top engineer

The Elomatic Magazine 2 · 2015

"Careful and systematic adherence to guidelines is key in delivering GMP compliant facilities and processes."
– *Heikki Niskanen*

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The winds of change

At the time of writing this editorial I have been the CEO of Elomatic for close on 20 years and employed within the Elomatic Group for 33 years. In October we announced that I will vacate my position as CEO and make way for Patrik Rautaheimo, who will take over the reins of the company on 1.1.2016. At the same time Elomatic founder, Ari Elo, will step down as Chairman of the Board of Directors and I will take up that post.

The fact that we have managed to make this smooth transition tells something about our corporate culture, values and the continuity of our operations. I, for one, am very excited about our future.

When I started out as CEO of Elomatic there was already a culture of investing in development, both in engineering methodologies and in people. We have further strengthened this over the years and have been able to turn this into growth and customer satisfaction. Our goal is to develop our employees' know-how so they can be leaders in their respective technical fields. To us it is clear that human capital is our most precious asset. It is the core of our value proposition to our customers.

Investing in our employees by encouraging them and giving them the freedom to enhance their know-how and develop new methods and technologies is also a key factor in creating concepts and products that can eventually be marketed as standalone or turnkey deliveries; a key element of our strategy to drive international growth.

A good example of this is the top know-how we have developed in the field of sterile manufacturing. In this edition of the Top Engineer we highlight this know-how in two of the articles. This top know-how has brought us to the point where we can with confidence offer turnkey sterile manufacturing plants worldwide. This is now a fast growing business area for us. This kind of know-how is, however, not developed overnight; it takes years of hard work by a dedicated team and a corporate culture that facilitates learning. It requires people with positive curiosity.

In Patrik Rautaheimo we have a future CEO that has bought into our culture of development during the few years he has worked with us and will no doubt take us to new heights in the years ahead. His career to date includes ambitious and successful design development projects in international environments and engineering directorships in Germany and Finland. We at Elomatic, and you as our highly valued client and partner, are in safe hands.

I look forward to the challenge of being part of and contributing to Elomatic in my new capacity as Chairman of the Board of Directors. Ari Elo will also continue as a member of the board and as such his wise inputs are not lost to us.

As autumn sets in the winds of positive change are blowing through Elomatic. We will adapt and change in our evolving environment, but stay true to the principles that have brought us this far. By investing in and valuing our people we invest in our own success, and that of our customers.

Olli Manner
Editor-in-Chief
President, CEO

Contents

Elomatic has donated this year's Christmas gift funds to develop the Tampere University Hospital's pediatric clinic in Tampere, Finland.

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Engineering for sterile product manufacturing facilities

– A GMP overview

Text: Elomatic India and Heikki Niskanen

Processing of sterile medicinal products is one of the most critical operations in pharmaceutical manufacturing due to the highly technique-driven processes and the potential detrimental impact on patients. Since sterile manufacturing is subject to inspections by different regulatory authorities, such as the US FDA, WHO and EMA, it is imperative to be thoroughly familiar with Good Manufacturing Practice (GMP) regulations and their application.

It is noteworthy that most GMP regulations describe what needs to be accomplished, rather than how it should be accomplished. A disciplined approach is, therefore, required to meet the requirements.

This article provides an overview of the regulatory guidelines and the fundamental GMP requirements with regards sterile manufacturing of medicinal products, with a particular focus on engineering aspects. It should be remembered, however, that engineering is only the basis and that quality assurance is vitally important. Manufacturing must strictly follow the carefully established and validated methods of preparation and prescribed procedures. An overview of the relevant regulatory authorities and their publications is provided in the info box (see overleaf).

Sterile manufacturing processes require close coordination and interaction between ***personnel***, ***equipment systems***, ***cleanroom and support facilities***, and ***sterilized components***.

Recommendations by the various authorities regarding premises, room classification, area classifications for various processes, equipment, personnel, processing, and sterilization are outlined in the following paragraphs (according to WHO's guidelines and with comparison to guidelines of other regions).

Risk management concepts (ICH Q9 guidance) and modern pharmaceutical quality systems (ICH Q10) should be introduced in the design and during production of pharmaceutical preparations. These concepts are already noted in the Sterile Product Manufacturing Facilities guide (Volume 3, Sept. 2011, ref. 9) by ISPE (International Society for Pharmaceutical Engineering) and are under preparation and discussion in the EU (Concept paper on the revision of Annex 1, February 2015) as well as in the Pharmaceutical Inspection Convention's co-operation scheme (PIC/S).

It needs to be kept in mind that the manufacture of sterile preparations should be carried out in clean areas, and operations are divided into two categories:

- products which are terminally sterilized; and
- products which are produced aseptically at some or all stages.

Tables 1a and 1b on page 8 illustrate typical production operations in different clean room areas in these two sterile manufacturing categories.

Manufacture of sterile preparations

Each manufacturing operation in the manufacture of sterile products requires an appropriate level of environmental cleanliness of the operational state to minimize the risk of particulate or microbial contamination of the product or materials being handled (ref. 5).

For ***processing*** it is recommended that separate facilities be used for products that contain live microorganisms and those that don't, except when the product contains properly inactivated organisms, or the deactivation/containment can be demonstrated/validated. All possible efforts should be made to reduce the bio-burden even before sterilization. These guidelines also guide the media fill procedure, media selection, batch size, frequency, and interpretation of simulation results for the validation of aseptic processing.

Minimizing and validating the time interval between various processing stages is recommended, for example, between equipment cleaning and sterilization, equipment sterilization and formulation, as well as between formulation and product sterilization. These guidelines also highlight specific precautions and advantages of isolator and blow-fill-seal technologies. The EU GMP and WHO focus on routine monitoring and frequent leak testing of isolators and glove/sleeve systems.

One of the most important laboratory controls is the environmental monitoring program. The monitoring program should cover all production shifts and include air, floor, walls, and equipment surfaces, in particular surfaces that come in contact with the product, container, and closure.

Sterilization

Various ***sterilization*** methods such as heat sterilization, filtration sterilization, radiation sterilization, and ethylene oxide sterilization are accepted by the authorities; but where possible, heat sterilization should be the method of choice. Each load type and load pattern has to be validated. Biological indicators should be considered as an additional method for monitoring sterilization and indicators such as autoclave tapes and radiation sensitive colour discs should be used to clearly distinguish the sterilization statuses of objects.

Whenever possible products intended to be sterile should be terminally sterilized with heat in the final container (ref. 5). Filtration sterilization is acceptable when sterilization in the final container is not possible due to the instability of a formulation or incompatibility of a pack type. Since sterile grade filters (≤0.22 µm or less) cannot remove all viruses and mycoplasma; consideration should be given to some degree of heat treatment to complement the filtration process.

It is recommended to use another sterile grade filter immediately prior to the filling point. The maximum usage duration of a single filter should be demonstrated by validation. Filter integrity testing requirements are also suggested in the guidelines and filters should be non-shedding and not affect the product composition via absorption/leaching.

The FDA requires ***sterility testing*** methods to be accurate and reproducible while the EU GMP and WHO point out that sterility tests applied to the finished product should only be regarded as the last in a series of control measures whereby sterility is assured. The test should be validated for the product(s) concerned.

Personnel

It is suggested that ***personnel*** be minimized in clean rooms. All personnel including housekeeping and maintenance staff should be trained in manufacturing (aseptic techniques), cleanroom behaviour, personnel hygiene, gowning and basic microbiology (ref. 1). To avoid cross contamination dedicated persons should be employed unless rigorous and clearly defined decontamination procedures have been followed.

Wrist-watches, cosmetics, and jewellery shall be strictly avoided (refs 3, 6). These guidelines also suggest appropriate gowning requirements with respect to clean room grades, gown material quality, frequency of changing clothes and gloves, sanitization of gloves, and requirements for dedicated and separate laundry.

Premises

With regards ***premises*** all the regulatory authorities agree that the design of a given area needs to satisfy microbiological and particle criteria defined for the operational activities along with the fulfilment of requirements for equipment, components, and products. The recommendation is for smooth, impervious, and sanitizable surfaces with sealed false ceilings. They advise against drains in grade A or B areas. For other grades they indicate that equipment drains should be equipped with air gaps and floor drains with water seal/traps.

These guidelines also provide the necessary input for room pressure differentials, air flow rates, air flow patterns, interlocks for change rooms, and the number of change rooms (separate changing rooms for entering and leaving may be desirable, ref. 3). They also indicate that swing doors should open into high-pressure areas and be provided with self-closers and that unnecessary access should be restricted to critical manufacturing areas.

