ABN CLEANROOM TECHNOLOGY

WHITEPAPER

DESIGN DRIVEN BY SOURCES

A science-based alternative to rule-of-thumb air change rates in cleanroom design

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Executive summary

Cleanroom air change rates are still set by habit, not by evidence. Across the industry, designers reach for the same familiar table: roughly 10–15 air changes per hour (ACH) for ISO 8, 20–30 for ISO 7, 40–50 for ISO 6. These numbers are convenient, but they describe an outcome rather than a cause. A cleanroom is clean not because a certain volume of air passes through it, but because the rate at which clean air is supplied exceeds the rate at which contamination is generated inside it.

The scientific literature is unambiguous on where that contamination comes from. In an occupied, non-unidirectional cleanroom, **people are the dominant source of airborne particles and viable contamination** — far ahead of the process equipment in most applications. And the emission rate of a person is not a constant: it is governed by how they move, how many of them are present, and above all what they wear. High-performance cleanroom garments can reduce human particle emission by a factor of several, and in the widest movements by an order of magnitude or more.

This white paper makes the case for **source-driven design** (also called science-based design): sizing airflow from the actual contamination source strength of a room, using the established cleanroom ventilation equations, rather than from a generic ACH table. A worked example for a typical ISO 7 room shows that source-driven design reduces the required airflow by around 61% versus a rule-of-thumb ACH of 25, and by around 84% when combined with high-performance clothing — with the corresponding reduction in fan energy, capital cost and carbon footprint that follows from moving less air.

> **THE CORE ARGUMENT IN ONE LINE**
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> Do not ask "how many air changes does an ISO 7 room need?" Ask "how much contamination is generated in this room, and how much clean air is needed to dilute it to the ISO 7 limit?" The two questions give very different — and very differently priced — answers.

1. The limits of the rule of thumb

Cleanroom classification standards such as ISO 14644-1 and EU GMP Annex 1 define cleanliness as a maximum permitted concentration of airborne particles per cubic metre. They do not prescribe an air change rate. Even ISO 14644-4, the standard that governs cleanroom design, construction and start-up, describes a process rather than a fixed ACH — and in its current 2022 edition it explicitly calls for energy-management design approaches to support energy-efficient cleanrooms [11]. The familiar ACH ranges — 10–15 for ISO 8, 20–30 for ISO 7, 40–50 for ISO 6 — are engineering conventions that grew up as a safe, one-size-fits-all way to reach those concentration limits without having to model the room.

Convenient as they are, these tables carry a structural weakness. As Zhou et al. observe, the "room cleanliness class versus air change rate" table **"ignores many other critical variables such as room particle generation, filter efficiency, particle surface deposition, particle entry through air supply, and particle exit through return and exhaust air"** [1]. A table cannot know how many people occupy a room, how they behave, or what they wear — yet those are precisely the factors that determine how much contamination has to be diluted.

The consequence is systematic over-design. Independent reviews report that cleanroom supply airflow rates are "often over-designed to meet the air cleanliness classes", and that this over-supply "can cause significant energy waste" [1]. The stakes are large: HVAC accounts for roughly 50–70% of the total energy consumption of pharmaceutical manufacturing [2], and the supply airflow rate is the single biggest lever within it. Airflow that is set higher than the source strength requires is, in energy terms, simply thrown away.

Part of the reason the table endures is not technical but practical. At the start of a project the very information that source-driven design needs — the machines, the process, the number of people — is often incomplete or uncertain, and it may still change over the life of the facility. Faced with that uncertainty, designers and clients fall back on a fixed table value: it is defensible after the fact — “we built as anyone would have, with the information we had” — and it appears to hedge against whatever comes later. The table, in other words, is often a proxy for missing data and an insurance against future change, rather than a considered engineering answer to the room in front of us.

WHY THE TABLE OVER-DELIVERS

A fixed ACH assumes a worst-case, generic room. When the real room is better than worst case — fewer people, disciplined behaviour, high-performance garments — the table cannot capture that improvement, so the saving is never realised. Source-driven design does capture it.

