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A REVIEW ON DESIGNING OF CLEANROOM OF CLASS 10000 (ISO -7)

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***ABSTRACT* - Class 10,000 (ISO Class 7) cleanrooms are increasingly utilized in food processing industries to achieve higher standards of hygiene, product safety, and regulatory compliance. According to ISO 14644-1, a Class 10,000 cleanroom limits airborne particulate concentration to 10,000 particles per cubic foot for particles ≥0.5 µm, making it suitable for critical food handling and packaging operations. This research paper presents a detailed design and performance evaluation of a Class 10,000 cleanroom developed specifically for food processing applications. The study focuses on essential cleanroom parameters including airflow distribution, air change rates, HEPA filtration efficiency, and maintenance of positive pressure differentials to prevent the ingress of contaminants from adjacent areas. Temperature and relative humidity are carefully controlled to inhibit microbial growth and preserve food quality in accordance with hygienic design principles recommended by international food safety guidelines. Furthermore, contamination control strategies related to personnel hygiene, gowning procedures, material transfer, and selection of cleanroom-compatible construction materials are analysed to minimize cross-contamination risks during food processing operations. The cleanroom performance is validated through airborne particle count testing, pressure differential measurements, and HVAC system assessment as per ISO and ASHRAE recommendations. The results indicate that the integration of an optimized HVAC system with strict operational and hygienic protocols significantly enhances environmental cleanliness, reduces contamination risks, and supports compliance with food safety regulations such as Codex Alimentarius and cGMP requirements. This study provides practical design guidelines and performance insights for engineers and researchers involved in the implementation of Class 10,000 cleanrooms for modern food processing facilities.**

I. INTRODUCTION

Cleanroom technology has been extensively studied for contamination control in pharmaceutical and semiconductor industries, and its application in food processing has gained significant attention in recent years. ISO 14644-1 provides the fundamental basis for cleanroom classification by defining allowable airborne particle concentration limits and measurement methods, which are widely adopted in food processing cleanrooms to ensure controlled environmental conditions [1]. The standard establishes Class 10,000 (ISO Class 7) as suitable for hygienic food handling and packaging operations.ISO 14644-4 focuses on cleanroom design and construction aspects, emphasizing airflow distribution, pressure differentials, and HVAC system integration to maintain cleanliness levels during operation. Several researchers have highlighted that proper zoning and pressure cascade design are critical for preventing cross-contamination in food processing facilities [2]. Whyte [3] presented comprehensive cleanroom design principles, highlighting the role of HEPA filtration, air change rates, and personnel behavior in controlling particulate contamination. The study emphasized that human activity is the dominant source of contamination, a finding highly relevant to food processing environments with frequent operator movement. Ljungqvist and Reinmüller [4] discussed hygienic cleanroom design and operational practices, stressing the importance of smooth surface finishes, material compatibility, and controlled material flow. Their work supports the adoption of cleanroom-compatible construction materials in food processing plants to minimize microbial growth. Food safety organizations such as the Codex Alimentarius Commission [5] have emphasized hygienic design, environmental control, and contamination prevention as key requirements for safe food production. Their guidelines align with cleanroom principles by recommending controlled air quality, personnel hygiene, and sanitation procedures. ASHRAE guidelines for clean spaces [6] provide HVAC design recommendations specifically addressing air change rates, filtration efficiency, and thermal comfort. Studies based on ASHRAE standards confirm that optimized HVAC design significantly improves cleanroom performance and energy efficiency in food processing applications.
Overall, the reviewed literature demonstrates that integrating ISO cleanroom standards with food safety guidelines and HVAC best practices provides an effective framework for designing and analyzing Class 10,000 cleanrooms for food processing industries.

1.1 CLEAN ROOM AND ITS REQUIREMENTS

Cleanroom is not just merely a room or space which is clean but it has a special meaning and is defined by the International Organization for Standardization (ISO) standard 14644-1 as “It is a room in which the

concentration of airborne particles is controlled, and is constructed and used in such a way to minimize the introduction, generation, and retention of airborne particles inside the room where other relevant parameters, e.g. pressure, temperature and humidity are controlled as per the requirements." Cleanroom is a room that minimizes the introduction, generation and retention of particles. This is achieved by (I) supplying large quantities of filtered air, (II) personnel use clothing that minimize the dispersion of particles and microorganism and (III) The material used to build cleanroom should not generate any particle. Food safety and quality are the two important factor which results in consumer food choices. Food safety means making sure that food does not contain anything harmful that can affect the health of consumers. It is essential and cannot be compromised. Food quality refers to the characteristics of a food product that determine its value and acceptability to consumers. This includes both negative and positive attributes. Negative attributes includes spoilage, contamination, discoloration, off-odours on other hand positive attributes include colour, flavor, texture and processing method of the food. This distinction between safety and quality has implications for public policy and influences the nature of the food control system. Food control is defined as a mandatory regulatory activity which provides consumer protection and ensures food to be safe, wholesome and fit for human consumption during production, handling, storage, processing, and distribution[7],[8].

