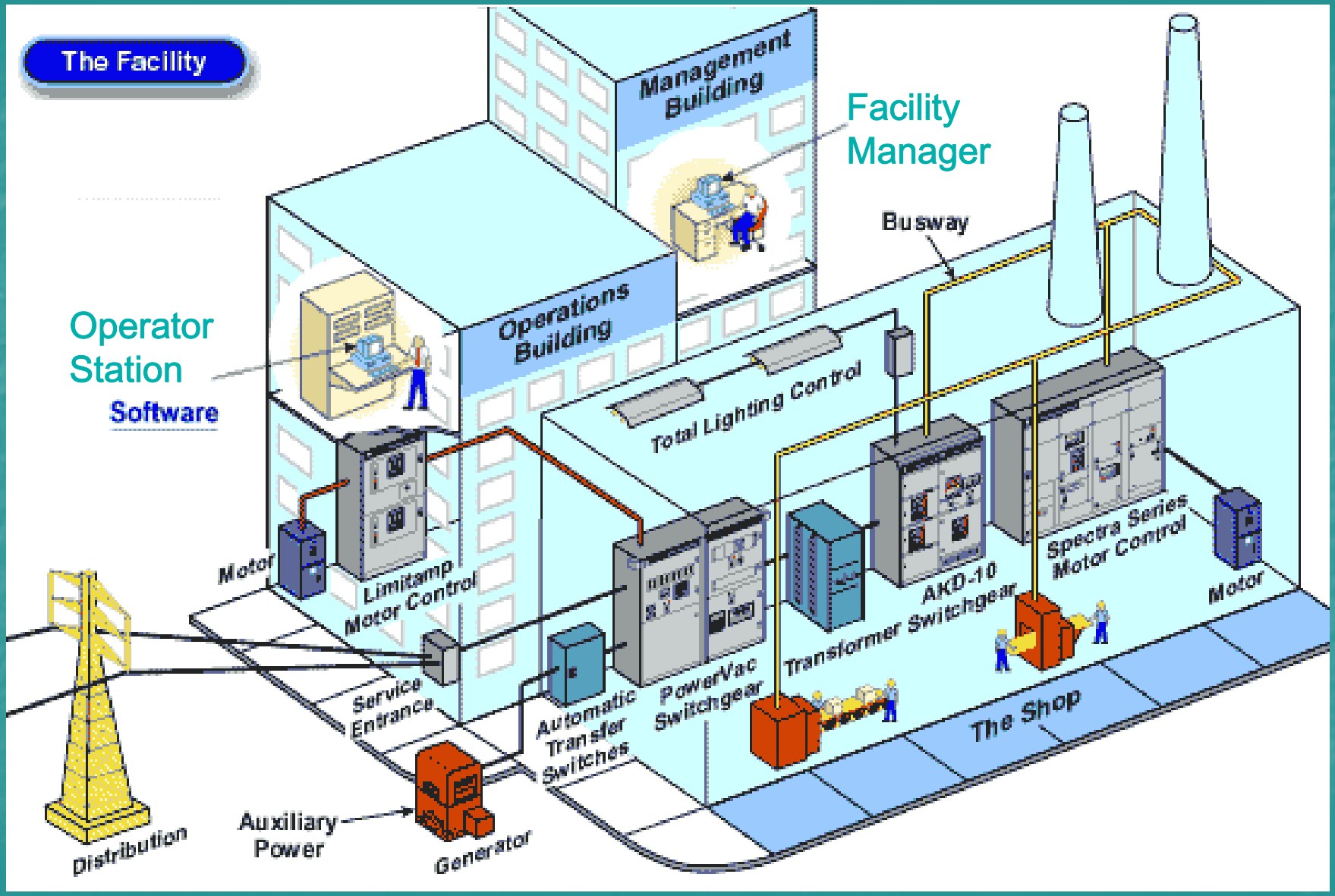


Electrical Distribution

- What are the major voltages used in a facility?
- 4,160 Volt: used for higher horsepower loads/equipment
- 480 Volt - most common for pharmaceutical equipment
- 277 Volt - used for lighting
- 240 Volt - used for small and medium size motors
- 208 Volt - used for small and medium size motors
- 120 Volt - most common - used for general purpose, offices, computers


UTILITY POWER
13 KV HIGH VOLTAGE LINES
Substation contains transformers that reduce the voltage to usable levels, typically 480 Volts
Unit Substation# 1
Motor control centers distribute power to motors and equipment, lighting, etc..
Motor Control Center #1
Motor Control Center #2
Motor Control Center#3
480 VOLT
TRSFR.
E-5
E-1
E-7
E-2
E-6
Power Panels
120 VOLT
Typical Electrical Distribution in a Plant


UTILITY POWER
13 KV HIGH VOLTAGE LINES
Unit Substation #1
DIESEL GENERATOR
Motor Control Center #1
Motor Control Center #2
Motor Control Center#3
480 VOLT
TRSFR.
E-5
E-1
E-7
E-2
E-6
Power Panels
120 VOLT


The Facility
Management Building
Facility Manager
Busway
Operator Station
Software
Operations Building
Total Lighting Control
Motor
Limitamp Motor Control
Service Entrance
Automatic Transfer Switches
PowerVac Switchgear
Transformer
AKD-10 Switchgear
Spectra Series Motor Control
Motor
The Shop
Distribution
Auxiliary Power
Generator

