1 Introduction　简介

1.1 Background　背景

The heating, ventilation, and air conditioning (HVAC) system is one of the most critical systems affecting the ability of pharmaceutical facility to meet its key objectives. HVAC systems which are properly designed, built, operated, and maintained can help ensure the quality of product manufactured in that facility, improve reliability, and reduce both first cost and ongoing operating costs of the facility. The design of HVAC systems for the pharmaceutical industry requires special considerations beyond those for most other industries, particularly in regards to cleanroom applications.

供热、通风与空调系统是影响制药设备达到其主要目的能力的关键的系统之一。恰当的供热通风与空调系统设计有助于保证此系统中设备的产品质量，加强可靠性，降低设备操作的初始成本和未来运行成本。制药工业的 HVAC 系统的设计，除了需考虑其他大多数工业中需考虑的事项外，还要求考虑许多特殊事项，尤其是用于洁净室时。

Each of the previously published ISPE Baseline R Guides for facilities (Active Pharmaceutical Ingredients, Oral Solid Dosage, Sterile Products Manufacture, Biopharmaceuticals, etc.) have included some discussion of the considerations for HVAC systems for facilities of that type. This good Practice Guide is intended to supplement those sections with more detailed information and recommended practices for implementation of HVAC systems in pharmaceutical facilities.

以前出版的《国际制药工程协会基准指南》中的设备版（活性药品原料，口服固体剂，无菌产品生产，生物制药等等）已经涉及了一些相关设备的 HVAC 设计的讨论。此优秀实践指南目的是给前面的讨论补充更多的具体详细的信息，为制药设备中的 HVAC 系统的执行提供实践建议。

1.2 Scope of This Guide　指南范围

The Guide provides supporting information and HVAC practices for facility types covered by Baseline Guides.

本指南为《国际制药工程协会基准指南》涉及到得设备类型提供了支持信息和空调净化系统的实践实例。

The Guide provides an overview of the basic principles of HVAC only to the extent required to facilitate a common understanding and consistent nomenclature.

本指南综述了空气净化系统的基本准则，其适用于要求普遍性理解和一致性命名的地方。

This guide addresses HVAC requirements in the following areas of facility lifecycles.

- Establishing User Requirements
- Design
- Construction
- Commissioning/Qualifacation
- Operation/Maintenance
- Redeployment for other use
- Decommissioning

本指南从以下几个设备生命周期来阐述空气净化系统的要求：

- 已确定的用户需求
- 设计
- 结构
- 调试/验证
- 操作/维护
- 其他用途所需的调整措施
- 停运
- 地方

The guide does NOT serve as a handbook for HVAC design (e.g. it does not discuss the details of sizing and selection of equipment. It does go into boring detail on the physics of air and humidity.)

本指南不用于作为空气净化系统的手册。如：它不讨论设备的大小与选型的具体细节；它讨论空气与湿度的详细理论。

The guide clarifies HVAC issues critical to the Safety, Identity, Strength, Purity and Quality (SISPQ) for the production of bulk and finished pharmaceuticals and biopharmaceuticals, and it considers the requirements for HVAC control and monitoring systems.

本指南明确了空气净化问题对原料药、成品药以及成品生物药的生产的安全性、一致性、剂量、纯度、质量都有关键的影响。本指南讨论了空气净化的控制与监控系统的要求。

This guide addresses how to implement the recommendations in the Baseline guide to meet FDA and EMEA regulatory expectations for HVAC design.

本指南说明了如何执行《国际制药工程协会基准指南》中的建议以达到美国食品药物管理局以及欧洲药物评审委员会对空气净化系统设计的监管预期

This guide references but does NOT reiterate the issues or content from the Baseline guides. The appropriate Baseline Guide should be consulted for regulatory expectations.

本指南并不是对于 Baseline guides 的反复重申，Baseline guides 适用于用来查阅监管预期。

The guide discusses the impact of external conditions on HVAC design.

本指南讨论了空气净化系统设计外部条件的影响。

This guide attempts to give information in I/P and SI units.

本指南尝试使用英制单位制 I/P 和国际单位制 SI 两种单位制来给出信息。

The user of this guide should apply good engineering practice in assessing which of the recommended practices is most applicable to a situation.

本指南的使用者应该运用优秀的工程实践来评估推荐的实践经验是否适用于某一特定的情形。。

1.3 Objectives of This Guide　指南目的

Provide the Pharmaceutical Engineering Community with common language and understanding of critical HVAC issues.

为制药工程共同体提供关于空气净化系统的普遍适用的语言规范与理解。

Provide guidance on accepted industry practices to address these issues.

提供公认的工业实践指南以解决现实问题。

Provide a single common resource for HVAC information currently included in appendices of the various Baseline© guides.

为目前不同基准指南附录中的 HVAC 信息提供了一个单一的通用的 HVAC 资料。

Target a global audience, with particular focus on US (FDA) and European (EMEA) regulated facilities.

本指南的目标读者是全球性的，且特别关注了美国食品和药物管理局以及欧洲药物评审委员会规定的设备设施。

1.4 Definitions　定义

This GPG uses terms as defined in the ISPE Glossary of Pharmaceutical Engineering Terminology and will not repeat these definitions here. Only new terms or terms specific to the content of this GPG are defined in the Glossary.

本优秀实践指南将不会重复定义在 ISPE 制药工程术语词汇表里已出现过的术语，只定义一些新的术语或者在本优秀实践指南里有着特定的适用范围的术语。

1.5 References 参考文献

a. ISO Standards for Cleanrooms and Associated Controlled Environments

- ISO 14644-1 Classification of air cleanliness
- ISO 14644-2 Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- ISO 14644-3 Test methods
- ISO 14644-4 Design, construction and start-up
- ISO 14644-5 Operations
- ISO 14644-6 Vocabulary
- ISO 14644-7 Separative devices (clean air hoods, glove boxes, isolators, and mini-environments)
- ISO 14644-8 Classification of airborne molecular contamination
- ISO 14698-1 Biocontamination control, Part 1: General principles and methods
- ISO 14698-2 Biocontamination control, Part 2: Evaluation and interpretation of biocontamination data.

a. 洁净室与有关受控环境的国际标准化组织标准

- ISO 14644-1 空气洁净度分级
- ISO 14644-2 与 ISO 14644-1 连续相配位的检测与监控规范
- ISO 14644-3 检测方法
- ISO 14644-4 设计、建造和启用
- ISO 14644-5 操作
- ISO 14644-6 词汇
- ISO 14644-7 分离设备（洁净空气罩、手套式操作箱、隔离器和微环境）
- ISO 14644-8 气态分子污染分类
- ISO 14698-1 生物污染控制，第 1 部分：一般原则和方法
- ISO 14698-2 生物污染控制，第 2 部分：生物污染数据的评定与说明

b. IEST Recommended Practices

- RP-CC034.2-HEPA and ULPA Filter Leak Tests
- RP-CC006.3-Teating Cleanrooms
- RP-CC012.1-Considerations in Cleanroom Design

b. 环境科学技术协会推荐实践

- RP-CC034.2-高效空气过滤器与超高效空气过滤器的渗漏试验
- RP-CC006.3-洁净室检测
- RP-CC012.1-洁净室设计需考虑事项

c. ISPE Baseline Guides

- Vol. 1- Active Pharmaceutical Ingredients
- Vol. 2- Oral Solid Dosage Forms
- Vol. 3-Sterile Manufacturing Facilities
- Vol. 4- Water and Steam Systems
- Vol. 5- Commissioning and Qualification
- Vol. 6- Biopharmaceuticals

c. 国际制药工程协会基准指南

- Vol. 1-原料药
- Vol. 2-口服固体剂型
- Vol. 3-无菌生产设备
- Vol. 4-水与蒸气系统
- Vol. 5-调试与验证
- Vol. 6-生物制药

d. ASHRAE- specific ASHRAE documents which are used in this GPG:

- ASHRAE standard 62.1 - Ventilation for Acceptable Indoor Air Quality
- ASHRAE standard 90.1 – Energy Standard for Buildings Except Low-Rise Residential Buildings
- ASHRAE standard 110 – Method of Testing Performance of Laboratory Fume Hoods
- ASHRAE Handbooks – Fundamentals; Applications; Systems & Equipment

d. 美国采暖、制冷与空调工程师协会-运用于本优秀实践指南的 ASHRAE 文件

- ASHRAE 标准 62.1–可接受室内空气质量的通风
- ASHRAE 标准 90.1–除低层住宅建筑外的建筑物能量标准
- ASHRAE 标准 110–检测实验室通风柜性能的方法
- ASHRAE 手册–基本法则、应用、系统与设备

e. ASTM Standard E2500-07 – Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

f. US FDA Guidance for Industry "Sterile Drug Products Produced by Aseptic Processing-Current Good Manufacturing Practice" (2004)

g. EudraLex Volume 4 "EU Guidelines to Good Manufacturing Practice"

- 'Medicinal Products for Human and Veterinary Use'
- Annex 1: Manufacture of sterile Medicinal Products
- Annex 2: Manufacture of Biological Medicinal Products for Human Use

e. 美国材料与试验协会标准 E2500-07-制药、生物制药制造系统与设备的规范、设计、检验的标准指南

f. 美国食品与药物管理局的工业指南：无菌工艺生产的无菌药物产品-当前优秀制造实践（2004）

g. 欧盟法律法规第 4 卷：欧盟优秀制造实践的指南

- 人与动物使用的药物产品
- 附录 1：无菌药物产品的制造
- 附录 2：人类使用的生物药物产品的制造

h. The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture

h. 制药工业的自动化系统验证的优秀自动化制造实践指南

i. WHO document on HVAC-proposed draft, does not apply to this document.

i. 世界卫生组织草拟的 HVAC 文件不适用于本指南

j. CFR Title 21 food & Drugs

- Part 11: Electronic records
- Part 210: Current good manufacturing practice in manufacturing, processing, packing or holding of drugs; general
- Part 211 Current good manufacturing practice for finished pharmaceuticals

k. FDA Guidance for Industry/ICH Guidelines

- Q7A: Good manufacturing practice guidance for active pharmaceutical ingredients
- Q8: Pharmaceutical /development
- Q9: Quality Risk Management
- Q10: Quality Systems

j. 美国联邦条例 Title 21 食品与药物

- Part 11: Electronic records 电子文件
- Part 210: 目前的关于制造、工艺、包装、药物持有的优秀制造实践-一般情况下的
- Part 211: 目前的成品药物的优秀制造实践

k. 美国食品药物管理局关于工业或 ICH 的指南

- Q7A: 原料药的优秀制造实践指南
- Q8: 制药/发展
- Q9: 质量风险管理
- Q10: 质量系统

2. Fundamentals of HVAC　空气净化系统的基本原则

2.1 Introduction　简介

Most people live in homes with equipment incorporated into the building to keep them comfortable. They have windows to allow natural ventilation and heating and cooling systems to maintain desired temperatures.

We have the same goal in our pharmaceutical manufacturing workplace-to make people comfortable, but we also have the more exacting requirement to control the impact of the environment on the finished product (i.e., product SISPQ).

This guide introduces the fundamentals of the HVAC systems that control the GMP workplace environment. Only three room environment variables may have an effect on product and processes (at the “critical locations”):

- Air temperature at the critical location may affect product or product contact surfaces
- Relative humidity of the air at the critical location may affect product moisture content , or may affect product contact surfaces (via corrosion, etc.)
- Airborne contamination at the critical location (may affect product purity or product contact surfaces)

Some variables, such as local contaminants, depend on other HVAC variables such as room pressure, air changes, airflow volume, airflow direction and velocity, and air filter efficiency.

大多数人住在有设备的建筑物中以使自己感到舒适。他们用窗户来提供自然的通风条件和供热与制冷系统以保持所需的温度。

我们在制药工厂中也有同样的目标：使人们感到舒适。不同的是我们还对成品对环境造成的影响有更严格的要求，如：产品的 SISPQ（安全性、一致性、剂量、纯度、质量）。

本指南介绍了关于空气净化系统的基本准则，此空气净化系统用于控制需满足药品质量生产规范的工厂环境。只有以下三个不同的室内环境可能对产品与工序造成影响（在关键的位置）：

- 关键位置的空气温度有可能对影响产品或产品接触表面。
- 关键位置的空气的相对湿度有可能影响产品的水分含量或产品接触表面（通过腐蚀等方式）。
- 关键位置的气体污染可能影响产品纯度或产品接触表面。

诸如局部污染的其他污染取决于其他的空气净化系统，如：室内压力、换气、气体流量、气流方向与速度以及过滤器的效率。

2.2 What is HVAC?

HVAC (Heating, Ventilation and Air Conditioning) is the generic name given to a system that provides the conditioning of the environment through the control of Temperature, Relative Humidity, Air Movement and air quality- including fresh air, airborne particles, and vapors. HVAC systems can increase or decrease temperature, increase or reduce the moisture or humidity in the air, decrease the level of particulate or gaseous contaminants in the air. These abilities are employed for comfort and to protect people and product.

空调净化系统是一个能够通过控制温度、相对湿度、空气运动与空气质量（包括新鲜空气、气体微粒和气体）来调节环境的系统的总称。空气净化系统能够降低或升高温度、减少或增加空气湿度和水分、降低空气中颗粒烟尘污染物的含量。空气净化系统的这些功能被利用来为工作人员以及产品提供保护和舒适的环境。

2.2.1 People comfort　人员的舒适

The first role of HVAC system is to make people comfortable. We notice the HVAC system's performance when we are uncomfortable, but what conditions are actually required to make people comfortable?

Four criteria are commonly considered for people comfort:

- Temperature
- Humidity
- Air quality (Contaminants, both particles and odors)
- Air movement (airflow direction and speed to control "drafts")

空气净化系统的第一项功能就是使工作人员感到舒适。当我们感觉到不适时，我们便会注意到空气净化系统的工作情况，但是使人们感到舒适需要对哪些条件进行控制呢？

以下四个方面是常见的考虑事项：

- 温度
- 湿度
- 空气质量（污染物，包括颗粒与气味）
- 空气运动（用以控制通风的气流方向与速度）

2.2.1.1 Temperature and Humidity　温度与湿度

The following drawing shows two boxes which define "comfort" conditions (Temperature and Humidity) that Americans find comfortable in winter and summer (from the ASHRAE Handbook). This standard varies across the world-for example, in parts the tropics people prefer an office at 75 degrees F (24 degrees C) to one at 72F (22℃).

It should also be noted that these are general guidelines, as many things affect these conditions apart from individual preferences-the type and consistency of work being performed, for example.

This is apparent in the office workplace, with the different levels of clothing people wear, some people dressed more heavily than others in order to be comfortable

以下的图表是从美国采暖、制冷与空调工程师协会手册里摘录的在冬天、夏天两个季节使人感到舒适的温度与湿度条件。这个条件标准随着地方的不同而不同。例如：部分热带的人们更喜欢办公的环境温度为 75 华氏度（24 摄氏度）而不是 72 华氏度（22 摄氏度）。

值得注意的是，此标准条件也仅仅是一个总体的指导原则，还有存在许多其他的影响因素（除个人偏好外），如：工作的类型和持续性。

很明显，在办公室人们穿着不同厚度的衣服，一些人需要穿比其他人更多的衣服来使自身感到舒适。

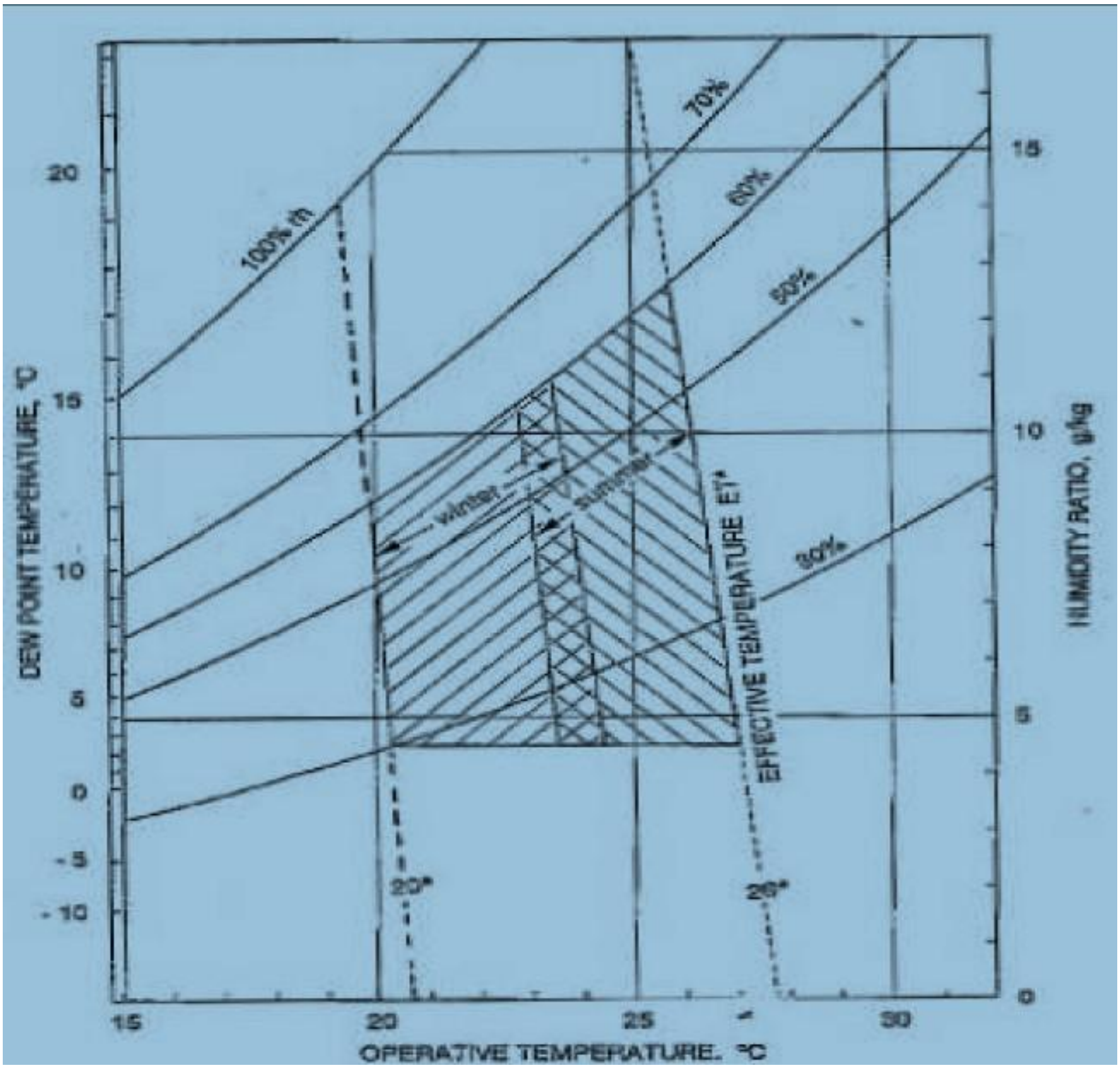


图 2-1 有效的温度标准和 ASHRAE 制定的舒适地带

2.2.1.2 Air Movement 空气运动

Some people prefer a light sensation of air movement and some prefer still air, so a typical design figure of 0.1m/s (3 ft/sec) is used in an office environment. Greater air velocities are usually needed for product protection.

一些人喜欢感受到空气的轻微运动，而另一些人喜欢静止不动的空气，所以在办公环境中，空气流动的典型设计数据为 0.1m/s(3ft/sec)。通常需要更大的风速来保护产品。

2.2.1.3 Air Quality空气质量

People need fresh air to dilute exhaled carbon dioxide and other environmental contaminants. The amount of fresh air required depends on the activity; the table below shows typical oxygen use for different levels of activity.

Level of exertion	Oxygen consumed L/min
Light work	LT 0.5
Moderate work	0.5 to 1.0
Heavy work	1.0 to 1.5
Very heavy work	1.5 to 2.0
Extremely heavy work	GT 2.0

Table 2-1 oxygen consumption by activity level

The amount of fresh air required to dilute environmental contaminants is a minimum of 15 to 20 cubic feet per minute (cfm) or 24 to 32 cubic meters per hour per person.

人们需要新鲜的空气来稀来呼出的二氧化碳和其他环境中的污染物。所需的新鲜空气的量由人们的活动所决定；下表列出了不同水平的活动需要的氧气消耗量。

活动水平	氧气消耗量 L/min
轻量作业	LT 0.5
中度作业	0.5 to 1.0
重作业	1.0 to 1.5
非常重作业	1.5 to 2.0
极度重作业	GT 2.0

Table 2-1 不同水平的活动的氧气消耗量

稀释环境中污染物的最小新鲜空气量是 15~20 立方英尺/分·人或者 24~32 立方米/小时·人。

2.2.2 Product and Process Considerations 产品与工艺注意事项

Product may be sensitive to temperature and humidity and to airborne contamination - from outside sources or cross-contamination between products. Process operators may need protection from exposure to hazardous or potent materials

It is usually possible to find the product's environmental requirements, ad they will be listed in the DBA when they are considered critical. The impact of conditions outside these ranges will depend on the duration of exposure-prolonged exposure time may reduce the efficacy of the product.

Control of airborne cross contamination and contamination are always major issues. These requirements are often interlinked with temperature and humidity-consider the effect of temperature for example;

Comfortable people work more efficiently-they are more productive, and make fewer mistakes. They also produce fewer environmental contaminants: A typical person will give off 100, 000 particles a minute doing relatively sedentary work (particles sized 0.3 micron and larger-a human hair is approximately 100 micron in diameter). A worker who is hot and uncomfortable may shed several million particles per minute in this size range, including more bacteria.

Environmental conditions inside a building can influence the product in other ways –higher temperatures and humidity tend to increase microbial growth rates, particularly with regard to mold.

If building conditions are significantly different from those outside and the fabric of the building does not have sufficient integrity, condensation in interstitial spaces can occur and can lead to microbial contaminant problem and deterioration of the building.

Operator protection also depends on air flow direction both within and between rooms. Airflow can entrain particles of product, product in other rooms, or other hazardous materials harmful to operators. Though differential pressure is commonly used as a control of contamination between two rooms, it is the airflow generated by the differential pressure that contains the product.

产品也许会对温度、湿度以及气体污染物（由外界污染源或不同产品间的交叉污染所导致）很敏感。工艺的操作人员也需要避免暴露在有害物质与潜在的影响物质中。

对气体污染与气体交叉污染的控制一直是主要的关注问题。而此控制问题又常常和问题与湿度想联系。以温度的影响为例来说明；

人们在舒适的环境下更有效率，所犯的错误也更少。他们也释放出更少的环境污染物：一个人在相对较轻松的工作条件下，每分钟大概释放 100000 颗粒物质（这些颗粒一般为 0.3 微米或更大，人类头发的直径一般为 100 微米）。而一个在燥热且不舒适的环境下工作的人每分钟能够释放出上百万的颗粒物质，包括更多的细菌。

建筑物内部环境条件能够以其他方式影响产品——较高的温度与湿度会是微生物的生产速度加快，尤其是霉菌。

如果建筑物室内环境条件与其外部截然不同或者建筑物不具备足够的整体性，间隙空间的冷凝将产生，导致微生物污染物问题，进一步破坏这个建筑物。

员工的保护工作受气流方向的影响，包括室内气流方向与不同房间间的气流方向。气流能够携带产品微粒、其他房间的产品微粒以及对操作员有害的物质。虽然压差系统用来控制不同房间的污染，但是压差系统产生的气流含有产品颗粒。

2.2.3 How does the HVAC system control these parameters? 空气净化系统如何控制这些参数？

2.2.3.1 Temperature and Humidity温度与湿度

The HVAC system controls the temperature and humidity in the room using the mechanism of supplying the room with air at a condition that, when mixed with the room air, will yield the desired temperature and humidity.

