Clearly defining specifications

dastex
REINRAUMZUBEHÖR

Cleanroom garment systems according to the modular principle

Carsten Moschner

Defining a garment system is still not one of the most popular tasks. The chance of making yourself unpopular with your employees or colleagues is relatively high.

Even if it may seem quite simple at first glance to define a cleanroom overall or cleanroom coat, a closer look reveals that the task can be complex. The following explanations, with one or two suggestions and recommendations, should therefore serve as a „central theme“.

Garment concepts are as individual as the user processes in the different cleanrooms.

	Requirements / fixed values	Evaluation		
		important	less important	not relevant
Air cleanliness class / GMP ranges				
Airlock concept (Personnel airlock)				
Employees' acceptance				
Requirements in the field of personal protective equipment (PPE)				
Further technical requirements such as ESD/EPA				
Temperature conditions in the controlled areas				
Selection of models				
Changing cycles and wearing cycles				
Purchase or lease				
Employee training				
Costs				
...				

Table 1:
Possible decision-relevant aspects when defining a garment system

The different requirements are first recorded and documented as precisely as possible for the future garment concept, because it is a fallacy to assume that the air cleanliness class (according to ISO 14644 Part 1) would be the sole decisive criterion. In addition to the typical cleanliness relevant topics, such as filtration efficiency and abrasion resistance, in most cases a number of other criteria must also be taken into account. Wearing comfort aspects or requirements from the field of personal protective equipment are mentioned here as examples.

Table 1 contains a list of possible aspects as well as an evaluation possibility with regard to the respective relevance, which could be relevant in the definition of a garment system. In addition, Figure 1 provides a graphical overview of the factors that directly and indirectly influence the definition process towards a garment concept.

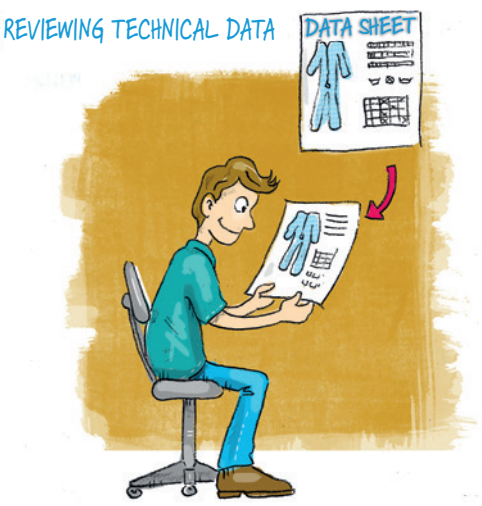
Once the first step has been taken and the most important aspects and requirements for a garment system have been compiled, it is necessary to filter out the data and indications that are relevant and trustworthy for one's own process from the various data and information provided. By now, there is a guideline (VDI 2083 Cleanroom technology, Consumables in the cleanroom Part 9.2, Issue German/English), at least in German-speaking countries, which offers deciders appropriate assistance. In addition to the generally applicable first part of this guideline, in which the various textile-specific properties are listed and explained, its appendices offer specific guideline values and recommendations for the respective properties.

Among other things, on the following criteria:

- Retention capacity towards
  - airborne particles (diffusion behaviour)
  - Mechanically transported particles (migration behaviour)
  - Microbiological contamination
- Air permeability (under consideration of the pump effect)
- Wearing comfort
- Electrostatic behaviour
- Abrasion resistance / roughening (signs of ageing)

Since many of these technical requirements are still not tested and verified in a standardised way internationally, deciders should not only question the source of the respective data, but also the test method and its practical relevance. It should also be checked whether these are data that describe the new condition of a cleanroom textile or (which would certainly be desirable) values that can be expected in the typical use condition – after e.g. 50 wearing cycles. The reproducibility resp. the re-qualification of such data is also interesting aspects from a quality point of view.

Apart from technical requirements that serve the process safety and have a high influence on the quality of the services provided in the controlled areas, the needs of the employees must not be disregarded under any circumstances. The employees' acceptance is a very important component of a well-functioning garment system. If a garment concept is completely rejected, this also has an impact on efficiency as well as on the quality of work in the cleanroom. The implementation procedure of a new or modified garment concept, as well as regular practice-oriented employee training, are two possible approaches that can increase the employees' acceptance. Both will be discussed in detail later.