Nowadays ISO 14644-1 standards for clean room classification should be used for the classification of cleanliness regarding the concentration of airborne particles (ref. 8). The maximum permitted concentration of particles, C_n (particles per cubic meter of air), for each considered particle size, D (micron), is determined from the equation:

$$C_n = 10^N \times \left(\frac{0.1}{D}\right)^{2.08}$$

where N is the ISO Classification Number.

Info box
Regulatory authorities and relevant publications

US Food and Drug Administration (FDA)

The FDA publishes regulations and-guidance documents. Its Code of Federal Regulations (CFR) is a codification of the general and permanent rules published by the Federal Government, which is divided into 50 titles that represent broad areas subject to federal regulation.

Title 21 of the CFR is reserved for FDA rules and updated annually on April 1. It contains general regulations for pharmaceuticals including manufacturing, processing, packing, or holding of a drug, and rules for design and construction features of buildings and facilities, ventilation, air filtration, as well as air heating and cooling and directions regarding the use of defined areas and controlled conditions to prevent contamination (Part 210, and 211). It also covers general instructions for equipment selection with respect to equipment design, size and location, construction, cleaning and maintenance, as well as guidelines for automatic, mechanical and electronic equipment and filters.

The CFR delineates GMP for complete manufacturing activities from raw material issuance to final product dispatch from the facility. There are also special regulatory parts for Quality Systems (Part 820) and Electronic Records (Part 11).

The FDA's guidance documents represent the agency's current thinking on a particular subject and as non-binding guides they act as *the reference* for inspectors and manufacturers. The most relevant guidelines for the manufacturing of sterile products are contained in Guidance for Industry: *Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice (Sep 2004), and Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination (April 2013).*

European Union GMP (EU GMP)

The rules governing medicinal products in the EU are published in various EudraLex volumes containing EU legislation and guidelines that support the basic legislation. Volume 4 of the European publication contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for human and veterinary medicinal products specified in EU directives.

Directive 2003/94/EC (8 Oct 2003) lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use while Directive 91/412/EEC (23 Jul 1991) covers the principles and guidelines of good manufacturing practices for veterinary medicinal products. Annex 1, *Manufacture of Sterile Medicinal Products, (Nov. 2008*) of Volume 4 of European Good Manufacturing Practice Guidelines specifically explores sterile medicinal product manufacturing.

World Health Organization (WHO)

One of the WHO's constitutional functions is to provide objective and reliable information and advice in the field of human health, a responsibility that it fulfils in part through its extensive programme of publications. WHO expert committees have made numerous recommendations contained in annexes to several WHO Technical Report Series (TRS). Today TRS 986 (2014) Annex 2 profiles the WHO's thinking with regards the main GMP principles for pharmaceutical products.

The *WHO Good Manufacturing Practices for Sterile Pharmaceutical Products (Annex 6, WHO Technical Report Series 961, 2011)* describes its regulatory requirements for sterile manufacturing.

International Organization for Standardization (ISO)

The ISO has published a number of standards relevant to pharmaceutical manufacturing, of which ISO 14644 for clean rooms and associated controlled environments is the most adhered to by industry.

ISO 14644
Cleanrooms and associated controlled environments

Part 1:	Classification of air cleanliness
Part 2:	Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
Part 3:	Test methods
Part 4:	Design, construction and start-up
Part 5:	Operations
Part 7:	Separative devices (clean air hoods, glove boxes, isolators and mini-environments)
Part 8:	Classification of air cleanliness by chemical concentration (ACC)
Part 9:	Classification of surface cleanliness by Particle Concentration
Part 10:	Classification of Surface Cleanliness by Chemical Concentration

Table 2 presents selected airborne particulate cleanliness classes and the corresponding particle concentrations for particles equal to and larger than the considered sizes shown.

The US FDA defined area classification is provided in Table 3. USFDA considers only In-operation condition and for 0.5 µm particle size only.

The EU GMP & WHO defined area classification is provided in Table 4. EU GMP & WHO considers limits 'at rest' as well as 'in operation'. Also, these regulations consider 5 µm particle size along with 0.5 µm particle size. These regulations don't define 'in operation' limits for Grade-D; the company should establish in operation limits based on a risk analysis and on historical data where applicable.

During operation the manufacturer should monitor airborne particles and microbiological contamination. In this context FDA accepts the use of settle plates only as optional for continuous air sample measurements (Table 5a); while for WHO / EU GMP, the use of settle plates and glove prints are compulsory (Table 5b).

A new version of EU GMP Annex 15 (Qualification and Validation) has been published describing the principles of qualification and validation for facilities, equipment, utilities and processes. Annex 15 takes into account current changes to other sections of EudraLex, Volume 4, Part I, the relationship to Part II, Annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation, and changes in manufacturing technology. This version has been operational from 1 October 2015.

Equipment

For ***equipment*** the guidelines suggest that a conveyor should not pass from a Grade A/B room to a lower grade room unless the conveyor is continuously self-sanitized. They also suggest that the technical parts of equipment should be placed outside clean rooms and that equipment and the clean room be cleaned, disinfected and/or

Table 1a: Operations in various grades for terminally sterilized products – EU GMP (ref. 3)

Terminally Sterilized Products	
Grade	Operations
A	■ Filling of 'unusually at risk' products
C	■ Filling of Products ■ Solution preparation of 'unusually at risk' products
D	■ Solution preparation ■ Components preparation for subsequent filling

Table 1b: Operations in various grades for aseptic preparations – EU GMP (ref. 3)

Aseptically Processed Products	
Grade	Operations
A	■ Aseptic Preparations ■ Product Filling
C	■ Preparation of solution to be filtered
D	■ Component handling after washing

Table 2: Area Classification – ISO (ref. 8)

ISO Classification Number, N	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below					
	0.1µm	0.2µm	0.3µm	0.5µm	1µm	5µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10000	2370	1020	352	83	
ISO Class 5	100000	23700	10200	3520	832	29
ISO Class 6	1000000	237000	102000	35200	8320	293
ISO Class 7				352000	83200	2930
ISO Class 8				3520000	832000	29300
ISO Class 9				35200000	8320000	293000

Table 3: Area Classification – US FDA (ref. 1)

Clean Area Classification (0.5 µm particles/Cu.ft)	ISO Designation	≥0.5 µm Particles /Cu. m
100	5	3,520
1000	6	35,200
10000	7	352,000
100000	8	3,520,000

Table 4: Area Classification – EU GMP / WHO (refs 1, 5)

Area Grade	Maximum permitted number of particles per cubic meter greater than or equal to the tabulated size				Remarks
	At rest		In Operation		
	0.5 µm	5 µm	0.5 µm	5 µm	
A	3520	20	3520	20	For both (at rest & in operation) ISO 5 for 0.5 µm particles & ISO 4.8 for 5 µm particles
B	3520	29	352000	2900	ISO 5 'at rest' & ISO 7 'in operation'
C	352000	2900	3520000	29000	ISO 7 'at rest' & ISO 8 'in operation'
D	3520000	29000	-	-	ISO 8 'at rest'

Careful and systematic adherence to guidelines is key in delivering facilities and processes that can pass strict GMP requirements.

sterilized after maintenance work (except when the cleanliness and asepsis is maintained during maintenance work). The WHO recommends using dry heat/moist heat to sterilize the equipment as far as possible.

It is further recommended that WFI be kept at temperatures (>70 °C or NMT 4 °C) that prevent microbial growth and that planned maintenance and validation of critical process equipment be conducted. Processing equipment and systems should be equipped with sanitary fittings and valves. The WHO also indicates that threaded pipe connections should be avoided.

Other guides

The International Society for Pharmaceutical Engineering (ISPE) has prepared a guide for engineering Sterile Product Manufacturing Facilities (ref. 9). It is a valuable book offering consistent interpretation of facility design, construction, commissioning and qualification. It takes into account the guidelines referred in this article and provides practical and illustrated examples of the implementation of good engineering practice.

It should be kept in mind that other standards and guidelines are available in this subject area. One of these is the ISO 13408-1 standard "Aseptic Processing of Healthcare Products", which adds value in the design of aseptic processes.

Careful and systematic adherence to the guidelines described in this article and others is key in delivering facilities and processes that can pass the strict Good Manufacturing Practice requirements. Getting it right is crucial in gaining access to markets and ensuring the safety of end users.