The heat gains and losses to and from the space are through the usual mechanisms of heat transfer-Radiant, conductive and convective heat transfer, these may be due to solar gain, external temperature outside the facility, and internal heat gains due to the process, equipment, people and lighting.

The changes in humidity are due to the process, people and the environment. Moisture migration into the controlled space from surrounding areas is governed by the difference in vapor pressure, as defined by Dalton's law, and can sometimes migrate against an air pressure differential

空气净化系是依靠以下机理来控制温度与湿度的：当提供给室内的空气与原来的室内空气混合时将产生所需要的温度与湿度。

空间热量的获得与失去是通过常见的热量传递机理实现——辐射、传导、对流传热，这些热量传递可能来自于太阳能，设备外部温度，由工艺、设备、工作人员以及光照等产生的内部供热。

湿度随工艺、工作人员、环境变化而变化。正如道尔顿分压定律所定义的，水分由周围区域向受控空间的转移是由蒸气压差来控制的，有时，水分还能逆空气压差转移。

2.2.3.2 Air velocity空气流速

In a working environment, air velocity is not as critical in terms of human comfort as it is in an office environment. Velocity is critical to proper mixing of air within the room and transport of airborne particulates.

在工作环境中，空气流速对工作人员的舒适度的影响不如在办公环境中大。但空气流速对室内空气的混合于气体颗粒的转移有着关键的影响。

2.2.3.3 Particulate/fume and vapor control 颗粒、烟尘与蒸气控制

The control of the particulate levels in the room, and in some cases vapors/fumes, may be by dilution and displacement, controlling the particulate levels in the supply air through filtration, and vapor/fume level by the use of exhaust and replacement (makeup) fresh air where necessary.

室内颗粒、烟尘、蒸气的控制室利用稀释和置换实现的。通过过滤来控制供气气体中的颗粒含量，通过在需要的位置排出废气和置换（补给）新鲜空气来控制烟尘或蒸汽的含量。

2.2.4 What can't the HVAC System do? 空气净化系统不能做什么？

HVAC systems are not a substitute for good process, facilities and equipment design and good operating procedures, HVAC can not clean surfaces that are already contaminated, and as a practical matter, it cannot control processes that generate an excess of contaminants or compensate for improperly designed or maintained facilities. HVAC, while a common suspect area for investigation, is rarely the cause –or the solution- for persistent contamination problems.

空气净化系统不是良好的工艺、设施、设备设计和良好的操作工序的代替物，它不能清洁已经污染的表面，需特别指出的是，他不能控制有过量污染物产生的工艺，也不能作为不良的设计或不良的设备维护的补偿措施。当调查一个普通的受怀疑的区域，空气净化系统很少会是持续性污染问题的原因或解决方法。

2.3 Airflow fundamentals 气流基本原则

2.3.1 Introduction 简介

As was discussed in section 2.1, HVAC can contribute to the control of temperature, humidity, and particulates within a space. In order to understand what equipment is needed to achieve this at the HVAC system level, we must first define what the air is intended to do at the room level.

Both the quality (temperature, humidity, filtration) and quantity of air introduced into a room affect its ability to maintain environmental conditions. This explores the effects of physical layout (geometry), air velocity and air volume in assuring effective ventilation.

正如 2.1 节所论述的一样，空气净化系统能够帮助控制空间的温度、湿度、颗粒含量。为了理解需要什么样的设备来满足空气净化系统的要求，我们必须首先定义预期的室内空气水平。

室内空气质量（温度、湿度、过滤）与数量会影响室内环境条件的维持能力。本节探索了物理布局（几何布置）、气体流速、气体流量对保证有效通风的影响。

2.3.2 Ventilation Fundamentals 通风基本原则

Ventilation is the movement and replacement of air for the purpose of maintaining a desired environmental quality within a space. Ventilation is responsible for the transport of airborne particles, the movement of masses of hot or cold air, the removal of airborne contaminants (e.g., vapors and fumes) and the supply of “fresh” 02 rich air.

Although the layman may be conscious of the term “air change rates” (more properly called “ventilation rate”), successful pharmaceutical HVAC design can be attributed to proper filtration and attention to the physical geometry of airflow in a space, the layout of inlets and outlets with relation to the sources of contamination/heat and accommodation for expected obstructions are key to controlling contamination and yielding effective HVAC design. The relationship between factors is expressed in the “effective ventilation rate” for a space. This measure expresses the efficiency of the HVAC system at removing contaminates expressed as a % of the theoretical performance of perfect dilution. When comparing the effective ventilation rate of various designs, it becomes clear that good layout and filtration can produce desired airborne particulate levels and recovery rates at lower than expected air change rates.

通风是一种空气的运动和置换，其目的是使某一空间内部保持所要求的环境质量。通风为以下行为提供了条件：气体颗粒的转移、成批的热/冷空气的运动、气体污染物（蒸气与烟尘）的移除以及新鲜空气的提供。

外行人也许会注意到换气率（更确切的说法是"通风率"），但成功的制药行业的空气净化系统设计应归功于恰当的过滤和对气流几何形状、进出气布局的特别关注。进出气布局与污染源、热源和设备位置有关，因为有效的预期气流障碍物是控制污染和得到高效的空气净化系统设计的关键。这些因素的关系在"高效的通风率"中论述。移除污染物的空气净化系统效率用在理想稀释条件下的理论效率 a%表示。当比较不同设计的有效通风率时，可以很明显的发现：良好的布局与过滤能够在比预期低的换气率条件下，产生出符合要求的气体颗粒水平与恢复率。

2.3.3 Contamination Control 污染控制

The primary factor that separates pharmaceutical HVAC from comfort HVAC is the need to control contamination. This stems from the need to assure the "…purity, indentity and quality…" of the product (21 CFR211). Pharmaceutical HVAC is one tool in preventing unwanted environmental contaminants from adversely affecting a product and to prevent products from contamination one another. It can also assist in limiting operator exposure to potent pharmaceutical compounds, ingredients or reagent vapors. Contamination control is generally achieved by filtering the incoming air, to assure that it does not carry particulates, and then introducing the air to the work space at sufficient velocity and volume to transport unwanted particulate out of the work zone, the orientation of these airflows can aligned so as to protect product or personnel by sweeping across one or the other (or both) on its way from the supply terminal to the extract point. Local supply or extraction can also assist in contamination control by creating a local environment that excludes or removes particulate.

Pharmaceutical HVAC can help control contaminants within a space, but these facilities must be designed with several additional features that contribute to this mission of limiting the migration of contaminants.

制药工业中的空气净化系统区别于提供舒适环境的空气净化系统的主要特征就在于它对污染的控制。污染控制由于制药工业对产品纯度、一致性、质量的要求所引起的。制药工业中的空气净化系统是预防产品遭受环境污染物的不良影响和防止产品污染另一产品的工具。它还能帮助限制操作人员与潜在的药物化合物、配料或反应物蒸气接触。污染物控制一般是通过过滤进入的空气（以确保空气中不含颗粒物质）来完成的，然后将空气以足够的速率和流量导入到工作空间以移除工作空间不需要的颗粒物。这些气流的方向可以从供风终端到排风点单向流动，用以保护产品和工作人员。具备供风与排风

产生了一个局部的排除或移除颗粒的环境，可以帮助有效地控制污染物。

2.3.4 Airlocks 气闸

In order to minimize the amount of air that is needed to maintain particle transport velocities (typically over 100fpm times 21 square feet of open door area equals 2100 cfm) it is desirable that the doors of a contamination controlled space remain closed, one way to do this is to provide airlocks or “ante rooms”. These rooms control traffic into and out of a space through a series of interlocked doors to assure that a door to the space is always closed.

Airlocks serve other purpose as wall:

- They maintain some differential pressure between the two areas they serve, such that the DP can not drop to zero
- They provide a location for gowning/de-gowning prior to entering/exiting a classified space
- They provide a location for sanitizing/decontamination of incoming or outgoing materials and equipment
- They can be designed with a small volume and high air change rate to allow them to recover quickly and function to minimize the particulate introduced to a classified space by door openings.
- They provide can provide a high or low pressure buffer to control the ingress and egress of contaminants.

为了让维持颗粒移除速率的空气供应量最小化(一般大于100英尺/分×21平方英尺=2100立方英尺/分)，需要将污染控制空间的门保持关闭。一种关闭方法是利用气闸或前置准备室。这些房间利用一系列的连锁门来控制室内空间的流进流出，以确保空间的门一直是关闭的。

气闸还用于以下目的：

- 维持其服务的两个不同区域的某些压力差，如DP压差不能降到零。
- 为进入/出特定空间之前提供穿衣/脱衣位置。
- 为进入/离开的物料和设备提供消毒净化的地方。
- 可以设计为容积小、换气率高的气闸来使气闸内空气能够迅速恢复，最小化开门时带入分类空间的颗粒量。
- 能提供一个高压或低压的缓冲设备以控制污染物的进入与外出。

2.3.5 Classified Space 分类空间

A key measurement of room environmental conditions for pharmaceutical operations is the concentration of total airborne particulate and/or microbial contamination within the space; this is referred to as the “classification” of the space. Several systems have been promulgated for the classification of space; however there is not consensus between international regulators on a single best standard for classification. To bridge the gap between the various standards, this guide provides the following reference to be used across facility types requiring air classification, (primarily facilities for sterile/aseptic manufacture and for controlled bioburden processing, such as bulk biopharmaceuticals). It should not be used for other facilities, such as bulk chemical intermediated or oral dosage finishing. See the appropriate Baseline Guide for specific air quality information.

一个衡量制药操作的室内环境条件的关键指标就是总的气体颗粒含量和空间的微生物污染物含量；这就涉及到了空间的分类。有许多系统颁布了空间的分类规定，但是目前还没有一个一致的国际通用的最佳分类标准。为了在不同的标准之间搭建一个沟通的桥梁，本指南提供了以下参考，这些参考可以被应用到要求空气分类的工厂类型中（无菌制造工厂和含受控生物处理工艺的工厂，如生物原料药厂）。它不能用于其他类型的工厂，如：化学中间体原料、口服固体制剂后续加工。具体的空气质量信息查询相应基准指南。

REFERENCE	DESCRIPTION			CLASSIFICATION				
ISPE STERILE BASELINE GUIDE Draft 2008	ENVIRONMENTAL CLASSIFICATION			GRADE 5	GRADE 7	GRADE 8	Controlled Not Classified with local monitoring	Controlled Not Classified
European Commission EU GMP, Annex 1, Volume 1V, Manufacture of Sterile Medicinal Products (1997) also PIC/S GMP Annex 1 2002	Descriptive Grade			A (Note1)	B	C	D	Not defined
	At Rest (Note 2)	Maximum no. particles permitted per m3 ≥ the stated size	0.5µ	3 500	3 500	350 000	3 500 000	-
			5µ	1	1	2 000	20 000	-
	In Operation	Maximum no. particles permitted per m3 ≥ the stated size	0.5µ	3 500 (Note 3)	350 000	3 500 000	Not stated	-
			5µ	1	2 000	20 000	Not stated	-
		Maximum number of permitted viable organisms cfu / m3		< 1	< 10	< 100	< 200	-
FDA, October 2004, Guidance for Industry Sterile Drug Products Produced by	In Operation	Maximum no. particles ≥ the permitted stated size	0.5 µ	ISO 5 Class 100	ISO 7 (Class 10 000)	ISO 8 (Class 100 000)	-	-

表 2-2 分类空间的对比

参考标准	描述			分类等级				
ISPE 无菌基准指南 2008 年草稿	环境分类			5 级	7 级	8 级	带局部监测器的受控但未分类区域	受控但为分类区域
欧盟 EU GMP，Ⅳ卷，附录 1，无菌药品制造和 PIC/S GMP 附录 1 2002	描述分类			A	B	C	D	无规定
	静态	每 m³ 允许的颗粒最大数量 颗粒直径≥所列大小	0.5μ	3500	3500	350000	3 500 000	-
			5μ	1	1	2 000	20 000	-
	动态	每 m³ 允许的颗粒最大数量 颗粒直径≥所列大小数量≥	0.5μ	3 500	350 000	3 500 000	无规定	-
			5μ	1	2 000	20 000	无规定	-
		每 m³ 允许的可见有机物数量 cfu/m³		＜1	＜10	＜100	＜200	-
FDA，2004 年	动态	每 m³ 允许的颗	0.5μ	ISO 5 100	ISO 7	ISO 8	-	-

10 月，工业无菌药品生产		粒最大数量 颗粒直径≥所列大小		级	10 000 级	100 000 级		

Pharmaceutical HVAC can help control contaminants within a space, but these facilities must be designed with several additional features that contribute to this mission of limiting the migration of contaminants.

制药工业中的空气净化系统能够控制空间中的污染物，但是它必须与许多其他的特征一起设计才能保证完成控制污染物的使命。

2.3.6 Total Airflow Volume and Ventilation Rate 总风量与通风率

Much has been made of the importance of “air change rate” (volume of air/hour ÷ room volume) or “ventilation rate”, the number of times in an hour that the air volume of a room is replaced. Little is said about the relationship between these rates and the classification of the space, recovery rates and the more important issue of total volume of ventilation.

When considering the design of classified space, designers will often first consider the requirement for 20 Air Changes/hour (AC/hr), expressed in the 1987 FDA Sterile Guide. In lieu of calculating the airflow required by the process, many will default to “rules of thumb” for ventilation rate by the class of space, typically in the ranges:

- 15-20 AC/hr for Controlled, Not Classified (CNC) spaces
- 20-40 AC/hr for Grade 8 (EU Grade C)
- 40-60 AC/hr for Grade 7 (EU Grade B)
- 300-600 AC/hr for Grade 5 (EU Grade A)

As seen below, these rules of thumb may be overkill, or may prove to be insufficient. The airborne particle levels depend more on a number of factors.

换气率和通风率非常被重视，其意为：一个小时内室内空气被置换的次数（空气流量/室内容积•小时）。换气率、通风率、空间分类、恢复率与通风总量之间的关系很少被提及，尤其是通风总量，它是一个更重要的问题。

设计人员进行分类空间设计时，常常首先参考 1987 年版美国药物与食品管理局颁布的无菌指南，以 20 AC/hr 为标准设计。常用不同类别空间的通风率经验规定来代替工艺过程的空气流量计算。常用的数据如下：

- 15-20 AC/hr 受控但不分类空间（CNC）
- 20-40 AC/hr for Grade 8 (EU Grade C)
- 40-60 AC/hr for Grade 7 (EU Grade B)
- 300-600 AC/hr for Grade 5 (EU Grade A)

如下节所示，此经验规定有可能超出要求的颗粒含量标准标也有可能达不到颗粒含量标准。气体颗粒含量由很多的因素共同决定。

2.3.6.1 Air change or Air Flow? 空气次数或空气流量？

These air change rates often drive decision regarding room size and airflows, and can have significant cost implications, but do not relate directly to the particle count in the room. Air change rate are related to the room's ability to recover from an upset, not the room classification-as is commonly assumed. To explain this difference:

Assume a 1 cubic foot volume with a process inside it that generates 10,000 particles per minute. If we purge the volume with 1 cubic foot per minute of clean air, the steady state (equilibrium) airborne particle level will be 10,000 particle per cubic foot (see the Appendix for equations). This 1 CFM creates an air change every minute, or 60 air changes per hour. This value (60/hr) is often assumed to be more than enough to keep a space well below 10, 000 particles per cubic foot (PCF).

换气率由室内容积与空气流量来决定，换气率对成本有显著影响，但它并不直接影响室内颗粒含量。换气率说明房间从混乱状态恢复的能力，而不是象大多数人假定的一样，与房间洁净度分类相联系。以下例说明：

假定一个工艺的空间为 1 立方英尺，每分钟产生 10000 颗微粒。如果我们通入 1 立方英尺/分（1CFM）的新鲜空气，那么空间内的颗粒含量将维持在一个静态平衡水平：10000 颗/立方英尺（10000CFM）。此 1CFM 的空气流量产生了 1 次/分（或 60 次/小时）的换气率。每小时 60 次的换气率常常被人们认为能够使空间的颗粒含量远远低于 10000 颗/立方英尺（10000PCF）。

Now put the same process into a 100 cubic foot volume and keep the airflow at 1 cfm, assuming good mixing inside the room. Now the room sees an air change every 100 minutes, or about 0.67 ac/hr. Yet, when we calculate the dilution, the equilibrium airborne particle counts are still 10, 000 PCF (10,000 particles per minute divided by 1 cubic foot per minute = 100 particles per cubic foot). If we would supply 1 air change per hour (100 CFM) of clean air, the room airborne counts drop to 100 PCF!!! So it's not air changes that determine airborne particle counts, but three factors (referring to the Appendix)

1. Particles generated inside the space
2. quantity of dilution air supplied to the space (cubic volume per time)
3. Cleanliness of dilution air (assumed to be negligible in pharma due to HEPA filtration)

现在，将相同的工艺置于 100 立方英尺的空间，空气流速为 1CFM，假定空间内部空气能够充分混合。这样，此空间的换气率变为 1 次/100 分钟（或 0.67 次/小时）。但是，空间内的颗粒含量仍然为 10000 颗/立方英尺(10000CFM)（$\frac{10000\text{颗/分钟}}{1\text{立方英尺/分钟}}=100\text{颗/立方英尺}$）。如果我们提供 1 次/小时的换气率的新鲜空气流量（即：空气流量为 100CFM），那么房间的颗粒含量将降至 100 颗/立方英尺（100PCF）!!! 由上可知，气态颗粒含量并不是由换气率决定的，而是由以下三个因素决定：

1. 室内颗粒的产生量

2. 向室内提供的新鲜空气量 （体积流量/时间）

3. 提供的新鲜空气的洁净度（假定由于高效空气过滤器的作用而完全净化，不对药品产生不利影响）

As is demonstrated elsewhere, a room receiving only 1 air change per hour will take hours to “recover” from in-use to at-rest conditions. With clean air supply of 20 air changes per hour, a 100-fold recovery in particle levels can happen in less than 20 minutes (see the ISPE Sterile Baseline Guide). So when it comes to Recovery, air changes are important, 20/hr often being the minimum for classified spaces.

Although the layman is conscious of the importance of “air change rate” (more properly called “ventilation rate”) successful pharmaceutical HVAC design can be attributed to proper filtration and attention to the physical geometry of airflow in a space.

若保持 1 次/小时的换气率将会需要数小时使室内空气从使用状态恢复到休息状态。而 20 次/小时的换气率能够在 20 分钟内使颗粒含量降低 100 倍（见 ISPE 无菌基准指南）。所以换气率对室内气体的恢复能力非常重要，20/hr 是常用的洁净等级分类空间的最小换气率。

虽然行外人员常常重视换气率（更确切的说是“通风率”），但成功的制药工业中的空气净化系统的设计却归功于正确的过滤设施和对空间气流物理几何形状的重视。

2.3.6.2 Impact of UDF (UFH) hoods on air change rates 单向气流罩对换气率的影响

Later sections will discuss “mixed flow” room with clean air supplied at the ceiling through terminal filters as well as clean air being introduced to the room from unidirectional flow hoods (UFH or UDF, ONECE CALLED “Laminar Flow”) operating inside the room. Since air leaving the space served by the hood is often orders of magnitude cleaner than the room it leaks into, the relatively clean hood air serves to dilute airborne particles in the room, along with the supply air from the HVAC. In many respects the added flow from the hood not only reduced airborne particles in its path, but can also accelerate the recovery time of the room from in-use to at-rest conditions, the entire flow from the hood will likely not be available to add into air change calculations, however, due to:

- Short circuiting of the hood air back to the hood inlet. Only areas near the airflow path will see the added dilution.
- Hood air is not as clean as HVAC supply air, even though the hood might be rated as Grade 5 (class 100) the air leaving the work space has collected additional contaminants from equipment and people outside the critical zone.

以后的章节将讨论由天花板上的终端过滤器提供洁净空气的混合气流室，还将讨论由室内单向气流罩引入洁净空气的混合气流室。因为由气流罩逸出的空气的洁净度常常比室内泄露的空气高出许多，所以相对洁净的气流罩空气能够与空气净化系统的空气一起，用于稀释室内的颗粒含量。许多时候，由附加的气流罩气流不仅能够降低它所经过的路径的气体颗粒含量，同时还可以加速室内空气从使用状态转变为休息状态的恢复过程。

但是，整个有气流罩气流将不计入换气率的计算中，原因如下：

- 气流罩气流的回流路径较短，只能稀释气流路径的附近空间。
- 气流罩流出的气体不如空气净化系统的气体洁净，即使此气流罩达到了 Grade 5（Class 100）级，流出的空气也已经聚集了关键地带外地设备和人员的污染物。

2.3.7 Room Distribution and Quality of incoming air 房间布局和进气质量

The layout of inlets and outlets with relation to the sources of contamination and accommodation for expected obstructions are key to controlling contamination and yielding effective HVAC design. The relationship between these factors is expressed in the “effective ventilation rate” for a space. This measure recognizes that good layout and filtration can produce desired airborne particulate levels and recovery rates at lower than expected air change rates.

Taking the example above, good air mixing (dilution) and faster recovery can be accomplished in a room where clean air supply is distributed over a high percentage of the ceiling and not just from one air outlet. Although it’s not necessary to create a “laminar flow ceiling”, numerous air outlets equally spaced with equal flow rates can create a “plug flow” for faster recovery (often less than 10 minutes for 20 ac/hr) and also prevent “hot spots” of high particle count in the room.

房间进气、排气需考虑污染源和预期的会对气流产生阻碍作用的其他位置，这是控制污染、设计出高效 HVAC 系统的关键。他们之间的关系在空间中的“高效通风率”中有论述。好的房间布局与过滤能够在比预期更低的换气率条件下产生出符合要求的颗粒含量水平与恢复率。

例如：一个房间如果拥有高比例的天花板进气和多个排气点就能获得良好的空气混合（稀释）和较快的恢复能力。虽然层流状态的天花板气流不是必须的，但是排气量等于进气量能够产生活塞流的状态，从而使房间获得更快的恢复率（一般在 10 分钟内达到 20ac/hr），防止产生室内高颗粒含量“热点”。

2.3.8 Airflow Direction and Pressurization 气流方向与增压

Since constructing a space that is totally airtight is not practical is normal construction, other means must be provided to assure that particulate can be prevented from migrating into or out of a space. Assuring that air is always flowing in the desired direction through the cracks in building construction (door gaps, wall penetrations, conduits, etc,) can influence contamination through the transport of airborne particulates. A velocity of 1-200 FPM will contain light powders and bioburden

One method to control this direction of airflow is by controlling the relative pressurization of adjacent spaces or the Differential Pressure(DP) between the spaces.

A simplified method (neglecting the orifice coefficient for the opening) to calculate the expected velocity of airflow from a given pressure is:

V=4005 (sqrt VP) or VP=(V/4005) (where V is velocity in ft/min, VP is pressure difference in inches w.g., A is area of the opening in square feet, Q is airflow in CFM)

-We can breakdown velocity as being volume divided by area, giving V=Q/A, or VP=(CFM/4005A) 2

-Assuming room DP converts fully to Velocity Pressure thru an opening (a conservative assumption), calculating the opening area, such as the crack area around a closed door between rooms, allows calculation of the airflow (CFM) required to create a pressure, or the velocity that results from a known DP.