Despite the huge efforts made by the food safety authorities and industries, food safety still remains a critical issue especially in India. In food industries, producers have to satisfy both safety and quality criteria for their products to the consumer. Food processors have multiple options in terms of different quality and management systems, they have to choose the most appropriate one for its specific activity and should establish, document and implement effective systems in the processing area for managing quality and safety of the product. Over the past few decades, food-borne illnesses have raised great concern about the safety of food. Considerable steps are taken by the food processor for understanding and managing the risks of airborne diseases. Among various systems, Hazard Analysis and Critical Control Point (HACCP) are effective tool which focus mainly on controlling hazards to ensure the production of safe and wholesome food [9].

For maintaining the safety and increasing the shelf life of food, traditionally it has been preserved by thermal processing, freezing, salting and drying. But nowadays consumers are demanding convenient, innovative, fresh foods, including new "minimally processed" products. To meet the expectations of modern consumers, food industries are adopting novel technologies with a dual objective 1.) To deliver improved quality attributes demanded by consumers and 2.) To ensure reliable assurance of food safety. The novel technologies will include various minimally processed technologies like high pressure processing (HPP)[10], pulsed electric field (PEF)[11], ohmic heating, dielectric heating, microwave heating, ultrasound, modified atmosphere packaging (MAP)[12] and cleanroom technology. Among these cleanroom technology have attracted great attention for maintaining the safety and quality of the food products as because it doesn't have any effect on the nutritional quality of the food being processed, it maintains the hygienic condition in the processing area, remove contaminants from the processing area and clean air in the processing area which in turn results in safe food product.

2. HISTORICAL BACKGROUND

The history of cleanrooms started from the USA. Since 1960s, the need and use of cleanrooms at manufacturing places emerges. First standard called Technical Manual 00-25-203 was made in 1961 by order of American Air Force. In the manual description is given about the entering, designing and cleaning and also about airborne particles requirements. After 2 years, Federal Standard 209 was published and it is entitled as "Clean Room and Work Station Requirements, Controlled Environments". It was the first document that regulates cleanroom facilities. In 1966, Federal Standard 209 4 was fixed and named 209A. Afterwards every revising letter was given in alphabetical order:

1973 (B), 1987 (C), 1988 (D) and 1992 (E). In 1999, Federal Standard 209 was replaced officially with International Organization for Standards (ISO) 14644-1. ISO was named "Cleanrooms and Associated Controlled Environments"; is used in European Union and in some other countries. The Institute of Environmental Science and Technology (IEST) gathered information regarding requirements of cleanrooms from all over the world and published other parts which are: 14644-2 (2000), 14644-4 (2001),14644-4 (2001), 14644-5 (2004), 14644-7 (2004), 14644-8 (2006), 14644-9
(Draft International Standard). Today there are standards: ISO 14644 and 14698 for Airborne Particulate Cleanliness, Classes in Cleanrooms and Clean Zones, and Cleanrooms and associated controlled environments- Bio contamination control respectively.
During World War II, problems like dirt and dust were found in small sized mechanical and electro mechanical devices. So to overcome the problems, high efficiency air filters were developed during the war and commercialized after it, for broader applications. Nowadays electronics became a military and commercial staple, Therefore, filtered and conditioned air, controlled procedures and behaviors, employee training, personnel clothing have been carefully selected. Construction, design and materials, and physical isolation from other parts of the manufacturing facilities came together in the earliest clean rooms. Over time, the use of cleanroom practices has increased, leading to a greater need for standards and further improvements. By the 1960s, contamination prevention became a separate field of study, with cleanroom technology at its center. As a result, the advantages of cleanroom manufacturing were adopted by many other industries.
The convergence of needs which underlay earlier developments remained an important developmental dynamic in contamination control. Post-war developments speak to the wide influence of military needs and defense agencies' roles in establishing both requirements and standards for cleanliness in processing. Miniaturization, increasing complexity, and the need for extreme reliability in both military and commercial equipment and systems helped to push cleanliness into new industries.

3. CLASSIFICATION OF CLEAN ROOM

3.1 BASED ON CLEANLINESS CLASSIFICATION (ISO & FED STD. 209E)

Cleanrooms are primarily classified by the concentration of airborne particles**.** The two most common standards are ISO 14644-1 and the now-retired Federal Standard 209E (FED STD 209E).

ISO Class	**Max. particles ≥0.5 µm per m³**	**Equivalent FED STD**	**Application**
ISO Class 1	10	Class 1	Microelectronics, nanotechnology
ISO Class 5	3,520	Class 100	Pharmaceuticals, biotech
ISO Class 6	35,200	Class 1,000	High-end electronics, aseptic food packaging
ISO Class 7	352,000	Class 10,000	Food processing, medical device assembly
ISO Class 8	3,520,000	Class 100,000	General food processing, packaging areas

3.2 BASED ON AIRFLOW DESIGN

Cleanrooms are also categorized by airflow patterns and how clean air is circulated:

3.2.1 UNIDIRECTIONAL (LAMINAR FLOW) CLEANROOM:

A Unidirectional (Laminar Flow) Cleanroom is a highly controlled environment designed to minimize airborne contamination through a constant, uniform airflow pattern. It maintains cleanliness by ensuring that air flows in a single, uniform direction—either vertically (top to bottom) or horizontally (side to side). The air is filtered through HEPA or ULPA filters before entering the cleanroom. Here's a concise breakdown of its key features and benefits: as shown in fig.1

Laminar (Unidirectional) Airflow: Air moves at a uniform speed in parallel streams, sweeping away particles and preventing turbulence.

