PRODUCT CLEANLINESS

In various industries there is an increasing need for guidance on nano- and microscale surface cleanliness for product development, part manufacturing, surface treatment, assembly, cleanliness measurements and cleanroom services. A VCCN project group therefore prepared the VCCN Guideline 12: Product Cleanliness. It does not prescribe solutions but describes what should be considered when dealing with product cleanliness, which should, among other things, enable and align the communication on product cleanliness between suppliers and customers, in order to help industries to realise and improve product cleanliness.

KOOS AGRICOLA

Cleanliness of product (or part) surfaces is important in many industries, such as aerospace, automotive, microelectronics, semiconductors, optics, nuclear, medical devices and life-science products. Surface cleanliness involves topics such as surface properties, manufacturing, cleaning, measures to keep a product clean during assembly, storage and transport, and measurements. Depending on the desired cleanliness of the product surface (with respect to particle and/or chemical concentrations), stringent methods must be used in the production flow to reach the cleanliness specifications. The product design should enable the realisation of a clean product. In case of application in high and ultrahigh vacuum (HV and UHV), additionally the selection of raw materials and the design of the part can influence the outgassing of the part.

Overview

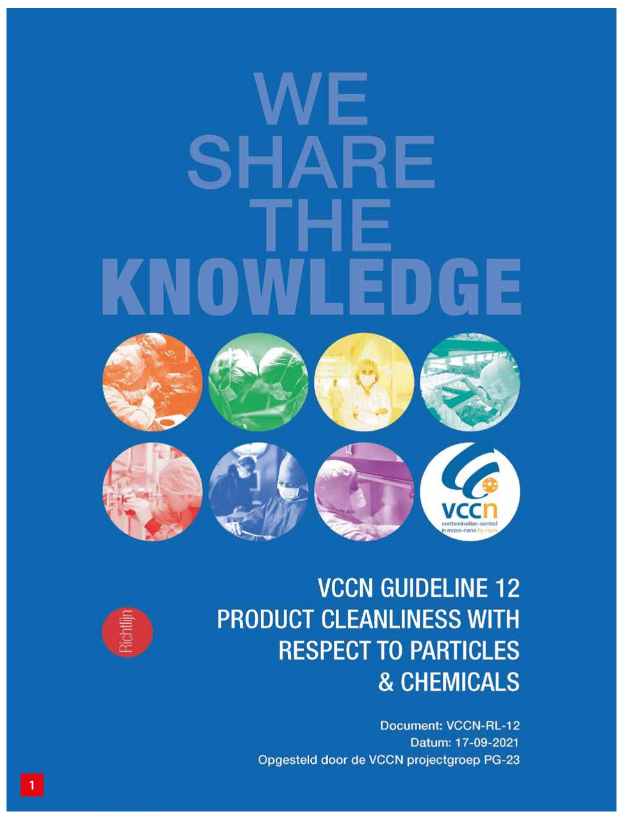
VCCN guidelines are associated with international cleanroom standards prepared and published by the technical committees ISO TC 209 (Cleanrooms and associated controlled environments) and CEN TC 243 (Cleanroom technology). They provide additional information on cleanroom technology and contamination or cleanliness control. The recently published VCCN Guideline 12 (Figure 1) describes surface cleanliness of parts and products with respect to particles and chemicals. For some applications (especially in UHV) the emission of vapours caused by chemical contamination is of interest (RL 12 Product Cleanliness - VCCN) [1].

For the specification, realisation and verification of surface cleanliness it is crucial to understand the functions and application of the product. This motivates the product cleanliness requirements. During manufacturing, from raw material to delivered specified part or assembled device, the required surface cleanliness should be achieved. In general, the design is the starting point, but to be able to design a clean product, product developers should have knowledge of all cleanliness aspects. Various aspects have impact on the product cleanliness (see Figure 2).

The following international standards on surface cleanliness are used [2]:

ISO 14644-9	Classification of surface cleanliness by particle concentration on surfaces, SCP.
ISO 14644-10	Classification of surface cleanliness by chemical concentration on surfaces, SCC.
ISO 14644-13	Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications.

Microbiological contamination topics are not specifically covered in the guideline, but various aspects such as design for cleanliness, specifications, assembly activities and controlled environments are also relevant for micro-



Cover of the recently published VCCN Guideline 12 document.

AUTHOR'S NOTE

Koos Agricola is an applied physicist with 35 years' experience in contamination control and cleanroom technology. He is product manager and contamination control specialist at the Brookhuis Applied Data Intelligence cleanroom division in Enschede (NL). In addition, he is active in education and various (international) societies, including VCCN, and technical committees, covering standards for cleanroom technology and other topics in this field.