Emission Control Systems Must be Considered by the Designer

Water:

- pH Control and Monitoring Systems
- Local sewerage authority has limits based on DEP requirements

Air (DEP Limits):

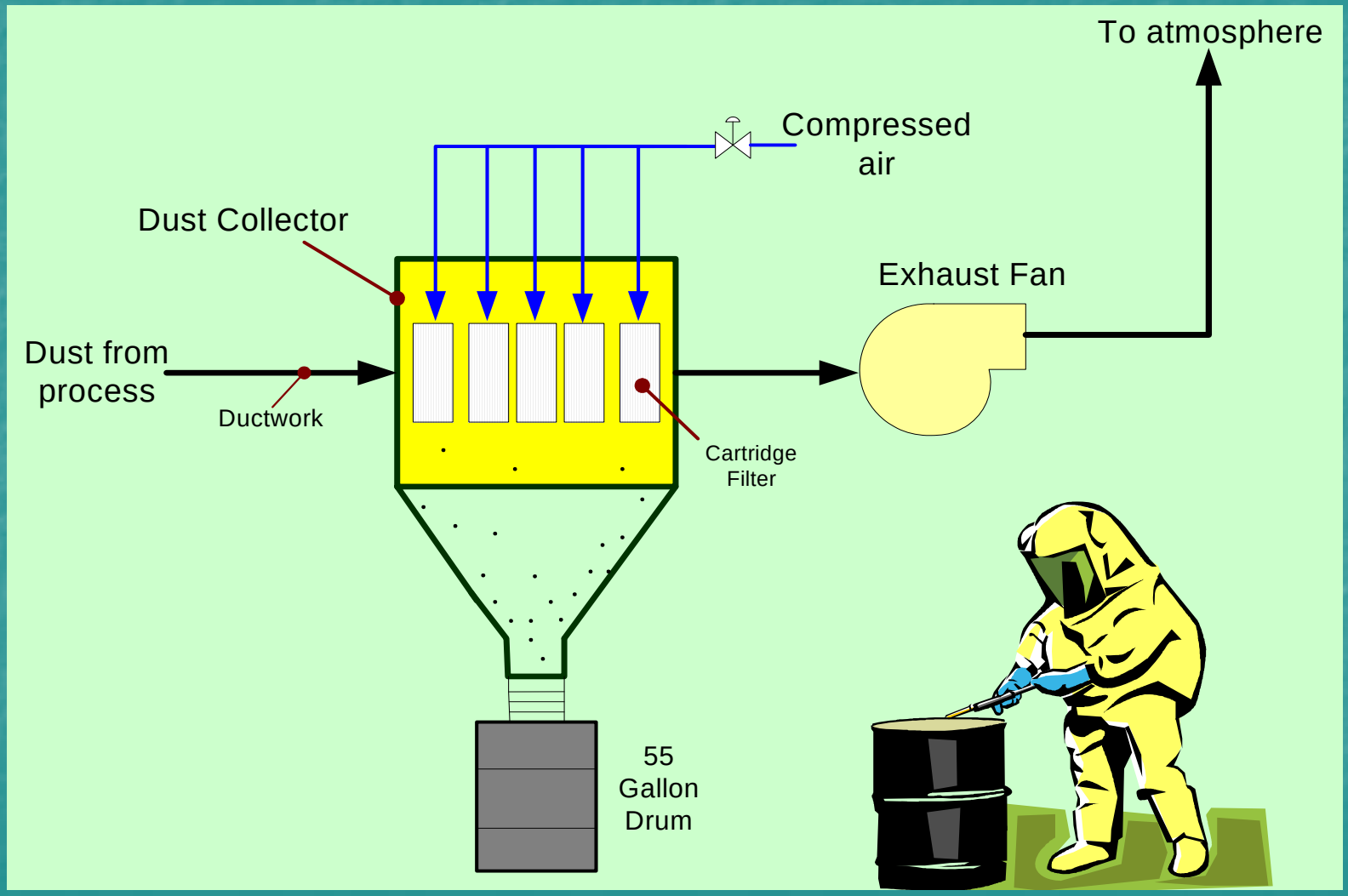
- Air emission control devices such as scrubbers and catalytic incinerators used to remove solvents (VOC's: Volatile Organic Compounds) from the air stream
- Dust collectors to pickup particulates.