Table 5a: Microbiological contamination limits – US FDA (ref. 1)

US FDA		
Area Class	Air Sample (CFU/m^3)	Settle Plates (CFU/4h)
100	1	1
1000	7	3
10000	10	5
100000	100	50

Table 5b: Microbiological contamination limits – EU GMP / WHO (refs 3, 5)

EU GMP / WHO				
Area Grade	Air Sample (CFU/m^3)	Settle Plates (CFU/4h)	Contact Plates (CFU/plate)	Glove Print (CFU/Glove)
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

References

1. Guidance for Industry: *Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice (Sep 2004), FDA*
2. Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination (April 2013), FDA
3. Annex 1, *Manufacture of Sterile Medicinal Products, (Nov. 2008)*, Eudralex Volume 4, EMA
4. Annex 2, *Main principles of good manufacturing practice for pharmaceutical products.* Technical Report Series (TRS) 986 (2014), WHO
5. Annex 6, *Good Manufacturing Practices for Sterile Pharmaceutical Products,* Technical Report Series (TRS) 961 (2011), WHO
6. Q9, *Quality Risk Management*, ICH
7. Q10, *Pharmaceutical Quality System*, ICH
8. ISO 14644-1. *Clean rooms and associated controlled environments. Part 1: Classification of airborne particles.* Geneva, International Organization for Standardization.
9. *Sterile Product Manufacturing Facilities* (Volume 3, 2nd Ed., Sept. 2011), ISPE (International Society for Pharmaceutical Engineering)

About the author

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Mr. Niskanen has worked over two decades in the pharmaceutical and biotech industry as a scientist, qualified person and quality director. At Elomatic his specialty is pharmaceutical engineering. He currently holds the position of Senior Consulting Engineer at the Elomatic Turku office.

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A practical approach and cleanroom

to GMP cleanrooms HVAC

Text: Markku Mäkinen

Identifying the most practical approach to achieve Good Manufacturing Practice (GMP) cleanrooms and cleanroom HVAC in the pharmaceutical industry does not require an "out of the box" or innovative approach. It rests, rather, on the comprehension of and adherence to a set of basic rules that have been penned by several GMP regulatory authorities. Rules are nevertheless open to subjective interpretation and herein lie some potential pitfalls. The International Society for Pharmaceutical Engineering (ISPE) provides invaluable and much needed guidance in this regard.

The most commonly used GMP regulations that govern the design of pharmaceutical cleanrooms and cleanroom HVAC systems include the EU GMP, PIC/S GMP, FDA cGMP, and WHO GMP.

What is clean and how particle-based cleanliness is specified depends on what standards are applied. The world community of cleanroom designers mostly follows the ISO 14644 standard family for this purpose. Cleanroom designers and builders should concentrate on the first five parts of the standard family depicted in Table 1.

ISPE has provided a set of tools that facilitates a clearer understanding of the application of different GMP regulations, standards and guidelines in everyday work. Without these baselines it would be difficult to find suitable solutions to GMP matters. ISPE creates a bridge between pharmaceutical engineers and regulative authorities by writing baselines, good engineering practices and monthly articles in its "Pharmaceutical Engineering" magazine.

The ISPE publication series includes ISPE Baselines, ISPE GAMP Guidance documents, ISPE Guides and Good Practice Guides, ISPE Investigational Products Resources, and ISPE Regulatory. This excellent source of reference information combined with engineers' practical experience allow most clients' GMP related questions to be solved. Local laws and codes naturally have to be applied in every aspect in order for project goals to be fulfilled. Once a project has started the ISPE general V-model should be followed (see Figure 1)

According to the V-model all GMP projects should start with a properly executed risk assessment based approach which leads to the appropriate Validation Master Plan (VMP) and finally to project-specific User Requirement Specification (URS). All GMP cleanroom projects should follow this generally accepted route:

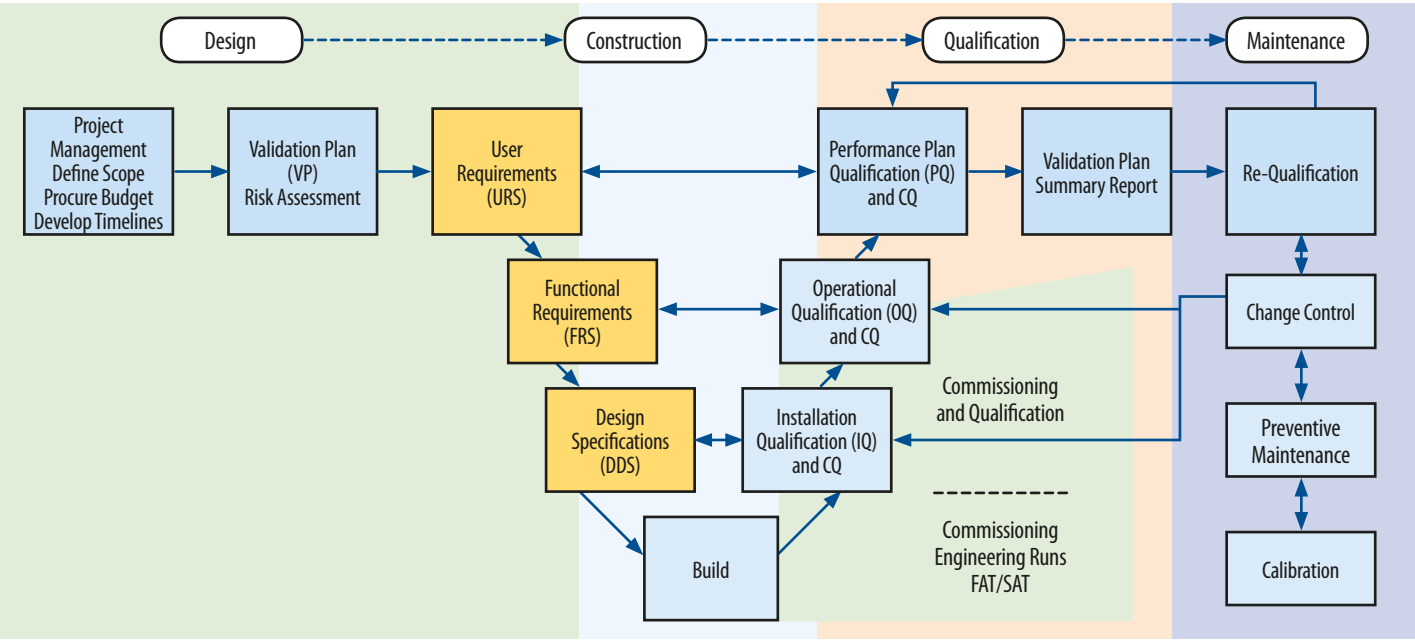
Conceptual Design
↓
Basic Design (or Functional Design)
↓
Detail Design
↓
Design Review and/or Design Qualification
↓
Implementation (Construction)
↓
Installation Qualification
↓
Operational Qualification
↓
Performance Qualification

Every phase has to be approved and completed with documented confirmation before proceeding to the next phase. It all starts from the user requirements and ends with the very

▶ *Table 1. The first five parts of the standard family are of importance for cleanroom designers.*

EN-ISO 14644-1	Classification of Air Cleanliness
EN-ISO 14644-2	Specifications for Testing and Monitoring to Prove Continued Compliance with ISO 14644-1
EN-ISO 14644-3	Test Methods
EN-ISO 14644-4	Design, construction and start-up
EN-ISO 14644-5	Operations

▼ *Figure 1. The ISPE general V-model*



same user requirements. All requirements in the URS need to be fulfilled or approved with documented deviations.

User requirements

When the URS for cleanrooms or cleanroom HVAC is written in the conceptual design phase by the plant operator (often with engineers' assistance) and approved, one can proceed to the basic design phase (or the functional design). the URS is arguably the most important document in the whole GMP project as it defines all the users' (GMP) critical demands for the process, clean utilities, cleanrooms, cleanroom HVAC and black utility. URS in the GMP context means a documented definition of the key requirements stated by the user.

The URS must state what GMP regulations should be followed and what cleanliness grades are required. EU GMP and FDA cGMP requirements are the two mostly referred to but also WHO and Japanese regulations can be used if applicable.

Cleanrooms can be constructed in various ways, but the first thing that has to be solved is the layout, which is governed by basic rules. Figure 2 displays the main principle of a shell-like barrier system where the cleanliness grades are always separated by personnel airlocks, material airlocks or pass-through cabinets.