2. What really drives cleanliness: the source term

In a non-unidirectional (turbulently mixed) cleanroom, contamination is controlled by dilution: filtered air enters, mixes with room air, and carries particles out through the returns. At steady state, the airborne concentration settles where the supply of clean air balances the generation of particles. This is captured by the cleanroom ventilation equation, derived by Whyte and co-workers and set out in ISO 14644-16 and the review by Chen, Butterworth and Jiang [3]:

$$Q = D / (\varepsilon \cdot C)$$

where Q is the required clean-air supply rate (m^3/s), D is the total particle dispersion (source) rate from people and machinery (counts/s), C is the target concentration for the class (counts/m^3), and ε is the air-quality index that corrects for imperfect mixing (the contaminant-removal or air-change effectiveness). If an air change rate is wanted, it follows directly from the room volume V:

$$ACR = 3600 \cdot D / (\varepsilon \cdot C \cdot V)$$

The equation says something that the ACH table cannot: the air change rate is an output, not an input. It falls straight out of the source strength D. Halve the contamination generated in the room and you halve the airflow needed to hold the same class. Perfect mixing corresponds to $\varepsilon = 1$; in real rooms ε typically lies between about 0.7 and 0.85, and good diffuser selection is what keeps it high [3].

The total source strength is simply the sum of the sources present:

D = (emission per person × number of people) + machinery emission

This is where design should begin. Every term is knowable, measurable, and — crucially — controllable. The number of people is an operational choice. Machinery emission can be obtained from the equipment manufacturer or measured per ISO 14644-14. And the emission per person, the term that usually dominates, is governed by behaviour and clothing.

The per-person source strength is not a guess — it is a measured quantity. The standardised method is the body-box (dispersal-chamber) test defined in IEST-RP-CC003.5, the IEST Recommended Practice for garment systems in cleanrooms [10]. A gowned subject performs a defined sequence of movements inside a small, HEPA-filtered stainless-steel chamber while particle counters record the emission, yielding a source strength in particles (or CFU) per person per second — precisely the term D that the ventilation equation needs. Every emission figure cited in this paper traces back to body-box measurements of this kind, which is what gives source-driven design a repeatable, auditable footing rather than a rule of thumb.

3. People are the dominant source

Once a process is enclosed or automated, the human operator becomes the principal contamination source in the room. The pharmaceutical literature is direct about this: operators "become the most important source of particles", they spend 85–90% of their time in the cleanroom, and "when operators work, millions of particles are released with every activity" [4]. A single person sheds on the order of **one billion skin cells per day, of which roughly 10% carry micro-organisms** [4] — the origin of most viable contamination in an aseptic space.

BEHAVIOUR: MOVEMENT SETS THE EMISSION RATE

Human emission is not a fixed figure; it scales strongly with activity. Reported whole-body rates range from about 50,000 to 180,000 particles per person per minute depending on movement intensity [4]. In a controlled-chamber material-balance study, Licina et al. found a sitting occupant released about 8 million particles per hour in the 1–10 μm range, with emissions rising sharply for upper-body movement and walking [5]. Yang et al., using fluorescent-aerosol measurement, measured mean emission of 5.3–16 million biological particles per person-hour, and showed the rate falls by 30–60% at higher humidity and 50% for older subjects [6].

The practical message for both operations and design is that **slow, deliberate movement and disciplined gowning behaviour materially lower the source term**. Fast movement, crowding and poor technique raise it. Behaviour is a design variable, not a footnote.

NUMBER OF PEOPLE: A LINEAR MULTIPLIER

Because emission per person multiplies directly by headcount, occupancy is one of the most powerful levers a designer and operator control. Two operators instead of four halve the human source term — and, at fixed effectiveness, roughly halve the airflow the human load demands. A source-driven model exposes this trade-off explicitly; an ACH table hides it entirely.

> **DESIGN IMPLICATIONS**
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> The right question at concept stage is not "what class is this room?" alone, but "how many people, doing what, wearing what?" Those three answers, fed through the ventilation equation, size the air handling far more precisely than any table.

4. Clothing: the single most effective control lever

If people are the dominant source, then the barrier between the person and the room — the cleanroom garment — is the most direct way to reduce the source term at its origin. The evidence for its effect is substantial and consistent.

Romano, Milani and Joppolo compared seven combinations of technical clothing and undergarments in a dispersal-chamber campaign. Their headline finding: sterile garment systems made entirely of synthetic materials achieve **10 to 30 times fewer particle emissions** in wider movements than non-sterile mixed systems, with almost zero microbiological release. They note explicitly that a low human emission rate "benefits the cleanroom design and operation, either reducing the energy consumption or increasing the number of personnel in clean environments" [7].