-for A=1 sq foot (0.1 sq. M) opening, 890 CFM (about 1500 CuM/hr or 0.45 CuM/sec) will create 0.05" w.g. (12.5 Pa) differential pressure (V=Q/A=890 FPM=4.5 M/s)

由于对于常规的建筑物来说，建造密封的气体空间是不现实的，所以必需采用其他方法来保证空间里面不会进入或转移出颗粒。假定气流能够一直按照预订的方向流动，气流便能够通过空气中的颗粒的传输来影响污染状态。

控制气流方向的一种方法是通过控制邻近区域的相对增压或空间之间的压差。

一种忽略开孔的锐孔系数，计算在一定压力条件下的气体流速的方法如下：

$$V = 4005 \times \sqrt{VP} \quad 或 \quad VP = \left(V/4005\right)^2$$

其中：V：气体流速，单位：英尺/分钟；

VP：压差，单位：英寸水柱；

我们可以把气体流速看成是单位面积流过的气体流量，即：

$$V = Q/A \quad 或 \quad VP = \left(CFM/4005A\right)^2$$

其中：Q：气体流量，单位：立方英尺/分钟（CFM）；

A：流通面积，单位：平方英尺；

假定室内压差完全可以转变为风压，计算出流通面积，（如：关闭的房间门的缝隙面积），然后便可通过气体流量（CFM）计算出所需压差，或通过已知的压差计算气体流速。

例如：A=1 平方英尺（0.1 平方米），气体流量为 890 立方英尺/分钟（约为 1500 米/小时或 0.45 米/分钟），那么相应产生的气压应为 0.05" w.g.（12.5Pa）（V=Q/A=890 FPM=4.5 M/s）。

2.4 Psychrometrics 湿度测定法

2.4.1 Introduction 简介

Psychrometrics is the science that involves the properties of moist air (a mixture of dry and water vapor) and the process in which the temperature and/or the water vapor content of the mixture are changed. Psychrometrics – "psychro" means moisture and "metrics" means to measure. A psychrometric chart is used to identify conditions of air and to illustrate the process of achieving the desired state of the controlled space. An in-depth knowledge of psychrometrics is impossible to impart in this document; the reader is referred to other sources such as the ASHRAE Fundamental Handbook.

湿度测定法是一种涉及潮湿空气（干燥空气与水分的混合物）性质以及其温度与水蒸气含量的变化过程的一种科学。Psychrometrics 这个词，psychro 表示水分，metrics 表示方法。湿度测定图用于判断空气状态以及阐述受控空间转变为要求状态的具体过程。本文没有深入介绍关于湿度测定法的相关知识，读者可以参考其他资料，如：ASHRAE 基本原则手册。

2.4.2 Basic Properties of Air 空气的基本性质

2.4.2.1 dry air is comprised of 78.1% nitrogen, 21% oxygen, and has trace amounts of ten additional elements totaling 0.9%. the air around us is a mixture of dry air and water vapor. When this moist air reached a level at which it can not hold any more moisture, it is said to be, “saturated”. The colder the air, the less moisture which can be held in the air while warmer air can hold larger quantities of moisture in the air.

2.4.2.1 干燥的空气由 78.1%的氮气、21%的氧气和 0.9%的十种其他气体组成。我们周围的空气是干燥的空气与水蒸气的混合物。饱和空气意指：不能再保持更多的水分含量的潮湿空气。空气温度与低，所能保持的水分越少；温度越高，所能保持的水分越多。

2.4.2.2 The moisture in dry air (its specific humidity) is measured in grains of moisture per pound of air (7,000 grains equal 1 pound). Air at 75℉ and 60% RH has a specific humidity of 78 grains of water per pound (7000 grains) of dry air. There for, one pound of this air contains 77 grains of water and 6923 grains of dry air.

2.4.2.2 干燥空气中的水分含量（比湿）由每一磅重的空气中含有的水 grains 表示（7,000 grains 等于 1 磅）。75 华氏度，相对湿度为 60%的空气的比湿为每磅干燥空气中含 78grains 水分，因此，一磅潮湿的空气中含 77grains 水分、6923grains 干燥空气。

2.4.2.3 A psychrometric chart provides an overview of thermodynamic properties of air-water mixtures, and shows the relationships of air at different conditions. Of any two properties of the air mixture are known, the chart allows an engineer to determine all its other properties. Air-water vapor mixtures have interrelated psychrometric properties that can be plotted on a psychrometric chart. (See Appendix for psychrometric chart discussion).

2.4.2.3 湿度计算图提供了关于空气-水混合物的热力学性质概述，说明了不同状态下的空气间的关系。只要已知空气混合物任意两个性质，工程师们便可计算出空气-水混合物的其他所有性质。空气-水混合物的湿度性质是相互关联的，且能够被绘制在湿度计算图中（见附录：湿度计算图讨论）。

2.4.2.4 Sensible heat causes a change in the temperature of a substance. Sensible heat can be “sensed” or felt and quantified by measurement with a dry bulb thermometer. Addition or removal of sensible heat will cause the measured temperature to rise or fall. Sensible heat shows on the psychrometric chart as a horizontal line; there is no resulting change in the amount of water vapor in the air.

2.4.2.4 潜热能够使物质的温度发生变化。干球温度计能够测量潜热的值。显热的增加或减少都将引起物质温度的上升或下降。显热在湿度计算图中为水平线；显热不会导致空气中的水蒸气含量的变化。

2.4.2.5 Latent heat comes from the Latin word meaning “hidden”. Changes in lateen heat are neither “sensed” or felt; however they will cause a change of state in the substance. Latent heat is the heat required to evaporate the moisture which the air contains.

For example, if sufficient latent heat is added to water in the liquid state, it will change state into a vapor or steam. The change of state from a liquid to steam is called the “latent heat of vaporization” and from a steam to a liquid is called “the latent heat of condensation”. The change of state form a liquid to a solid is called “the latent heat of fusion” and from a solid to liquid the “latent heat of melting”. Latent heat appears on the psychrometric chart as a vertical line.

2.4.2.5 “潜热”一词源于表示“隐藏”之意的拉丁文。潜热的变化不能被测定或量化；但是潜热的变化能够导致物质状态的变化。潜热是空气中的水蒸发所需的热量。例如：如果足够的潜热被加入液态水中，此液态水将转变为气态水蒸气。从液态转变为气态叫气化潜热；从气态转变为液态叫冷凝潜热；从液态转变为固体叫凝固潜热；从固态转变为液态叫溶解潜热。潜热在湿度计算图中为垂直的直线。

2.4.3 Psychrometric Properties of Air 空气的湿度性质

See the “Appendix for a discussion of the terms used in Psychrometrics and for an explanation of the Psychrometric Chart.

Measurable Psychrometric Properties		Calculable Psychrometric Properties	
Dry-bulb temperature	t_{DB}	Specific enthalpy	h
Wet-bulb temperature	t_{WB}	Specific volume	V
Dew-point temperature	t_{DB}	Humidity	W
Relative humidity	RH	Water vapor pressure	p_{WV}
Barometric pressure	P_{BAR}		

Table 2-3 Psychrometric Terminology

见附录 湿度测量中使用的属于讨论以及湿度计算图的解释

可测量的湿度性质		Calculable Psychrometric Properties	
干球温度	t_{DB}	比焓	h
湿球温度	t_{WB}	比体积	V
露点温度	t_{DB}	湿度	W
相对湿度	RH	水蒸气压	p_{WV}
大气压力	P_{BAR}		

表 2-3 湿度术语

2.5 Equipment 设备

2.5.1 Introduction 简介

Each piece of HVAC equipment helps contribute to sustaining the user requirements for room environmental conditions. HVAC equipment serving GMP areas are intended to work in conjunction with associated controls and sequences of operation systems to:

- Maintain room temperature
- Maintain room pressurization and differential pressure cascades
- Provide make up air for ventilation and room pressurization
- Condition the air stream to remove an/or add moisture content of the air
- Minimize airborne contaminatin to the condition space
- Provide required air change rates to maintain room cleanliness classification when required

The following major components of an HVAC system for GMP spaces are discussed in more depth in Chapter 6.

每件HVAC系统设备都是为用户对室内环境条件要求服务的。为GMP区域服务的HVAC设备都是与其他的辅助控制与操作系统紧密联系的：

- 室内温度的维持
- 室内增压和压差的维持
- 为通风和室内增压提供补给空气
- 移除或添加空气中的水分含量
- 使受控空间的气体污染物最小化
- 提供所需的换气率以维持要求的室内洁净度类型

第 6 章深入讨论了为 GMP 服务的 HVAC 系统的主要构件。

2.5.2 Air Handing Unit (Ahu) 空气处理单元

An equipment package that includes a fan or blower, heating and/or cooling coils, air filtration, etc. for providing heating, ventilation, and air conditioning (HVAC) to a building.

一个包括风机、加热或冷却旋管、空气过滤器的设备集合，能够为建筑物提供加热、通风和空气控制。

2.5.3 Fan 风机

An electrically driven air moving device used to supply, return of exhaust/extract air to or from a room through ductwork to generate air in sufficient amounts to provide ventilation, heating, cooling or to overcome air pressure losses.

一个用于向室内提供空气、返回排出的空气的电动的空气转移设备，它通过管道系统产

生足够的空气以通风、加热、冷却或克服空气压力损失。

2.5.4 Fume Exhaust/ Extraction System 烟尘排除系统

A system made up of ductwork, fans and possibly filters that discharges unwanted air outside into the atmosphere to a safe distance from buildings and people.
由管道系统、风机以及可能的过滤器组成，用于排除不需要的空气到与建筑物和工作人员有足够的安全距离的大气中。

2.5.5 Heating Coil 加热旋管

A heat transfer device consisting of a coil of piping which increases the sensible heat into an air stream, using steam or hot water or glycol as the heating medium. And electric air-heating element can also be called a “heating coil”.
一系列旋管组成的传热装置，使用蒸汽或热水、热乙二醇作为加热介质，向空气气流中添加热焓。电热的空气加热构件也被称为加热旋管。

2.5.6 Cooling Coil 冷却盘管

A heat transfer device consiting of a coil of piping, which reduces the sensible heat and possibly latent heat (via condensation of water vapor) from the airstream using chilled liquid or refrigeration as the cooling medium.
一系列旋管组成的传热装置，以冷冻液体或冷冻剂为冷却介质，降低空气气流的显热和可能的潜热（通过使水蒸气冷凝）。

2.5.7 Humidifier 增湿器

A device to increase the humidity within a controlled space by means of the discharge of water vapor into the supply air stream or directly into the room.
通过向受控空间直接添加水蒸气或在供气气流中添加水蒸气的方式来增加受控空间的湿度的装置。

2.5.8 Dehumidifier 除湿器

A special device that removes water vapor from the air to reduce humidity.
从空气中移除水蒸气以降低湿度的装置。

2.5.9 Air Filtration 空气过滤器

Devices to remove particulate material from an airstream by means of various media types.
通过不同的媒介移除空气气流中的颗粒物质的装置。

2.5.10 Ductwork 管道系统

A network of air conduits distributed throughout a building, connected to a fan to supply,

return or exhaust/extract air to or from zones in a building.
在建筑物内部分布的空气管道网，连接风机以提供空气、返回已被排出的空气至建筑物的指定地带。

2.5.11 Damper And Louver 风门和天窗

2.5.11.1 Found in ductwork, a damper consists of a movable plate (or numerous plates), plunger, or bladder that opens and closes to regulate airflow. Dampers are used to regulate airflow to certain rooms.

2.5.11.1 存在于管道系统，由一块或多块可移动的平板（或多个平板）、活塞、袋子组成，这些部件通过开关来调节气流量。风门用于调节某一室内空间的气流。

2.5.11.2 A louver is an assembly of sloping vanes intended to permit air to pass through and to inhibit transfer of water droplets from outdoors into air systems. A louver may also be found in return air ductwork at room interfaces.

2.5.11.2 天窗是一系列倾斜的叶轮的集合，它能够在允许空气通过的同时阻止水滴进入空气系统。检测窗还会位于房间之间管道系统的回风处。

2.5.12 Diffuser and Register 扩散器和调风器

Air distribution outlet or grille designed to introduce air to a space using direct airflow in desired patterns. Air diffusers are usually located to distribute the air as uniformly as possible through out a space.

用于向空间中引入特定形态的单向气流的空气分布出口或格子。空气分布器常常尽量使空气均一的通过空间。

2.5.13 Ultraviolet (UV) Light 紫外灯

A UV light used precise ultraviolet light wavelength to destroy microorganisms.
用恰当波长的紫外光来破外微生物有机体的紫外灯。

Equipment	Heating	Cooling	Humidification	Dehumidification	Room static Pressure	Airflow	Air Quality
Air Handler	x	X		x	x	x	x
Fan					x	x	
Fume Exhaust/Extract Systems							
Heating Coil	x						
Cooling Coil		X		x			
Air Filter							x

Humidifier			x				
Dehumidifier				x			
Ductwork					x	x	
Damper & Louver					x	x	
Diffuser & Register						x	
UV Light							x

Table 2-4 System components and their primary function relating to environmental parameters

设备	加热	冷却	增湿	除湿	室内静态压力	气流	空气质量
空气调节单元	x	X		x	x	x	x
风机					x	x	
烟尘排除系统							
加热旋管	x						
冷却旋管		X		x			
空气过滤器							x
增湿器			x				
除湿器				x			
管道系统					x	x	
风门与检测窗					x	x	
分布器与调风器						x	
紫外光							x

表 2-4 系统组件及其与环境参数相关的功能

2.6 HVAC system configuration HVAC 系统配置

2.6.1 Introduction 简介

This section gives a brief overview of the key factors to consider, the options available to an HVAC system designer, and the factors influencing the decision to choose a particular system type.

This section should be read in conjunction with section 4 “HVAC APPLICATIONS BY PROCESS AND CLASSIFICATION”.

本节简单叙述了需考虑的关键因数，可供 HVAV 设计人员选择的办法，影响选择系统类型的因数。

本章应该与第 4 章“HVAC 处理工艺和分类的应用”联系阅读。

One question to answer is 'how many Air Handling Units should be used'?

It is common practice to divide a manufacturing area into zone, and use a separate Air Handling Unit per zone – a zone in general Building Services design would be an area with similar heat gains and losses, a similar approach is used within the pharmaceutical industry – and is usually considered as an area with one type of manufacturing process of area classification, e.g. a tablet compression suite or all Grade 7 areas, as the area requirements will be similar. Other factors that are considered when dividing a facility into zones include:

- Use of multiple units improves reliability of the area – it would be unusual for all of the units to fail.
- The use of multiple smaller units might make air balancing easier
- The use of multiple smaller units means that the main distribution ducts are smaller, making then easier to route in small ceiling voids.
- It is easier to make modifications to parts of the facility in future an upgrade a small unit than change a large single unit
- Use of multiple units allows for easier separation of areas within a multi-product concurrent manufacturing plant.

The decisions regarding AHU system zoning are very important as a factor in subsequent facility commissioning, qualification and related documentation.

一个需回答的问题：应该用多少个空气调节单元？

常见的实践做法是将一个制造地方分成不同的区域，在每一个区域使用一个单独的空气调节单元——建筑设计常将制药工厂中具备相似热量得失与相似制造方法的地方划分为一个区域——一个区域常被认为具备相同的制造工艺，如：压片间或所有 7 级空间，它们的空间要求都是相似的。以下是在划分工厂区域需考虑的其他事项：

- 使用多重单元以提高区域的可靠性——所有的单元都同时失效时不常见。
- 使用多重更小的单元可以使空气平衡更加容易达到。
- 使用多重更小的单元意味着主分布管道更小，使更容易控制小面积天花板的空气分布。
- 多重单元的使用使生产多种产品的工厂的分区更加容易。

空气调节系统分区的判断非常重要，它是随后的工厂的调试、验证以及相关文件记录的一个要素。

2.6.2 Basic System Types 基本系统类型

There are three basic categories of HVAC system;

HVAC 系统有三种基本类型。

2.6.2.1 Once through – uses treated outside air to provide the design internal conditions, this air is then extracted from the space and discarded.

2.6.2.1 一次穿流类型——利用外部处理后的空气提供设计所需的内部空气条件，然后将

进入的空气排除空间外不再使用。

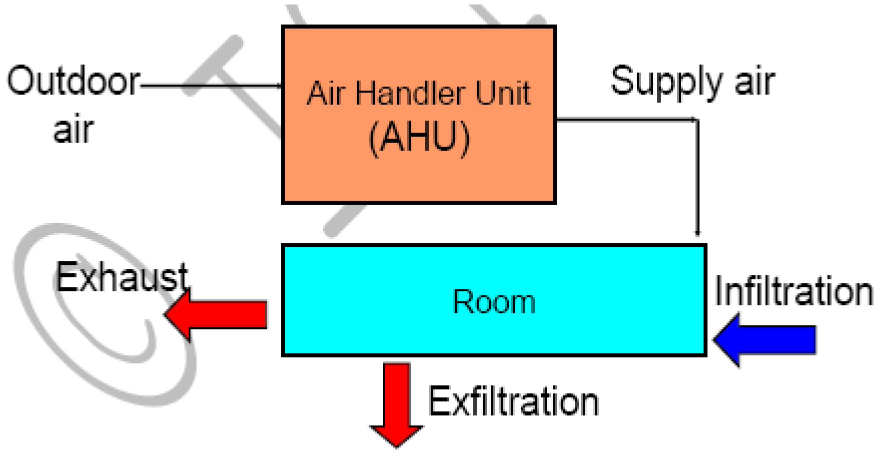


Figure 2-2 Once-through HVAC 一次穿流 HVAC 型

Advantages of this system:

- This system provides an abundance of 02 rich fresh air to dilute contaminants
- The system can handle hazardous material, though the extracted air may need treatment before it is discarded.
- Lower risk of cross contamination of products from another room via HVAC
- Exhaust fan may be located remote from the AHU making duct routing simpler
- As there are less concerns about the ductwork noise in the extract ductwork, it can usually be sized for a high velocity, making it easier to route as high velocity = smaller diameter.

Disadvantages of this system:

- More expensive to operate than an equivalent recirculating system, especially when cooling and heating.
- Filter loading very high = frequent replacement
- Potential need for exhaust air treatment (scrubbers, dust collectors, filters)
- Room conditions more difficult to maintain

此系统的优点：

- 此系统可提供大量的充足的 02 富新鲜空气来稀释污染物。
- 此系统能够处理有害物质，但排除的空气有可能需要在抛弃前预处理。
- 通过 HVAC 系统发生不同产品间的交叉污染的风险低。
- 排气风机可被置于远离空气条件单元的地方，使管道更加简化。
- 由于此系统可以不用过多的关注排风管道系统的噪音，所以可通过控制管道大小来提供高的气体流速，高的气体流速即代表更小的管道直径，而小的管道直径使得布管也更加容易。

此系统的缺点：

- 较回流系统的操作费用更高，尤其是存在制冷或加热的时候。
- 过滤器的负载非常高=频繁的置换。
- 对排气的预处理（洗涤器、灰尘收集器、过滤器）有潜在的需求。
- 更加难以维持室内条件。

2.6.2.2 Recirculation systems – This category is much more common – the room supply air is made up of a percentage of treated outside air mixed with some of the air extracted from the space. A percentage of the air is either discarded of lost through leakage to adjacent areas, due to local area pressurization. 回流系统——更为常见的类型——室内供气由外部处理后的空气与从房间排除的空气混合组成。进入的空气部分被抛弃，一部分由于相邻区域的增压泄露到了邻近区域。

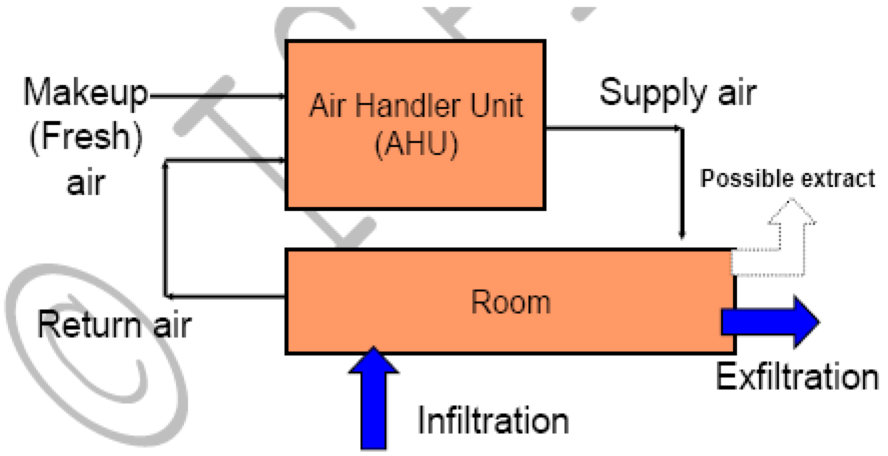


Figure 2-3 Recirculated HVAC

Advantages of this system:

- Usually less air filter loading = lower filter maintenance and lower cost opportunity for higher grade air filtration
- Lower energy cost than once through
- Less challenge to HVAC means that it is simpler to obtain better control of parameters (T, RH, etc)

此系统的优点：

- 较低的过滤器负载=较低的过滤器维护和较低的过滤成本，因为过滤对象空气的等级较高。
- 比一次性通过类型的能量成本低。
- 对 HVAC 系统的挑战更小，即：更容易控制相关参数（温度、相对湿度等）。

Disadvantages of this system

- Return air ductwork routing to air handler may complicate above ceiling
- Chance of cross contamination via HVAC = Requires adequate supply air filtration (and

sometimes return air filtration to prevent contamination of the air handler)

- Chance of recirculation of odors and vapors and of inadequate fresh air supply

此系统的缺点：

- 天花板上的通向空气调节器的回流空气管道系统路线可能变复杂。
- 通过 HVAC 系统发生交叉污染的机会=要求充分的过滤供气（有时需过滤回流空气以阻止对空气调节器的污染）。
- 发生气味、水蒸气的回流以及不够充足的新鲜空气供应。

2.6.2.3 Exhaust (Extract) system – sometimes a stand-alone system that remove airborne contaminants, either solid particles or gasses/vapors. It may be interlinked to a once-through or recirculated air supply system. Used alone, the extract/exhaust system will create a negative differential pressure in the room or enclosure it serves

排气系统——有时为一个独立存在的移除气体污染物或固体颗粒或水蒸气的系统。有可能与一次穿流系统或回流供气系统向联系。当单独使用此系统时，可能造成室内或系统服务的封闭空间形成负压差。

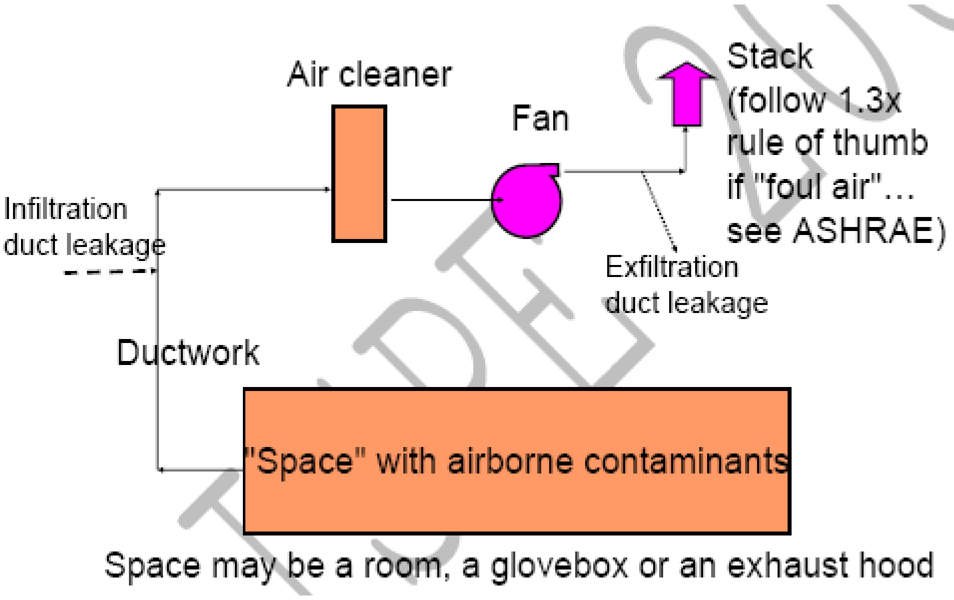


Figure 2-4 Exhaust System

Advantages of this system:

- Simple to operate. Makeup air is pulled from surrounding spaces.