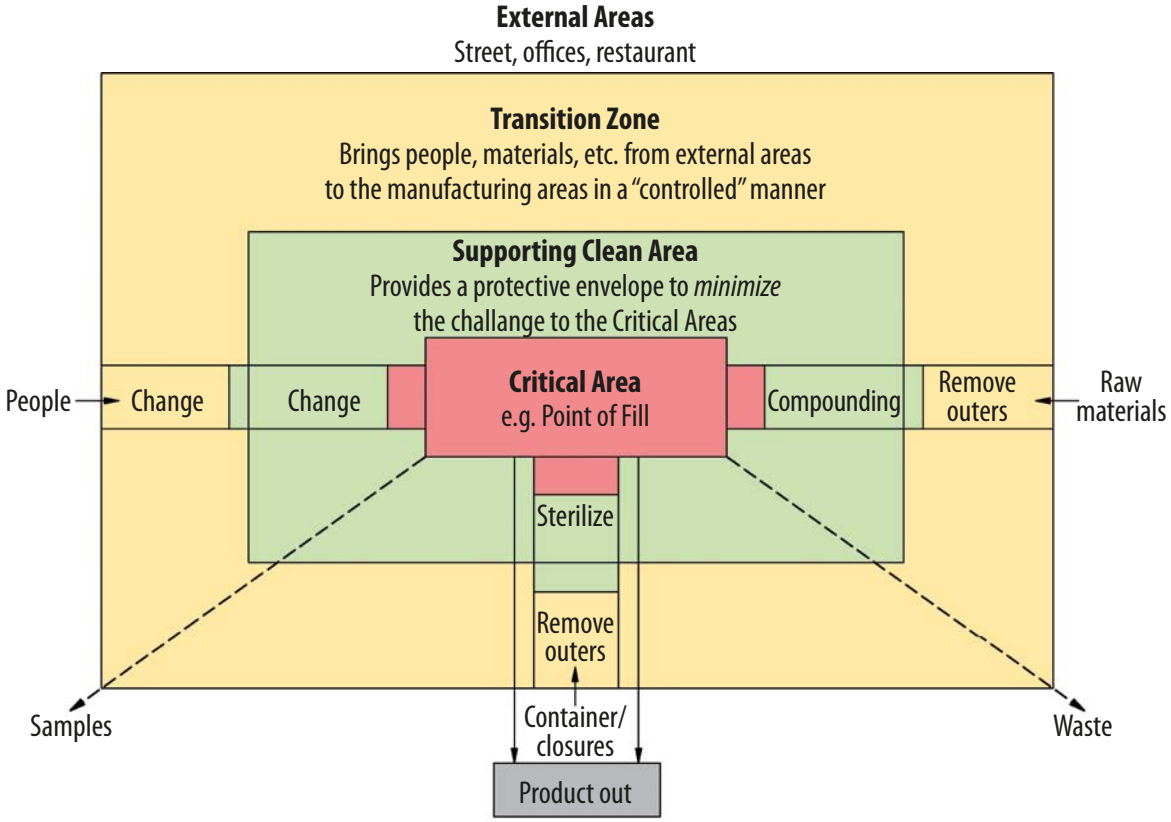
Layout design should only be started once a clear understanding of the user requirements has been gained. The basic rules for airlocks and pressure cascading regimes should, however, be checked first. Here again ISPE has some useful models. See Figure 3 (overleaf) for a layout with cleanliness grades and pressure cascading.

There are some differences in cleanliness grades between the US and EU which need to be kept in mind when designing cleanrooms for different regulatory environments. US GMP covers three cleanliness grades: supporting clean areas in two grades and critical areas. EU GMP includes four cleanliness grades: A, B, C and D. This difference affects design especially when sterile drugs are produced in aseptic processing.

The crucial role of HVAC

Once layout work is completed the HVAC designer can begin working. HVAC is only a small part of a cleanroom – but a very important part. Without a well-functioning HVAC system the desired conditions for production might not be achievable. HVAC systems for cleanrooms are relatively expensive and take up much space, but are essential for the critical product parameters.

► *Figure 2. A shell-like barrier system*



HVAC systems also represent large operating costs. It firstly needs to be decided what type of ventilation principle would best satisfy the URS requirements: recirculated air or outside air? Recirculated air means a ventilation system where e.g. 80% of air flow is in constant circulation and only 20% is replaced with fresh air from outside. A 100% fresh air system uses non-recirculated air from the outside.

It is preferable to use recirculated air in a cleanroom ventilation system if it is not prohibited for any reason as the use of recirculated air reduces energy consumption and emission levels.

Direct and indirect impact systems

It is of critical importance to determine whether the HVAC system has a direct or indirect impact on the product. According to the ISPE guidelines a direct impact system "is expected to have a direct impact on product quality. These systems are designed and commissioned in line with Good Engineering Practice and in addition, are subject to qualification practices that incorporates the enhanced review, control, and testing against specifications or other requirements necessary for cGMP compliance." ISPE indicates that an indirect impact system "is not expected to have a direct impact on product quality, but typically will support a direct Impact system. These systems are designed and commissioned following Good Engineering Practice only. Indirect impact systems can affect the performance or operation of a direct impact system."

Once the impact type of the system has been determined, the appropriate commissioning and validation activities can be applied.

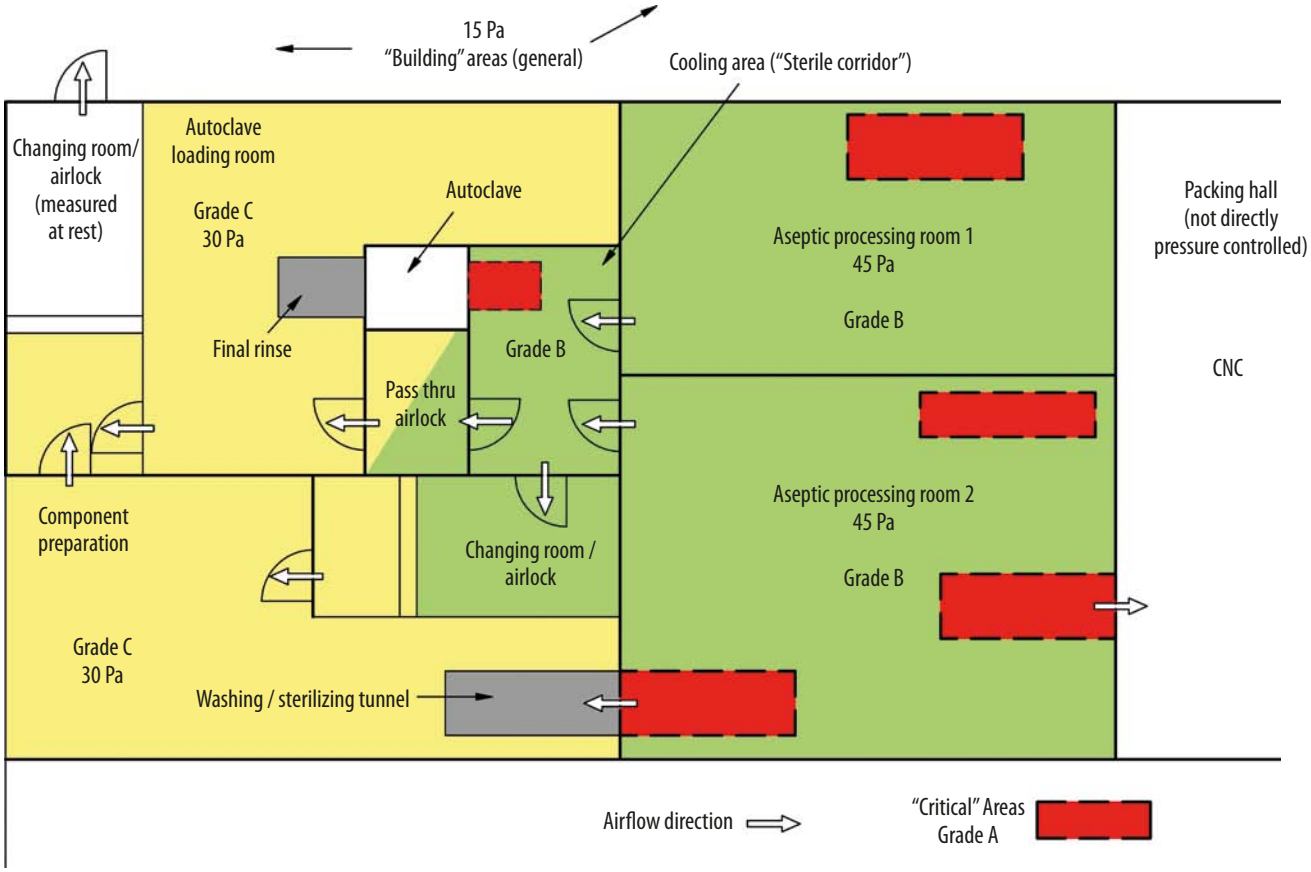
Critical parameters

The so-called critical parameters for products manufactured in a cleanroom environment need to be specified in the URS. According to the ISPE guidelines there are several factors that need to be considered and the onus is on the designer to gather all the relevant information (see the info box for details):

Validation of cleanrooms and cleanroom HVAC

The first validation activity in cleanroom and cleanroom HVAC projects is the DQ whereas the last is the approval of all the

▼ *Figure 3. A layout with cleanliness grades and pressure cascading.*



HVAC is a small but crucial part of any cleanroom implementation.

required design documents. When everything is complete a design qualification (DQ) report is drawn up and signed. It is a generally applied approach that construction work cannot be started before design qualification is done.