Different influencing factors on the definition process of a cleanroom garment system

A further requirement for a garment system from the point of view of product protection is often the issue of ESD (Electro Static Discharge) or EPA (Electrostatic Protected Area). In addition to the textile properties (keyword: conductive fibres / filaments), the construction, design and processing (seams) can have a significant influence on these requirements.

If activities carried out with cleanroom garments under controlled conditions are subject to additional requirements in the area of personal protective equipment (PPE), almost all reusable solutions are currently ruled out for legal reasons. Typical applications are, for example, the handling of cytostatic drugs, highly effective active substances or hazardous chemicals. The certification under PPE aspects, which is mandatory in many cases, cannot be easily implemented for reusable garments that are to be regularly reprocessed (decontaminated).

Already the question of how often a garment that has been cleaned several times can be used without hesitation can hardly be answered or certified accordingly. If a reusable solution is nevertheless offered, it is recommended to clarify this question in particular „how often" in a secure way.

In cases where a reusable garment system cannot meet the stipulated PPE requirements, a correspondingly certified disposable solution is recommended. However, not all garment variants based on a disposable material are suitable for use in controlled conditions. Even if the filtration performance of the disposable material appears to be sufficient, „inherent contamination", i.e. the risk of contamination from the garment itself, is often an exclusion criterion.

Disposable garments are in many cases manufactured in simple industrial environments. Any particulate and microbiological contamination from the production process of the disposable material and derived from the production of the garment models is locked in unhindered one-to-one into the controlled areas, if the garment has not been decontaminated beforehand according to cleanroom standards.

The environmental conditions in the controlled areas can also affect the garment system. Heat generation and sweating in/under the cleanroom garments are partial aspects.

But also exactly the opposite requirement profile is increasingly being addressed. Ambient conditions with 8 – 10 °C or workplaces that are exposed to an increased air supply demand solutions in which the employees must be protected accordingly. Here, practical solutions are often found under the cleanroom garments. But also special solutions with special cleanroom suitable textiles for cleanroom garments are conceivable.

In the course of the definition process, from a certain point in time on, the definition of the garment models also has to be made. Certainly, the required air cleanliness class (according to ISO 14644-1 or GMP ranges) plays a certain role in the respective definition of the models, but here, too, further partial aspects must be taken into account. Wearing a lab coat in an ISO 5 cleanliness class or in GMP A/B ranges is rather unlikely and also not recommended.
Conversely, however, from a process-technical point of view, wearing a coverall in an ISO 8 class or in a GMP D range would also be quite conceivable. With the addition of undergarments suitable for cleanrooms (see below), compromises in cleanroom garments are conceivable. The change cycle, i.e. how often the garments are worn before they are decontaminated, can also influence the model selection. The model selection is accompanied by the specification of optional „special equipment", such as bags, flaps, adjustment options, etc.

Here it is important to weigh very carefully which accessories are really essential and which ones can rather be waived. A pocket poses a considerable risk of contamination because it acts like a lint filter during the decontamination process. Compared to a cleanroom fabric, knitted cuffs are much more difficult to reprocess for cleanroom use, to name but a few examples.

Another aspect in this context is the design, cut and sizing of the garments. With different colour designs, for example, it is easier to distinguish between different cleanroom applications in a plant or to realise zone concepts. Colour applications may also make it easier to convince employees to accept the new garment concept.

The cut and thus the fit not only influence the acceptance by the wearer - but also the risk of contamination from the garment. If the garment is too large, contamination can be released where it does not fit properly due to the wrong size and/or design. In the case of a coverall with a sewn-on (integrated) hood, for example, there is always the problem of how well the hood fits. If the wearer requires an XL coverall, the sewn-on hood is inevitably also made in XL. However, if the optimum hood size for the wearer is M, it often happens that the person in question will turn into the hood with a corresponding head movement, thus increasing the risk of cross-contamination.