Meng et al. quantified garment construction directly. The emission rate of 0.5 μm particles from split-type garments was about **2.0–3.5 times higher** than from integrated one-piece garments, and 7.0–22.7 times higher for 5.0 μm particles. Fabric barrier, not the fabric itself, dominates: they attribute at most 3.89% of emission to shedding from the garment surface, the remainder passing through and around it — which is exactly why coverage and seal matter [4]. Yang et al. add a complementary detail: fuller coverage changes the size distribution and biological fraction of what escapes [6].

Garment performance is also not static. Washing, drying and sterilisation (WDS) cycles gradually degrade barrier fabrics, and emission rises with laundry count [4][8]. Sustaining performance over a garment's life therefore depends on a controlled laundry process — the domain of EN 14065, which defines a Risk Analysis and Biocontamination Control (RABC) system for laundry-processed textiles [9]. A source-driven design that assumes a given garment performance is only valid if that performance is maintained in service.

Control lever	Effect on human emission	Source
Sterile synthetic vs. non-sterile mixed system	10–30× lower (wider movements)	Romano et al. [7]
Integrated vs. split-type garment	2.0–3.5× lower at 0.5 μm; 7–22.7× at 5 μm	Meng et al. [4]
Slow vs. vigorous movement	≈ up to 3–4× swing in emission rate	Licina et al. [5]
Full vs. partial body coverage	Alters emission size & biological fraction	Yang et al. [6]

Table 1 — Levers that reduce the human source term, with the effect reported in the literature.

5. Worked example: rule of thumb vs. source-driven

To make the difference concrete, consider a representative ISO 7 cleanroom and size it three ways.

ROOM AND TARGET

Dimensions: 10 × 15 × 3 m → volume V = 450 m³

Target class: ISO 7 → limit 352,000 particles/m³ at ≥0.5 μm. Design target: 10% of that limit (a ×10 margin for recovery, imperfect mixing and at-rest classification), so C = 35,200 particles/m³

Air-change effectiveness ε = 0.8 (realistic mixed-flow value)

Machinery emission: 4,000 particles/s (enclosed, largely automated process — about one person-equivalent)

APPROACH A — RULE OF THUMB

The conventional table gives ISO 7 an ACH of 20–30. Taking a mid-range value of 25 fixes the airflow independently of what actually happens in the room:

$$Q = 25 \times 450 = 11{,}250\ \text{m}^3/\text{h}$$

APPROACH B — SOURCE-DRIVEN, STANDARD GARMENTS

Now size from the source. Assume 10 operators in standard cleanroom garments, each emitting 3,000 particles/s (a body-box-based value for gowned operators, consistent with §3), plus the machinery:

D = (10 × 3,000) + 4,000 = 34,000 particles/s.

Then Q = 34,000 / (0.8 × 35,200) = 1.21 m³/s = 4,347 m³/h→ ACR ≈ 10.

APPROACH C — SOURCE-DRIVEN, HIGH-PERFORMANCE GARMENTS

Keep everything identical, but upgrade to a high-performance sterile synthetic garment system that cuts per-person emission by a factor of three — a conservative reduction, well inside the 2–3.5× measured between garment types by Meng and far below Romano's 10–30× [4][7]. Per-person emission becomes ≈ 1,000 particles/s:

D = (10 × 1,000) + 4,000 = 14,000 particles/s.

Then Q = 14,000 / (0.8 × 35,200) = 0.50 m³/s = 1,790 m³/h→ ACR ≈ 4.

Approach	Airflow (m³/h)	ACR	vs. rule of thumb
A — Rule of thumb (ACH 25)	11,250	25	reference
B — Source-driven, standard garment	4,347	10	−61% airflow
C — Source-driven, high-perf garment	1,790	4	−84% airflow

Table 2 — The same ISO 7 room sized three ways. Source-driven design cuts airflow by 61%; combined with better clothing, by 84%.

The energy consequence is larger still. Fan power rises roughly with the cube of airflow, so moving 61% less air cuts fan shaft power by more than 90%, and the 84% case by well over an order of magnitude, relative to the rule-of-thumb baseline. (The cube law holds for fan shaft power at a fixed system curve; thermal conditioning — cooling, reheat and humidity control — scales roughly linearly with airflow, so the total HVAC saving is smaller than the fan figure alone.) Every case delivers ISO 7 — the difference is entirely in how much air, energy and cost are spent to do so.