The next step is construction, which is followed by commissioning (C), installation qualification (IQ), operational qualification (OQ) and finally performance qualification (PQ). Each has to be approved before the next step can start and approval of all steps has to be documented.

ISPE defines commissioning as a "well planned, documented, and managed engineering approach to the start-up and turnover of facilities, systems, and equipment to the end-user that results in a safe and functional environment that meets established design requirements and stakeholder expectations".

Validation on the other hand "ensures that the facility and system qualification (DQ, IQ, OQ and PQ) requirements are communicated and met."

Conclusion

The procedures outlined in this article provide a practical guide to GMP cleanrooms and cleanroom HVAC in the Pharmaceutical industry. The basic rules change frequently and it is the responsibility of designers and engineers to follow this and keep up to date with related developments. This is the best way to ensure that the quality of our skills and services consistently meet the demand of our clients worldwide.

Info box

Critical Attribute	A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality (ICH Q8(R2))
Critical Process Parameter	A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality (ICH Q8(R2))
Critical Parameter (in HVAC)	A room variable (such as temperature, humidity, air changes, room pressure, particulates, viable organisms, etc.) that, by law or by determination from pharmaceutical product development data, affects product strength, identity, safety, purity, or quality (SISPQ)
Acceptance Criterion	The predetermined result of a special test. In HVAC, the upper and lower limits of the room environment (critical parameters). If these limits are exceeded, the exposed pharmaceutical product may be considered adulterated.

About the author

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Mr Mäkinen has worked within the Finnish and Swedish building construction industry, pharmaceutical industry and food industry for the last 34 years. His experience and know-how covers feasibility studies, conceptual design, basic design, detail design and site supervision. In recent years he has focused on pharmaceutical cleanroom HVAC projects. Mr Mäkinen joined Elomatic in 1982. After gaining experience further afield in 2006 he rejoined Elomatic in 2009 where he currently works as a Senior Design Manager.

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Raising competitiveness and innovation potentials

– EU funded RePCI project leading the way

In many industrial fields Europe is finding it increasingly difficult to compete with low-cost countries that are successfully challenging the value proposition of European technologies. European welfare is nevertheless still dependent on its industries and mechanical engineering know-how in general. In order to compete now and in the future the European Union, industrial companies and educational institutions have to think out of the box and create new synergies that foster the creation of competitive advantages. A recently completed EU funded project named Reshaped Partnerships for Competitiveness and Innovation Potentials in Mechanical Engineering (RePCI), which was coordinated by the JAMK University of Applied Sciences in Finland, is a good example of such thinking.

Since the inception of the EU it has provided funding for universities and companies via several different programmes. The Erasmus program, which was established in 1987 and is currently continuing under the Erasmus+ umbrella, is the EU's flagship education and training programme in the field of higher education. It not only supports mobility, but also provides co-funding to higher education institutions (HEI) through transnational cooperation projects. Within Erasmus the Life Long Learning Programme provides funding for higher education purposes in Europe. There is also large scale national funding available for universities. These resources have, however, not been optimally utilized to support the competitiveness of industrial companies and one of the purposes of RePCI project was to find and use those resources more effectively and in new way.

Participants from Finland, Hungary, Romania and Germany

The JAMK University of Applied Sciences in Jyväksylä, Finland led the EU funded RePCI project from 2013 to 2015. The RePCI project was tasked with creating a new strategic cooperation model between universities and industry that does not rely on individual interests and/or particular cases. The project participants included JAMK and Elomatic from Finland, Miskolc University, Konecranes and Fux from Hungary, Cluc-Napoca University and Prototip from Romania, as well as the Esslingen University of Applied Science in Germany. Festo from Germany participated in the project without EU funding.

The effectiveness of the cooperation was based on commonly selected competence areas between the companies and universities. The crux of the idea is that universities are able develop their educational offering better when they are thoroughly familiar with the competence requirements of industry players.

During the RePCI project cooperation agreements were signed between the universities and partner companies where the strategic areas of cooperation and the commitment to a systematic approach were confirmed. SWOT analyses of the partner companies and universities were conducted and served as the basis for competence de-

When universities are thoroughly familiar with the competence requirements of industry players they can develop a better educational offering.

◄ *A RePCI project meeting in Jyväskylä, Finland. On the far left, Arto Sampo, and on the far right, Pasi Ahonen.*

velopment, while action plans based on the common areas of development were also agreed.

The RePCI project allowed all participants to become more familiar with how other European HEIs cooperate with industry players. This information is extremely useful when planning new projects and cooperation activities. The possibility to benchmark teaching at HEIs in different countries and student competencies internationally is important for international companies and HEIs.

Another significant achievement of the project was the acquisition of the information and connections required for international student exchange. During the RePCI project student groups worked together on partner company tasks.

Product R&D projects in university laboratories

A further useful aspect of RePCI was that it provided the partner companies with information regarding the use of laboratory capacities at foreign universities for product research and development projects. The key point was understanding that HEIs are not only a source for new engineers, but have the potential to be partners in a continuous dialog about the future competencies required in the competitive global market of mechanical engineering products.

A competence coaching concept was also tested in Hungary and Romania during RePCI. The concept is based on the use of pedagogical approaches used in HEI institutions in the development of knowledge in partner companies. Staff from the HEIs worked as coaches in training projects inside partner companies. As a result the first competence matrix of job descriptions was created, which outlined what skills are required by industry players going forward. The industrial partners were also involved in ensuring that these identified competences were included as intended in the teaching programs.

A key result of the project was that it deepened the cooperation between the universities and companies involved and elevated the cooperation from an operational level to a more strategic level. Both the HEIs and their partner companies will reap the benefits of the deeper strategic cooperation over the long-term.

In some countries legislation needs to be adjusted to make the cooperation between educational institutions and companies easier. Development work is also required to identify the optimal interface and how to retain flexibility in scheduling. It is clear, however, that precisely the kind of novel cooperation seen during the RePCI project is what is needed on a much larger scale to bolster European competitiveness.

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Cyber-security enables automation

Text: Juhani Kääriäinen

more intelligent solutions

Cyber-security is becoming increasingly prominent when it comes to automation. It is noteworthy that technical solutions can only remove 33% of all security threats and that two out of three attacks originate from within our own organizations. Firewalls cannot prevent an attack if malware is installed directly to the target on-site. How can and should cyber-security be handled and what does the future hold?

Illustration © tigerlily713

The cyber-security mind-set combines information security, continuity management and societal crisis preparation. As a concept, it covers the so-called digital world, which is connected to physical world practices and society as a whole where individual actions and human error are an additional challenge.

Cyber-security can be divided into three different levels: ***strategic***, ***operative*** and ***technical***. At the strategic level, the company creates a cyber-security strategy that defines the actions that have a significant effect on performance. Actions that are greatly cyber-dependent can then be identified. Resources can thereafter be allocated to secure these critical actions and ensure that the residual risk is acceptable. It will then, for example, be possible to insure the residual.

The operative level directs the strategy towards real actions, and the technical level implements the technical actions according to the strategy. It is, then, important that cyber-security is managed and influenced by corporate management as a strategy. Management needs to work closely with the ICT department and ICT solutions must be based on management-defined strategic goals.

Taking cyber-security into account in automation

In automation, cyber-security is created through the chosen solutions. Equipment must be reliable, and from known operators. Cyber-security concerns all "intelligence" connected to the network or channel.

The creation of a new automation network, or the expansion of an existing one, must proceed in phases so that cyber-security is observed. Work must always begin with a risk assessment to determine the cyber-security risks of the automation system. After this, the company's cyber-security strategy, if one exists, comes into play, along with how that strategy is taken into account in the design or expansion of the automation system.

For technical reasons, the network must be segmented correctly and sensibly (DMZ, isolated, etc.) while determining access to company and other (external) networks. Equipment security surveys are an important part of cyber-security. Inspections of equipment with or without network connections include their identifier, type and explanation in addition to passwords.