High-Efficiency Filtration: HEPA (99.97% efficiency @ 0.3 µm) or ULPA (99.999% @ 0.12 µm) filters are used.

- Air Changes per Hour (ACH): Can range from 300 to over 700, depending on the cleanroom class.
- Positive Pressure**:** Maintains a pressure differential to prevent outside contaminants from entering.
- ISO Classification**:** Typically used in ISO Class 1 to 5 cleanrooms (most stringent environments).
- Air flows in one direction, usually vertically or horizontally

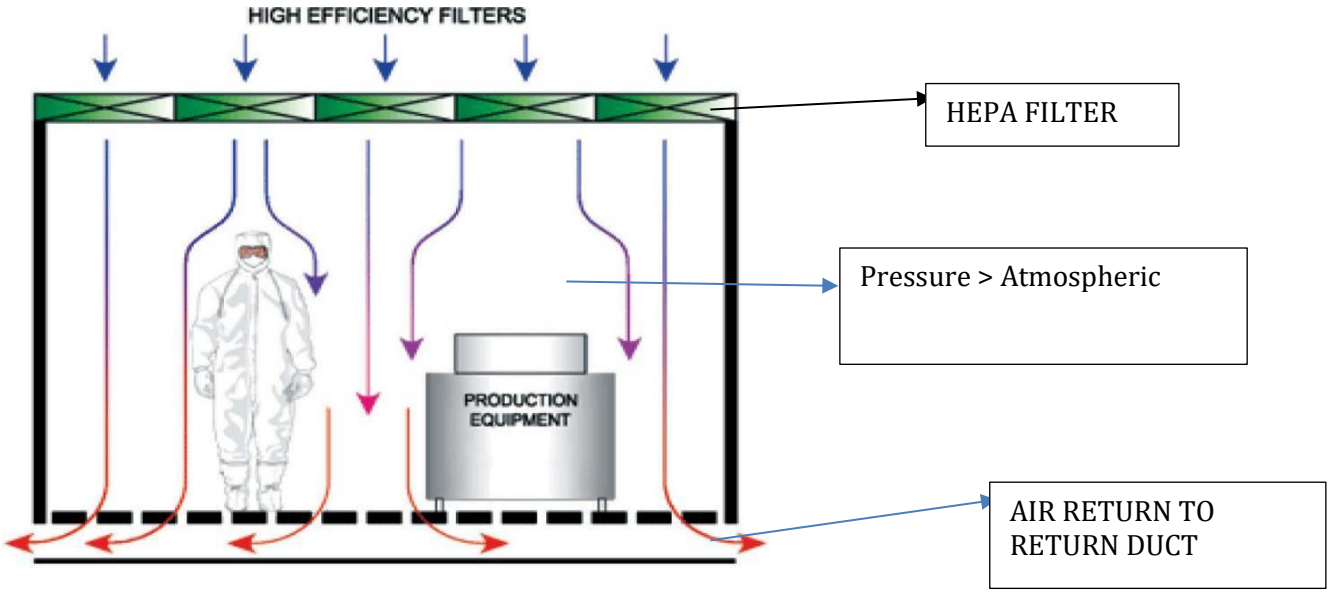

Fig: - 1.) Unidirectional (Laminar Flow) Cleanroom

3.2.2 NON-UNIDIRECTIONAL (TURBULENT FLOW) CLEANROOM:

A Non-Unidirectional Cleanroom, also known as a Turbulent Flow Cleanroom, uses high-efficiency particulate air (HEPA) or ultra-low penetration air (ULPA) filters to supply clean air into the room, but the air does not flow in a single uniform direction. Instead, it is distributed through diffusers in the ceiling and mixed with room air in a turbulent fashion, helping dilute and remove contaminants. As shown in fig -02

- Air is mixed and recirculated randomly
- Suitable for less strict classes
- Lower cost, easier maintenance