NOTE ON FILTER GRADE

A common instinct is to chase cleanliness through filter efficiency. It barely matters for airflow: the difference between an H14 (99.995% on MPPS) and a U15 (99.9995%) filter changes the required supply air by a negligible amount (of order 0.01% in a recirculating cleanroom) — negligible against the choices above. Airflow is set by the source term, not by the last decimal of filter penetration.

6. What source-driven design delivers

Lower energy and operating cost. Airflow is the dominant driver of cleanroom energy use, and HVAC is 50–70% of pharmaceutical manufacturing energy [2]. Sizing to the real source term removes the systematic over-supply that rule-of-thumb design bakes in, cutting fan energy, conditioning load and running cost for the life of the facility.

Lower capital cost. Smaller air volumes mean smaller air handlers, ducts, filters and plant space — savings that land at construction, not only in operation.

More usable capacity. Because occupancy is an explicit term, a source-driven model can tell an operator how many people a room can hold at a given class — or how much cleaner clothing would let them add a workstation. The model becomes an operational planning tool, not just a design calculation.

A defensible, auditable basis. Regulators increasingly expect airflow reductions to be justified through Quality Risk Management under ICH Q9 [3], and ISO 14644-4:2022 itself now directs designers toward energy-management approaches [11]. A source-driven calculation, grounded in body-box emission data per IEST-RP-CC003.5 [10] and documented assumptions, is exactly the kind of transparent, risk-based rationale that supports such a case — where "we used the standard table" does not.

Sustainability. Less air moved is less electricity, less conditioning and a smaller carbon footprint — an outcome that aligns cleanroom performance with corporate environmental targets rather than trading one off against the other.

7. From principle to practice

Source-driven design is only useful if the source term can be established reliably at the point a room is conceived. That is a data problem as much as an engineering one: it requires knowing, per room, the intended occupancy, the activity profile, the equipment emission and the garment specification — and turning them into airflow through the ventilation equations with a realistic effectiveness.

This is the philosophy behind ABN Cleanroom Technology's **Configure-to-Order+** approach and the **ADAPTUS** platform: a data-driven path from design through delivery, in which a room's parameters — not a generic table — drive its configuration. Bringing emission rates, occupancy and clothing performance into that same data model lets airflow be sized from sources by default, with the class limit as the constraint and energy as the quantity to minimise. The result is a cleanroom that meets its ISO or GMP class demonstrably, at the lowest airflow — and therefore the lowest energy and cost — that the physics allows.

Flexibility without over-design. A fair objection to sizing tightly from today's sources is that tomorrow's may differ — a new machine, a changed process, more operators. There are two ways to absorb that change. One is to over-size the installation up front so it can cope with whatever might come; an engineer-to-order design, tailored once to a fixed brief and hard to alter afterwards, has little alternative, so its flexibility is bought through over-dimensioning — the very over-supply that source-driven design sets out to eliminate. The other is to make change cheap by design. ABN's configure-to-order approach assembles the cleanroom from axiomatically independent building blocks configured to this room's source term: adding, removing or swapping a block leaves the others untouched, so the installation can follow changing requirements over its life without being over-sized for them from day one. Flexibility then comes from the concept, not from spare airflow.

> **THE SHIFT IN ONE SENTENCE**
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> Rule-of-thumb design sizes a room for an imaginary worst case; source-driven design sizes it for the real one — and lets clothing, behaviour and occupancy earn their keep.

8. Conclusion

The ACH tables that still dominate cleanroom design were a reasonable heuristic in an era without room-level data. They are no longer the best available tool. The science is settled on the essentials: cleanliness is a balance between clean-air supply and contamination generation; people are the dominant source in occupied rooms; and their emission is governed by behaviour, headcount and — most controllably — clothing. The ventilation equations that connect these to airflow are well established and standardised.

Designing driven by sources turns those facts into airflow. For a typical ISO 7 room it cut required airflow by 61% on source strength alone, and by 84% when paired with high-performance garments — every case still meeting the class. The prize is a cleanroom that is cleaner where it matters, cheaper to build and to run, more flexible in use, and easier to defend to a regulator. It is time for cleanroom design to be driven by sources, not by habit.

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