Info box

The International Organization for Standardization defines the "preservation of confidentiality, integrity and availability of information in the Cyberspace" in its standard, ISO/IEC 27032:2012.

Security standards for industrial automation systems:

IEC 62443-1-1: Terminology, concepts and models

IEC 62443-2-1: Establishing an industrial automation and control system security program

IEC 62443-3-1: Security technologies for industrial automation and control systems

Cyber-security – visions for the future

Technological progress and digitisation enable the market of applied cyber-security. The growth of computing power and its distribution, storage capacity and network traffic create possibilities for growth in the IT business and cyber-security will, eventually, become a thing of utmost importance for everyone.

It is clear that *everything* that can be digitised will be!

Openness, networking and internationality will continue expanding and companies will communicate openly and learn from each other. A company's credibility won't be questioned if it is targeted in a cyber-attack. It is more credible to admit to having been attacked than not.

- Digital and physical security will merge and be referred to simply as *security*.
- Digital information will become an asset and a commodity.
- The reliability of digital data will become more important.
- The importance of personal information security will increase: identity theft, privacy, etc.
- We will have to learn to live with "hackers" who will gain access to our systems no matter what.

In the future data itself and refining raw data into useful formats will become a commodity.

The passwords should be strong and the equipment password list must be kept in a secure location. In addition, the possibility of upgrading old devices with new ones must be investigated.

In many cases, industrial networks are completely disconnected from the Internet, which means they can only be accessed on-site. Even in this case, the risk of a virus being installed on an on-site computer remains, regardless whether done on purpose or by accident. This is where "hardening" a computer is helpful.

Not all automation networks are, however, entirely disconnected from the Internet. Inspecting firewall configurations is integral to finding out whether unnecessary traffic has been blocked and default settings changed appropriately. For example, in a worst-case scenario, routers/firewalls may have been left in "nearly default" settings, and the connections to removed devices unrevoked.

In many cases, it is necessary to access an automation system from the outside. Remote access is provided with industrial-grade VPN equipment. The devices contain a firewall and a VPN server. A static IP address or dynamic DNS is required and the use of an Industrial VPN Appliance rather than a cloud-based remote connectivity service is recommended.

The design must also take physical information security into account, which entails limitations to access / disposal of sensitive papers / locking doors, etc. If necessary, a training session for proper use of the system can be held as a part of the delivery.

Usability is an integral part of cyber-security and also connected to physical information security. If a device becomes overly difficult to use due to security concerns it can in itself constitute a cyber-security risk. If a device's user experience is poor, it is possible that it may be misused or used in a way that is less secure. An example of this would be writing down complicated, frequently-changed passwords on a post-it note next to devices.

Manufacturing execution systems (MES)

Manufacturing execution systems add intelligence to manufacturing execution and optimisation. Intelligent field devices that are connected to an industrial-grade system with remote access require a secure framework to ensure their functionality. There is a large amount of information that can be gathered from the manufacturing process and that creates the possibility for, among other things, industrial espionage.

When discussing mobile devices, the term "fleet management" is often used. Workstations maintain a connection to a server that gathers a host of information and creates reports on, for example, working hours, machine location and its working condition.

Storing information (Big Data)

As MES and Fleet Management solutions become more common, it will be increasingly important to gather data. Over 99% of data is stored in digital format and the amount of stored data is constantly growing. As the Internet of Things (IoT) expands, intelligence is distributed ever further and linked via the Internet. Smart devices communicate with host machines, which increases the amount of gathered information. Raw data can be used to collect information and draw conclusions on cost efficiency, among other things. Some examples include actions related to preventive maintenance, such as measurements related to bearing heat or abnormal vibrations in a device.

As the amount of data grows, more attention will certainly have to be paid to data integrity and confidentiality. In the future data itself and refining "raw data" into a useful format will become a commodity. As this happens, it is paramount that the information is correct and unmodified.

About the author

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Juhani Kääriäinen holds a graduate degree in process automation from the Oulu University. After graduating in 2000 he has worked in research and training as well as in consulting and engineering. He also has several years' experience in sales and marketing. Currently Juhani works at the Elomatic Jyväskylä office as the Design Manager of the Electrical and Automation Engineering Team.

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Structural Analysis

– A brief history: 1980s to 2010s

Text: Timo Rauma

All consulting work comes with its own challenges and responsibilities – fiscal for the company and moral for the individual designer. In the field of structural analysis, this is abundantly clear at all times. Incorrect analysis can lead to personal injuries and significant economic ramifications. Structural analysis as a field of engineering has gone through many changes in the past four decades. In this article I take a closer look at these changes as I experienced them.

I signed my name on a work contract in September 1984, as a freshly graduated Master of Science from the University of Oulu. This meant moving from East Lapland to Finland Proper in the south, which was like moving to another country; I almost couldn't understand the dialect. I faced structural analysis with the same bewilderment.

Elomatic had employed structural analysts before, or at least so I understood, but the company didn't have any material on any performed structural analyses. At first, the work was much like laying a foundation – fortunately no rocket science was required in the beginning.

Changes in data transfer have turned more than just my field upside down. In the beginning, all we had were telephones and the post, along with customer meetings, which we definitely had more of than we do now. Structural analysis, especially in the early days, was a challenging field for gaining customers' and colleagues' trust.

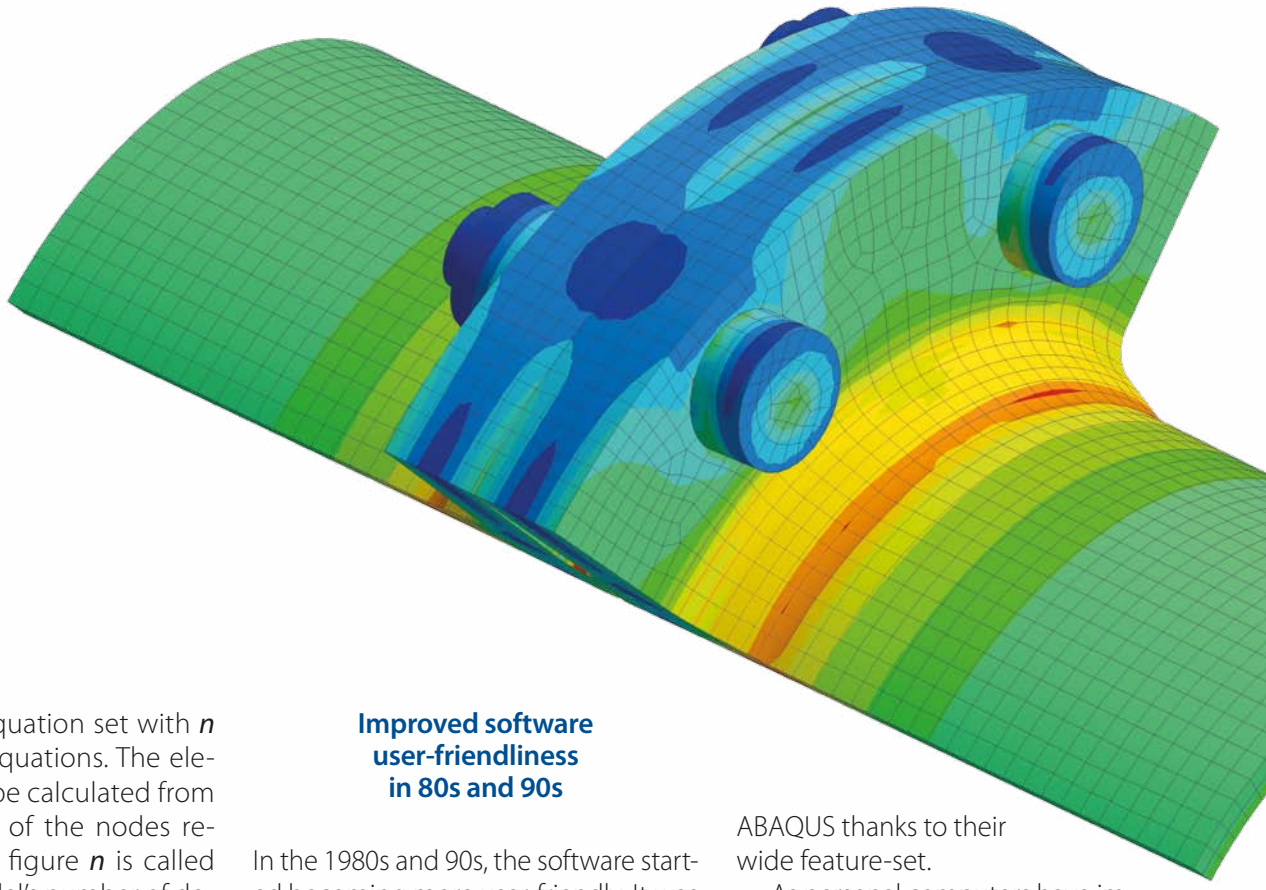
Calculation methods and tools have seen many changes

The fact that I was among the first to be allowed to use a calculator instead of having to use a slide rule in my matriculation exam tells its own story.

