



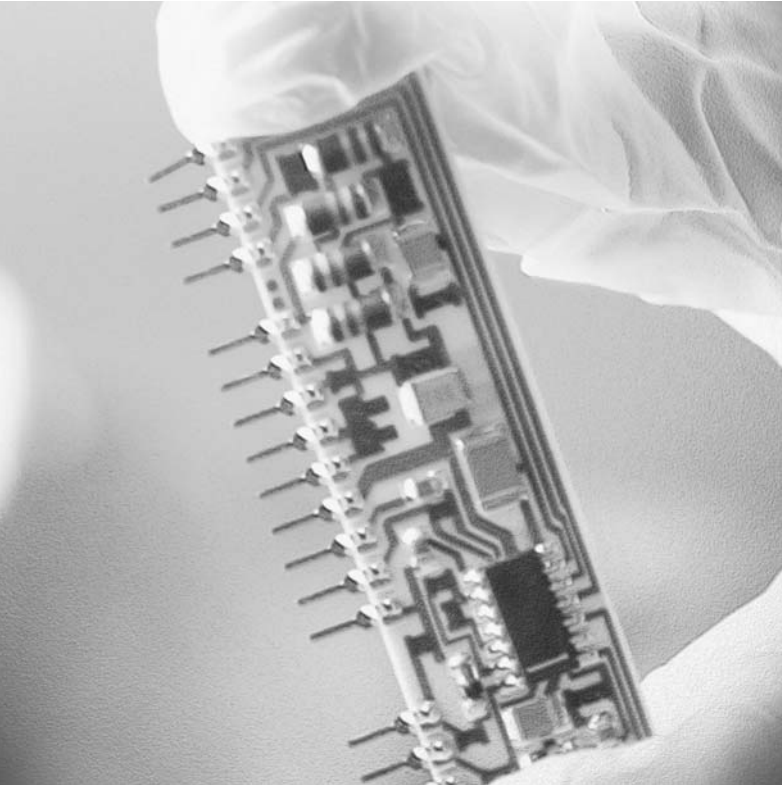
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# Cleanrooms acc. to ISO 14644

## Cleanrooms and associate controlled environments

### High requirements and increasing significance



#### Motivation and benefits

Cleanrooms are rooms that have special requirements on air quality. In many organizations, audits have, up to now, been conducted by customers in order to ensure maximum product quality for the manufactured products.

Cleanrooms and associate controlled environments increasingly form the basis of the development and production of high-quality products, above all in the fields of pharmaceuticals, bio-technology and genetic technology, microelectronics, food industry, packaging technology, medical products, super-clean medicine, laser and glass fibre technologies, PCB (Printed Circuit Board) technology and precision mechanics. Still other fields of application can be found in optics, aviation and aeronautics, surface technology, automotive industry, foil production, coating technology, solar industry, data carrier technology, multimedia technology as well as in laboratories and hospitals. The underlying standards are EN ISO 14644ff – Cleanrooms and associate controlled environments – and the sector specific variations, such as EN ISO 14698.

Each cleanroom has an own cleanroom management system, which defines regulations about test intervals, orderliness and tidiness in cleanrooms, behavioural rules, warning and action limits, evidencing documents, control of monitoring and measuring devices, etc.

In 2005, customers contacted Quality Austria in order to find an opportunity of reducing the number of the internal audits, which were quite expensive. The benefits that may be drawn from certification are that an independent organization reviews cleanroom management and documents conformity with the specifications by issuing a Certificate. This makes repetitive reviews made by customers unnecessary. The expenditure of time and money for evidencing is reduced. Clarity and transparency in the cleanroom processes create safety and certainty and promote product quality.

#### Objectives

- assuring quality in cleanrooms and associate controlled environments – at overall planning, execution and operation
- ensuring transparency and complete and uninterrupted traceability
- the fact that acting according to ISO 14644 provides legal certainty in cases of dispute (judicial certainty)
- review made by an accredited Certification Body and qualified auditors
- reducing the costs for internal audits and external reviews made by customers and authorities

#### Target group

Organizations active in the following fields:

- nano-tech and precision mechanics
- aerospace industry
- microelectronics, electrical engineering, surface treatment
- medical technology, hospitals
- genetic technology and bio-technology, pharmaceutical industry
- laser technology, glass fibre technology and PCB technology (PCB – Printed Circuit Boards)
- food sector
- laboratories



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## Criteria

Cleanrooms and associated controlled environments make it possible to control contamination due to air-borne particulates to a reasonable extent. As a rule, the cleanroom classes and requirements are defined by the client or authorities. For this purpose, there are particulate purity classes in the air acc. to ISO 14644, which must be kept. Cleanrooms are not only made up of ventilation systems. Many other components, such as walls, ceilings, sluces, clothing or infrastructure, must work adequately in cleanrooms.

The distinction between the following audits is made: according to planning (approval of planning), execution (approval of execution), commissioning (approval of functions) and operation (approval of operation).

## Basic requirements

The basic requirement is compliance with specified contamination classes. A distinction is made between nine ISO Classes.

## Critical parameters

Critical parameters of cleanrooms are:

- air cleanliness, air exchange rate, air volumes
- choice of the adequate cleanroom class
- clothing in cleanrooms
- choice of suitable operating materials
- air filters, filter classes, mode of action of filters
- planning of sluces and access areas
- air flows

## Clothing in cleanrooms

Clothing in cleanrooms and the overall behaviour of the cleanroom personnel are critical success factors. Clothing must be adapted to the respective needs. Of course, the contamination class acc. to ISO 14644 also is an indicator to be observed.

## Other relevant standards

ISO 9001, HACCP, ISO 14698

## Quality Austria introduces itself

Quality Austria was founded as a limited company for training, certification and evaluation in 2004. It includes

the four organizations OQS, OVQ, OQA and AFQM and stands for competence in the fields of quality, environmental and safety management and relating to the industry standards.

Our close relationship with the partner organizations IQNet, EOQ and EFQM enables the mutual exchange of topical and global know-how. On a global scale, Quality Austria cooperates with around 100 member organizations in almost 50 countries. Thanks to regional managements, its own offices and exclusive partners, Quality Austria is also represented at the site in Eastern and South Eastern Europe, Northern Africa, Asia and South America.

Quality Austria covers the three business areas certification, evaluation and validation, provides training and individuals' certification as well as information, expert knowledge and service. This means that Quality Austria is a one-stop shop for comprehensive services. More than 500 trainers, auditors and assessors and technical experts combine know-how specific to standards and sectors with a significant focus on practical issues. This secures successful implementation within the organization.



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