Disadvantages of this system:

- If used to capture large quantities of contaminants, such as from open processes, a large energy cost will be associated with conditioned air being thrown away (see once-through system above)

此系统的优点：

- 操作简单。补给供气是从周围空间得到。

此系统的缺点：

- 如果用于捕捉大量的污染物，如：从一个开放的工艺捕捉污染物，由于系统的空气没有回流而是直接被抛弃，所以会产生巨大的能量成本（参见一次通过系统）。

2.6.2.1 Use of Air Handling Units in parallel of series

It is possible to put units in series, for example if a higher air pressure is required to offset the pressure drop through HEPA filters in one area served by an HVAC system.

The use of parallel units is common practice where large areas are being conditioned, for example warehouses and large research laboratories, where this approach may make it possible to maintain acceptable conditions in the area should one unit fail. When configuring units in parallel, care must be taken to assure that the fans can be isolated and started independently. Automatic isolation dampers and variable fan drives assist in managing these factors.

2.6.2.1 并行系统中的空气调节单元的使用

将多个单元放到一个系统里面是可能的，例如：如果需要一个较高的空气压力来抵消经过HVAC系统中的HEPA过滤器的压力损失。

在控制大面积的区域使用并行单元很常见。如：在仓库和大的研究实验室中，并行单元可以维护其可接受的空气条件，而单个的单元却不能。当配置并行单元时，必须注意保证风机能够独立运行和单独启动。自动隔离风门和不同的风机驱动器是帮助管理以上要素的。

2.6.2.2 Configurations and combinations

The basic components and concepts outlined above can be assembled in an infinite variety of ways. Shown below are a few examples of design concepts commonly used.

(Note: Add some basic block diagram schematics to illustrate these combinations.)

2.6.2.2 构造与集合

以上提到的基本的构建和概念能以不同的方式集合在一起。以下是一些经常使用的设计概念。（注：添加一些基本框图来阐述这些集合）

2.6.3 Air Handling Unit Configurations 空气处理单元的构造

There are two basic types of AHU configuration – blow through or draw through. The term describes the relationship of the fan to the coils in the air handling unit. The two approaches have distinctive characteristics;

存在两个基本的空气处理单元构造类型——输入式或输出式。此术语描述了空气处理单元中风机与旋管之间的关系。这两个类型具有不同的特点

2.6.3.1 Blow through units 鼓入穿流式单元

Air is drawn into the unit, typically through a set of pre-filters used to reduce the dirt load on the (usually more expensive) final filters, and to prevent build up of dirt onto the heating and cooling coils, which would quickly reduce their efficiency. One advantage of this type of unit is that it allows the AHU discharge temperature to be at the cooling coil discharge air temperature, because the fan heat is removed in the cooling coil. This is particularly useful when heat loads are particularly high and supply air temperature must be as cold as possible. It is not advisable to follow a blow through unit immediately with a set of HEPA filters unless special precautions are included to prevent moisture carryover from the cooling coil. Another advantage is that if the drain trap on the cooling coil runs dry, then air will blow out through the trap –wasting a small amount of treated air. The disadvantage - the unit typically needs to be longer to allow a diffuser to be installed after the fan to ensure that the airflow is spread over the entire coil area, and not concentrated on the middle, which would cause a drop in system performance.

空气被输入单元中，尤其是通过一系列的预过滤器来降低终端过滤器（较预过滤器更贵）的杂物负载量，这些杂物会极大地降低终端过滤器的效率。此类型的一个优点是空气处理单元出口温度等于冷凝旋管释放的空气温度，因为风机的热量是由冷凝旋管移除的。这个优点尤其适用于热负荷特别高，供风温度必须尽量低的情况。除非有特别的预防措施防止冷凝盘管中的水分被携带，一般不建议在输入式空气处理单元后面马上安置一系列的高效空气过滤器。另一个优点是如果冷凝旋管的排水盘变干了，空气将会从排水盘中排出——浪费了少量的经处理后的空气。此类型的缺点是分布器需要安装在距离风机较远的地方以确保气流在整个旋管中传输，而不是仅仅集中在旋管中间。在旋管中间传输会导致水滴的产生。

2.6.3.2 Draw through units 吸入穿流式单元

These units are typically arranged with the pre-filters and coils before the fan. The advantage of this is that the unit is often smaller, and the motor and fan provide a small amount of reheat (usually 1-2 degrees F) to the air coming off the cooling coil. This lowers the RH of the air and prevents the problems with wetting final AHU HEPA filter banks. One precaution with draw through units is that if the drain trap is dry, then untreated air can be drawn into the unit through the trap, with only the final filter to protect the conditioned environment. The design must include provisions for maintaining a wetted drain trap, which can be several inches in height.

这次类型一般与预过滤器、旋管一起安装在风机前。优点是这种单元更小，马达和风机给从冷凝管进入的空气提供微量的再加热（一般加热1~2度）。这将降低空气的相对湿度RH和阻止被湿润的空气处理单元的终端过滤器产生问题。如果排水盘变干，则未经处理的空气会通过排水盘进入空气处理单元，只有终端过滤器保护受控的环境。所以必须采取预防措施以维持排水管（可能几英尺高）的湿润。

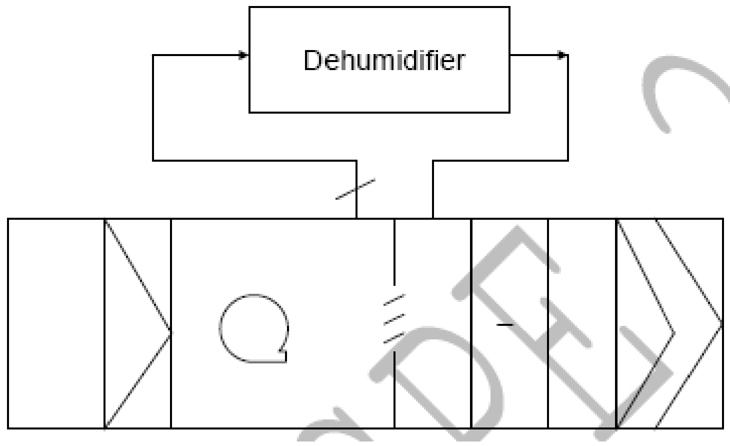
2.6.3.3 Air Handling Unit Design variations 空气处理单元设计变动

A design variation worth considering is the use of a face and bypass damper – the concept is shown below – a portion of the air passing through the AHU is redirected through a treatment stage, with the volume altered to vary the condition of the resulting output air. This is a useful concept to use to gain improved accuracy, particularly if the treatment process is not easily controllable – e.g. chemical desiccant dehumidification.

A similar concept is often employed in the first mixing box of the AHU when enthalpy control is used – in all cases careful sizing of the dampers, to ensure adequate velocity for control, is necessary to obtain proper operation of these systems, maintaining constant system volume as the proportions of the air streams are varied.

端面通道和旁路通道风门的使用是一个值得注意的设计变动——其概念如下所示——经过空气处理单元的一部分空气会在处理阶段改变方向，流量也会变化，导致结果输出的空气状态变化。这种设计概念对获得高精度非常有用，尤其是当处理过程不好控制时，如：化学除湿剂除湿器。

当使用焓控制时，空气处理单元的第一个混合室也常常使用相似的概念——在所有的情况中，为了系统的适当操作，都需要大小合适的风门，以确保控制能达到足够的气体速度。由于水蒸气的比例是不同的，所以此概念对于系统获得正确的操作，维护持续不变的气体流量是必须的。



2.6.3.4 Air Handling Unit Components空气处理单元部件

Numerous design options are possible within the 2 basic types. Here will establish a lexicon of design components, or modules, that can be assembled into an AHU design and discuss the motivations that drive the selection of each. To illustrate the possible options, the following demonstration uses a draw-through, Recirculating AHU:

在两基本空气处理单元中，存在着很多的设计选择。这里，我们将列出设计构件（或各个模块）的词汇表，这些设计构件能被组合到一个空气处理单元中，同时我们还将讨论这些构件的动力方式。为了阐述可能的设计选择，下面使用吸入穿流式循环空气处理单元为例说明：

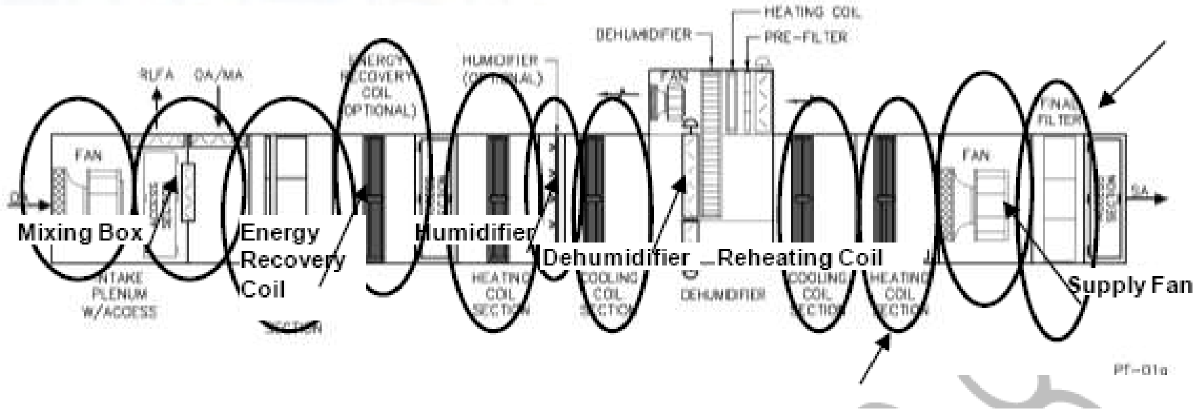


Figure 2-6 Air Handler Unit Components

Return Fan回风风机

Most recirculating air systems will utilize a return fan. This fan allows return pressure and flow to be managed independently from the supply. This is particularly important if the downstream system has volume control boxes on both the supply and return. It also allows the return air to be diverted to exhaust when outside air conditions are closer to desired discharge conditions than return air. This function is referred to as an “economizer” and is generally employed in offices or other spaces that are not pressure controlled.

绝大多数的回风系统都会使用回风风机。此类风机能够独立于供风系统，管理回风压力与回风流量。如果下游系统需要对供气流量和回风流量都进行控制，则回风风机非常重要。如果室外空气状态比回风空气状态更接近于规定的抛弃空气状态，那么回风风机能够将回风转向室外被排出。这项功能被视为一种经济节约，被广泛应用于对压力无控制的办公室或其他地方。

Mixing Box混合室

This pieced of equipment is also common in recirculating air systems. The return air can be directed to exhaust or to recirculate, it is then mixed with outside air for pressurization and/or ventilation. The resulting air stream is referred to as “mixed air”. In very cold environments the mixed air may be subjected to a turbulence inducing device to assure thorough mixing and avoid stratification.

此设备在空气回流系统中也很常见。回风能被直接排出或被回流，它与室外的空气混合提供增压和通风。混合后的气流就称为“混合空气”。在极端寒冷的环境条件下，混合空气可能会被湍流诱导装置使气体彻底混合，避免气体分层。

Prefilter or Prefilter and Intermediate Filter预过滤器或预过滤器与中间过滤器

Filters are typically provided upstream of coils in an air handler to protect the coils from fouling with dirt or debris. The system typically employs a low efficiency “dust stop” (MERV 7) filter followed by a medium or high efficiency intermediate filter (MERV 7-14).

过滤器一般位于空气处理单元中盘管的上游，以保护盘管不被赃物或碎片污染。一般做法是：在低效率的“烟尘阻留“（MERV 7）预过滤器后面衔接中等效率或高效的中间过

滤器(MERV 7-14)。

Energy Recovery Coil能量回收盘管

Once through air systems, or other systems with high amounts of exhaust may employ an energy recovery coil to return a portion of the energy employed in conditioning the exhausted air to the incoming air. These coils are typically upstream of all other coils and may be placed upstream of the filters if used to melt snow in cold climates. These systems may also employ a bypass damper to decrease pressure drop across the coil when energy recovery is not advantageous.

一次性穿流系统或其他有大量废气排出的系统需要使用能量回收盘管，此盘管会回收排气与进气控制过程所使用的部分。能量回收盘管位于其他盘管的上游，当需要融化寒冷气候下的冰雪时，盘管还可能位于过滤器的上游。当能量回收不带来有利效果时，可设置旁通气门以降低空气穿过能量回收盘管的压降损失。

Preheat Coil预热盘管

Once through air systems, or other systems with high amounts of outside air in cold climates may employ a preheat coil to condition the incoming or mixed air. These coils are always upstream of cooling coils, to protect them from freezing and may be placed upstream of the filters if used to melt snow in cold climates. These coils do not typically impose a large pressure drop, so a bypass damper is not common.

在寒冷气候下运行的一次性穿流系统或其他需要大量外部空气的系统可能需要使用预热盘管，以控制进入的空气或混合空气。这些盘管永远位于冷却盘管的上游，以保护冷却盘管不被冰冻。当需要融化极端寒冷气候的的冰雪时，预热盘管可能被置于过滤器的上游。预热盘管通常不会造成大量的压力损失，所以一般没有必要设置旁通气门。

Humidifier增湿器

Once through air systems, or other systems with high amounts of outside air in cold climates may employ a humidifier to inject water vapor to condition the incoming or mixed air. These devices are typically downstream of the heating coil and may even be mounted in ductwork where turbulence and high velocity promote absorption of water vapor. When employed in an AHU, mounting upstream of cooling coils provides a natural baffle to prevent carryover of liquid water droplets.

在寒冷气候下运行的一次性穿流系统或其他需要大量外部空气的系统可能需要使用增湿器，通过增湿器向进入的空气或混合空气添加水蒸气以控制进气状态。增湿器一般位于加热盘管的上游，有时甚至被安装在湍流高速促进吸收水蒸气的管道系统中。当在空气处理单元中安装增湿器后，上游的冷却盘管是阻止携带液态水滴的自然阻碍。

Cooling Coil冷却盘管

Cooling to maintain environmental conditions is common, if not always required in Pharmaceutical applications. These coils can eliminate both sensible and latent heat and can be upstream or downstream of the fan. If latent cooling is expected drainage of these coils is a key design issue and mist eliminators may be employed to eliminate carryover of liquid water droplets that condense on the coil. These coils do impose a large pressure drop so a bypass damper can be employed, but can pose a risk of unconditioned air leakage and non-attainment of humidity goals.

即使冷却不是制药生产必须得工艺，它在环境控制维护中也是很常见的。冷却盘管可以消除显热与潜热，也可位于风机的上游或下游。如果预知会发生冷凝，则盘管的污水是盘管设计的主要问题。除雾器能够用来除去由于盘管内空气冷凝产生的液态水滴。冷却盘管会造成巨大的压力损失，所以需要使用旁通气门。但是这也会造成不受控制的空气泄露和不合格的湿度的危险。

Dehumidifier除湿器

Dehumidifiers employ a chemical desiccant to remove moisture from the supply air stream when humidity below 30-40% is required. The dehumidifier is often located downstream of the cooling coil as they work most efficiently when airstream relative humidity is high (but within desired limits). However care must be taken to assure that excessive relative humidity or liquid water droplets do not damage the dehumidifier. The choice of desiccant may vary, depending on the application but all desiccants are regenerated using heat; therefore, air leaving the dehumidifier is both dryer and hotter than upon entering.

当要求湿度小于30~40%时，除湿器利用化学干燥剂来除去供气中的水分。除湿器常常位于冷却盘管的下游，因为除湿器在相对湿度高的气流条件（但不能超过限制）下工作更有效率。过大的相对湿度或过量的水滴并不会破坏除湿器。根据不同的用途干燥剂可选不同的类型，但是所有的干燥剂都需能用加热的方式再生。因此，离开除湿器的空气比进入除湿器的空气更加干燥、温度更高。

Recool Coil再冷盘管

These coils are only commonly installed downstream of dehumidifiers to eliminate sensible heat from the supply air. They are also employed downstream of cooling coils to provide additional latent heat removal. In this second application they operate below chilled water temperature and are typically filled with refrigerant or a low temperature brine of water and glycol (ethylene or propylene). If latent cooling is expected drainage of these coils is a key design issue and mist eliminators may be employed to eliminate carryover of liquid water droplets that condense on the coil. These coils do not typically impose a large pressure drop so a bypass damper would be unusual.

再冷盘管只安装于除湿器的下游，用来减少供气的显热。再冷盘管利用下游的冷却盘管来移除供气的附加潜热。在执行第二项功能时，再冷盘管在低于冰水温度下运行，盘管被冷冻的或低温的盐水和乙二醇（乙烯或丙烯）充满。如果预知会发生冷凝，则盘管的污水是盘管设计的主要问题。除雾器能够用来除去由于盘管内空气冷凝产生的液态水滴。再冷盘管通常不会造成大的压力损失，所以一般不设置旁通风门。

Reheat Coil再热盘管

Systems that require over-cooling to achieve humidity control (in lieu of dehumidification) may also employ a preheat coil to condition the air leaving the cooling coil. These coils are always downstream of cooling coils, to increase the discharge temperature of the air handler and avoid condensation in the ductwork or overcooling of the space.

需要过度冷却来达到湿度控制（代替除湿器）的系统可能需使用再热盘管来调节冷却盘管排出的空气。再热盘管位于冷却盘管下游，以增加空气处理器排除的空气温度，避免在管道系统发生冷凝或空间的过渡冷却。

Supply Fan供风风机

All air systems will utilize a supply fan. This fan provides the motive force for distribution of air throughout the air handling system.

所有的系统都会使用供风风机。它提供整个空气处理系统中空气的分布动力。

Final Filter终滤器

Filters may be provided as the last treatment step in an air handler. These filters provide assurance of air quality (with reference to particulate) downstream of all air handling operations and are particularly valuable in protecting terminal filters from fouling with dirt or debris and in providing filtration for classified spaces. This is of particular interest in systems that employ fan drive belts which shed particulate into the airstream. Systems typically employs a high efficiency filter in this location (MER V 14+).

终滤器在空气处理系统中式最后一步工序。他们为下游的所有空气处理操作提供了空气质量（以颗粒含量为参考）保证，对防止终端过滤器被污物和碎片污染、为洁净分类空间提供过滤具有重要的价值。风机驱动皮带会带入颗粒物质到气流中，所以终滤器对于带风机驱动皮带的系统是尤其有用的。系统经常使用高效过滤器作为终端过滤器。

2.6.4 AIRLOCK STRATEGIES 气闸方案

2.6.4.1 PRESSURIZATION增压

Airlocks are usually interposed between areas if airflow between the spaces needs to be controlled when they are entered or exited. Airlocks may also serve as material transfer / decontamination rooms, and gown or degown rooms. Three types of airlock pressure arrangements are indicated below:

当区域中流入或流出的气流需要被控制时，气闸常安装在区域间。气闸可作为物质转移室、脱除污染室、穿衣/脱衣室。以下是三种气闸类型的示意图：

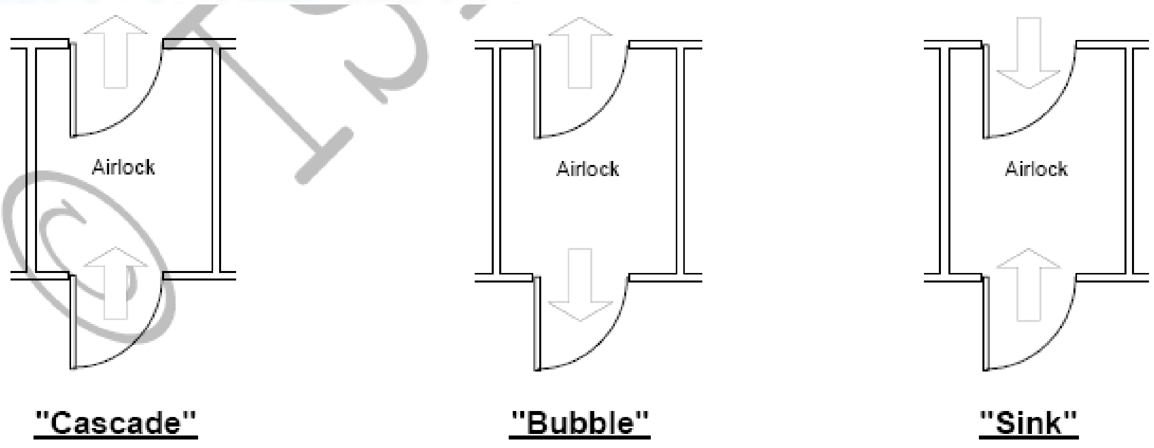


Figure 2-7 Airlock configurations

The "cascade" pressurization scheme should be used when there are area cleanliness classification requirements but no containment issues, or where there are containment issues but no cleanliness classification requirements. (i.e., cascade outward from the room for aseptic operations, but cascade into the room for hazardous compounds.) Doors are usually interlocked to allow only one to be open at a time. The normal differential from one air class to the next (ACROSS the airlock) is 10-15 Pa(0.04 to 0.06" w.g.). The pressure INSIDE the airlock is somewhere between the two classes, depending on which door is open. It is not necessary to have 10-15 Pa between a room and its airlock (see "Not required" in the drawing below).

级差增压方案的适用范围：存在区域洁净度分类要求但是无污染问题时，或存在污染问题但没有洁净度分类要求（如：级差方向是从无菌操作室流入有害物质房间）。为了使在同一时刻只有一扇门打开，门经常是相互锁的。从一个空气级别到另一空气级别（即穿过一个气闸）常见的压差为10~15Pa(0.04 to 0.06" w.g.)。气闸内的气压间于两个不同空气等级气压之间，具体值由开的门而定。在房间与气闸间保持10~15Pa的压差是不必要的（见下图的"非必要项"）。

If there are requirements for both area cleanliness classification and product containment, then the use of pressure sinks and bubbles may be necessary. Pressure bubbles are usually used for 'clean' operations (i.e., such as gowning or material entry airlock) and pressure sinks are usually used for 'dirty' operations (i.e., de-gowning material decontamination/exit airlock). Normal design pressure differential between classifications should be 0.06" w.g. (15 Pa) with the doors closed. Pressure differential will drop momentarily while one door is opened, but will not drop to zero (as it would with no airlock or if all airlock doors were opened). In no case should pressure differential reverse.

如果对区域的洁净度和产品污染物都有控制要求，则使用"气泡"增压方案和"卧槽"增压方案。气泡增压方案常用于清洁操作（如：穿衣气闸或物料进入气闸），卧槽增压方案常用于有污染的操作（如：脱衣气闸或物料去污室气闸）。两个类型的空间的压差（气闸门关闭）一般设计为0.06"（15Pa）。当一扇门打开后，压差将会即刻下降，但不会降

全零（没有气闸或气闸门全部打开发生的情况）。气压是不可逆的。

For unclassified areas the minimum suggested pressure differential is 0.02” w.g. (5 Pa), being the minimum reliably detectable by current pressure sensor technologies.

The pressure differential is measured across the airlock, not across each door.