The early calculations were often based on standards and used analytical solutions we found in literature. Some well-informed customers provided very helpful dimensioning guides. I also spent some time looking for help in my study materials, but it soon became apparent that the theoretical slant was of little use for practical purposes.

Those analytical solutions, while being theoretically accurate, could only be used for structures with a simple and clear geometry. There are tables for beams supported in different ways that show the distribution deflections and internal forces that the point load or distributed loads can exert. Similar calculations also exist for plates. Calculation for more complicated structures was not, however, achievable with usual mathematics, so instead we had to settle for near-solutions gained with numerical methods. The most efficient of those methods we've found is the ***Finite Element Method*** (FEM), which is what we now use almost exclusively. The method is also often called Finite Element Analysis (FEA).

The finite element method involves creating a simplified calculation model on a computer for the structure under analysis using solution-appropriate structural parts that are called elements. The elements are joined together with node points. The solution of node displacements (translations and rotations) is, in fact,



a solution for an equation set with ***n*** unknowns and ***n*** equations. The element stresses can be calculated from the displacements of the nodes related to them. The figure ***n*** is called the calculation model's number of degrees of freedom, which indicates the magnitude of the solution.

This simplified description of a finite element method can be used as a bridge to our current level of progress. Financially sensible computers and software in the 1980s were able to calculate a solution with a few hundred degrees of freedom, and today we even use calculation models with millions of degrees of freedom. I remember a calculation we did on a train sleeper carriage's partition wall supporting structure – it took two weeks on a workstation machine (rough shell element model and non-linear large deflection calculation). Today, that would have taken no more than a few seconds.

The finite element method came into use in the 1950s in the USA. The method improved along with computers and a large amount of commercial software was already available in the 1970s. The software ran on mainframes and was hard to use, as the inputs had to be made manually in numerical format. Even the results had to be read in numerical form in massive tables. The analyst had to have an excellent understanding of what the calculation was, and confirmation of the results was necessary as well.

Improved software user-friendliness in 80s and 90s

In the 1980s and 90s, the software started becoming more user-friendly. It was called graphical interactivity: when creating a calculation model, the analyst would be given immediate graphical feedback, and the results were viewable in graphical form as well. As the development of personal computers kicked into full force in the 1990s, the finite element method started becoming a more useful and efficient tool.

We have used FEM calculations in structural analysis since the early 1980s. At the time we performed our beam calculations on HP computers, using Stafra software, which was made with HP Basic. For shell and solid calculations we used British software called Pafec (on a UNIX mainframe). Both of these 1980s software programs were slow and labour-intensive to use. The scope of the calculation models was extremely limited. We had to simplify the structural models and use symmetry and asymmetry constraints whenever we could. Since the 1990s and the personal computer "revolution", we've had access to a wealth of financially sensible structural analysis software suites. During the DOS era, we used Beamex for beam structure calculations and ANSYS for shell and solid element model calculations. In Windows, we used Finnsap at first, and in the last few years our analysts have been using both ANSYS and ABAQUS thanks to their wide feature-set.

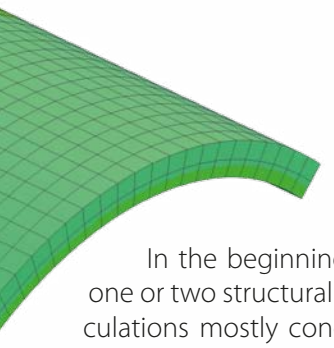
As personal computers have improved, they have become far more cost-effective solutions. The calculation software suites have become more user-friendly. The geometry of a structure can be transferred directly from 3D design software to the structural analysis suite. Using different non-linear analyses (large displacement, plasticity, stability, etc.) provides us with more possibilities to use the finite element method.

Role and challenges of structural analysts

Generally speaking, the role and challenges of a structural analyst are dependent on the nature of their place of employment. In extreme situations, companies that focus on a specific product or group of products can tailor the calculation methods to meet the needs of that specific product. The calculation involves the development, improvement and optimisation of a product the company has extensive experience in.

Engineering companies have a larger portfolio when it comes to both engineering and structural analysis – the analytics bring variety and challenges to our work.

A calculation that took two weeks in the 1980s can now be done in a few seconds.



In the beginning, when we had one or two structural analysts, the calculations mostly concerned our own engineering projects. Many assignments in the 1980s and 90s began with brainstorming, preliminary design and structural reviews. The analyst would take part in the project, if not as the project lead, in a capacity that helped carry the project through. Analysts would in other cases fill the time between calculation projects by taking part in engineering work. This helped them understand how structures work and to become familiar with manufacturing requirements.

Today, the structures under analysis are often already engineered or even manufactured, when for some reason, a structural analysis is required (by an authority or an inspection body, or when the structure does not meet requirements for some reason, etc.).

The "hand-in-hand" development of information technology and structural analysis software has, over the years, ended up with us using different pieces of software. The competition between analysis suite providers often leads to an accelerating versioning cycle as they add features and correct mistakes. Keeping up with their pace while providing competitive structural analysis services poses its own challenge. Today, students become familiar with the use of FEM program packages while studying for their degrees. The youth are growing up using information technology and are better equipped to adapt to the current world of calculation.

As calculation capacity increases and software develops, it has become possible to create very specific calculation models for very significant structures. Even in real situations, a structure's points of discontinuity are subject to peak tensions (or "hot spots") that are limited to the material's yield strength. The hot spots shown by calculation models may also be caused by an inappropriate element grid. It can be said that sometimes, the more you know, the more you suffer when interpreting the results.

The amount of norms and standards used in calculation is constantly growing, partly thanks to common EU standards and the internationalisation of work.

Balance between technology and practical know-how

Despite all the technological advancements and changes we have witnessed in the field of structural analysis over the years there are some things that haven't changed. It is, for example, still vitally important that analysts are convinced of the results of their work in one way or another. The modern analyst relies to a great extent on software tools and the immense processing power of modern computers to conduct analyses instantly. We could not even dream of such calculations 25 years ago. One nevertheless still has to be able to look at results and use your experience and common sense to question and verify results.

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After working as an assistant for one year at Oulu University, Timo joined Elomatic in September1984. His experience covers strength calculations of steel structures (e.g. cranes, harbour equipment etc.).

A standout project in his career was the strengthening of the bow structures and visors for all Viking Lines' car ferries. The work was based on rule modifications caused by the Estonia catastrophe and consisted of preliminary design, strength calculations, applying for maritime class approval and leading the drawing design work.

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Corrosion in district cooling systems

Text: Anita Vuorenmaa

District cooling is becoming an increasingly popular way of cooling properties and special facilities. In such cooling systems corrosion represents a serious risk to the integrity of the steel pipes used. The conditions in district cooling systems differ from those in district heating systems and are in many ways unique. In order to mitigate the threat posed by corrosion many factors have to be considered and controlled.

Corrosion refers to the deterioration of materials, usually metals, via chemical interactions with their environment (see the info box for an overview of the corrosion process). Corrosion can take many forms: *General* or *uniform corrosion* proceeds uniformly over the entire surface area as the oxidation and reduction occur on the same surface while the anode and cathode change their positions continuously. In water, though, corrosion tends to occur more often in its local forms. *Pitting corrosion* often originates from a scratch or a crack in a protective film and results in holes in the metal surface. A scratch or a pit functions as a local anode while the surface around it serves as a cathode. In district cooling systems local corrosion appears often as *crevice corrosion* where a crevice, joint or a hidden pit under a deposit can create a micro-environment that enhances the corrosion attack.

Galvanic corrosion can take place where different metals are present in electrical contact with each other – the less noble metal will become an anode and corrode. There are many components made of different materials in a district cooling system, which means

Photo © Turku Energia, Elina Kivil. Photo for illustration purposes.

that galvanic corrosion is also a potential threat in cooling networks.

Moreover, pipelines in a cooling system can also be damaged by *erosion corrosion*. This is due to chemical corrosion as well as mechanical wearing caused by high velocity fluids in the system. Loose particles, such as solid corrosion products, that are drifting in the flow can accelerate the wearing effect.