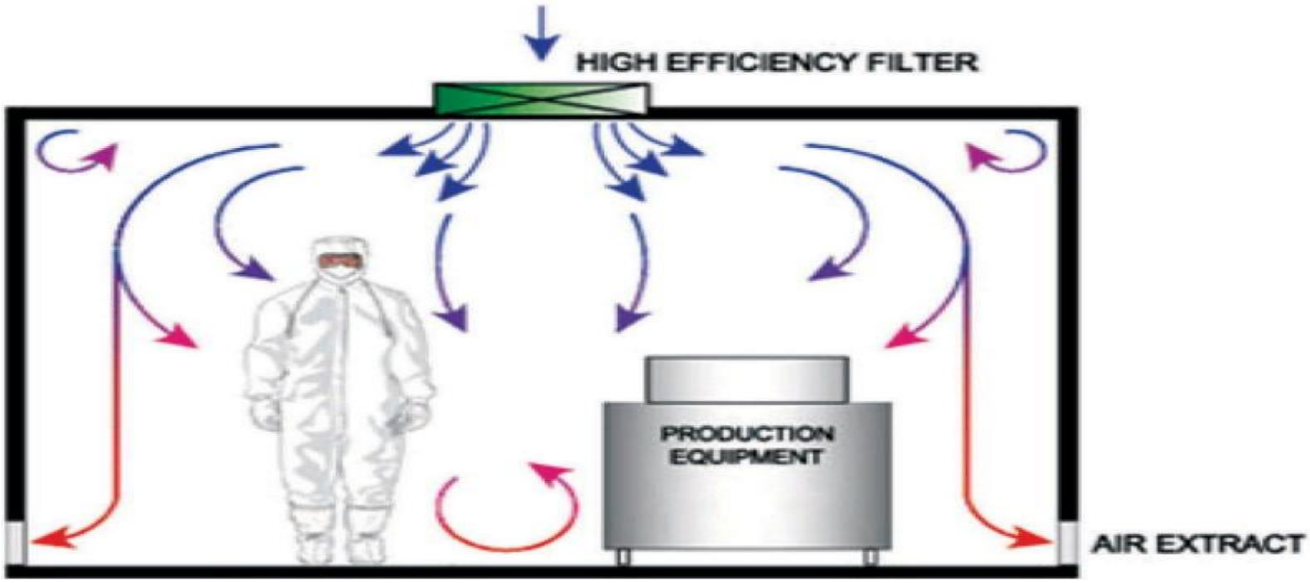

Fig :- 2) Non-**unidirectional (Turbulent Flow) Cleanroom**

Turbulently ventilated cleanrooms are also known as 'non- unidirectional' or 'conventional'. This type of air flow is generally used in offices, shops, etc. in this air is supplied by an air-conditioning plant through diffusers in the ceiling. Unidirectional flow cleanrooms are also known as 'laminar flow'. The unidirectional cleanroom uses large amount of air than the turbulently ventilated room but, because of the directed air movement, it minimizes the spread of contamination about the room and sweeps it out through the floor. Clean air mixes with the room air and removes airborne contamination by extracting the air at the bottom of the walls. The air changes are normally 30to 60 air changes per hour time depending on the use of clean room, this being much greater than that used in ordinary rooms, such as in offices. In this style of cleanroom, the contamination generated by people and machinery is mixed and diluted with the filtered air and then removed.

3.3 TYPES OF CLASS 10,000 CLEANROOMS BASED ON APPLICATION

3.3.1 PHARMACEUTICAL & BIOTECHNOLOGY CLEANROOMS (CLASS 10,000 / ISO 7)

Cleanrooms in the pharmaceutical and biotech industries are critical controlled environments designed to prevent contamination of products during manufacturing, packaging, or handling. Contamination could be particulate (dust), microbial (bacteria, fungi), or chemical (vapours, residues), and cleanrooms are designed to eliminate or minimize these risks.

Purpose of Cleanrooms in Pharma/Biotech

1. Protect Product: Ensure drug products remain sterile or uncontaminated.
2. Protect Patient: Contaminated medicine can harm or kill patients.
3. Comply with Regulatory Requirements: Meet GMP (Good Manufacturing Practice), ISO, and FDA standards.
4. Control Cross-Contamination: Especially in multi-product facilities.
5. Prevent Human Contamination: Personnel are the biggest source of contamination.

3.3.2 FOOD PROCESSING CLEANROOMS

A class 10,000 (ISO class 7) Cleanroom in the food processing industry is a controlled environment designed to maintain low levels of air particles, microorganisms and other contaminants during the production and packaging of high -sensitivity food products. These cleaners are essential in areas where product safety, hygiene and extended durability are important, such as infant melding packaging, powder products, foods, eating, spices and neutrakt. The air is filtered to remove 99.97% particles through HEPA

filters with high efficiency. Usually turbulent or mixed air flow is used, leading to changes in air, which is 30 to 60 times an hour to ensure continuous weakening of the containers. Cleanroom surfaces are made of food quality, non-nutrients and single clean materials, and personnel should follow strict dressing procedures, including the use of covers, masks, gloves and hair. Cleaning environment is continuously monitored for particle count, microbial load, temperature, humidity and pressure differences. Compliance with standards such as ISO 14644, HACCP, ISO 22000, FDSAI or FDA rules ensure that food products produced in these cleaners meet both domestic and international food security requirements. By applying class 10,000 cleanroom, food producers can significantly reduce the risk of pollution, improve product quality and fulfil regulatory bodies and global consumers' expectations. As shown in fig.

Fig: - 3 Food Processing Cleanrooms

Above diagram shows that the food processing work is going on inside the clean room.

3.3.3 ELECTRONICS & SEMICONDUCTOR CLEANROOMS

A Class 10,000 (ISO Class 7) cleanroom in the electronics and semiconductor industry is a highly controlled environment designed to minimize particulate contamination that can damage or interfere with sensitive components like microchips, sensors, printed circuit boards (PCBs), and optical devices. These cleanrooms maintain a particle count not exceeding 10,000 particles (≥0.5 µm) per cubic foot of air, achieved through the use of HEPA filtration systems, which remove at least 99.97% of particles. While more critical semiconductor processes may require ISO Class 5 or 6 environments, Class 10,000 cleanrooms are commonly used as background zones where supporting operations like inspection, assembly, soldering, and packaging take place.