目前气压检测技术能检测到可靠数据的最小压差为0.02”w.g.(5Pa)，所以对于未定义类别的区域，其最小压差建议为0.02” w.g. (5 Pa)。

压差是指穿过整个气闸的压力之差，而不是穿过气闸门。

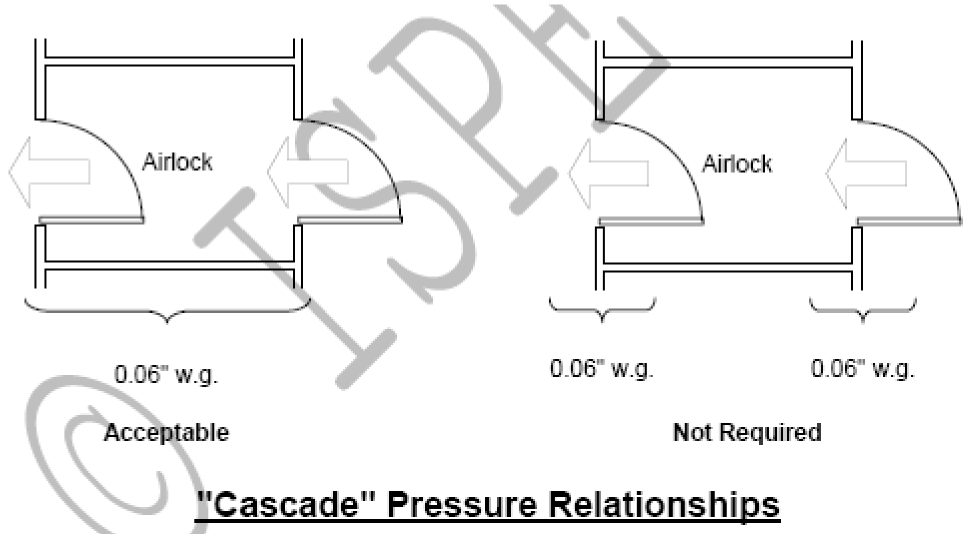


Figure 2-8 Example of Cascade Pressure Relationships

When using the —”bubble” pressurization scheme, the normal design pressure target, with doors closed, between classifications should be 0.06” w.g. (15 Pa). There may be different pressure drops across each door due to building tolerances, or adjacent room conditions, this is not considered a problem. If protecting non-sterile processing (areas not classified) a lower pressure is acceptable, but should be measurable. The pressure of the very clean airlock ‘bubble’ is usually designed to be about 0.02 to 0.03 in. w.g (about 5-8 Pa) above the higher of the two room pressures.

The positive pressure airlock provides a robust means of segregating areas using positive airflow.

气泡增压方案常用的不同类型空气间的目标设计压力（气闸门关闭时）为0.06”w.g.（15Pa）。由于建筑物容量的不同或相邻房间空气状态的差异，气流通过每扇门的压力损失不同。这并不会成为一个问题。若保护对象是非无菌工艺（未定义空气分类的区域），那么较低的压力也是可采用的，但采用的压力应该是可被检查的。非常洁净的气泡气闸的压力一般较相邻的两个房间的压力高0.02~0.03”w.g.(大概5~8Pa)。

正压气闸使用带正压的气流为不同的区域的隔离提供了一个强有力的手段。

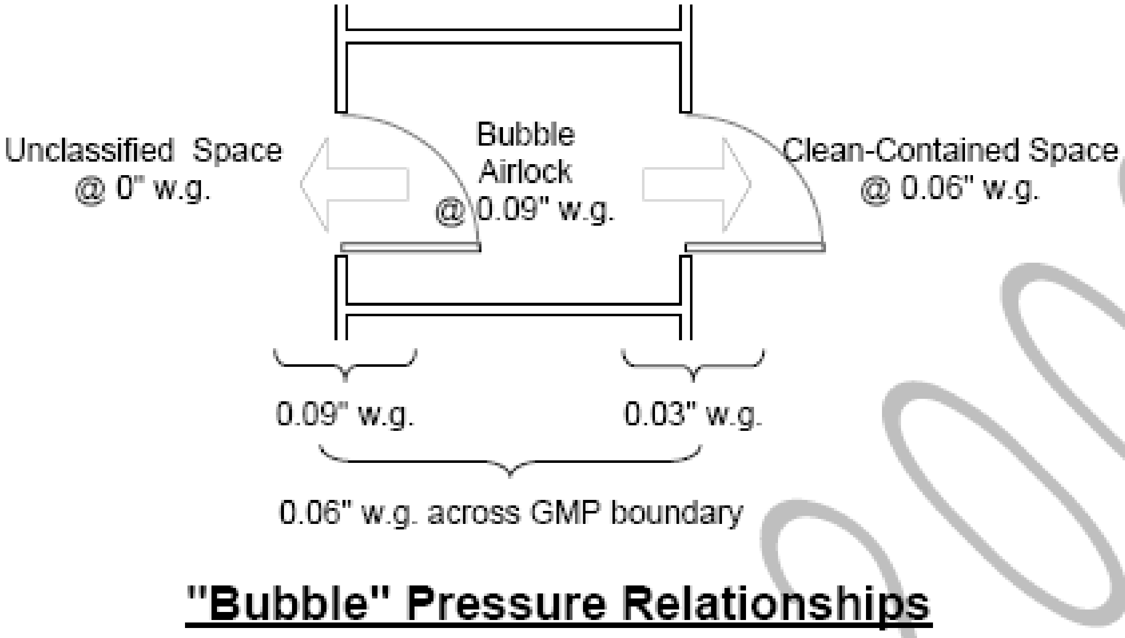


Figure 2-9 Example of "Bubble" pressure relationships

Similarly, with the —"sink" pressurization scheme, the normal design pressure between classifications should be 0.04 to 0.06" w.g. (10-15 Pa) with doors closed. As with the —"bubble" there may be different pressure drops across each door. The pressure of the contaminated airlock 'sink' is usually designed to be about 0.02 to 0.03 in. w.g (5-8 Pa) below the lesser of the two room pressures.

同样，卧槽增压方案在不同类型空气间的目标设计压力（气闸门关上时）为0.04~0.06"w.g.(10-15Pa)。也如气泡增压风闸一样，卧槽增压风闸中经过每气闸门的气流压力损失也不同。污染的卧槽气闸压力常在设计为比相邻的房间压力低0.02~0.03 w.g (5-8 Pa)。

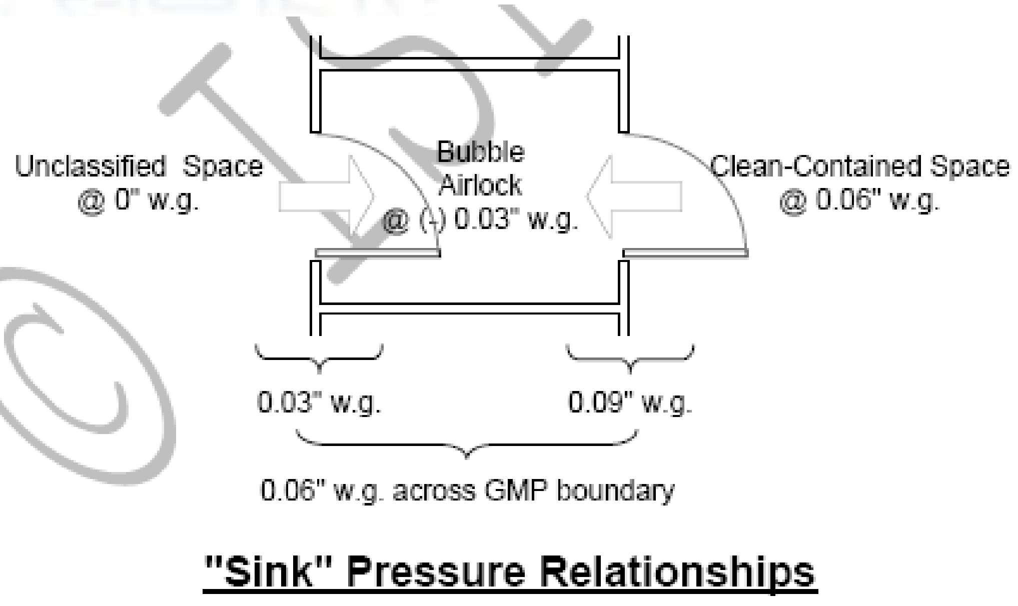


Figure 2-10 Pressure "sink" relationships

It is often necessary to have pressure differentials at boundaries within the same air class area for operational reasons. The minimum operational differential between areas of the same classification (where required) is suggested to be 0.02"w.g. (5 Pa), with a design target of 0.04" (10Pa) suggested. It is also sometimes necessary to have directional air flows for operational reasons without a measurable pressure differential, such as may be found in non-classified areas, such as oral dosage manufacture.

由于现实操作的原因，相同空气等级的不同区域的交界处也应该具备压力差。相同空气等级的不同区域之间的目标设计压差为0.04" w.g. (10Pa)，最小压差应为0.02"w.g. (5 Pa)。有时，由于现实操作限制，需使用固定风向气流，其压差不能被测量，如未分类的区域、口服固体制造区。

Pressure may be maintained across doors between air classes when no airlocks are present. However, without the added protection provided by the airlock, significant airflow volumes and pressure actuated dampers are required. (See the Appendix) This scheme should be adopted only when airlocks are not possible.

没有气闸也能够维持不同空气类型之间的压差。但是，由于没有气闸提供的保护，需要大量的气体流量和压力控制风门。（见附录）这种方案只能用于不能使用气闸的时候。

The airflow leakage rate should be calculated for each room. This calculation must be based on the design pressure differential established in the project documents and not on some rule of thumb method, e.g., percentage of supply air. Door seals are the primary path of room air leakage. Therefore, doors and doorframes are crucial components of the facility construction, as more leakage air must be designed into the system for doors with poor seals. The HVAC design engineer should consult with the facility architect to assure specifications are adequate for pressurization requirements. Door frames may include continuous seals which would reduce leakage required to maintain the desired pressure, as well as provide isolation in case of airflow failure. Doors may be provided with a provision for operable floor sweeps which drop down as the door closes, but these may present cleaning problems. Where double doors are used in the facility, gasketed astragals are required. Door grilles should be avoided unless part of a pressure scheme without airlocks (as discussed in the Appendix). Figure 14, Chapter 27 of the 2005 ASHRAE Handbook-Fundamentals should be used in calculating the air leakage rate of doors. Common practice is to design for a 0.10” average crack between the door and frame on sides, top, and bottom. Note that corrections are to be applied for design pressure differentials using the formula contained in Figure 14. A similar leakage calculation is discussed in the article, Airlocks for Biopharmaceutical Plants, del Valle, Pharmaceutical Engineering, Volume 21, Number 2, March/April 2001.

房间的气流泄露量应该是可计算的。这种计算建立在项目文件指明的设计压差的基础上，而不是使用一些经验的计算方法。因此，门和门框是设备建设的关键部件，因为密封性较差的门需要在设计时设计更大的泄露量。HVAC设计工程师应咨询设备设计师以确保设计规范满足增压要求。门框可能包含连续的密封条用于减少气体泄漏、维持要求压力，同时提供隔离环境以避免气流不能良性流通。门常配备operable floor sweep的监视器，当门关闭时，operable floor sweep会松开，但是这会引起清洁问题。当双门被用于设备时，需使用密封圈。除了无气闸的情况，门栅格都不应被使用（附录中有讨论）。

Figure 14, Chapter 27 of the 2005 ASHRAE 手册——基本原则应被用于计算门的空气泄漏率。一般的做法是将门与门框之间的空隙（侧面、上部、底部）平均设计为0.10”。注意：为达到设计压力，可利用Figure 14, Chapter 27 of the 2005 ASHRAE 手册来修正空隙值。以下是一个类似的空气泄露计算（Airlocks for Biopharmaceutical Plants, del Valle, Pharmaceutical Engineering, Volume 21, Number 2, March/April 2001.）

物质转移开口是另一个室内空气泄露的主要途径。为了计算，其他的固定开口用一下公式。

Material transfer openings are another key room air leakage path. To calculate leakage through these and other fixed openings use the formula,

Q = A × 4005sqrt (VP) (“Sqrt”= square root)

Q = airflow (CFM)

A = area of opening (sq. ft.)

VP = velocity pressure - the velocity pressure at the opening (in. w.g.) is roughly the same as the differential pressure across the opening, (or the, room differential pressure),

This method provides a conservative leakage number. In most cases, a slightly smaller leakage airflow will produce the desired pressure differential for a given leakage path. Because of this, during commissioning there may be more return air leaving the room than designed, so return air dampers should have some extra capacity.

此法提供了一个常用的泄露数据。在大多数情况下，对于预设定的泄露通道，稍小的泄

露气流也能产生要求的压差。因此，在调试时，需要比设计更多的回风。这也导致回风风门应该具备额外的处理能力。

In some cases the calculated room leakage may exceed the minimum air change rate for small rooms such as airlocks. In these instances the total supply air to the space must match the calculated leakage. However, provisions should be made in the design for some return air from the space in case the actual leakage is less than calculated. A good rule-of-thumb is to size the return for half the supply air flow into the room. In applying this approach, care should be taken in sizing any volume control (damper or CV box) on the return air side to ensure that the actual flow rate is with the operable range of the control device.

有时，小房间的计算室内泄漏率也许会超过最小换气率，如气闸。在这种情况下，总供风应于计算的泄漏率相匹配。设计时应该对回风量进行监控，以避免出现实际泄露率小于计算泄露率的情况。合适的经验值是回风量是进入房间的供风量的一半。使用这种方法时，需要在回风侧控制气体流量（风门或CV盒）以确保实际流量在控制设备的可操作范围内。

For this reason it is a good engineering practice to put a tighter specification on the supply air volume, being more critical to maintain the room conditions, and a larger design range on the return, which will be whatever value is needed to maintain desired differential pressures.

由于以上原因，对供风风量和室内空气状态进行严格的规范，使回风风量设计范围扩大是优秀的工程实践。回风风量设计范围大对维持要求压差有利。

Two methods of measurement are commonly applied to monitor room pressure relationships; room-to-room and common reference point. While both have been used successfully, the preferred is the common reference point method in order to minimize compounded error. Here, one port of the differential pressure transmitter (usually, but not always, the ‘High’ side) is piped to the room being monitored and the other side (usually, but not always, the ‘Low’ side) is piped to a common reference in the interstitial space.

有两种常用方法检测室内压力关系：室对室法、公共参考法。当两种方法都能使用时，偏向于使用公共参考法，因为可以使总体错误降到最小。压差传送器的一端（一般为高压端，但并不绝对）置于被检测房间的，另一端（一般为低压端，但并不绝对）置于空隙空间的公共参考点。

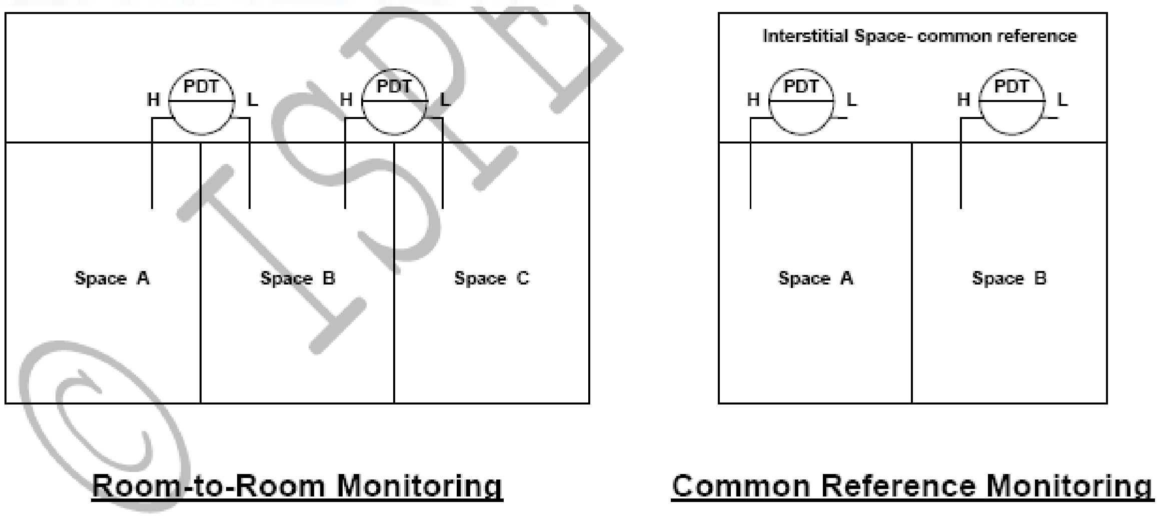


Figure 2-11 Differential Pressure Sensor Locations

图 2-11 压差传感器位置

The common reference point should not be outdoors, as the effect of wind direction may give unstable readings. Where room to room monitoring is used it is a good practice to confirm through the system balancing that net airflow into the facility is greater than the extract/exhaust.

公共参考点不应在室外，因为风向会影响读数的稳定。当使用室对室法时，良好的做法是确保在整个系统平衡中，进入工厂的纯净气流量大于排气/抽气量。

All signals are sent to the control system where differentials are calculated by means of an algorithm. In the event that the reference (interstitial) space is partitioned by fire walls or other means, it may be necessary to provide multiple common reference points by building ‘zone’. In this case the pressure relationship across a ‘zone’ will need to be room-to-room or the use of two differential pressure transmitters, one to each reference point, will be required. For information on monitoring system see section 2.7 Control and monitoring.

信号被送至控制系统，在控制系统内通过计算法则算出压差。在此情形中，如果参考空间（间隙空间）被防火墙或其他物品隔开，那么需要修建“区域”用来提供多重的公共参考点。这样，穿过“区域”的压力关系的测量需要室对室法或两种压差传送器一起使用，且一点对相应的参考点。监控系统的有关信息键第2.7章 控制与监控。

2.6.5 Ventilation/supply strategies 通风/供风方案

2.6.5.1 Room Air Distribution: 室内空气分布：

There are two basic types of room air distribution: dilution and displacement air distribution. In a dilution design, room air is mixed continuously with supply air to help achieve uniform air temperatures within the space. In areas where temperature uniformity is the only factor, aspirating-type diffusers are used to allow turbulent mixing of room air with supply air. From a particulates perspective, dilution also mixes ‘less clean’ room air with the clean supply air. Aspirating-type diffusers are not acceptable in any of the clean classified rooms. Even though non-aspirating diffusers do not eliminate turbulent air patterns in the room, using non-aspirating diffusers in clean rooms reduces the mixing effect. The particulate level in the room can be reduced with dilution by increasing the air-change rate of clean air supply. Dilution distribution with non-aspirating diffusers (typically perforated face plate over the terminal HEPA media) is acceptable to clean classified areas up to ISPE-7. In a displacement design, room particulates are displaced by clean terminal HEPA filtered unidirectional air. This design requires continuous HEPA coverage at the ceiling and properly sized and located low level return or exhaust grills. ISPE-Grade 5 should use displacement air distribution (typically a unidirectional flow hood – UFH).

存在两种布风方案：稀释布风和置换布风。在稀释布风型设计中，室内空气与供气被不断混合以达到均匀的空气温度。当温度均一是空间条件的唯一因素时，使用除尘型扩散器以产生室内空气与供气的湍流混合。从颗粒含量的角度来说，稀释布风使相对不洁净的室内空气与清洁的供风相混合，除尘型扩散器不能在有洁净度等级的室内中使用。虽然非除尘型扩散器没有消除室内空气的湍流，但减小了混合作用。通过增加新鲜供风的换气率，稀释室内气体，以减小室内颗粒含量。使用非除尘型扩散器（常为终端高效过滤器的端面孔板）的稀释布风能够在洁净ISPE7级的空间中使用。在置换型设计中，室内颗粒被中断高效过滤器的单一风向空气置换。此设计需要持续不断的天花板高效过滤器的覆盖，合适的过滤规模，低水平位置的回风或排气栅格。ISPE第5级的洁净室等级应该使用置换空气布风方式（常用单向气流罩-UFH）.

2.6.5.2 Room Air Distribution options室内空气分布方式选择

Conventional air distribution techniques are generally acceptable for administrative, warehouse, and unclassified spaces. Large warehouse spaces, however, may see hot and cold spots with poor air distribution. GMP spaces and cleanrooms require more stringent methods. Supply air should be introduced at the ceiling level and return/exhaust air should be extracted near the floor. The use of non-aspirating diffusers on the face on terminal HEPA filters may improve airflow patterns. Within mixed airflow rooms, airflow patterns should be from clean side of the space to the less clean. For example, within a space that contains an ISO 5 micro-environment/zone with an ISO 7 background, airflow should always be from the cleaner zone into the less clean background area.

常规的布风技术常用于行政、仓库、未分类空间。巨大的仓库空间可能会由于不合格的布风而产生热点或冷点。GMP 空间和洁净房对布风方法要求更为严格。应从天花板供风，从接近地面处排风。安装在终端高效过滤器上的除尘型扩散器的使用能够改进气流的形态。在混合的气流室，气流形态应该从空间较洁净的一面流通到较不洁净的一面。如一个 ISO 第 7 级的空间中包含一个第 5 级的微空间，气流需要一直从较洁净的区域流向较不洁净的区域。

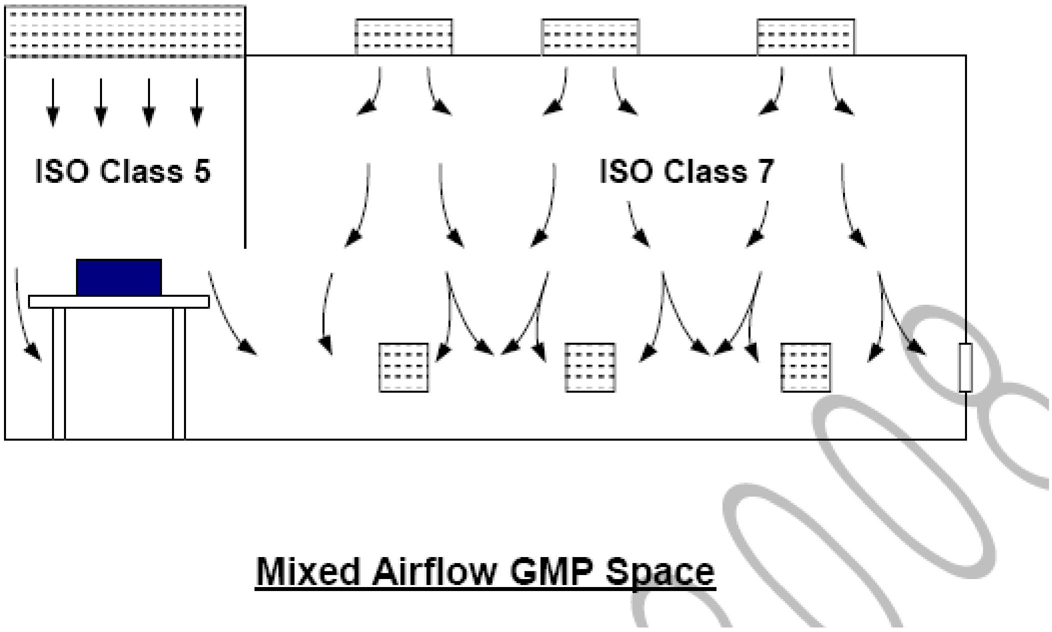


Figure 2-12 Mixed Airflow Space

图 2-12 混合气流空间

Some process operations, i.e., centrifugation, are inherently particle generating. Airflow patterns within the spaces that contain these processes should take this into account by locating returns/exhausts at floor level near the particle generating operation.

Airlocks and gown rooms are usually divided, often by a physical line on the floor, into clean and 'dirty' zones in accordance with the flow of personnel, material, and equipment. Within such spaces, the air pattern should from the clean to the 'dirty' side of the airlock. Therefore, HEPA supplies should be located on the clean side and low wall returns should be located on the opposite side of the room.