Emission Control Systems

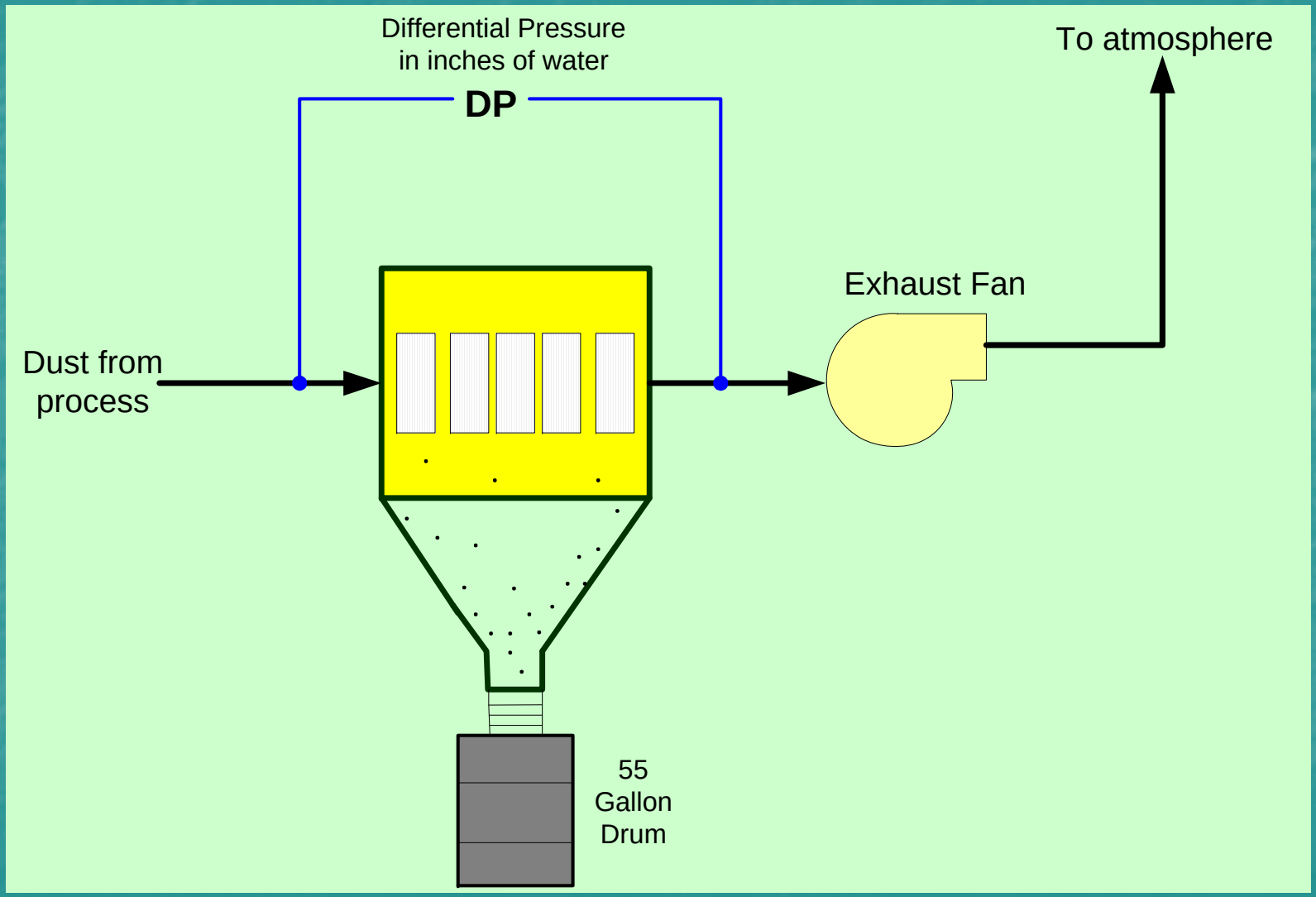
Air (DEP Limits):

- Dust collectors to pickup particulates
  - Cartridges or bags inside the unit traps the dust
  - Replace filters on a regular basis
  - Monitor the air side differential pressure to determine change-out time.
  - Compressed air injected into filter to blow-out dust on surface
  - Dust collected in drum

Dust Collection



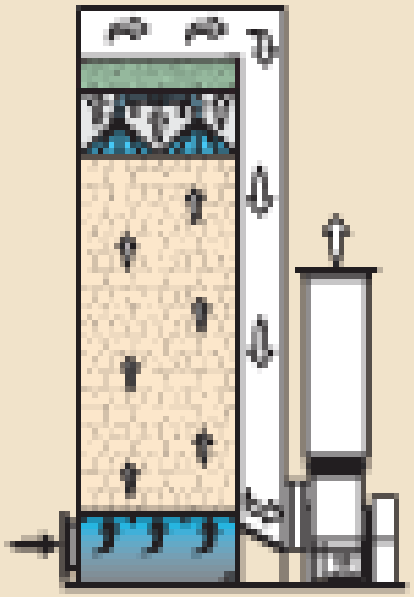
Dust Collector w/Differential Pressure Monitor



Emission Control Systems
VOC Emission Control

Air (DEP Limits):
Scrubbers

- Scrubbers – remove solvents (VOC's), soluble odors and fumes from the air stream
  - Wet-type packed scrubber – water comes in contact with air and absorbs the solvent.
  - Solvent mixes with water and goes to drain