Cleanroom compatible undergarments

An essential component of a garment system, which has been demonstrated by many sources in the meantime, are undergarments suitable for cleanrooms, which are worn directly under the cleanroom garments. The results of various studies have shown that the contamination risk from one person can be reduced by 50% or more by using cleanroom compatible undergarments. This applies both to particulate contamination and microbiological contamination. Undergarments suitable for cleanrooms (in many cases also called underwear) are characterised by the fact that, due to the material properties hardly/no abrasion is generated under cleanroom garments. In many cases, however, this special clothing also offers other functional properties. Whether that the wearing comfort of the garment system can be improved or that those garments have an antimicrobial effect and thus reduces unpleasant odours.

The (professional) cleaning and decontamination

However, once the choice of garments and undergarments has been made, the process of defining the garment system is far from complete. In order to ensure that the cleanroom garments are fully functional, they must be professionally cleaned regularly – decontaminated in accordance with cleanroom standards. An improper cleaning of the cleanroom garments can verifiably lead the complete system ad absurdum. At this point, too, it is important to include some aspects in the decision-making process. In addition to the required air cleanliness class, the complete process sequence in a cleanroom laundry must also be considered.
Where is loading and unloading done? Is the decontamination process supported by the tumble dryer? Is the cleanliness of the garments or the decontamination regularly checked and documented? Which packaging materials are used and how are they specified and controlled? Are there backup plans in case of an accident? All of these are partial aspects that have to be taken into account in addition to the cost issue, which often comes first. VDI Guideline 2083 Part 9.2 also provides corresponding indications and recommended values for the so-called residual contamination levels. The residual contamination levels are information that every cleanroom laundry should provide with every delivery of processed cleanroom garments in order to be able to prove that they can be used without hesitation in the respective cleanroom areas of the end customer.

Hint:
The residual contamination levels (usually determined using the Helmke drum or following ASTM-F51) are not measured values that prove the general cleanroom suitability of a garment.

Purchase or lease concept?

When choosing a cleanroom laundry, in most cases the decision whether to purchase or lease the garments is also made. The obvious arguments in favour of a leasing concept are the outsourcing of the complex logistics, the issue of capital commitment, the increasingly complex documentation requirements with regard to quality-relevant data (e.g. tracking of individual parts, number of washing cycles, allocation of washing and sterilisation batches), etc. However, these aspects must be paid for!

It is therefore necessary to weigh costs and benefits accordingly. At the same time (but independently of the commercial decision to purchase or lease) further decisions have to be made: How many garment sets should a wearer receive? Of course, this depends on the user's cleanliness requirements for the clothing and how often the garments are picked up/delivered by the internal or external service provider. An example: cleanroom garments for hygiene areas A/B (according to GMP) must be changed with every entry. With a daily 4-fold change and a weekly one-time supply (delivery and collection) this would be (for a 5-day week) 20 sets per wearer! These twenty sets will now be reprocessed / decontaminated during the next week, so that the wearer needs another twenty sets.

In addition, there is a daily supply for the day of delivery and collection (= 44 sets). To this, a buffer stock should be included to cover the risk of eventualities such as evacuation or other unforeseen events.

Wearing cycle resp. replacement cycle

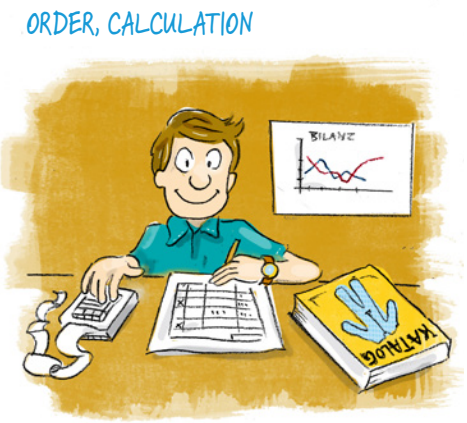
This part of the definition process also includes determining how often a garment may be worn in total, i.e. after how many wear cycles it must be renewed/replaced. This decision also depends on the cleanroom class in which the garments are to be used. It also depends on the mechanical stress to which the garments are exposed on a daily basis.