Low wall returns should be located no more than 12" above the floor. Returns should be generously sized with a maximum grille face velocity of no more that 400 FPM. Ductwork should be sized for a maximum pressure drop or 0.1" per 100' or a maximum velocity of 850 FPM, whichever is more restrictive. The heel of the connecting elbow should have a minimum 6" radius to facilitate cleaning. The elbow and connecting ductwork, up to an elevation of 5 feet above the floor, should be Type 304 or stainless steel.

诸如离心操作之类的工艺操作自然会产生颗粒。在包含这些工艺操作的空间应特别此工艺带来的颗粒，在靠近颗粒产生操作点的接近地面处设立排风点。

气闸与穿衣室常常按人员、物料、设备的流动分为洁净区域和污染区域，分界常为地面的一条线。因此，高效过滤器供奉装置应该被置于洁净区域而低墙回风应该被置于室内的另一区域。

低墙回风应该置于离地面12"之内的位置。回风应该控制在最大栅格流速不大于400FPM（英尺/分钟）。管道系统应该以最大的压力损失或0.1"/100'或最大流速为850FPM为指标来设计管道大小。连接弯管的半径应不大于6"以使清洁更加便利。离里面5英尺高的弯

管和连接的管道系统应该使用不锈钢或304型钢材。

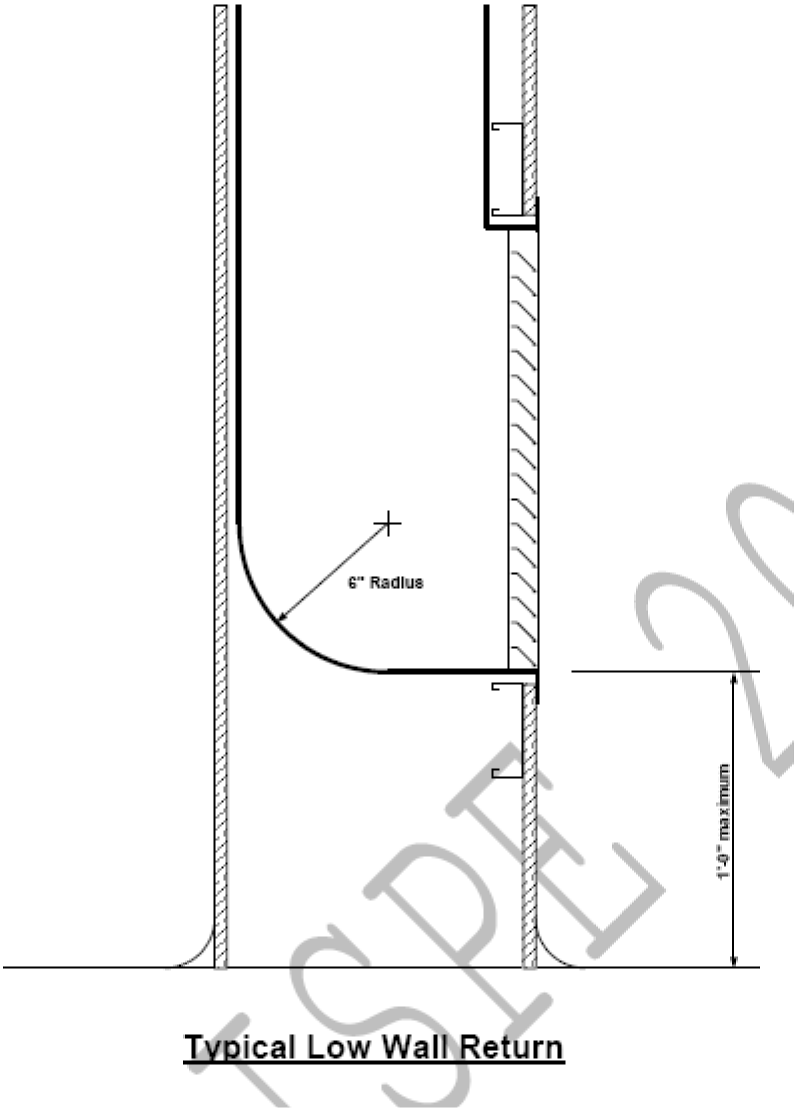


Figure 2-13 Typical Low Wall Return

图2-13 典型低墙回风

Return air ducts located in stud wall spaces need not be insulated within the walls. Insulation shall terminate at the top of the wall. The mechanical engineer should consult with the facility Architect to assure that, where needed, wall cavities are adequate to contain low wall returns.

安装在立柱墙墙体内的回风管道不需要绝热。墙的顶部应不绝热。机械工程师应咨询工厂建造设计师以确保在适当处墙腔足够以控制低墙回风。

2.6.6 EXTRACT (EXHAUST AND / OR RETURN) STRATEGIES 抽气（排气和回风）方案

Why we use low level or high level extract, the area affected by an extract point – do we want to cover dust extract systems at all here??

我们为什么使用高水平位置抽风或低水平位置抽风，既然区域会受抽风点的影响，那么

我们时候要控制系统中的所有的灰尘抽风点？

2.6.7 DISTRIBUTION 分布

Design concepts for ductwork distribution systems – equal velocity, static regain etc are covered in the ASHRAE Handbooks. Such calculations should be performed by only qualified HVAC professionals, who should be familiar with ASHRAE.

管道分布系统(流速、静压等)的设计思想在ASHRAE手册中有报道。这些计算应由熟悉ASHRAE的合格HVAC专业人员来承担。

2.7 HVAC CONTROLS AND MONITORING HVAC 控制与监测

2.7.1 Introduction 简介

This section will give a brief overview of the options available for controlling and monitoring HVAC systems and the environments that they provide, providing guidance on the points to consider when designing a new system or reviewing an existing installation. An important early decision is to decide if the control system will also be the quality 'system of record' providing the alarms and recording that the environment is being maintained within the specified limits, or if there will be an independent system to do this, with the HVAC control system providing only 'engineering' information and alarms.

本节对可用于HVAC的控制与监测的选择以及这些选择所提供的环境做了总述。为设计新的HVAC系统或改进已存在的HVAC系统提供了指导思想。一个早期的重要决定就是：决定是否将控制系统设计为包含"记录系统"功能的系统，或采用单独的"记录系统"，控制系统仅仅提供工程信息和工程警报。记录系统是为环境是否被维持在规定的范围中提供警报与记录的一个系统。

2.7.2 Controls 控制

There are many types of equipment that can be used to control an HVAC system, each with advantages and disadvantages, three of the more common variations are described below;

存在多种类型的设备能被用于控制HVAC系统，每种都有其优点与缺点，以下是三种常用的类型。

2.7.2.1 Basic control system 基本控制系统

A basic system may use packaged controllers (Packaged 'PID' units) for each of the controlled variables. There may be independent control units – e.g. temperature, humidity, or a single combined unit, with the sensors and controlled items – dampers, valves etc connected to the controller. The controller may also have the capability of providing alarms. This option provides a low purchase and installation cost, control panels in a large installation can be standardized and complete panels held as spares. However there is no ability to monitor the system performance, or analyze trends or component performance with this system, hence it is rarely used. A picture of a typical control unit is shown below.

基本控制系统根据控制对象的不同使用不同集合的控制器（混合单位制）。带传感器和控制器（风门、阀门）的独立控制单元连接到控制器上，如温度控制单元、湿度控制单元或单一的组合控制单元。这些控制器也许自带警报功能。这些配件能够提供较低的购买和安装成本，大量安装的标准化的控制板和备用的完整控制板。但是，此系统没有监测系统运行，分析趋势或分析系统部件状态的功能。因此，它很少被采用。典型的控制单元如下所示。

Figure 2-14 Typical Single Loop Control (Courtesy of _____)

图 2-14 典型单线控制器

2.7.2.2 Building Management System (BMS) 建筑管理系统

The most common solution found in the industry is the BMS or BAS (Building Automation System) system. This is a proprietary packaged system typically comprising of a number of local independent control panels, field panels or outstations with the software / control logic installed – the panel may control one or several HVAC or other building systems. This panel is then connected by a network cable to one or several 'supervisors' – computer terminals which allows a user to see the input and output signals, set up the system to record, and allow the user to review plant performance data and trends, change set points and have alarms reported / printed in a central location. This type of system is more expensive, but brings additional capability allowing system performance to be monitored remotely, with adjustments made to set points from a central location if required - a hierarchy of alarms can also be easily set up. The large scale use of these systems has reduced the cost significantly. Figure 2-15 – (to be added)

在工业中最常用的解决方案就是BMS（建筑管理系统）或BAS（建筑自动化系统）。它是专有集合系统，由大量的局部独立控制板、现场控制板或远距离控制板组成。远距离的控制板安装了相关软件或控制逻辑，它能够控制一个或多个HVAC或其他的建造系统。系统中的各种控制板被网络缆线连接到一个或多个"监督者"——终端电脑。终端电脑能够使工作人员看到输入输出信号，建立记录系统，使工作人员检查工厂运行数据和趋势，改变初始设置点，在中心位置生成报警报告。这种系统比较昂贵，但是它有许多附加性能：远距离的监测系统运行状况，在需要时从中心位置调整初始设置——很容易设置系统警报。大规模的使用此系统会显著的降低成本。

Figure 2-15 – (将添加)

2.7.2.3 Fieldbus Systems 现场总线系统

The 'next generation' BMS uses 'intelligent' sensors and valves connected via a network cable to the control system. There are a number of industry standard communication protocols which mean that the owner is not tied to a single supplier, e.g. Hart or Foundation Fieldbus.

The software is held within the control system which communicates with the devices; the device can self diagnose faults, automated components can also self calibrate to the control signals.

This type of system is the most expensive to install, but should be more reliable, and simple to maintain as they are self checking. The cost typically limits the use of this type of system to process operations at present, but this may change as the costs reduce.

现场总线系统个是BMS（建筑管理系统）的下一代，使用了智能传感器和阀门，这些稚嫩传感器和阀门通过网络缆线连接到控制系统中。存在大量的工业通信协议标准，使现场总线系统的用户能够选择不同厂商的产品，如：基金会现场总线规范，HART协议。

控制系统的软件能够与各种设备相联系；设备可以自我诊断错误，自动化构件能够自行使控制型号标准化。

此类型的系统的安装是最昂贵的，但是更具可靠性，而且由于它们能够自我监测，所以很容易维护。目前，昂贵的使用成本限制了此类系统的使用，但是随着使用成本的下降，情况会得到逐步改善。

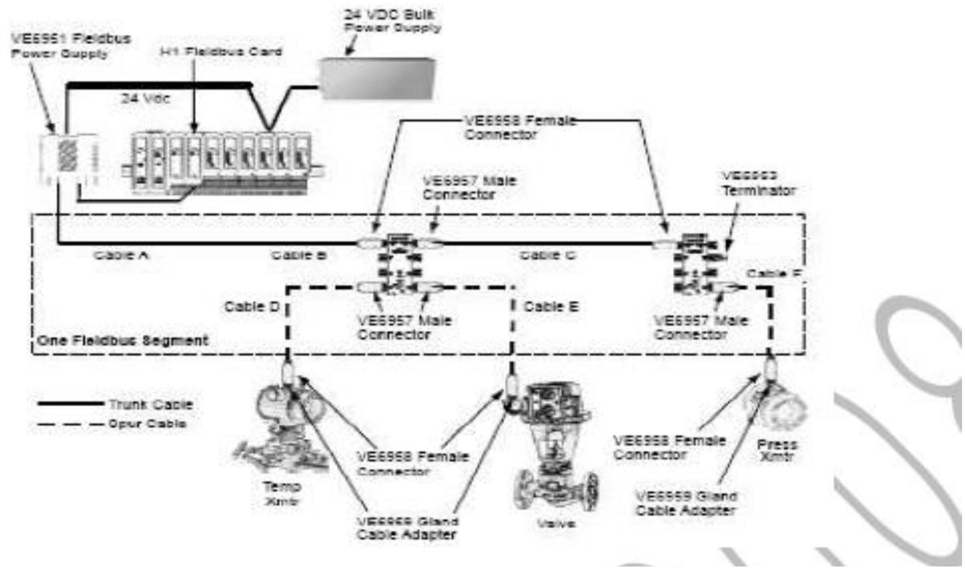


Figure 2-16 Field Bus system (courtesy of ____)

图 2-16 现场总线系统

2.7.3 Actuation methods 驱动法

There are two common means of actuating components – electrical and pneumatic.

存在两种常见的驱动**构件的方法-电**驱动**法和气动**驱动**法。**

2.7.3.1 Electrical/Electronic 电/电子驱动法

The actuator will use a low voltage control signal, to control an electric motor, the units can be on off, or proportional.

These systems are used where the speed of actuation can be slower, typical times for a valve to go from fully open to fully closed are in the range of 1-2 minutes.

Installation is simple, as all signals are by cable – e.g. control signal, power supply, and any feedback, such as valve position, or open/closed signals.

The actuators can be supplied as fail open, fail closed, or with a manual override facility.

驱动器使用低电压控制信号控制电动机，信号单位可能为开关，也可能为按比例输出。

此系统用于驱动速度可降低的地方。阀门从完全开到完全关的时间一般为1~2分钟。

由于所有的信号由电缆传送——如控制信号、动力供应、反馈信息（如：阀门位置，开/关信号），所以安装过程简单。

驱动器具备故障自动打开、故障自动关闭或人工控制设备等功能。

2.7.3.2 Pneumatic 气动驱动法

The control signal is used to vary the output pressure from a pneumatic controller, which is fed to a pneumatic actuator on the controlled component. The system requires the use of an I/P (control signal to pneumatic) converter, with an instrument quality air supply, then local tubing to the actuator. In order to get the best response time the converter should be as close as possible to the actuator. Fully pneumatic controls are available but seldom used with large installations and BMS.

The units use air pressure one way, with an opposing spring to return the controlled item to the fail position. The system is naturally proportional control – i.e. the controlled item position is proportional to the control signal. These units typically have a faster response time than an electric or electronic unit. The pneumatic system is also ideal for hazardous areas requiring intrinsically safe installations.

气动控制器的控制信号是不同的输出压力，再反馈到受控构件的气动执行元件上。此系统需要使用I/P转换器（控制信息转为电动信息），伴随仪表质量供风，然后再通过管道输送到执行元件上。为了得到最佳的反应时间，转换器应尽量靠近执行元件。全气动控制是可以实现的，但是由于需要大量的安装操作和BMS，在实际中很少使用全气动控制。

此单元使用空气压力是一种方式，同时使用反向传输，传回位置失败的受控对象。系统使用比例控制法——如，控制的对象的位置按控制信号的比例来确定。这种单元一般比电动单元具备更快的反应时间。气动系统也是要求内部安全安装的有害物质区域的理想选择。

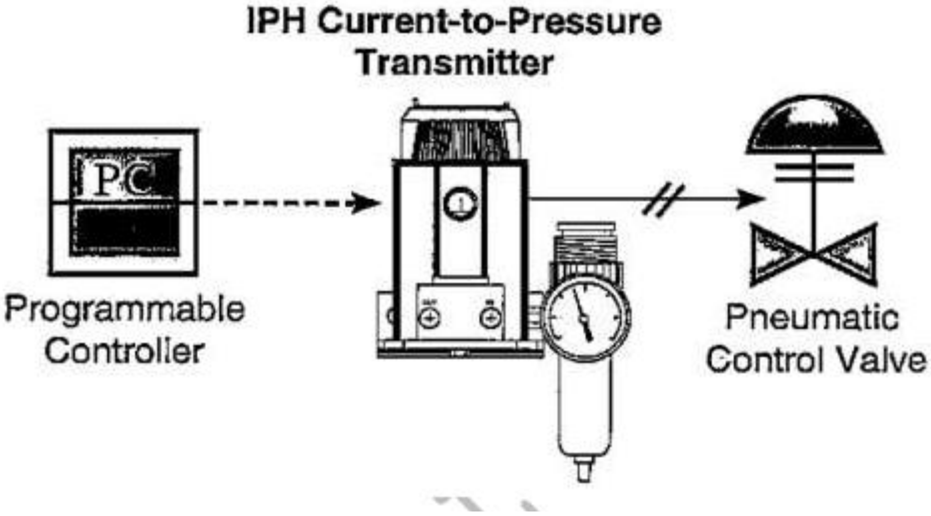


Figure 2-17 I/P transmitter
图 2-17 I/P 传感器

For HVAC applications response time is not usually critical, as the response time of the overall system is slow, e.g. if the full equipment heat load is added instantaneously, the room temperature will rise slowly, not instantaneously, similarly the rate of change of external conditions is typically slow.

对HVAC实际运用来说，反应时间并不是关键的因素，因为整个总系统的反应时间慢。如：如果瞬间将所有设备加入热负荷，房间的温度还是会缓慢升高，而不是立即升高。同样，外部环境的变化率也常常很小。

2.7.4 Instrumentation 测量仪表

It is important to consider the requirements for the instrumentation to be used, in order to select the most cost effective type, and to define the appropriate calibration/verification regime. There is a lot of difference between domestic and commercial building type sensors and industrial type units, the latter being in general more reliable, and certainly more robust – for this reason on this grade of instrument should be considered. For some instruments accuracy and repeatability are important, e.g. measuring room temperature, for others accuracy is not important, but repeatability is, e.g. measuring a system flow rate in order to maintain constant flow through the control of a variable speed fan. Thus three point calibration may be required, or single point verification may be justifiable. The parameters usually requiring monitoring include:

为了选择成本有效地类型和定义合适的校准/验证方法，测量仪表要求是非常重要的。家居、商用、工业三种不同类型的建筑物之间有很大区别。工业用的建筑物对可靠性和耐用性有更高的要求，所以测量仪表的级别应被考虑周到。精确性和重复性对一些仪表来说很重要，如测量室内温度仪表。对于一些仪表，精确性并不重要，而重复性很重要，如通过不同速度风机控制维护持续不变的气流流量的系统流量测量仪表。因此，要求使用三点刻度校正法，或确认单点验证的正确性。常要求监测的常数包括：

2.7.4.1 Airflow 气流

Measurement of airflow is typically done to allow control of airflow in a system. For classified spaces, airflow should be kept constant to assure that particle counts, recovery, and room pressure are in control.

This may be done using a flow grid – The Grid consists of a row of tubes with closed ends, some of the tubes are perforated with small holes facing upstream sensing total pressure, while others have holes facing downstream to sense throat sub-static pressure the tubes are connected by manifolds with the distribution designed to compensate for non uniform flow profile in the duct. The difference in pressure signal between the two sets of tubes is proportional to the square of the mean velocity in the airway. By connecting the output tubes to a suitable instrument, the pressure difference and hence the volume flow rate can be easily measured. In order to get an accurate reading the installation should have straight duct runs equivalent 2-3 times the duct diameter upstream and downstream of the flow grid.

测量气流量常常是为了控制系统气流量。对于已分类空间，气流应该保持持续不变，以确保颗粒含量、恢复功能、和室内压力在控制之中。

气流栅格可以控制气流流量。气流栅格由一排带封闭管口末端的管道组成。一些管道带有小孔，这些小孔正对上游气流，可以感应总压力。另一些管道带正对下游气流的小孔，可以感应管口的次静态压力，这些管道与多个支管相连，支管分配空气，以弥补管道中不均匀的气流状态。管道两点的压力信号的差值与气流平均速度的平方成正比。将输出管道与合适的测量设备相连接，压力差和气流量能被容易的检测。为了得到精确的读数，应该在气流栅格安装直管，其长度需在栅格上下都超出2-3倍直管直径。

A similar grid system uses hot wire anemometer elements. Because flow sensing is not dependent on the square root of pressure, better accuracy at low flows is possible. Another system gaining popularity is the fan venturi meter, either retrofitted to or an integral part of the system fan inlet (evase) –with the advantage of established accuracy. Its performance is independent of the ductwork design - hence is a useful commissioning aid. The wiring is all local to the fan/AHU, simplifying installation. It should be noted that the usual function of the grid is not to get an accurate reading, but to maintain a preset reading determined during system commissioning, whether actual flow or not. Due to the square law operating principle, differential pressure flow measurements have a limited turndown capability. For specialized applications such as the monitoring of unidirectional air flow protection devices (laminar flow hoods) hot wire anemometers are used. Vane anemometers are commonly used for commissioning as they tend to have an averaging affect over the fan area compared to the spot reading from the hot wire unit.

另一相似的栅格系统使用热线式风速计原理。因为气流传感不由压力的平方根决定，低流量下更精确的结果将成为可能。另一个正流行的系统利用文丘里流量计风机的原理，重新定义系统风机气流进入量或将各个系统风机气流进入量集合起来——能达到预订的精确度。线路一直都位于风机上/空气处理机组上，安装方便。值得注意的是栅格的常

用功能不是提供准确的读数，而是维持系统调试中已预定的读数，无论是实际气流或其他。由于平方操作规则原理，压差流量测量法的下限测量值是有限的。热线式风速计用于有特别用途的之处，如监测单向气流保护设备（层流罩）。叶轮风速计也常常用于调试，因为与热线式系统相比，它们对风机区域产生的影响较均匀。

2.7.4.2 Flow control 气流控制

The most common form of flow control is the damper – these can be manually adjusted, or actuated, use a single blade, or be multi blade parallel or opposed blade.

These items are fairly basic, and the relationship between air flow and position is non linear improved control is available using devices such as a ‘pneumatic’ damper – this uses a bladder inflated with low pressure compressed air to open aerodynamically shaped blades. These provide more linear control with better pressure recovery and turndown.

常见的流量控制方法是风门——它可以用单叶片风机、平行多叶片风机、或对置叶片风机实现手动调节或驱动。

这些类型都是比较基本的，气流和位置之间的关系式非线性的。可使用诸如气动风门等设备来改进气流控制——气动风门使用被低压压缩空气充满的叶轮形成空气动力型叶轮。这种方式具备能提供更加线性的控制，从而使压力恢复能力和减小能力更优秀。

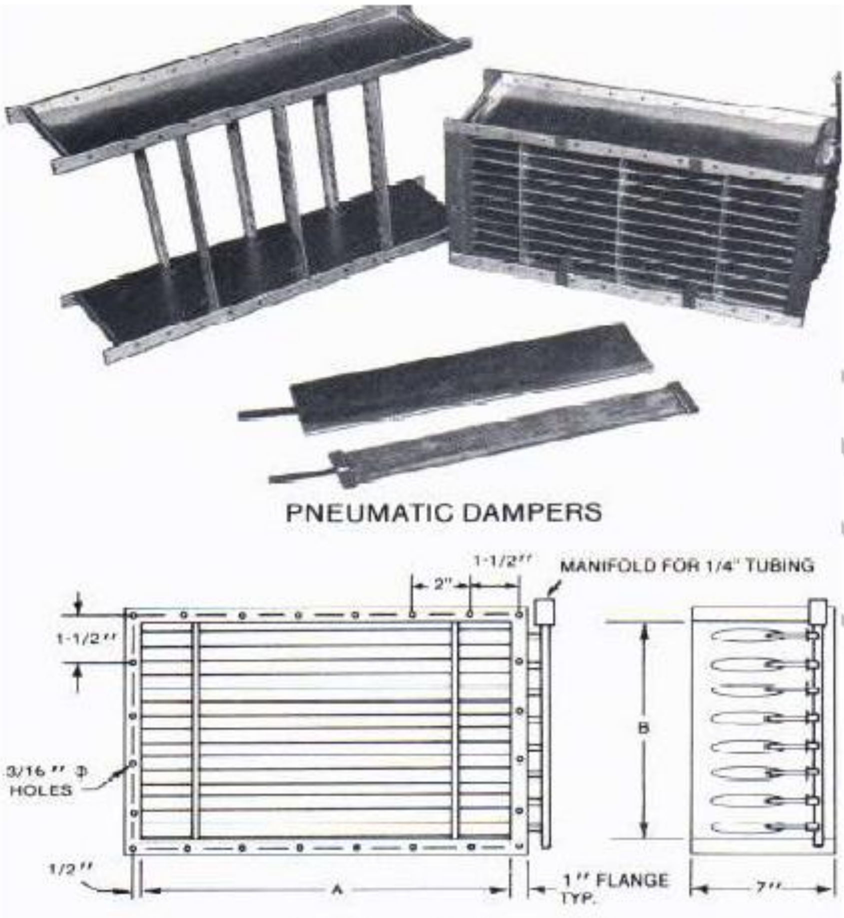


Figure 2-18 Pneumatic (“Bladder”) damper

图 2-18 风动（“Bladder”）风门

Another device that may be used to provide better control is a variable orifice, such as the item shown below: 另一个能提供更好控制的设备是可变节流孔，如以下所示：

Figure 2-19 Variable Orifice (Venturi) Damper GRAPHIC MISSING

2.7.4.3 Control Valves 控制阀

The correct selection of fluid (liquids or steam) control valve is critical for good system performance, together with tuning of the control loop.