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organisms. Their behaviour is comparable to that of particles (deposition, contact transfer) and molecular contamination (airborne transport of viruses), with the major deviations being the potential growth of micro-organisms and need for disinfection methods.
To achieve clean controlled environments, the following standards on air cleanliness with respect to particles and chemical concentrations can be used:

ISO 14644-1	Classification of cleanrooms.
ISO 14644-2	Monitoring air cleanliness with respect to particle concentration.
ISO 14644-8	Monitoring air cleanliness with respect to chemical concentration.

Additionally, ISO 14644 provides standards on cleaning, design, construction and start-up of cleanrooms, separative devices, as well as suitability of materials, consumables and equipment with respect to particle and chemical emission. For control of micro-organisms the use of EN17141:2020 “Biocontamination” is recommended [3].

VCCN Guideline 12 provides guidance on the major aspects of cleanliness of solid surfaces of parts, products, tools and equipment. The purpose is to align the communication between customer and supplier, on surface cleanliness specification and qualification and to provide guidance on means to reach and maintain specific cleanliness levels.

Surface cleanliness involves the determination, reduction and prevention of contamination by particles and/or chemical compounds and/or trace elements. Important aspects are:

- Specification — Expression of the required level of surface cleanliness with respect to particles and chemicals.
- Measurement — Determination of the level of surface cleanliness with respect to particles and chemicals as can be used in qualification and monitoring.
- Raw materials — Impact on surface cleanliness and outgassing behaviour.
- Manufacturing — Process conditions and part treatment during manufacturing with respect to surface cleanliness.
- Cleaning — Selection and evaluation of methods for cleaning to a specified degree of surface cleanliness.
- Assembly — Maintaining initial surface cleanliness by proper environmental cleanliness, operational procedures and working methods.
- Packaging — Impact of packaging on the surface cleanliness of solid surfaces.
- Design — Aspects that have impact on the achievable surface cleanliness and cleaning.

Surface cleanliness starts with the specification of the customer demands. During this phase, the requirements are set that must be met during a chain of activities. A typical chain of activities is shown in the process flow in Figure 3. The process flow of the manufacturing of a clean product starts with the specification of the raw material and ends with the delivery of a specified part or assembled device to the customer.

For specification of surface cleanliness, product functions and types of contamination that can harm the function or application of a part (or the function of the device in which the part is used) must be described. The contamination can consist of specific particles and/or chemicals. Particulate contamination can cause electric opens or shorts, geometric defects, obscuration and (micro)mechanical defects. Chemical contamination can cause unacceptable off-gassing or outgassing of a product and unacceptable chemical interactions, such as corrosion, and have an unacceptable negative impact on adhesion of coatings and adhesives, etc.

Surface cleanliness levels are expressed in contamination concentration (mass and particle area or number) per surface area. Levels are described according to the ISO standard or guideline the customer and supplier agree(d) to use. The next step is to select the appropriate measurement method(s). Preferably the surface cleanliness is specified with respect to the recommended measurement method.

Contamination control

The starting point of manufacturing is the raw material that is used to make a part. Composition, purity and structure will have impact on the achievable surface cleanliness. An important fabrication (material transformation) process is machining and this will have impact on the surface contamination and cleanability.

After transformation, a dirty or unclean surface needs to be cleaned to a specified surface cleanliness level. There are many cleaning methods that can be used to clean a part. The selection depends on the levels to be reached, type of contamination, the material and the acceptable level of damage by the cleaning process. For the selection of a cleaning method, the cleaning efficiency and/or effectivity of the cleaning method should be evaluated.

Clean parts can be contaminated during assembly of the product. Often, assembled surfaces cannot be cleaned afterwards. A risk assessment on the likelihood and consequences of contamination during product assembly will help to identify locations where contamination should be prevented. To limit and control unwanted contamination, a clean environment and specific operational measures are required. The complete set of measures to achieve and maintain relevant and sufficient cleanliness levels is called contamination control.

When a part is ready and its cleanliness has been verified, it can be packed and sent to the customer. The selection of packaging material with respect to emission of contaminants and surface cleanliness is important in retaining the optimal initial surface cleanliness. Packaging can also be used as an intermediate step to keep a part clean.

Looking at all cleanliness aspects, it becomes clear that product cleanliness can be less challenging to realise in case cleanliness aspects are taken into account during the design phase.

Standards

Many industries use surface cleanliness requirements that are derived from their own measurement method or measurable functional properties. For suppliers it is difficult to deal with the various different surface cleanliness definitions and specifications. Therefore, industries are encouraged to use ISO 14644 surface cleanliness standards, or at least to translate their requirements into these standards. Various exercises have demonstrated that this is possible.