The cleanroom layout typically includes localized laminar flow zones or clean benches over workstations for critical tasks, while the rest of the area operates under turbulent or mixed airflow. Air change rates range from 30 to 60 ACH (air changes per hour), and the cleanroom is kept under positive pressure to prevent infiltration of contaminated air. Humidity and temperature are carefully controlled (often around 21–24°C and 40–60% RH) to prevent electrostatic discharge (ESD), which can permanently damage microelectronics. Cleanroom materials include antistatic flooring, stainless steel furnishings, and sealed

lighting. Personnel must wear ESD-safe garments, including smocks, gloves, shoe covers, and sometimes face masks or hoods, depending on the task. Environmental monitoring for particle levels, airflow, temperature, and pressure is performed regularly to ensure compliance with ISO 14644 and ESD protection standards (e.g., ANSI/ESD S20.20). These cleanrooms are vital for achieving high product yields, ensuring component reliability, and maintaining quality in the fast-paced and miniaturized world of electronics manufacturing.

3.3.4 AEROSPACE CLEANROOMS

A Class 10,000 (ISO Class 7) cleanroom in the aerospace industry is a contamination-controlled environment used for the assembly, testing, and integration of highly sensitive aerospace components such as satellites, spacecraft, optical instruments, and avionics systems. These components are often precision-engineered and must operate in extreme conditions like outer space, where even a microscopic particle can cause critical failure. To ensure their integrity and reliability, aerospace cleanrooms are designed to limit airborne particles to **no more than 10,000 particles ≥0.5 microns per cubic foot**, using **HEPA filtration systems**, positive pressure zones, and strict environmental controls.

The cleanroom environment typically features a combination of **laminar flow zones** for ultra-sensitive tasks (such as lens or sensor integration) and **turbulent or mixed airflow** for general assembly areas. Air change rates are maintained between **30 to 60 ACH**, with airflow direction carefully designed to sweep contaminants away from mission-critical hardware. **Temperature and humidity** are tightly regulated (e.g., 20–22°C, 45–55% RH) to prevent material expansion, contraction, and static electricity, which could affect delicate components. Floors are made of **low outgassing, antistatic materials**, and all surfaces are smooth and easy to clean to avoid particulate shedding.

Personnel entering aerospace cleanrooms must follow strict **gowning protocols**, including full cleanroom suits, gloves, face masks, and often ESD-safe apparel. Items and equipment must be cleaned or wiped down, and may pass through **airlocks** or **air showers**. Additional design considerations often include **vibration control**, **cleanroom cranes**, and **electromagnetic shielding**, depending on the payload.

Aerospace cleanrooms are governed by standards such as **ISO 14644**, **NASA-STD-8739**, and **ESA ECSS-Q-ST standards** for space equipment cleanliness. These environments are critical to ensuring **mission success**, **long-term reliability**, and **cleanliness validation** of flight hardware before it leaves Earth.

Fig: - 6. Aerospace Cleanrooms

6. WORKING PRINCIPLE OF A CLEANROOM

The working principle of a cleanroom is based on the control of airborne particles, microorganisms, temperature, humidity, and pressure to maintain a clean and controlled environment. Cleanrooms operate by continuously supplying filtered air and removing contaminated air to limit the concentration of airborne particles within specified limits defined by cleanroom standards.

The primary mechanism used in cleanrooms is High-Efficiency Particulate Air (HEPA) or Ultra-Low Penetration Air (ULPA) filtration, which removes particulate contaminants from incoming air. HEPA filters are capable of removing at least 99.97% of particles of size 0.3 μm, ensuring a high level of air cleanliness [13], [14]. The filtered air is supplied uniformly into the cleanroom, usually through ceiling-mounted diffusers.

Cleanrooms maintain **controlled airflow patterns**, either unidirectional (laminar) or non-unidirectional (turbulent), to sweep particles away from critical areas. This airflow helps prevent particle accumulation and transports contaminants toward return air outlets for removal [15].

Another important principle is **positive pressurization**, where the cleanroom is maintained at a higher pressure than adjacent areas. This prevents the ingress of contaminated air when doors are opened [16]. In addition, **temperature and relative humidity** are precisely controlled to ensure product quality, operator comfort, and microbial control, especially in food and pharmaceutical applications [17].

Strict **operational protocols**, including gowning procedures, controlled personnel movement, and material handling practices, further support the cleanroom's function by minimizing contamination generated by humans, who are the primary source of particles [13]. Continuous monitoring of particle counts, pressure differentials, and environmental parameters ensures that the cleanroom consistently meets required cleanliness standards.

7. PARAMETERS INFLUENCING CLEAN ROOM PERFORMANCE

The performance of a cleanroom depends on several interrelated design, operational, and environmental parameters that directly affect the level of cleanliness and contamination control. The key influencing parameters are discussed below.

A. Airflow Pattern and Air Change Rate

Airflow pattern plays a critical role in removing airborne contaminants from the cleanroom. Unidirectional (laminar) airflow provides better particle control in critical zones, while non-unidirectional airflow is commonly used in Class 10,000 (ISO 7) cleanrooms. Adequate air change rates are required to dilute and remove particles generated during operations [18], [20].