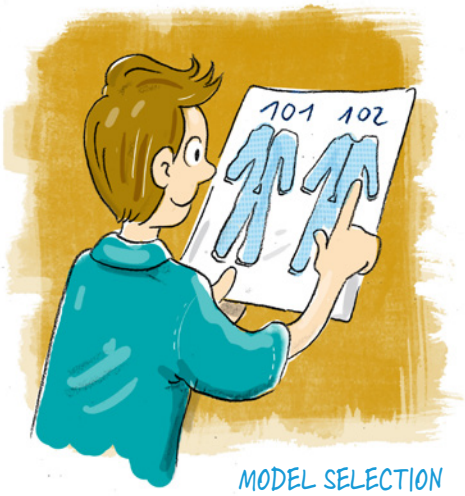
A mechanic uses the garments to a completely different extent than an operator who may mainly use a touch panel.
If the cleanroom garments are additionally sterilised, they must be replaced much earlier than garments that are only decontaminated (washed) due to the stress.

In this context it should be noted that the sterilisation process makes special demands on the actual cleanroom garments. Some components such as zippers, elastic bands, buckles or soles (for overboots) react differently to the different sterilisation procedures. At this point, it is also necessary to determine whether individual item tracking is necessary and useful for each garment, and thus whether appropriate labelling must also be provided in the respective garments. In addition, specifications must be drawn up as to whether a garment may be repaired and if so, to what extent.

Below is a short summary list for this part of the definition process:

- Purchase or lease
- Sterilisation → yes/no → Sterilisation procedure
- Number of sets per employee
- How many deliveries or pick-ups per week
- Holiday and vacation regulations shall be determined
- Delivery points/collection points on site
- Cabinet service → yes/no
- Maximal wearing cycles





MODEL SELECTION

- Repair management
- Single part tracking ➞ yes/no
- Batch documentation
- Defining of an emergency plan (in case something goes „wrong" with the cleanroom garments).

Airlock concept

However, a garment concept also includes an airlock concept adapted to the requirements. If, for example, private items of clothing come into direct or indirect contact with the cleanroom garments without hindrance, it should not be a surprise if cotton fibres are detected in the controlled areas sooner or later. It is not sufficient to separate a personnel airlock by simple division into a black area (in which private clothing is still worn) and a grey area (in which the defined cleanroom garments are worn). There should also be enough space for changing clothes so that the wearers do not contaminate each other during the changing process. If cleanroom garments are to be used several times in a row on one or more days – without being discarded for decontamination in the meantime – they must be hung up in such a way that the risk of cross-contamination from outside is minimised.

Further topics for an airlock concept may include the following:

- Material flow and personnel flow
- Storage facilities and dispenser units for supplementary garment components, such as gloves, face masks, etc.
- Waste disposal of packaging materials, disposable garments, including separation of hazardous waste if necessary
- Fitting with mats to reduce contamination of shoes soles etc.
- Cleaning tasks and cleaning cycles
- Dressing procedures

Well informed and trained employees

The fact that employee acceptance is a very important factor for a well-functioning garment concept has been emphasised above. Adequate employee training is helpful for this acceptance. It not only serves to convey the necessary basic knowledge, but should also strengthen the motivation to live the garment system correctly. If the employees understand the effort involved in creating and implementing a cleanroom garment concept, it is certainly much easier to understand why these garments have to be worn at all, why it is so important to put them on or take them off correctly and why certain behaviour patterns are not acceptable in a controlled area. If, in addition, the appropriate appreciation can be conveyed that working in a cleanroom is something special in every respect, then, in many cases, both the training content is more easily absorbed and the motivation is increased in the right direction. Finally, it should be pointed out that a well-prepared introduction and implementation concept can certainly also contribute to successfully establish a new garment system resp. a modified one.

If the employees are informed early and in detail about the upcoming changes and do not simply feel „overrun", the necessary acceptance increases in advance. Wearing tests in advance, posters that clearly explain one or the other or an informative meeting (e.g. with external experts) are possible starting points for such an introduction concept. At the latest at this point in time, the sizes of the garments should also be recorded and determined in the company. Each employee should personally select the appropriate size for itself.