The ISO 14644 surface cleanliness standards separate the specifications for particles and chemicals (molecular contamination). When this separation is not possible, it is recommended to express the total amount of contamination in g/m^2.

ISO 14644-9:2012 deals with the surface contamination by particles. It uses a particle size distribution in which the number of particles is inversely proportional to the particle size determined by the diameter D of the circumference of the particle silhouette on a surface. The surface cleanliness level is related to the number of particles ≥ 1 µm per m^2. The measurement result must be expressed in the cumulative number of particles ≥ D µm per m^2: N_D. The surface cleanliness level then is $N_D \cdot D$ for different particle sizes. The maximum surface cleanliness level for the considered particle sizes determines the overall surface cleanliness level SCL. In the ISO standard then the 10-log SCL is taken to determine the ISO SCP class.

The particle size distribution on a surface correlates with the contamination of a surface by particle deposition. However, when a surface just has been cleaned, most larger particles will have been removed and the particle size distribution becomes inversely proportional to D^p, where $p > 1$ and up to 2-4. During exposure of the surface to particle deposition from the air, the p value will move towards 1.

Aspects of product cleanliness.

ISO 14644-10:2013 deals with surface cleanliness by chemicals. The surface cleanliness level is given by the mass of the chemicals of interest or group of chemicals of interest in g/m^2. Some measurement methods do not give the contamination in mass, but rather state the number of molecules. In that case, the number of molecules is multiplied by the molar mass and divided by the number of Avogadro. In that way, the molecular contamination can be expressed in g/m^2. In the ISO standard then the 10-log of the surface mass is taken to determine the ISO SCC class. Since the mass is < 1 g/m^2 the ISO SCC classes will be negative.

Measurement methods for surface cleanliness are discussed in VCCN Guideline 12 and also in the mentioned ISO standards.

Manufacturing chain

For product cleanliness, the complete manufacturing chain should be known. This starts with the way the raw materials are made, followed by the transformation processes, such as machining, then various cleaning, interconnection and assembly processes. Sub-assemblies or parts can be transformed again, etc. In the complete chain, one should be aware of potential contamination sources. In case these are critical, they should be measured to be able to keep them within an agreed limit or they should be avoided.

A cleaning process can be a decoupling point in the chain, but depending on the vulnerability for chemical contamination in particular, one should still know potential contamination sources. Contamination sources can be found on surfaces, in liquids, gases and air within the processes concerned or in surrounding processes, or on other products made in the observed facility of a supplier. The impact of these sources can be reduced by prevention and removal by filtration and cleaning of process media and environment.

Cleanliness strategy

The cleanliness strategy will be a combination of preventing or limiting unwanted contamination and removing contamination by cleaning. Each process will contaminate the product. One can analyse the product cleanliness backwards, from the final cleanliness towards the start of the manufacturing chain. In the final process, the initial surface cleanliness should be better than the final surface cleanliness. The difference gives the acceptable contamination. This knowledge is used to develop the measures to limit the contamination within the given process latitude. During cleaning, the surface cleanliness is reduced depending on the initial surface cleanliness and the cleaning efficiency. Unclean products can also become a source of contamination for subsequent products and/or the environment.

The cleanliness strategy determines where contamination control measures are taken and where cleaning processes are required. The optimal strategy depends on product design, quality of processes, suppliers, transport, storage, available cleaning facilities and monitoring of product cleanliness. Analysing costs and risks of quality loss, the optimal cleanliness strategy can be determined.