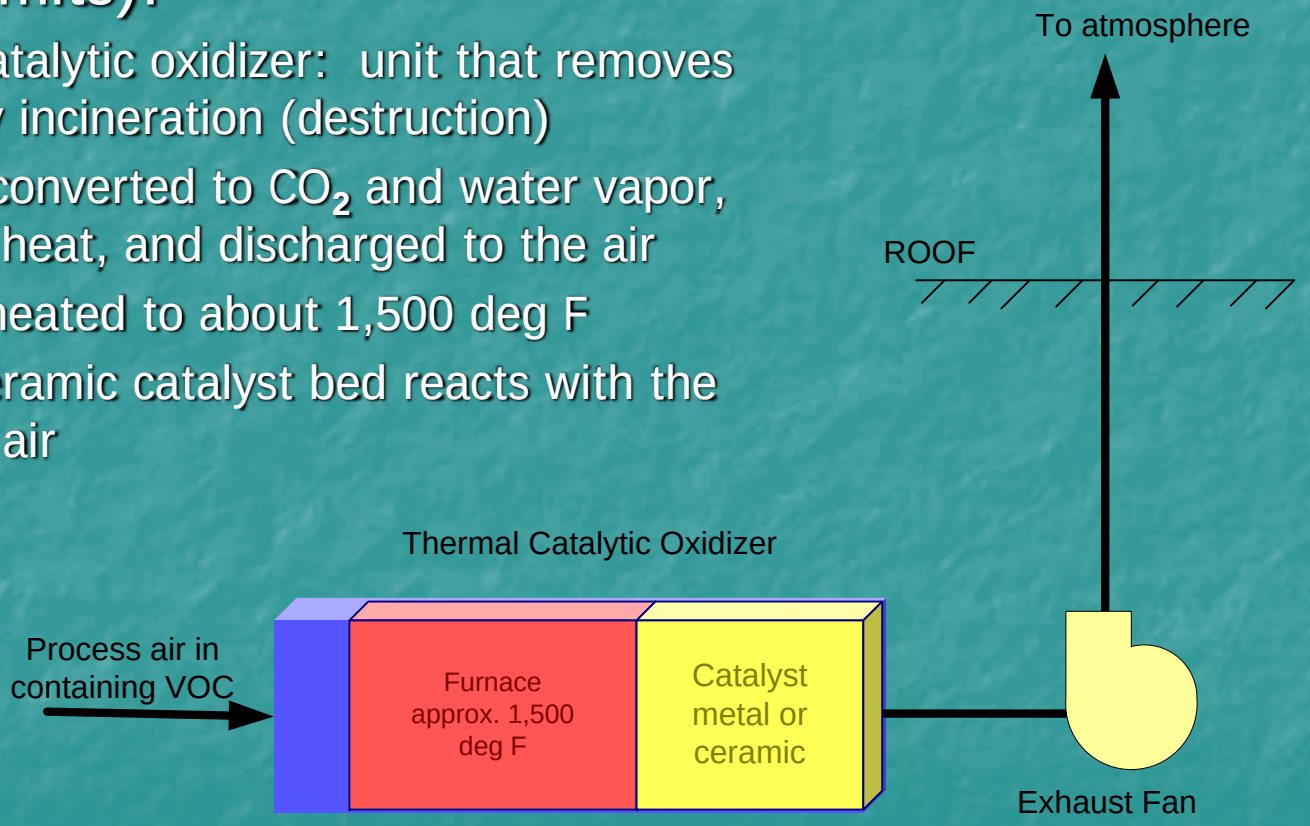


Packed Bed

Emission Control Systems
VOC Emission Control

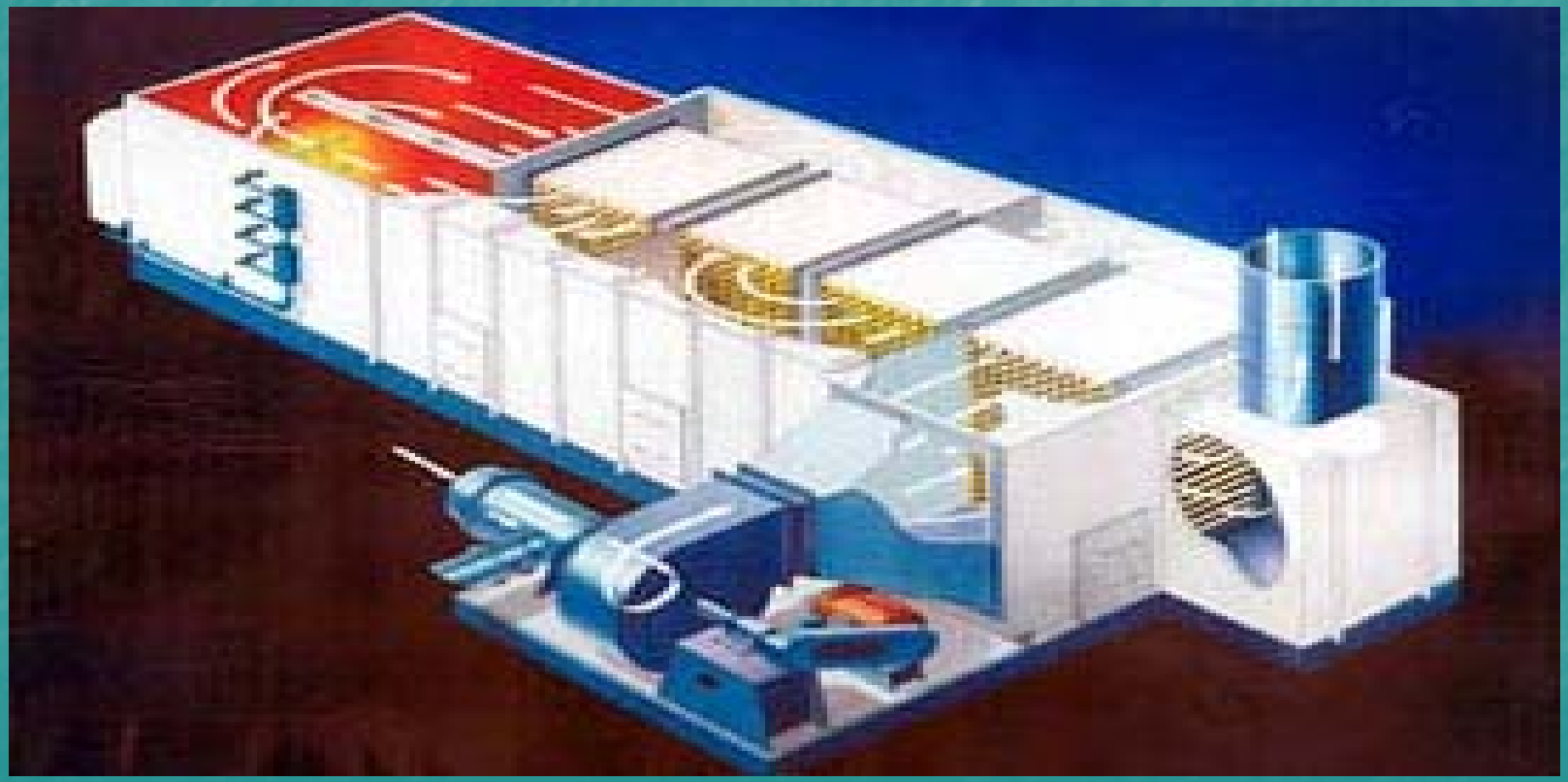
Air (DEP Limits):