B. HEPA Filter Efficiency and Integrity

High-Efficiency Particulate Air (HEPA) filters are essential for maintaining cleanroom air quality. Filter efficiency, proper installation, and regular integrity testing significantly influence cleanroom performance. Any leakage or filter damage can result in increased particle levels [19], [21].

C. Pressure Differential

Maintaining a positive pressure differential between the cleanroom and adjacent areas prevents the ingress of contaminated air. Pressure imbalance can lead to cross-contamination and degradation of cleanroom conditions [21].

D. Temperature and Relative Humidity

Controlled temperature and humidity are important for product quality, microbial control, and operator comfort. Improper environmental control can promote microbial growth and affect process stability, particularly in food and pharmaceutical cleanrooms [22].

E. Personnel Behavior and Occupancy

Personnel are the largest source of contamination in cleanrooms. The number of occupants, movement patterns, gowning practices, and adherence to operating procedures have a significant impact on airborne particle generation [20].

F. Material and Equipment Flow

Improper material transfer and equipment movement can introduce contaminants into the cleanroom. Controlled material flow, airlocks, and pass-through systems are essential for maintaining cleanliness [18], [21].

G. Cleaning and Maintenance Practices

Regular cleaning, disinfection, and maintenance of surfaces, filters, and HVAC components are necessary to sustain cleanroom performance. Poor maintenance can lead to particle accumulation and microbial contamination [19].

H. Monitoring and Validation Systems

Continuous monitoring of particle concentration, pressure differentials, and environmental parameters ensures consistent cleanroom performance. Validation and periodic requalification help maintain compliance with cleanroom standards [18], [19].

8. PARAMETERS TO BE CONSIDERED FOR DESIGNING A CLEANROOM

The design of a cleanroom requires careful consideration of multiple parameters to ensure effective contamination control, operational efficiency, and compliance with cleanroom standards. The key parameters influencing cleanroom design are discussed below.

A. Cleanroom Classification

The required cleanroom class (e.g., Class 100, Class 1,000, Class 10,000 or ISO Classes 5–8) determines the allowable airborne particle concentration and directly influences all design decisions, including airflow rate, filtration level, and room layout [23].

B. Airflow Pattern and Air Change Rate

Selection of airflow pattern, either unidirectional (laminar) or non-unidirectional (turbulent), is critical for particle removal efficiency. Adequate air change rates must be maintained to dilute contaminants generated during operation [24], [25].

C. Filtration System

High-Efficiency Particulate Air (HEPA) or Ultra-Low Penetration Air (ULPA) filters are essential for removing airborne particles. Filter efficiency, coverage area, and accessibility for maintenance are important design considerations [23], [26].

D. Pressure Differential and Zoning

Positive pressure differentials between clean and less-clean areas prevent the ingress of contaminated air. Proper zoning and pressure cascade design help minimize cross-contamination [26].

E. Temperature and Relative Humidity Control

Temperature and humidity must be controlled to ensure product quality, microbial control, and operator comfort. These parameters are particularly important in food and pharmaceutical cleanrooms [27].

F. Material and Personnel Flow

The layout should ensure unidirectional flow of materials and personnel to avoid cross-contamination. Airlocks, pass-through chambers, and gowning rooms should be incorporated into the design [24].

G. Construction Materials and Surface Finishes

Cleanroom surfaces should be smooth, non-porous, easy to clean, and resistant to chemicals and microbial growth. Proper selection of flooring, wall panels, and ceiling systems is essential [25].

H. Lighting and Electrical Systems

Lighting should provide adequate illumination without generating excessive heat or particles. Electrical fixtures must be sealed and cleanroom-compatible to prevent contamination [26].

I. Cleaning, Maintenance, and Accessibility

The design should allow easy access for cleaning, filter replacement, and maintenance without disrupting cleanroom operations [23].

J. Monitoring and Control Systems

Continuous monitoring of particle count, pressure differential, temperature, and humidity is necessary to maintain cleanroom performance and compliance with standards [24].

9. DESIGNING / ANALYSIS OF CLEANROOM

The existing Class 10,000 (ISO Class 7) cleanroom is analysed to evaluate its performance in terms of airborne particulate control, environmental conditions, HVAC efficiency, and operational practices. Class 10,000 cleanrooms permit a maximum airborne particle concentration of 10,000 particles/ft³ for particles ≥0.5 µm, as specified by ISO 14644-1 [28]. The analysis is carried out under both *at-rest* and *operational* conditions.

A. Airborne Particle Concentration

Particle count measurements indicate that the cleanroom generally complies with ISO Class 7 limits under at-rest conditions. However, during operational conditions, particle levels approach the upper permissible limit due to increased personnel movement and material handling. This suggests limited dilution capacity and a lack of adaptive airflow control.

B. HVAC System Performance

The existing HVAC system operates with a constant air volume (CAV) approach, providing approximately 30–40 air changes per hour. While this meets minimum cleanroom requirements, it results in high energy consumption, particularly during low-occupancy periods. HEPA filters (99.97% efficiency at 0.3 µm) are installed at terminal supply points; however, filter pressure drop monitoring is manual and periodic, increasing the risk of delayed maintenance [29].