Cleaning

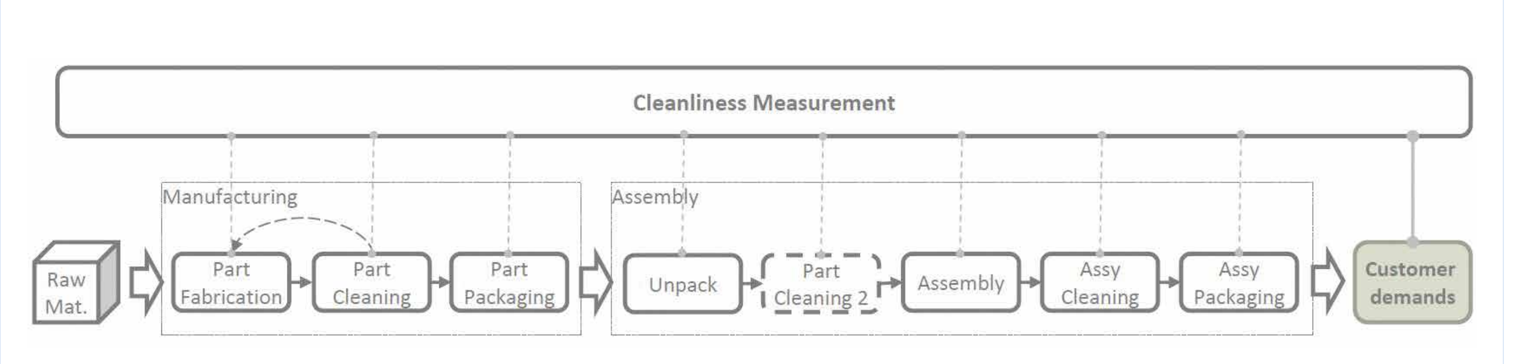
Cleaning processes are applied to remove particulate and chemical contamination. A dirty product first needs precleaning since cleaning processes that remove particles and/or chemicals need a sufficiently low initial surface contamination level to be able to reduce this contamination level sufficiently. A cleaning process has a specific cleaning efficiency depending on the cleaning method, process parameters and products to be cleaned. A cleaning process will have a negative impact on the product surface. It is therefore selected in such a way that the surface damage by the cleaning action is acceptable. The cleaning action is a combination of mechanical and chemical energy. In addition, cleaning temperature and time are important. Cleaning parameter settings can be interdependent.

ISO 14644-13 describes the way to select a cleaning process and gives a simplified overview of cleaning techniques. An important aspect is the investigation and testing of the suitability of a specific cleaning method for the intended application. Cleaning processes can be either wet or dry. The major cleaning action can be either chemical or physical (including mechanical and thermal).

Cleanroom

Cleanroom technology can be applied to control surface cleanliness and to prevent and limit contamination during assembly of clean products. The basics of contamination control is the creation of a separated clean space and controlling the cleanliness of everything that enters this space. The space is under overpressure and it has entry locks to prevent introduction of contaminants by air. Within the space only goods and equipment that are suitable with respect to the allowed emission of contamination are admitted, while the surface cleanliness of everything that enters should be within set limits.

Within the clean space, airborne contamination is diluted and removed by ventilation with clean air. All surfaces should be cleaned efficiently and frequently. A very important factor is personnel. Their number should be as low as possible. Ideally, they should be hygienic, non-smoking, without cosmetics and able to follow entry and working procedures. Personnel should wear clean(ed) occlusive cleanroom clothing to shield the environment from human contamination. Working procedures should be developed to minimise contamination during assembly. The goal is to limit deposition of particles and chemicals onto vulnerable product surfaces.



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Process flow of manufacturing a clean product.

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The VCCN project group that prepared the new VCCN Guideline 12. Fifth from the right, the author of this article, Koos Agricola.

Monitoring

Various cleanliness parameters should be monitored to visualise the quality of the manufacturing chain with respect to cleanliness. For this, data on surface cleanliness of product, tools and equipment, media and environment can be used. With respect to particles in a controlled environment, the air cleanliness, particle deposition rate and surface cleanliness should be monitored. A light-scattering airborne particle counter can be used real time to provide information on particles < 10 µm. A real-time particle deposition monitor can be used to monitor particles > 10 µm, especially particles > 25 µm that are not removed by the ventilation system. ISO 14644-17:2021 gives guidance on the interpretation and application of the measurement results of particle deposition rate.

All surfaces in a clean environment can introduce particles into the air when agitated by activity and turbulent air flows. Therefore, also the cleanliness of floors, work benches, tools and equipment should be monitored.

With respect to chemicals, it is important to prevent unwanted chemicals to enter the clean space. Surfaces should be cleaned in case there is a chance of unwanted chemicals. Surface samples should be taken to measure the cleanliness. The air cleanliness can be measured by taking air samples in absorption tubes and analysing these in advanced measurement equipment for chemicals.

Conclusion

The VCCN Guideline 12 was prepared by a VCCN project group (Figure 4) with members from the various stakeholders. It does not prescribe solutions but rather describes what should be considered when dealing with product cleanliness. Considering the various topics that are addressed, industries should be able to realise and improve product cleanliness. The guideline can enable and align the communication on product cleanliness between suppliers and customers. It also includes a few examples.

It is important to develop a helicopter view on potential contamination during the complete manufacturing process and to understand the impact of design and process options on the product cleanliness.

REFERENCES
[1] *www.vccn.nl/rl-12-product-cleanliness*
[2] *www.iso.org*
[3] *www.nen.nl/en/nen-en-17141-2020-en-275425*