- Thermal Catalytic oxidizer: unit that removes solvents by incineration (destruction)
- VOC's are converted to CO_2 and water vapor, along with heat, and discharged to the air
- Air is first heated to about 1,500 deg F
- Metal or ceramic catalyst bed reacts with the VOC laden air



Emission Control Systems
VOC Emission Control

Thermal catalytic oxidizer



Emission Control Systems Must be Considered by the Designer

Pharmaceutical MACT (Max. Achievable Control Technology)

- Sets emissions limits or control efficiencies
- Four areas:
  - Process vents
  - Storage tanks
  - Wastewater treatment units
  - Fugitive emissions
- Complicated to apply

Security & Access Control

- Has to be considered during facility design
- Much more attention recently from Pharmaceutical Industry
- Must have a well-thought-out security plan
- Security systems need to be effective, but subtle
- Want employees focused on their job – don't want a fortress mentality
- Security Plan starts off with defining your critical assets

Security & Access Control

Vehicle Access

- **Define and establish controlled site entrance(s)**
- **Station Security Guard**
- **Remotely Controlled Gate**

Closed Circuit TV (CCTV) Surveillance

- **Interior Areas**
- **Perimeter Areas**
- **Older systems are analog – video tape**
- **Newer systems are digital – preferred**
- **Very useful for investigations**

Security & Access Control

Intrusion detection

- Door Monitors/Alarms
- Glass Break Detection (shock sensors and acoustical sensors)
- Motion Sensors

Access Control Methods

- Lock and Key
- Card Access – more desirable
  - Can be imprinted with an individuals photograph
  - More convenient than keys
  - Can double as an ID badge
  - Provides electronic record of entry/exit
  - Provided with unique access level
  - Can be card swipe or proximity
- Other technologies: palm scan, retina scan
- **Useful for controlling access to sterile core areas – gowning qualification**