There are two types of control valve; the three port valve, which can be used as a mixing or diverting valve to supply the controlled equipment, or the two port valve, which directly controls flow to the equipment.

The three port valve was once the industry standard, however the use of two port valves with variable flow rate systems is becoming far more common, as a well designed system is as effective, and has a lower capital and operating cost.

正确选择流体（液体或气体）的控制阀对良好的系统性能有重大影响，包括控制回路。

控制阀有两种：用于混合或改变流向的三通阀门；直接控制流体的两通阀门。

三通阀门曾是工业标准阀门，但是由于带流量调节系统的两通阀同三通阀门一样有效，而且操作成本更低，所以带流量调节的两通阀门正逐渐变得普遍。

Correct valve selection is important for the correct operation of a system, a brief over view of the process follows, but for readers who require more information references are given in the references section.

正确选择阀门对于系统的良好操作非常重要，以下是对选择过程的简要介绍。对于需要更多信息的读者，可以阅读参考文献部分的参考书目。

Valve characteristic　阀门特性

The valve characteristic is the ratio of flow through the valve to the valve lift (opening) at a constant differential pressure. There are three main types of valve characteristic:

阀门特性即是在恒定的压差下，穿过阀门的流体的比率。阀门主要有三种：

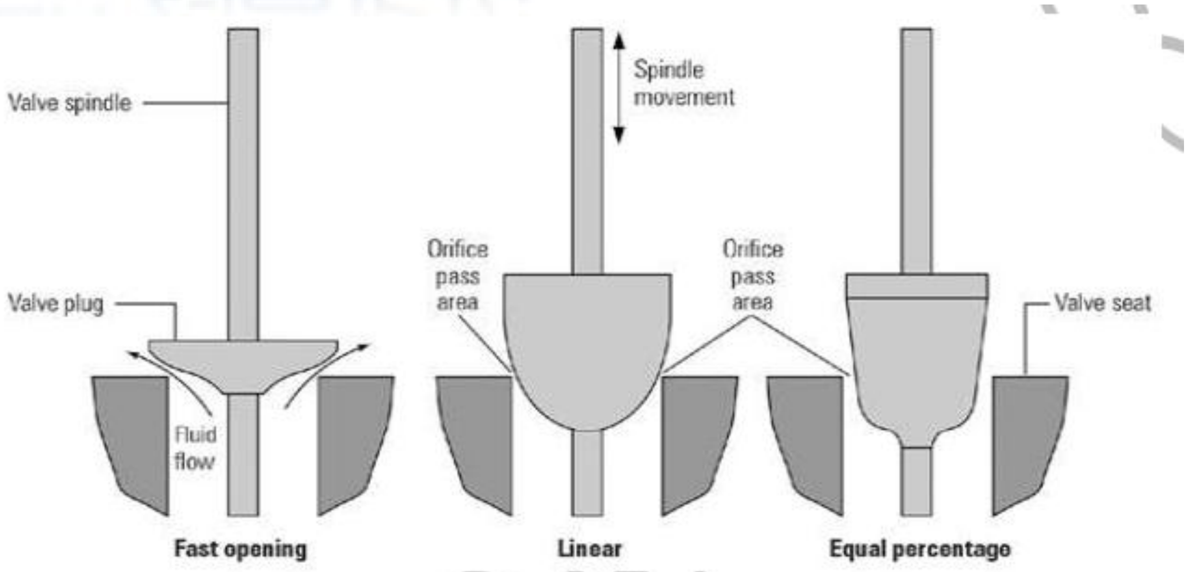


Figure 2-20 Valve Characteristics (Courtesy of ____________)

Figure 2-20 Valve Characteristics (Courtesy of ______) 阀门特性

These are shown graphically as in a globe valve; 以球阀为例图示；

- The fast opening valve is typically used for on / off control. 快速开启阀属于典型的开关控制。
- The Linear valve has a flow rate directly proportional to the amount it is open, and is commonly used for diverting applications in HVAC supplying water to heating or cooling coils.. 线性阀的流量与阀门开启面大小成正比，常被用于 HVAC 系统中的流量改变处，为加热或冷却旋管提供水。
- The equal percentage valve is more commonly used in two port applications. 等百分比阀常用于 two port application.

The characteristic should be chosen with respect to the application of the valve. The installed characteristic is the relationship between the flow and valve lift in the system where it is installed. Where the pressure drop across the valve decreases with increasing flow the EP valve will produce a more desirable linear characteristic.

应根据不同的用途来选择不同的阀门特性。安装特性是指安装的系统中流体与阀门升程的关系。随着流体流量的增加，通过阀门的压力损失逐步下降，等百分比阀将会具备更合符要求的线性特征。

Simple Flow coefficient calculation or Cv for liquids 流量系数计算实例或流体的 Cv 计算实例

Cv= design flowrate (gpm) x sqrt (Specific Gravity of the fluid/ Allowable pressure drop[1])

Cv=设计流量（加仑/分钟）×(流体比重/允许压差)的平方根

脚注:1 Calculation should be based on the allowable pressure drop to determine the CV needed. Selected valve should have that CV at 90% opening or less. 需根据允许的压差来确

定所需的 Cv 值。选定的阀门在小于等于 90%开度时应具备此 Cv 值。

Select a valve where the required Cv is in the 10-80% range of the stroke – use of a valve that is too small (typically less than half the line size) or too large (line size or greater) would be wrong – the valve will not have the ability to control the flow accurately, i.e. not have adequate authority. If the valve normal operating condition results in operation in a near closed condition control can be erratic, particularly if installed where flow tends to close the valve.

所需的 Cv 值应该在阀门行程的 10~80%范围内达到。使用的阀门行程太小（小于管道尺寸的一半）或太大（大于等于管道尺寸）会导致错误，阀门将不具备精确控制流量的能力，如：不具备足够的权度。如果阀门的常用操作条件是近似关闭状态，阀门将会极其不稳定，尤其在流体使阀门有关闭倾向处。

Valve Authority 阀权度

This is defined as the percentage of total system pressure drop assigned to the valve, i.e. in a circulation system the pump will deliver some head to overcome pipe and heat exchanger losses and some to overcome valve resistance. If the latter is small in comparison to the former the valve will have less ability to control effectively.

阀权度是指通过阀门的压力损失占总的系统压力损失的百分比。如：在一个循环系统中，泵提供扬程以克服流体流经管道、热交换器和一些阀门的压力损失。如果用于克服流经阀门扬程于前两者相比较小，则此阀门的控制能力低。

Differential Pressure 压差

There are three applications for the measurement of differential pressure: 测量压力降有三个用途：

- The use of a differential pressure monitor to interpret the readings from a flow measuring device.
- The use of a pressure switch to detect:
- Flow failure of a fan (not usually necessary if the system has flow monitoring)
- Detection of high pressure across a filter or filter set, to provide an indication that the filters require changing.
- The detection of low differential pressure between rooms to provide an indication of the incorrect airflow direction (non sterile areas), or failure of a design differential pressure (sterile areas).
- 利用压力降检测器解释流量测量装置的读数。
- 利用压力继电器检测：
- 风机流量故障（如果系统具备流量监示器，则通常不是必须的）。
- 检测经过过滤器或过滤器组的高压力降，以提供过滤器需要更换的信息。

- 检测房间间的低压力降，为不正确的流体方向（非无菌区域），或设计的压力降出现故障（无菌区域）提供线索。

2.7.4.4 Differential Pressure sensing/Indication 压力降检测/表示

There are a number of options here; 存在大量的选择；

One of the most basic instruments is the Magnehelic gauge, a robust device based on the measurement of the deflection of a metal diaphragm which provides a visual indication of differential pressure. This device is also available with a switch output, or a variable output. An alternative is a simple device using a colored ball mounted in an inclined tube, as shown below – this type of unit operates from first principles, so does not require calibration, the disadvantage is that there is airflow through the unit, so it requires routine cleaning.

最基本的仪器是电磁式压力表，它是基于测量金属隔膜偏离的装置，为压力降提供了可显示的数据。这种装置可以提供开关输出或可变输出。另一种仪器是利用一个置于斜管里的彩色球体的简单装置。如下所示——此类型的仪器是根据基本原理运行的，所以不需要格外的校准，缺点是流体要通过此仪器，需要进行常规清洁工作。

Figure 2-21 Visual DP indicator (courtesy of ___)
可视化压差显示仪

Where greater sensitivity is required, or a control function based on a differential pressure an electronic pressure transducer can be used – these are available with or without indicator LEDs to allow an operator to see if conditions are acceptable or not. The most sophisticated DP sensors are pressure diaphragms with an accuracy of +/- 0.005” (0.25 Pa). Output is commonly 4-20 mA. When specifying these units be careful to consider the operating pressure range, and ensure that the device is robust enough to handle the occasional pressure spike.

当需要更强的敏感度或控制压力降时，使用电子压力传感器——在带或不带有二级管显示情况下，能够使操作人员观测到运行状况时候在可接受范围内。最精密的差压传感器

是压力隔膜，它的精确度为+/- 0.005” (0.25 Pa)。输出一般在 4-20mA。在选择差压（压力降）测量仪表时，需要慎重考虑压力操作范围，确保设备能够处理偶尔发生的压力陡变。

2.7.4.5 Temperature sensor 温度传感器

The almost universal industrial sensor used to monitor temperature is the resistance thermometer (RTD). Liquid and gas expansion systems are used for self acting controllers and switches. 100 Ohm RTDs with a 38.5 Ohm fundamental interval are the industry standard and are available with different accuracy standards, some as accurate as ________. Some HVAC systems may utilize 1000 Ohm sensors of a lower accuracy.

热电阻温度计（RTD）是最普遍的检测温度的工业传感器。流体和气体膨胀系统被用于自我控制和开关。工业标准是具备 38.5 欧姆基本间距的 100 欧姆的热电阻，它能够满足不同的精度标准的要求，如------。一些低精度要求的 HVAC 系统使用 1000 欧姆的传感器。

2.7.4.6 Humidity sensor 湿度传感器

It is far more common to monitor relative humidity, though there are applications where it may be advantageous to monitor absolute humidity, for example in a system used to supply multiple areas, each equipped with a local branch re-heater, so that the moisture reading is independent of the temperature (in the example given the supply temperature would be reset to minimize the use of the re-heaters, thus each change in supply temperature would require the supply RH to be reset, whereas the humidity would be constant). The sensors used industrially to monitor relative humidity now are generally units which measure the change in capacitance between two plates due to the variation in humidity. Accuracy is in the range of __________.

虽然有时候需要检测绝对湿度，但是检测相对湿度更为常见。每个设备都配备有个本地的分支再热器的为多重区域服务的系统，，检测绝对湿度能可以使水分含量的读数独立于温度的变化（在此例中，为了使再热器的使用频率降到最小，供温会发生变化，供温的每一个变化都会使供应的相对湿度值发生变化，而绝对湿度是恒定不变的）。目前工业上检测相对湿度的传感器基本上都是检测由于湿度变化而引起的两块薄膜的电容变化的元件。精确度为————。

2.7.5 Environmental Monitoring 环境检测

2.7.4.1 It is a regulatory requirement to monitor critical process parameters. These vary depending on the product, but commonly include; 检测关键工艺参数是管理的要求。根据产品的不同，检测的参数有所不同，但基本都包括一下项目；

- Temperature 温度
- Humidity 湿度
- Air flow direction / area differential pressure (as it is difficult to monitor air flow,

differential pressure is the parameter typically monitored) 气流方向或区域压差（由于检测气流非常困难，所以常常以压差作为检测参数）

- And may include particle monitoring for classified areas or for airborne hazardous particles for worker protection 还可能检测分类区域的颗粒含量，或为保护工作人员而检测空气中的有害颗粒。

Viable particles (CFU - Colony Forming Units) for classified spaces

分类区域不同

It is now common practice in the industry to validate the monitoring system (sensors, transmitters, indicators, recorders, alarms) for those parameters defined as critical (usually in the process monitoring computer system), and use GEP to ensure the development and maintenance of a robust control system (via the HVAC control system). This approach provides the quality organization with a record of the conditions from a validated system, without the need for cumbersome quality change control process on the control system (an engineering change control system is still required, which typically is less cumbersome, and less extensive in its scope – e.g. may not include all set points).

工业上常常对关键的参数的检测系统进行验证（传感器、传送器、指示器、计量器、警报器），同时使用 GEP 来确保一个强有力的控制系统的运作和维护（通过空气净化控制系统）。这种方法从已验证的系统中为质量机构提供了运行条件记录，而不需要控制系统上大量冗繁的质量变更控制程序（一个工程变更控制系统仍然需要，但不冗繁，而且更廉价，例如：有可能并不需要包含所有的设定点）

2.7.5.1 With any monitoring system the main factors to consider are: 对于任意一个检测系统，需要考虑的因素主要为：

- Accuracy & repeatability required 要求的精确性和重复性
- Long term stability & failure modes 长期的稳定性和失效模式
- Sensor location / locations 传感器位置
- Alarm requirements 警报要求
- Record requirements 记录要求

2.7.5.2 Accuracy required 要求的精确度

The accuracy of the monitoring system should be subtracted from the defined limits, in order to ensure that the product requirements are met – thus it is cost effective to use a reliable high accuracy sensor, allowing the maximum latitude for the control system. For example if the conditions are 18 – 25 degrees C, and the monitoring system has an accuracy of ±0.5 degrees, the space can be maintained within the limits 18.5 – 24.4 degrees C; if the monitoring sensor has an accuracy of ±2 degrees C, then the conditions need to be maintained between 20 and 23 degrees C.

为了确保满足产品质量要求，定义的控制范围需要减去检测系统的精确度。使用可靠的高精度的传感器能是成本更有效，使控制系统的控制范围最大化。例如：如果需控制的条件为：18 – 25℃，检测系统的精确度为±0.5℃，则被控空间实际能在 18.5-24.4℃范围内维持；如果检测传感器的精确度为±2℃，则被控空间只能在 20-23℃范围内维持。

2.7.5.3 Long term stability and failure modes　长期的稳定性和失效模式

2.7.5.4 Sensor location / locations 传感器位置

This is an area of great discussion, let us consider temperature and humidity (typically Relative Humidity) – the most important thing to remember is that conditions are very rarely uniform throughout a room – see fundamentals of HVAC systems.

The traditional location for the monitoring sensor was in the common return air duct – this is still a good location, giving an average of the conditions in the space, assuming that the supply diffusers are doing a good job of mixing the supply with the room air.

此项需要大量的讨论，我们从温度和湿度（一般式相对湿度）谈起。对值得提醒的是：很少遇到一个房间内的温度和湿度完全一样的情况（参见 HVAC 系统基本原理）。

传统上，检测传感器位于空气管道的回路中。如果供风设备能够将供风与室内空气良好混合，空气管道回路中的检测传感器能够测量室内空气的平均性质。

It may be necessary to study the relationship between worst case conditions in the room and the mixed condition in the return duct. 有必要对室内最坏的情况与回路管道中的混合情况之间的关系进行研究。

If there are any significant heat or humidity gains then the local conditions near the source will be different. 如果出现显著的温度或湿度增加，那么靠近源头的局部的情况将会不同。

When considering sensor locations also consider the process as seen by the product – for example consider a typical tablet compression room; 当考虑传感器位置时同时需要考虑产品自身的工艺，如：典型的压片室。

The raw material sits in a hopper typically near a supply register, so that the area is flushed with clean air, it is then fed into the dies, where it is compressed – the process generating a significant amount of heat – the compressed tablet is then released into a de-duster/metal detector, into a collection bin, where it is cooling and exposed to the room conditions – due to the localized heat, the local RH will be lower.

原料位于靠近供风设备的进料口，所以此区域被洁净的空气冲洗着。然后原料被送到模具中被压缩——此过程产生大量的热量，压缩后的药片被放入除尘/除金属检测器中，再进入收集料斗，在此处被冷却并暴露在室内环境中。由于局部的热量释放，此局部的相对湿度将降低。

As the equipment generates a significant amount of heat the air change rate is high – typically around 20 times per hour, to keep the supply air temperature differential reasonable – circa 0.5

degrees.

由于设备产生大量热量，为了保持供气的合理温差（大概 0.5℃），空气换气率应较高——大概 20 次/小时，

The most critical area is the feed hopper, which is covered by the supply air – thus in this instance it could be argued that this would be the location to monitor.

此工艺中最重要的区域就是进料斗，它完全被供气覆盖，因此在此例中，进料斗位置被认为是安放检测器的合适位置。

There are also a number of options to consider for Differential Pressure, it is common practice to measure across the doors of the airlock, though the requirement it maintain the difference between the rooms, as it is usually desirable to maintain a positive pressure in the manufacturing area where there is any risk of ingress of outside air, hence some may prefer to monitor the room pressure compared to an external reference point.

检测压力差需要考虑很多事项。虽然我们常检测穿过风门的压差以保持不同房间的压力差，但是由于制造区域常需保持正压以避免外部空气危险成分的进入，所以有些人会更愿意直接检测室内的压力，而不是检测外部参考点压力。

2.7.5.5 Alarm requirements 警报要求

It is important to consider the desired response to an alarm state. Many alarms will provide early warning to the facility engineering staff of an unusual state requiring some attention or adjustment, but not indicating any transgression of required operating conditions. Other alarms often for the same variable at a worse condition may indicate that operating conditions have exceeded the specified states and production need to take action with the process to ensure product quality is not compromised. These alarms need to be relayed to the appropriate business unit.

我们需慎重考虑对警报状态的相应反应。许多警报会为工厂工程人员提供要求额外注意或调整的非正常状态警示，但并意味着违反了规定的操作条件。常有另一些警报为同样的参数提供更糟糕的情况的警报，它的警报意味着操作条件超出了制定的范围，需要采取措施以确保产品的质量未受到影响。这些警报需要传达给恰当的商业设备。

The regulatory requirement is for a local alarm, notifying the operator when the conditions are outside the defined limits.

对本地警报的常规要求是：在操作条件超出制定范围时，传达给操作人员使其了解。

This may be by an audible and or visual indication – e.g. a horn and flashing light mounted in a common area of the production suite, where it can be seen or heard from the whole suite.

It is a good practice to set this action alarm at the extreme conditions, and have an engineering "alert" alarm at conditions just outside the normal operating range, to alert the engineering staff of a potentially unusual condition as soon as possible, so that action may be taken to prevent an action alarm.

这可能通过一个听觉或视觉显示器实现——如：安装在生产房间的，在整个房间都能看

到或听到的，带警报声的闪光灯。

为极端情况设置一个操作警报，为刚刚超出正常操作范围的情况设置一个工程"预警"警报是推荐的做法。这样可以尽快的警示工程人员潜在的非正常情况，使其采取相应措施，从而阻止操作警报的出现。

This engineering alarm may come from the validated monitoring system, or the GEP control system. 这种工程警报可能来自与以验证的检测系统，也可能来自于 GEP 控制系统。

2.7.5.6 Record requirements 记录要求

Every company has its own standards – it may be acceptable to just have a record of any alarms during manufacturing – or lack thereof! – recorded on the batch record sheet.

It may be preferred to have an actual record.

With current data logging systems this may be in the form of a continuous chart, or a daily printout of min, max average, Standard Deviation.

每个公司都对记录有自身的个性要求——有可能只是对制造过程中警报的记录，或甚至不记录警报！而是批次记录表的记录。

推荐进行实际记录。

以目前的数据资料记录系统而言，实际记录一般包含连续记录表、或每日的最小/大平均数、标准偏差的记录。

2.7.6 Equipment monitoring 设备监测

There are a number of ways that HVAC equipment can be monitored; consider a fan motor:

有许多途径监测 HVAC 设备，以风机马达为例：

- The control contactor can be wired so that an alarm is given if the unit goes into overload. 将控制接触器连接电线，以便当设备元件过载时能够发出警报。
- The motor current can be monitored 马达的当前情况可以被监测。
- The motor temperature can be monitored 马达温度可以被监测。
- Vibration or acoustic output may be monitored. 震动或声音输出可能被监测。
- The airflow from the fan can be monitored using an in duct device, or a in fan device 在管道或风机中安装设备可监测风机的气流量。

The unit which measures the flow is the unit which will detect all of the fan failure modes, the others have potential limitations, depending on the fan drive arrangement, this measurement is also likely to be the most sensitive. With the new generation of accelerometers it is cost effective to monitor the performance of rotating equipment to ensure early detection of system wear (due to vibration). The sensors can be wired to a BMS, or be wireless, transmitting data to a base station for monitoring.

测量气流的元件也是监测风机失效模式的元件，此方法也很可能是最灵敏的监测方法。其他的元件根据风机驱动方式的不同存在潜在的局限。随着新一代的加速器的应用，监

测旋转设备的成本较合理，这种方法可以确保尽早监测出由于震动引起的系统磨损状态。传感器可以使用电线或无线电连接至 BMS 管理系统，将监测数据传输到基本站点。

2.7.5.1 Other equipment parameters may also be monitored, primarily as part of GEP to ensure lowest life cycle cost: 其他一些可能监测的设备参数，主要做为 GEP 的一部分以确保生活周期成本最低：

Fan speed (or current draw, to indicate added pressure drop due to filter loading)

Supply duct pressure

Damper actuator positions (to predict need for re-balancing of the HVAC)

Filter pressure drop (where filters tend to load quickly)

Cooling coil leaving temperature

Other HVAC parameters, to aid in predicting maintenance and in troubleshooting performance problems

风机速度（或实际电流，以显示由于风机负载量而增加的压力损失）

供风管道压力

风门驱动器位置（用于估计 HVAC 系统是否需要重新平衡）

过滤器压力损失（过滤器负载快速处）

冷却盘管出口温度

其他 HVAC 常数，以帮助预计维护和故障维修问题。

2.7.5.2 Sensor mounting considerations 传感器安置注意事项

The things to consider when selecting where to mount a sensor are:

The instrument needs to be mounted so that it is easy to calibrate.

The instrument specification and mounting need to consider any local cleaning required

It is best to keep pneumatic control lines as short as possible.

安置传感器需考虑：

安置在容易校准的位置。

仪器说明和安装需要考虑局部清洁要求。

尽量保持风动控制线最短。

2.8 SYSTEM ECONOMICS 系统经济

2.8.1 Introduction 简介

The pharmaceutical industry is unusual in that the potential impact of an HVAC system failure could be financially very significant, for example causing loss of a batch of product, or the loss of control of the conditions in a research laboratory, potentially invalidating the results of a long term test. Thus the risk assessment of a system‘s failure must encompass the product quality issues as well as the potential business issues. The benefit of providing a clear definition of the potential impact of system failure is that it can influence and justify the allowable budget for the system.