INTRODUCTION TO THE COMPANY

The typical unisex sizes, such as S, M, L, XL, etc. can vary considerably between the different suppliers, so it makes sense to request size sets from the selected garment manufacturer for size fitting.

These size sets should in any case be pre-washed i.e. properly decontaminated and if autoclaved garments are required for a sterile room, these garments should also have been autoclaved in advance in order to take into account the unavoidable shrinkage of the garments when determining the size.

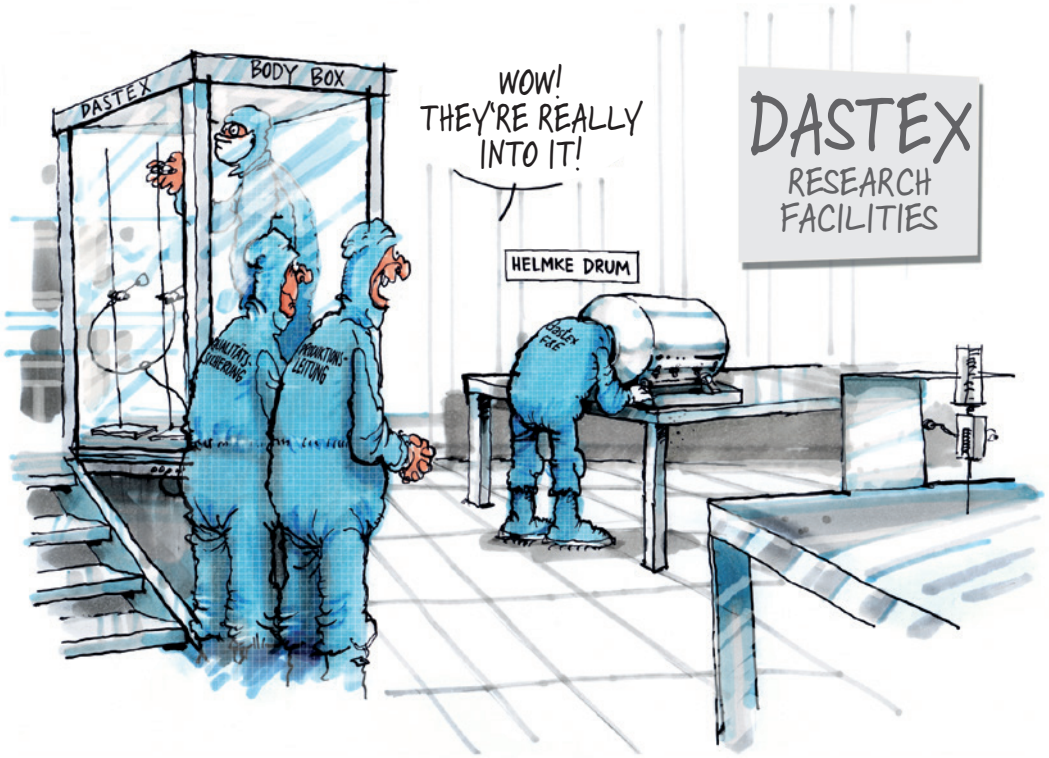
It is just as important to determine a realistic timeline. High-quality cleanroom garments are in many cases not stock items but have to be ordered. Longer delivery times must therefore be taken into account. In addition, the cleanroom laundries also need their time to prepare the garments properly, i.e. to decontaminate and code them.

Conclusion

The definition and implementation of a cleanroom garment system is anything but trivial.

Many points have to be considered and coordinated. Technical requirements have to be harmonised with the needs of the wearer, costs and logistics have to be considered carefully. In certain cases, special additional requirements must be met. It is also advisable to compile a meaningful documentation of the garment system which can be presented to an auditor at any time.

All points listed are recommendations. Each cleanroom requires an individually tailored concept, which should always be drawn up together with the associated service providers if possible.



Author

Carsten Moschner

Article published (in German)
ReinRaumTechnik 1/2018,
Offprint
Revised version 8/2020

Dastex Reinraumzubehör
GmbH & Co. KG
Draisstr. 23
76461 Muggensturm
GERMANY
Telephone +49 7222 9696-60
Telefax +49 7222 9696-88
E-mail info@dastex.com

www.dastex.com