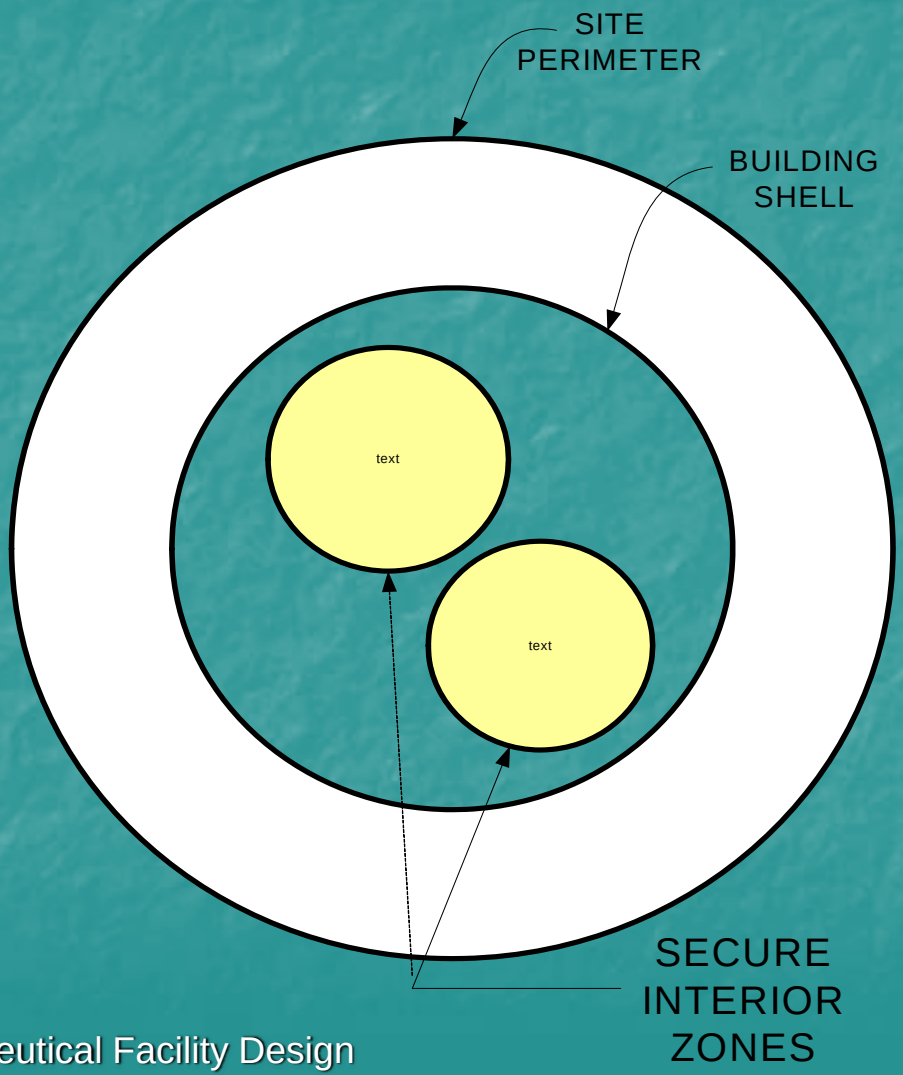
Security & Access Control

Fundamental Security Concept:

Concentric Rings of security

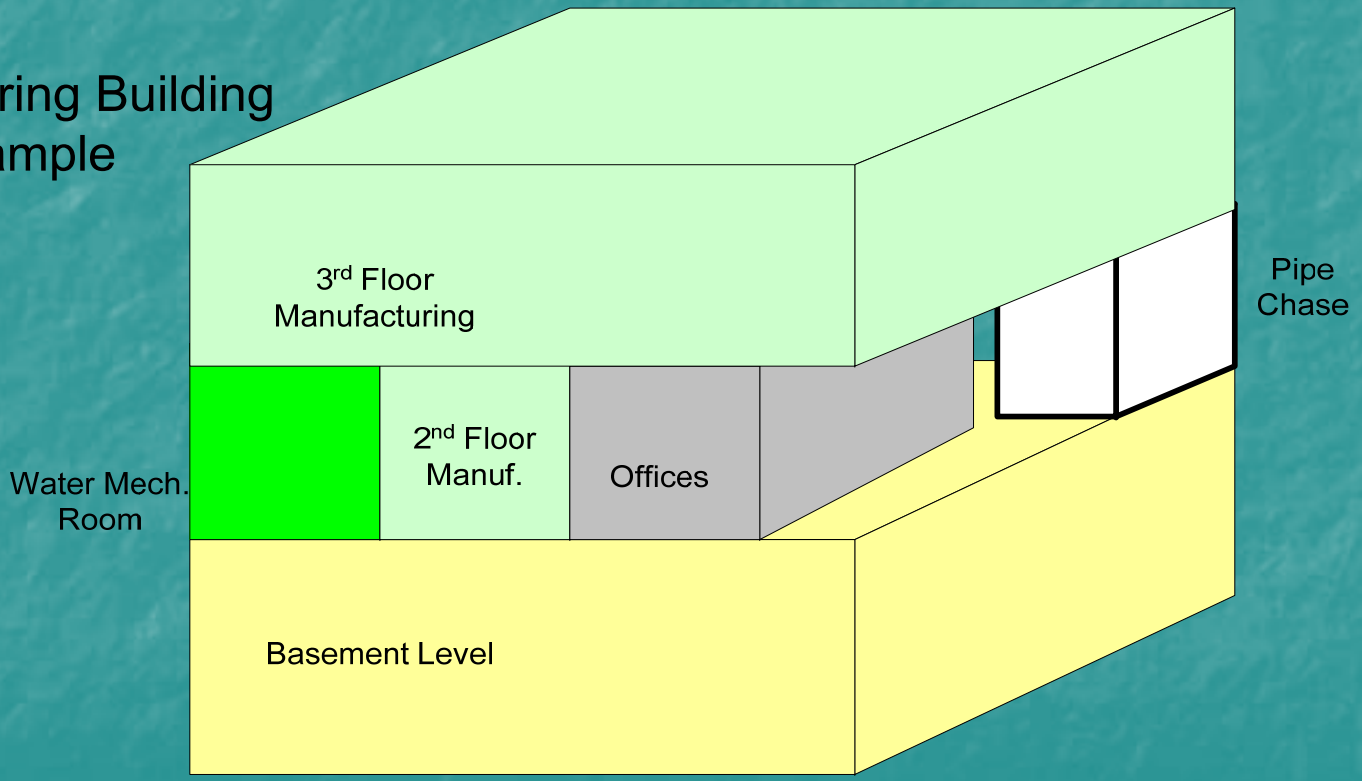
Increasingly more secure areas as you proceed toward the critical areas.

Each zone boundary has controls to prevent against threats.