C. Airflow Pattern and Pressure Differential

The cleanroom utilizes non-unidirectional (turbulent) airflow, which is acceptable for Class 10,000 applications. Positive pressure differentials of 8–10 Pa are maintained relative to adjacent areas. Occasional pressure fluctuations are observed during door openings, indicating inadequate airlock design and pressure recovery control [30].

D. Temperature and Relative Humidity Control

Temperature is maintained in the range of 20–24°C, and relative humidity is controlled between 45–60%. Although these conditions are suitable for food processing operations, minor fluctuations are observed during peak operational hours due to fixed HVAC settings and lack of real-time load adjustment [31].

E. Contamination Control and Operational Practices

Personnel movement is a major source of contamination in the existing cleanroom. Gowning procedures are followed; however, the absence of continuous environmental monitoring limits immediate corrective actions. Cleaning and sanitation activities are performed at fixed intervals rather than condition-based schedules, potentially affecting cleanliness consistency [32].

F. Monitoring and Validation

Environmental monitoring relies on periodic particle counting and manual record keeping. Continuous monitoring of particle concentration, pressure differential, and filter performance is not implemented. Validation and requalification are conducted annually, which may not adequately capture short-term performance deviations [28], [29].

G. Key Limitations Identified

- Near-limit particle concentration during operational conditions
- High energy consumption due to constant airflow operation
- Manual monitoring and delayed maintenance response
- Limited adaptability to changing operational and occupancy loads

Earlier cleanroom designs primarily relied on conventional HVAC systems with fixed air change rates, manual monitoring, and periodic validation. Cleanroom performance was maintained using predefined airflow rates, HEPA filtration, and pressure differentials as recommended by ISO 14644 and ASHRAE standards [33], [34]. Monitoring of particle concentration, temperature, and humidity was generally carried out using standalone sensors with limited data analysis capabilities. Maintenance and corrective actions were mostly reactive, leading to higher energy consumption and increased risk of contamination events due to delayed response [35].

Several studies have reported that traditional cleanrooms often operate at constant maximum airflow, resulting in excessive energy usage and higher operational costs, especially in Class 10,000 (ISO 7) cleanrooms used in food processing industries [36].

10. PROPOSED CLEANROOM DESIGN USING ADVANCED EQUIPMENT AND AI

In the proposed design, advanced cleanroom equipment integrated with Artificial Intelligence (AI) and Internet of Things (IoT) technologies is employed to enhance performance and efficiency. Real-time particle counters, pressure sensors, temperature and humidity sensors, and energy meters continuously collect operational data. AI algorithms analyse this data to dynamically adjust airflow rates, filtration load, and environmental conditions based on actual contamination levels and occupancy patterns [37], [38].

Predictive maintenance is another key advancement in the proposed design. AI-based analytics identify early signs of HEPA filter clogging, airflow imbalance, or equipment degradation, enabling proactive maintenance and reducing downtime. This intelligent control strategy results in lower particle concentration, reduced energy consumption, fewer contamination incidents, and optimized maintenance costs compared to traditional cleanroom systems.

11. COMPARATIVE PERFORMANCE ANALYSIS

The comparative analysis between traditional cleanroom design and the proposed AI-based cleanroom design is illustrated below. The comparison considers critical performance parameters such as airborne particle concentration, energy consumption, contamination events, and maintenance cost index.

- **Particle Count:** AI-based control significantly reduces particle concentration by optimizing airflow and filtration in real time.
- **Energy Consumption:** Adaptive airflow control lowers HVAC energy usage compared to constant-volume traditional systems.
- **Contamination Events:** Continuous monitoring and rapid response reduce the frequency of contamination incidents.
- **Maintenance Cost:** Predictive maintenance reduces unplanned servicing and operational costs.