HVAC 系统故障对制药工业的影响非同寻常，她对经济的影响很显著。例如导致某一批次的产品损失，或使实验室的控制失常从而不能验证长期实验结果。因此系统故障的风险评估必须包括产品质量问题和潜在的商业问题。清晰定义有潜在影响的系统故障是非常有利的，这样能够使系统的预算更加合理。

If the cost and likelihood of failure is high, duplication of systems/equipment may be viable. But a better recourse is to redesign the system or process to reduce the risk. The potential impact of redundancy will not only influence the HVAC system design and maintenance but also the design requirements for the supporting utilities – for example, there may be no sense having duplex air conditioning systems if there is only one chiller and one circulating pump for the chilled water supply to the HVAC cooling coil.

如果故障的成本和可能性较高，需要采用备用系统或备用设备。但是更好的方法是重新设计系统或工艺以降低危险。备用设施不仅将影响 HVAC 系统设计和维护，而且将影响公共设施的设计要求。例如：当只有一台制冷机和一个循环泵为 HVAC 系统冷却盘管供应冷却水时，没有必要安置双重空气调节系统。

There is another “softer” consideration – appearance. The industry is open for audit, typically by internal as well as external agencies, and there is a strong desire to maintain the appearance of the facility. Thus the cost of the equipment installed may be higher than in equivalent plant in other industries.

另外还有一个软件条件需要考虑——外观。工厂常开放以供内部人员或外部机构审查，需要维护工厂的外观。所以制药工业相同设备的安装成本会高于其他工业。

These requirements present Engineers with a unique set of challenges which vary from system to system. The engineer needs to review the risk and potential impact of system failure considering all of the potential modes of failure, for example;

- Airflow failure
- Filter failure (loss of control of airborne particles or cross-contamination)
- Failure of temperature control
- Failure of humidity control

以上要求对工程人员提出了一系列的挑战，这些挑战根据系统的不同而不同。工程人员需要预计各种模式的系统故障带来的危险与影响。例如：

- 气流故障
- 过滤器故障（控制空气颗粒或交叉污染失效）
- 温控故障
- 湿度控制故障

This risk analysis assessing the potential impact of system failure can significantly influence the HVAC system design, and maintenance, as well as the design of the supporting utilities.

The scope of the analysis may include business as well as quality aspects – simplistically put if the system fails, and the qualified (verified) monitoring system advises quality that the area is not within specifications, there is no patient risk, but the coat to the business could be considerable.

危险分析估计了系统故障的潜在影响，能够显著影响 HVAC 系统设计和维护以及公用设施的设计。分析的范围包括质量和商业两方面——如果发生系统故障，合适的检测系统将提示产品质量为：工作区域不在指定范围内，不存在病人危险，但商业包装应该被考虑。

These considerations are on top of the conventional economical considerations balancing capital and operating costs.

The user requirements have serious implications on the design, and need to be carefully considered and defined, they should include the following:

以上事项是平衡资本成本与运行成本的常规经济考虑的首要考虑因素。

用户要求影响在多方面影响设计，需要仔细考虑和定义，用户要求包括一下方面：

- Internal conditions - How much variation is acceptable, - a wider operating range will mean a lower cost system, both to install and operate. Many believe that if they specify closer operating ranges, they will get a “better” i.e. more robust system, this is not necessarily the case, in order to maintain closer tolerances the plant may be selected with greater capacity and faster responding sensors, and actuators, which are more sensitive and require careful tuning, and maintenance. Having specified these closer tolerances the system must be commissioned to operate to meet these specifications. The capital and operating costs of this more complex system are likely to be higher.

- External conditions - If the facility is to kept operable 365 days a year then the plant needs to be sized to handle the peak external design conditions. If it is acceptable to have a few percent downtime during peak seasons, then the HVAC system and supporting utilities can be downsized to suit, or a system of load shedding incorporated into the design of the support utilities, with the HVAC system components being sized to suit the extremes.

- 内部条件——可以接受的不同范围，更宽的操作范围意味着更小的成本，包括安装成本和操作成本。许多人认为如果指定了近似的操作范围，则会获得更好的系统，如控制更有力的系统。事实并非如此。为了获得近似的范围，工厂需要选择能力更大、响应更快的传感器或敏感元件，这些元件更加敏感，也需要小心的调节和维护。当指定了近似的操作范围，系统必须在这些指定范围内操作。这些更复杂系统的资金成本和操作成本很可能将更高。

- 外部条件——如果工厂一年 365 天都在运行中，那么工厂需设计成能处理极端外部设计条件。如果在极端的季节里可以停运一段时间，那么 HVAC 系统和公用工程单元就可以降低其设计要求，或者在公用工程单元设计中添加另外的负载系统，而 HVAC 系统部件则使其能够满足极端条件需要。

Other factors will affect the system economics: 其他影响系统经济的因素：

- Building envelope - A low cost poorly insulated facility will mean a corresponding increase in the operating cost and capital cost of the HVAC system, for a given set of internal conditions. Similarly a review of the facility construction/insulation may be beneficial – for example improving the insulation may allow a warehouse facility to require only a heating system, rather than air conditioning.

- 建筑围护设计——对给定的一系列的内部条件来说，低成本、隔热效果差的工厂同时也意味着相应的 HVAC 系统的操作成本和资本成本的增加。同理，预计工厂的结构和隔热效果是有效的方法——例如：改进隔热也许可以使仓库工厂变得只需要加热系统，而不是空气调节系统。

- Internal layout/design - A well developed design will keep the influence of major heat loads outside the conditioned area, or use the other utilities required to minimize the internal loads, for example a dust extract unit can also extract heat from a motor in the room, reducing space heat gains. There may be benefits from grouping the environmentally critical areas within the building, keeping them away from the external walls, to reduce the external load variations.

- 内部布局/设计——一个先进的设计会将主要的热负荷的影响置于被控制区域之外，或者使用其他设施来减小内部负荷。例如：除尘单元也能够转移室内马达的热量，减少空间获得的热量。将建筑物内关键环境区域分组是很有好处的，它能够使关键区域远离外部墙面，减小外部负荷的变化。

2.8.2 Life Cycle Cost Analysis 生命周期成本分析

Typical method – Evaluate payback against incremental cost of options e.g. design types – for dehumidification chemical dehumidification vs. chilled water or DX systems optimizing air distribution, use of Computational Fluid Dynamics (computer airflow modeling), allowing larger room supply air temperature differences, humidification using local electric boilers, water spray injection (ultrasonic or air blown.) Ductwork design based on static regain, requiring minimum balancing. Typical HVAC Economic Issues: 典型方法——评估选择的边际成本的收益，例如：设计类型——对比冷却水或优化布气的 DX 系统在化学除湿中的应用，使用计算机流体动力学（计算机气流模型），使较大房间的供风温度能发生变化，使用局部电热锅炉来增湿和水分注入（超声波或空气吹入）。管道设计建立在静态获得基础上，需要最小的平衡。典型的 HVAC 经济问题包括：

- Availability 有效性
- Sizing 大小
- Volume vs. temperature to achieve “Q” 溶剂与达到“Q”所需要的温度
- Waterside vs. Airside energy reductions 水量和风量的能降。
- Energy Recovery 能量回收

TABLE 2-5 WHAT IS IT? Table to go in!!

When reviewing potential solutions, the life cycle cost should be analyzed – the analysis will encompass the following aspects, considering capital cost and lifetime operating costs.

当考虑潜在的解决方法时，应该分析生命周期成本——考虑到资本成本和寿命操作成本，分析应包括一下方面。

2.8.2.1 First Cost vs. life cycle cost 一次性成本与生命周期成本

There is a balance between first cost and operating cost, as well as considering the factors described in this section, the designer must consider: 一次性成本与生命周期成本之间存在一个平衡，需考虑到下节所描述的因素，设计人员必须考虑：

- The system design life 系统设计寿命
- Labor costs and trends 劳动力成本和劳动力成本发展趋势
- Energy costs and trends 能量成本和能量成本发展趋势

The maximum capital spend that will make the project financially viable

项目财政能够运行条件下的最大资本花费。

2.8.2.2 The system design life 系统设计寿命

If the facility has a short life, then it may be possible to save money on the equipment, and not invest in plant of the quality that would be optimum for a facility with a long predicted operating life. Maintenance costs (as discussed below) extend over the entire facility life, becoming more cost-significant as the facility life increases.

如果工厂的寿命短，那么可能在设备上节约很多钱，不用购买预期为长时间操作寿命服务的设备。维修成本（下面有论述）在工厂寿命内不断增加，随着工厂寿命的增加维修成本会变得越来越显著。

2.8.2.3 Labor costs and trends 劳动力成本和劳动力成本发展趋势

The decision to invest in performance monitoring and, for example centralized lubrication systems will similarly be influenced by the anticipated facility life and the cost of labor.

决定了在运行监测上的投资，例如集中润滑给油装置的投资受预期寿命和劳动力成本影响。

2.8.2.4 Energy costs and trends 能量成本和能量成本趋势

The cost of energy must be considered not only from the system design concepts, but the perspective of component selection, for example:

- AHU housing – low cost units may be made of pre-finished steel, and have minimal insulation. The unit may suffer from high air leakage, causing increased operating costs, and sweating, causing external corrosion and a shorter working life.
- Fan – the fan may be direct drive, with a variable frequency supply to vary the fan speed to maintain a constant supply volume. It may use a high efficiency flat belt drive instead of the traditional V-belts to improve energy efficiency.

- 我们不仅需要从系统设计概念来考虑能量成本，还需从部件选择的未来趋势来考虑，例如：
- 空调处理机组房屋——低成本的元件可能由预先经过处理的钢铁构成且绝热层极少。这些元件可能产生大量的泄露，导致操作成本增加，以及产生凝结水，导致外部腐蚀和更短的工作寿命。
- 风机——风机可能是直接驱动，使用频繁变化的供应使风机速度变化以维持不变的供风流量。这就可能使用高效的平带式驱动来替代传统的 V 带以改进能量效率。
- Filter selection – the optimum selection of pre-filtration systems will balance labor cost, filter cost, the contaminants in the local environment, the capacity of the filter, energy costs and the cost of cleaning the AHU during changing of the filter – this may be the conventional panel / bag, or may be a bag / bag filter combination.
- 过滤器的选择——预过滤系统的最优化的选择将平衡劳动力成本，过滤器成本，局部环境的污染，过滤器能力，能量成本和换修过滤器时，清洁空调处理机组的成本。换修过滤器有可能是换修常规的控制面板或过滤袋，也可能是过滤袋与袋滤器的组合。
- Chillers cooled using cooling tower water rather than air cooled condensers. 冷却水使用冷却塔水，而不使用空气冷凝器。
- Chilled water cooling vs. direct expansion　冷却水冷却与直接制冷

Energy Recovery 能量回收

The potential risk of cross contamination means that some of the simpler means of heat recovery, such as the rotating wheel are not acceptable, however other systems such as heat pipes, and run around coils are and should be reviewed to see if there is a payback.

交叉污染的潜在危险意味着热量回收更简单方法，例如旋转盘是不被允许的。但是其他系统如热管、缠绕盘管可以也应当评估能否使用旋转车轮，以判断能否带来收益。

Similarly systems which use the measurement of enthalpy to vat the amount of fresh air may be economic, though the design and sizing of the dampers needs to be more carefully considered for an application where it is important to maintain system volumes, and room pressure differentials.

相似的系统利用测量焓来维持新鲜空气的数量可能是较经济的做法，虽然采用这种做法会导致在维持系统容量和室内压差很重要时，风门的设计与大小预计变得更加慎重。

2.8.2.5 Consumables Costs 损耗成本

The life and cost of each consumable component must be considered - filters are an obvious example – the optimum selection of pre-filtration systems will balance labor cost (for the actual replacement and the cleaning required when a filter is removed prior to installing the new filter), filter cost, the contaminants in the local environment, the capacity of the filter, rate of change of pressure drop, energy costs in order to recommend an optimum selection – this may be the conventional panel / bag arrangement or may show a bag / bag filter combination to be more cost effective. Another example would be the drive belt – V-belts have a significantly shorter life than a flat belt, but cost less. They are not as energy efficient as a flat belt though, thus the savings in maintaining a stock of spare belts, energy savings, and saving in labor costs to replace the belts, and re-tension them may make them cheaper over the plant operating life.

每种易耗部件的寿命和成本必须被考虑——过滤器是个典型的例子——为了提出一个过滤器系统的最优选择（可能是传统的面板/布袋布置，或成本更加有效的布袋/布袋过滤器组合），需要平衡劳动力成本（过滤器在替换和清洁时被转移的劳动力成本大于初次安装新过滤器的劳动力成本）、过滤器成本、局部环境污染物、过滤器能力、压力损失变动率、能量成本。另一个事例是传动带——V 型传动带比平型传动带的寿命更短，但是更便宜。V 型传动带的能量利用率不如平型传动带，但是 V 型传动带在维护空闲传动带方面节约、能量节约、更换传动带、重新拉紧的劳动力成本节约，这些都使 V 型传动带在整个工厂操作寿命期间比平型传动带更加便宜。

2.8.2.6 Impact of system failure　系统失效的影响

If the cost and likelihood of failure is very high, and product value and risk are also high, duplication of systems/equipment may be advisable. The potential impact of system failure will not only potentially influence the HVAC system design and maintenance but affect design of the supporting utilities.

如果失效的成本和可能性很高，同时产品价值高，危险性高，建议采用备用系统和备用设备。系统失效的潜在影响不仅仅影响 HVAC 系统设计和维护，同时也影响辅助公共设施。

2.8.2.7 Appearance is another factor many believe influences plant room, system and equipment design and specification. The industry is open for audit, typically by internal as well as external agencies, and there is a strong desire to maintain the appearance of the facility – in addition to complying with the GMP requirements, ensuring that not only the equipment but the plant room area and is easily cleanable.

许多人认为外观是另一个影响工厂房屋、系统和设备设计与分类的因素。工厂会被开放审查，有时是内部审查有时是外部机构审查，（此段与前面某个段落重复，可能是 ISPE 排版错误）

2.8.2.7 Reliability / Maintenance Costs 可靠性/维护成本

The life cycle cost analysis must also consider reliability / maintenance aspects.

Consider the lowest cost material used for a cooling coil, aluminum fins on copper tube. In a poor environment there will be corrosion on the fin material, reducing the efficiency of the unit, with the fins eventually corroding to the extent that the unit will not perform adequately.

There are options for the specification of this item, each increasing the first cost, but increasing the operating life: Copper tube with polyester coated aluminum fins or Copper tube with electro tinned copper fins.

A fan specification with a long design bearing life will allow for extended operating periods without maintenance. Grouped lubrication points will minimize costs, and allow lubrication when the plant is in operation.

The cost of routinely calibrating instrumentation should not be overlooked – it may be cost effective to have one calibrated differential pressure switch across a bank of filters, with un-calibrated ‘engineering information’ pressure gauges across each filter.

生命周期成本分析必须考虑有效性/维修方面。

冷却盘管上最低成本的物质：铜管上的铝翼。在较差的环境中，这些翅片将被腐蚀，元件的有效性降低，翅片最终将腐蚀致元件无法充分运行的程度。

对此问题的详细说明，每种都使第一次成本增加，但也延长操作寿命。带铝翼铜管，铝翼使用聚酯材料涂层，或者带铜翼铜管，铜翼被电镀。

具备长时间的设计寿命等级的风机能够在没有维护情况下长时间持续使用。将润滑点分组会减少成本，当工厂在运行时能够加入润滑油。

常规的校正仪器的成本不应该被忽略。这样的做法是成本有效地：在过滤器组中安置一个校准过的压差传感器，而每个过滤器安置一个未经校准的工程信息压力计。

2.8.2.9 As well as the obvious factors there are other ‘political’ factors to consider to vary the ratio of direct (capital) vs. indirect (operating) cost;

- There may be grants available to assist with capital costs
- There may be incentives to make the system more energy efficient

在考虑直接成本（资本成本）和间接成本（操作成本）时，除了上述的明显因素外，还有一些“政治的”因素需要考虑

- 可能需要对资本成本应用的允许。
- 可能需要刺激因素才能使系统更加能源有效。

2.8.3 User Requirements Specification 用户要求说明

As a project is considered justifiable, before the design details are developed the quality critical environmental requirements must be defined by the user, typically in a User Requirement Specification – this may include;

- Temperature for product and for workers
- Humidity for product and for workers
- Air flow directions / differential pressures for contamination control
- Area classification (particles – viable and non-viable (classified spaces)
- Clean up times from in-sue to at-rest (classified spaces)

The user requirements can have a significant influence on system cost, and need to be carefully considered and defined. For example:

当一个项目被认为合法后，在设计细节之前，用户必需提供质量关键环境要求。常常包

含在用户要求说明中——可能包括：

- 产品温度和工作人员温度
- 产品湿度和工作人员湿度
- 气流方向/污染控制的压差
- 区域分类（颗粒——可见的和不可见的）
- 从再使用状态至静态状态的清洁时间（分类区域）

用户要求对系统成本有显著影响，需要仔细考虑和定义，例如：

2.8.3.1 Air Change rates 换气率

There is a common misconception within the Pharmaceutical Industry of a regulatory requirement of a minimum air change rate for an area – typically held to be 20. This is generally not true, especially for non-classified areas. In the European regulations there is a requirement for a 'clean up' time of 15 to 20 minutes in a sterile product processing facility – calculating this based on a clean air supply to a room, completely uniform mixing from class 10,000 to class 100 gives 14 minutes recovery time – in practice neither of these assumptions are realistic.

在制药工业，存在一个常见的误解——一个区域的最小换气率的常规要求是 20。这是不合符事实的，尤其是对于未分类区域来说。在欧洲条例中，要求无菌产品工艺工厂的清洁时间在 15~20 分钟之间——这建立在对室内的洁净空气供气的基础上，从 10 000 级完全均匀混合洁净空气，变为 100 级的恢复时间是 14 分钟——从实践来看，这种假设是不切实际的。

However, the 2004 FDA "Guidance for Industry for Sterile Drug Products Produced by Aseptic Processing -Current Good Manufacturing Practice" gives the following guidance:

For Class 100,000 (ISO 8) supporting rooms, airflow sufficient to achieve at least 20 air changes per hour is typically acceptable. Significantly higher air change rates are normally needed for Class 10,000 and Class 100 areas.

但是，2004 版 FDA"无菌工艺生产无菌药品的工业指南——目前优秀的制造实践"给予了以下指示：

对于 100 000 级的房间，气流足够达到至少 20 次/小时的换气率是常规可以接受的。在 10 000 级与 100 级的房间长需更高的换气率。

Some companies specify their own arbitrary air change rates – this is not a good practice; the designer should take responsibility for defining this based on a number of factors.

There may be a benefit in assuming air change rates to use as a basis for establishing an initial project concept cost used to determine the viability of a project.

In order to define the actual air change rate required the designer must consider the following interrelated factors:

一些公司指定自行拟定换气率——这种做法是不可取的；设计人员应该在参考大量的因

素的基础上再来定义换气率。

假定换气率，以此作为基础估计原始项目概念成本，从而决定项目的可行性是推荐的做法。

为了确定实际的换气率，要求设计人员必须考虑一下相关因素：

- Heat gain to the conditioned space due to external influences – e.g. solar gain
- Heat gain to the space due to internal influences – e.g. equipment
- Moisture gain to the conditioned space due to external influences – e.g. external humidity
- Moisture gain to the space due to internal influences – e.g. occupants
- The number and location of the occupants in the space
- The tasks the occupants are doing
- The clothing (gowning level) of the occupants
- The process
- The cleanliness of the supply air
- The means and efficiency of coverage of distributing the supply air
- The means and location of extracting the air from the conditioned space
- Where the control and monitoring sensors are located
- The locations where the specified conditions are critical – e.g. in a tablet compression room the process will add a considerable amount of heat to the product – the critical area is likely to be where the raw material is exposed.
- The cost of putting in a system capable of higher air change rates than those actually required is significant both in terms of the capital and system operating costs. As discussed earlier, a process that generates low volumes of particles, in a large room, may need fewer air changes to maintain desirable particle levels.

- 由于外部因素（如：太阳能）而使受控空间获得的热能。
- 由于内部因素（如：设备）而使空间获得的热能。
- 由于外部因素（如：外部湿度）而使受控空间获得的水分。
- 由于内部因素（如：工作人员）而使空间获得的水分。
- 工作人员的数量和位置
- 工作人员正在做的工作任务
- 工作人员的着装
- 工艺
- 供风的洁净度
- 供风分布的覆盖方式和有效性
- 控制和检测传感器的位置
- 指定条件的位置非常重要——如：在压片室，处理工艺将会给产品带来大量的热能——其关键区域很可能就是原材料暴露的区域。
- 使系统具备比其实际要求更高的换气率的成本，无论从资本角度还是系统操作成本

角度来看，都是非常显著的。正如前面所讨论的，一个位于大房间的、颗粒产生量低的工艺工程，也许只需要较低的换气便能维持要求的颗粒水平。

2.8.4 Life Time Operating Costs 寿命运行成本

These are the total costs of building and operating the installation, including design, purchasing, installing, commissioning, operating and maintaining (including labor, energy and spare parts) the system during the working life of the asset, and its dismantling. Cleaning and disposal cost. Refer to 2.8.2, and 2.8.4 for the factors affecting this.

此成本指建造和运行安装的总成本，包括在资产工作生命期内的设计、采购、安装、试车、运行、维护（包括劳动力成本、能量成本和备件成本）以及拆卸成本。清洁与处理成本，参考 2.8.2 和 2.8.4 中提及的影响因素。

2.8.5 Comparing Options 对比选择

Most companies have internal accounting systems that will facilitate the evaluation of different design concepts, evaluating payback against the cost of the different design options, (investment analysis) considering the design life of the facility e.g. chemical dehumidification vs. chilled water or DX systems, humidification using suitably treated plant steam, local electric boilers, water spray injection (ultrasonic or air blown), or clean steam, water cooled vs. air cooled chillers.

大多数公司有内部的会计系统来计算评估不同设计概念，估计不同设计选择带来的收益。投资分析考虑了工厂的设计寿命，例如：化学除湿、冷却水或远距离系统；增湿使用合适的以处理过的工厂蒸汽、或局部电锅炉、或注水系统（紫外式的或空气吹入式的）、或洁净蒸汽、冷却水或空气冷却机组。

Some of the areas to consider are provided below:

- Energy sources
- Airflow management – through the use of flow measurement and fan speed control
- Energy efficient ductwork design based on low velocity static regain, requiring minimum balancing
- Night setback of temperature and or humidity, reduction in airflow if no production
- Fume hood velocity control and fume hood diversity
- Minimizing the use of local heating/cooling batteries
- Energy recovery systems – air to air or air to fluid to air (e.g. rotary wheels, heat pipes, run around coils).
- Recovery and use of cooling coil condensate
- Reuse of cooling tower blow down water
- Use of non storage water heater (calorifier)

一些需要考虑的事项如下：

- 能量源。

- 气流管埋——通过气流测量计的使用和风机速度控制。
- 基于低流速静态获得的有效能量管道设计，要求最小的平衡。
- 夜晚温度与湿度的下降，如果在无生产的情况下，可减少气流量。
- 通风橱流速控制和通风橱多样化。
- 尽量减少局部加热或冷却管组的使用。
- 能量恢复系统——空气对空气或空气对流体或流体对空气（例如：旋转车轮、加热管道、盘管）。
- 回收利用冷却盘管的冷凝物。
- 重复使用冷却塔排出水。
- 使用无容器式热水器（水加热器）。