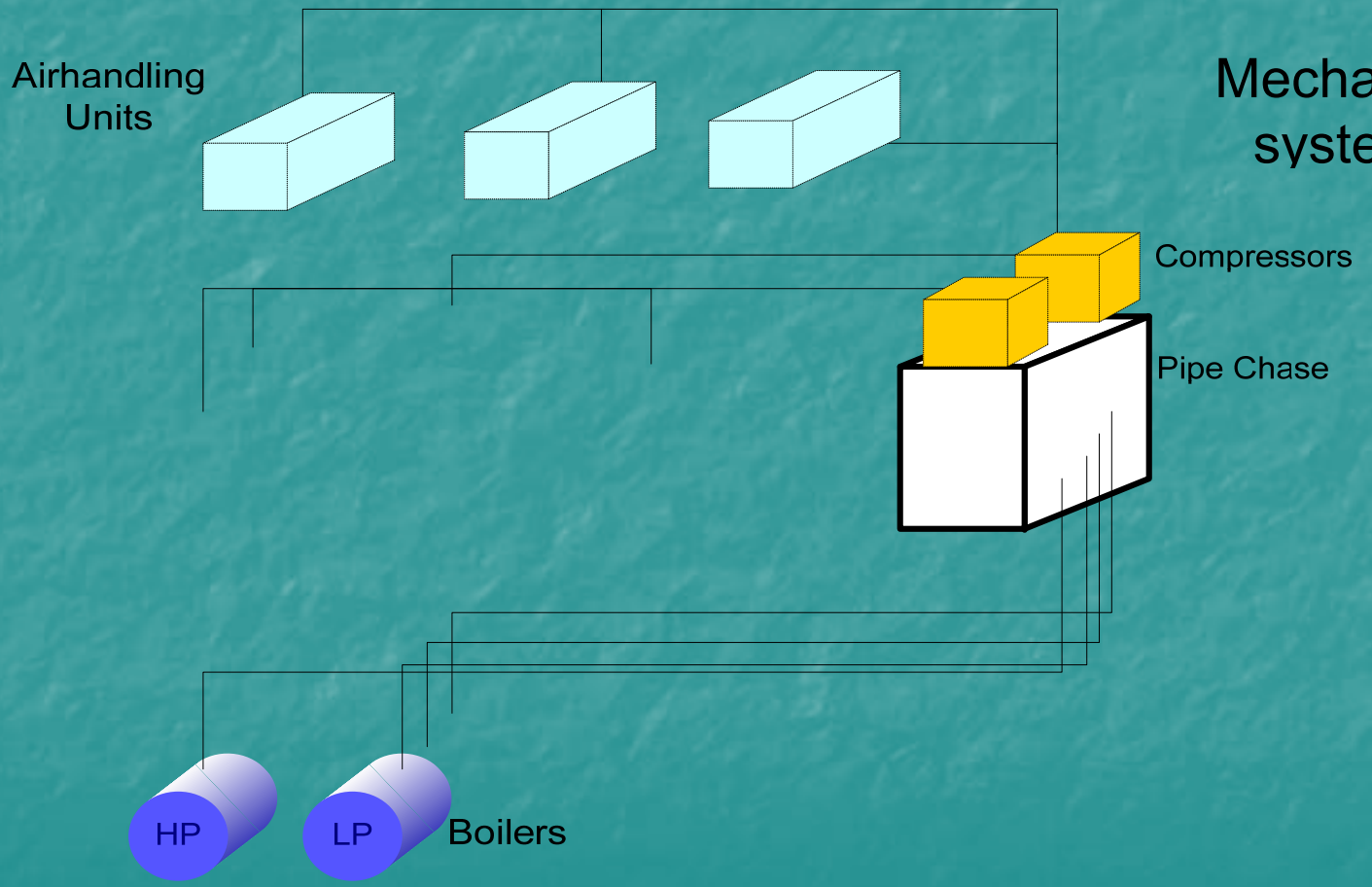


Putting it all together – Visualizing the building and utility systems

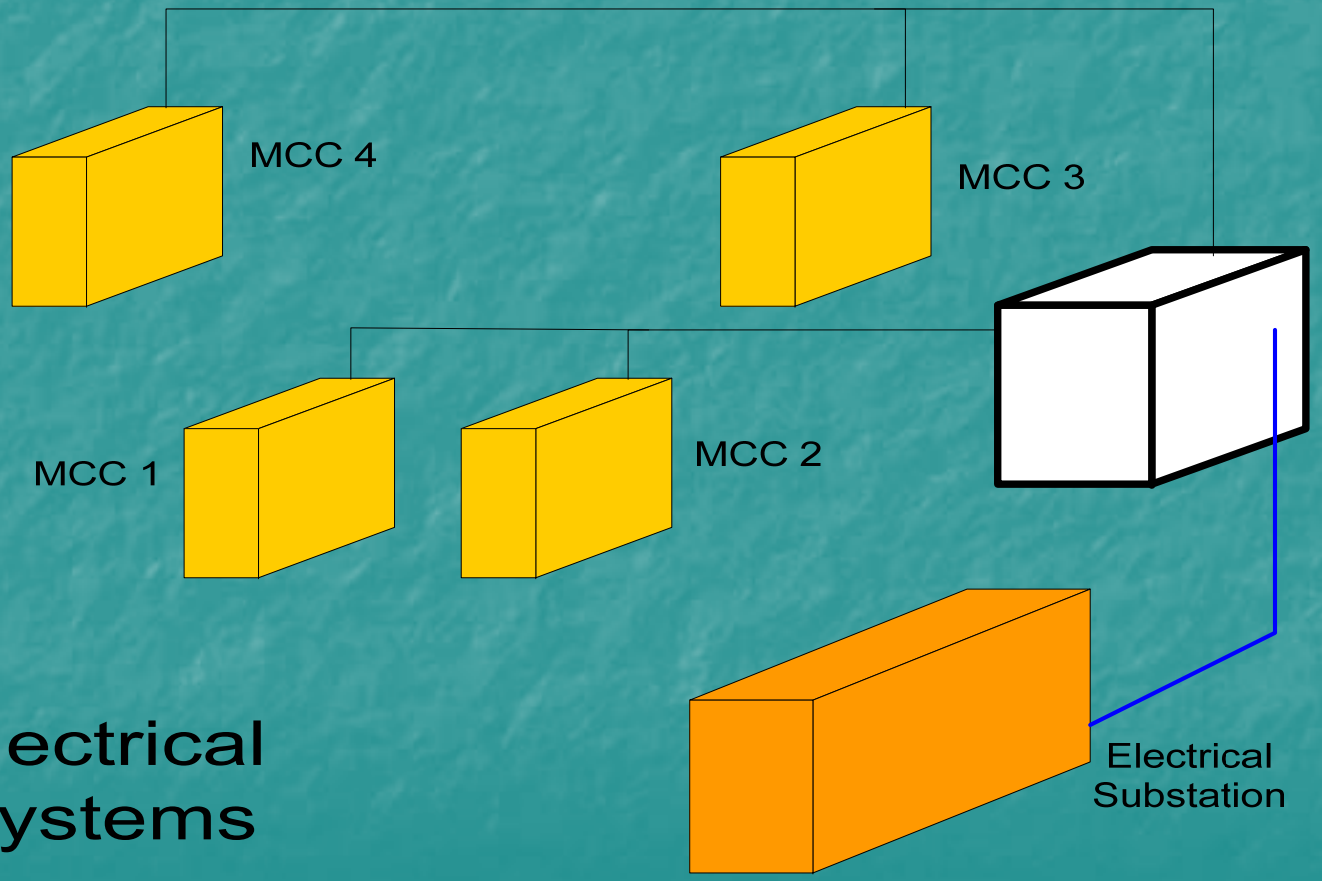
Manufacturing Building Example



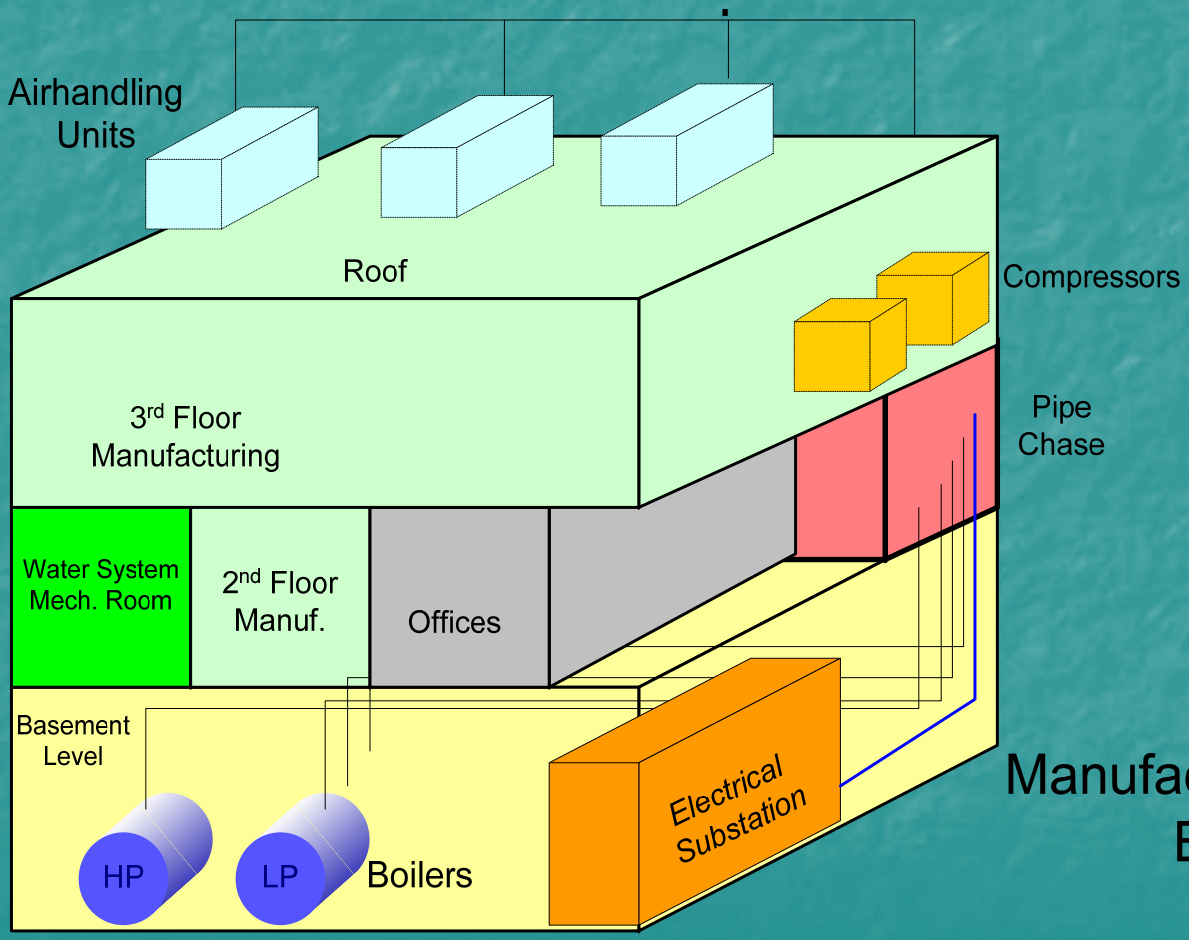
Putting it all together – Visualizing the building and utility systems



Putting it all together – Visualizing the building and utility systems



Putting it all together – Visualizing the building and utility systems



Manufacturing Building Example