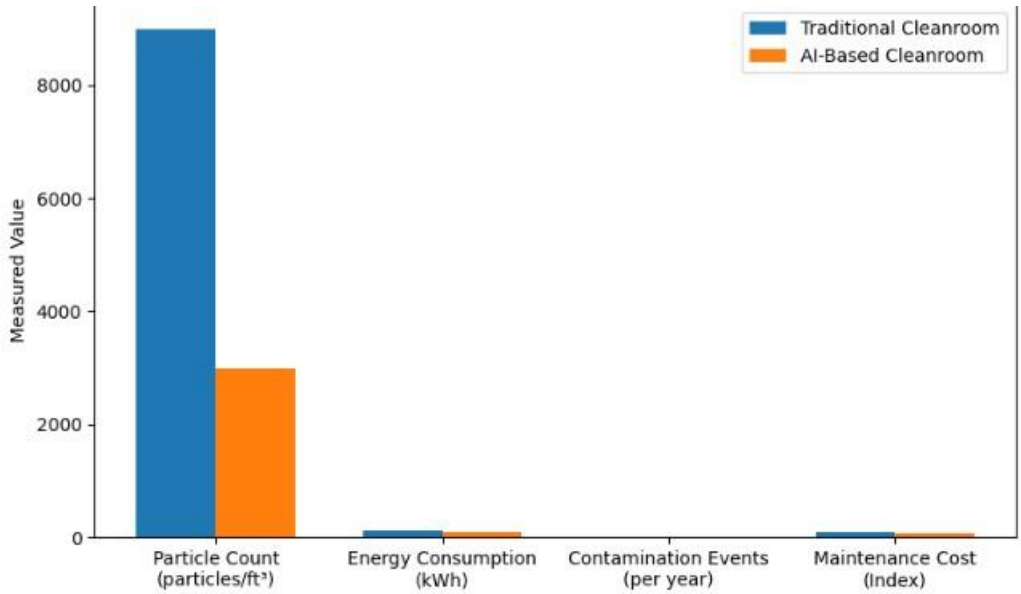

Fig. 7 Performance Comparison of Traditional and AI based Cleanroom

12. CONCLUSION

This study analysed the performance of an existing Class 10,000 (ISO 7) cleanroom for food processing applications and compared it with an advanced cleanroom design incorporating modern equipment and AI-based control strategies. The analysis revealed that although the existing cleanroom meets basic regulatory requirements, its performance is limited by constant air volume operation, manual monitoring, and higher energy consumption. The proposed AI-enabled cleanroom design demonstrated improved control of airborne particles, enhanced HVAC energy efficiency, higher coefficient of performance, and better pressure stability. These improvements contribute to enhanced food safety, consistent product quality, and reduced operational costs. Therefore, the integration of intelligent monitoring and control technologies offers a promising approach for the development of efficient, sustainable, and future-ready cleanroom facilities in the food processing industry.

REFERENCES

[1] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.
[2] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.
[3] Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.
[4] Codex Alimentarius Commission, *General Principles of Food Hygiene (CXC 1-1969)*, FAO/WHO, Rome, Italy, 2020.
[5] U.S. Food and Drug Administration, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*, FDA, USA, 2018.
[6] ASHRAE, *HVAC Applications Handbook—Clean Spaces*. Atlanta, GA, USA: ASHRAE, 2019.
[7] World Health Organization (WHO), *Food Safety*, Geneva, Switzerland, 2020.
[8] Codex Alimentarius Commission, *General Principles of Food Hygiene (CXC 1-1969)*, FAO/WHO, Rome, Italy, 2020.
[9] Codex Alimentarius Commission, *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*, FAO/WHO, Rome, Italy, 2020.
[10] D. Knorr, M. Heinz, and H. Buckow, "High pressure processing of food: Microbiology and quality aspects," *Journal of Food Engineering*, vol. 111, no. 1, pp. 1–15, 2012.
[11] J. Raso and V. Heinz, *Pulsed Electric Fields Technology for the Food Industry: Fundamentals and Applications*, New York, NY, USA: Springer, 2006.

[12] J. Ahvenainen, "Modified atmosphere packaging of fresh foods," *Food Reviews International*, vol. 12, no. 3, pp. 279–297, 1996.

[13] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.

[14] ISO 14644-3, *Cleanrooms and Associated Controlled Environments—Part 3: Test Methods*, International Organization for Standardization, Geneva, Switzerland, 2019.

[15] W. Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.

[16] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.

[17] ASHRAE, *HVAC Applications Handbook—Clean Spaces*. Atlanta, GA, USA: ASHRAE, 2019.

[18] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.

[19] ISO 14644-3, *Cleanrooms and Associated Controlled Environments—Part 3: Test Methods*, International Organization for Standardization, Geneva, Switzerland, 2019.

[20] W. Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.

[21] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.

[22] ASHRAE, *HVAC Applications Handbook—Clean Spaces*, Atlanta, GA, USA: ASHRAE, 2019.

[23] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.

[24] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.

[25] W. Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.

[26] B. Ljungqvist and B. Reinmüller, *Cleanroom Design*. Boca Raton, FL, USA: CRC Press, 1997.

[27] ASHRAE, *HVAC Applications Handbook—Clean Spaces*, Atlanta, GA, USA: ASHRAE, 2019.

[28] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.

[29] ISO 14644-3, *Cleanrooms and Associated Controlled Environments—Part 3: Test Methods*, International Organization for Standardization, Geneva, Switzerland, 2019.

[30] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.

[31] ASHRAE, *HVAC Applications Handbook—Clean Spaces*, Atlanta, GA, USA, 2019.

[32] W. Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.

[33] ISO 14644-1, *Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness by Particle Concentration*, International Organization for Standardization, Geneva, Switzerland, 2015.

[34] ISO 14644-4, *Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Start-up*, International Organization for Standardization, Geneva, Switzerland, 2001.

[35] W. Whyte, *Cleanroom Technology: Fundamentals of Design, Testing and Operation*, 2nd ed. Hoboken, NJ, USA: Wiley, 2010.

[36] ASHRAE, *HVAC Applications Handbook—Clean Spaces*, Atlanta, GA, USA: ASHRAE, 2019.

[37] S. Wang, Y. Chen, and X. Ma, "Artificial intelligence–based monitoring and control of cleanroom environments," *Building and Environment*, vol. 148, pp. 268–280, 2019.

[38] J. Kim and H. Park, "IoT and AI-enabled smart cleanroom for energy-efficient contamination control," *IEEE Access*, vol. 8, pp. 215430–215442, 2020.