If a pipeline is exposed to residual or applied stresses in a corrosive environment *stress corrosion cracking (SCC)* may be induced. High pH levels and nitrite ion concentrations increase the risk of SCC for carbon steel pipes.

Info box
Basics of corrosion

When a metal corrodes it is oxidized and emits electrons (1). These electrons are consumed in reduction reactions at the cathode. Usually reduction occurs with oxygen or with water that contains oxygen (2) or with hydrogen ions (3).

$Fe \rightarrow Fe^{2+} + 2e^-$ (1)

$O_2 + 2H_2O + 4e^- \rightarrow 4OH^-$ (2)

$2H^+ + 2e^- \rightarrow H_2$ (3)

However, a corrosion cell will form and corrosion can occur only if all the following conditions are met:

1. There is both an anode (a surface to be oxidized) and a cathode (a surface where reduction takes place).
2. There is an electric potential difference between the anode and cathode.
3. There is a metallic path between the anode and cathode that allows the transfer of electrons.
4. The anode and cathode are submerged in the same conductive solution (electrolyte).

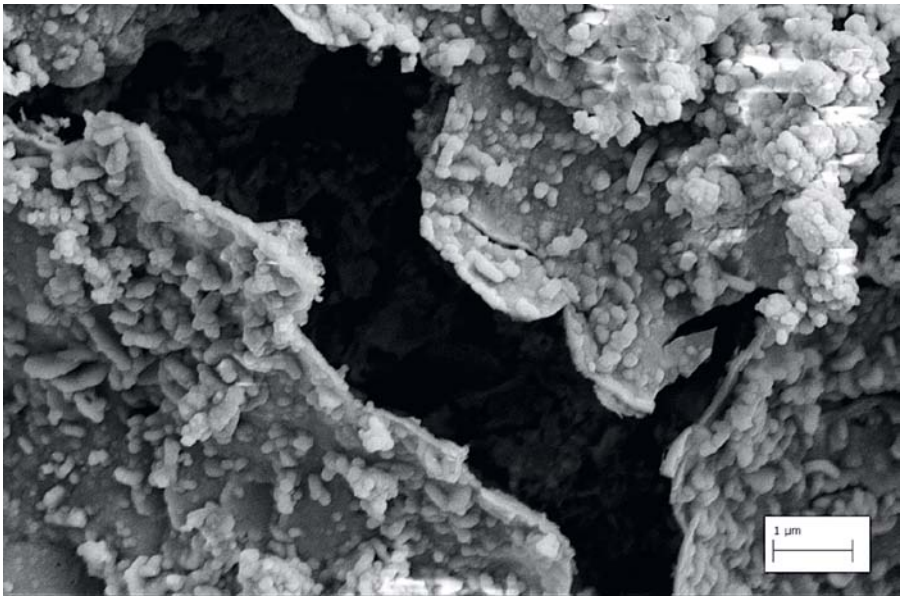

Photo © VTT

◀ *A scanning electron microscopy (SEM) image of microbial growth on the inside surface of a carbon steel pipe.*

The role of microbes in corrosion

Corrosion that is induced or affected by microbes, i.e. *microbiologically influenced corrosion (MIC),* has often been given too little attention. There is much evidence indicating that microbes can play a highly significant role in corrosion attacks. Many microbes are tolerant of harsh conditions and can live in unfriendly environments such as those found in district cooling systems. However, relating the observed corrosion attack to microbes can be difficult; finding microbes at the damaged site does not necessarily prove that microbes are to blame.

There are several ways microbes affect corrosion and not all of these are fully understood. Microbes essentially influence corrosion by changing the electrochemical conditions at the metal-solution interface. Micro-organisms, of which the most abundant are bacteria, live on a pipe surface in the form of a biofilm. Microbes can produce organic or inorganic acids and extracellular corrosive metabolites or concentrate chloride, oxygen, hydrogen or metal ions under the biofilm. The biofilm can act as a barrier that blocks the free movement of molecules and ions, thus affecting the concentrations of chemical substances. Consequently, the conditions under a biofilm can differ significantly from the conditions elsewhere in the system, potentially creating a corrosive microenvironment.

The role of microbes is made even more complicated by the fact that they can also inhibit corrosion. They can, for example, consume oxygen that is needed for cathodic reaction, produce inhibitory metabolites, or stabilize the protective film on the metal surface. Some microbes can also produce antibiotics that inhibit the growth of corrosion-inducing microbes.

A district cooling system is mostly an oxygen depleted environment. The most important microbes that cause MIC under anaerobic conditions are sulfate reducing bacteria (SRB). They can promote corrosion in different ways and cause severe corrosive damage. It has to be remembered though, that microbial communities consist of many different microbes and there are numerous complicated biochemical reactions and interactions involved.

Factors affecting the corrosion rate

The maintenance of proper water chemistry in piping systems is crucial in minimizing the corrosion risk. There are, however, many elements in water chemistry that interact, thereby making the system highly complex. Optimal control over the corrosion rate in a cooling network may still require some fine-tuning of the conditions and different elements in the system.

The two most critical factors in respect of the corrosion rate are the oxygen content and pH level. Oxygen typically accelerates corrosion markedly, but the relation is not that simple: a small amount of oxygen promotes the formation of an oxide layer that can protect the metal surface from corrosion. This kind of protective or passivating film on the surface of carbon steel usually consists mostly of magnetite Fe_3O_4 which – when conditions are favourable – forms a dense layer that adheres tightly to the steel surface.

However, excess oxygen or destabilization or destruction of the magnetite layer can increase the corrosion rate. In district heating systems hydrazine is used as a scavenger for residual oxygen, but its reaction rate is very slow in cooling network temperatures, which means that it does not really work in such conditions. There is still a lack of a simple and practical oxygen scavenger for district cooling systems.

Typically fluid acidity speeds up corrosion. A high hydrogen ion concentration accelerates the cathodic reaction, but a low pH also destabilizes the magnetite layer which makes the metal surface more susceptible to corrosion attacks. This is why water is kept alkaline in cooling systems. A very high pH can, however, also damage or destabilize the oxide layer. Thus the optimal pH in respect of corrosion control is usually 9–10.

"The maintenance of proper water chemistry in piping systems is crucial in minimizing the corrosion risk."

Water treatment is also used to gain low hardness and low conductivity. Chloride and sulfate ions are examples of strongly corrosive elements, but some salts that affect conductivity can also be corrosion inhibitors. A temperature rise is known to accelerate the corrosion rate as it usually does for chemical reaction rates.

However, the final effect is a sum of several factors. As the temperature rises the diffusion rate of oxygen increases, oxygen solubility decreases, pH falls, conductivity is enhanced and the properties of corrosion products can change.

The temperature also affects the growth rate of microbes. In district cooling systems temperatures are relatively cool and the differences are not that large: the temperature is usually about 8 °C in supply pipes and about 16 °C in return pipes.

Other factors in the system that affect the corrosion rate are e.g. the flow rate, materials and compounds that act as nutrients for microbes, and different metals that can cause galvanic corrosion. Loose particles such as magnetite deposits can induce corrosion through erosion and also by sedimentation – as particles deposit on the pipe surface they can form pockets that function as a suitable microenvironment for corrosion to develop or microbes to grow. In addition, differences in altitudes in the network can affect the distribution of gases, including oxygen.

Can plastic pipes be a corrosion risk?

In the future, high-density polyethylene (HDPE) plastic pipes may be used in district cooling systems. HDPE pipes have many advantages compared to steel pipes: They are light and flexible and therefore easy to install. They are also not vulnerable to corrosion nor do they erode easily. Moreover, the heat conductivity of HDPE is much lower than that of steel, which reduces the need for insulation.

The problem with HDPE pipes in water systems is that plastic allows some oxygen diffusion, which may lead to corrosion of steel parts. The level of oxygen diffusion is dependent on the material density, the wall thickness, the size of the exposed area, temperature, and whether the pipes are buried in soil or placed in tunnels or cellars.

Studies indicate, however, that there is only minor oxygen diffusion through HDPE pipes in district cooling systems. Oxygen leaks through pipe accessories during network operations in fact pose a much larger corrosion risk. Oxygen diffusion should not be a problem with HDPE pipes as long as there is sufficient steel in the network.

It is clear that corrosion control in district cooling systems requires careful water quality management, prevention of oxygen leaks, particle and sediment removal, and appropriate installation work to avoid contamination. Biocides are not usually a long-term solution in MIC mitigation. A much more sustainable way is to control the habitat conditions of microbes.

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Anita Vuorenmaa has worked at Elomatic since 2013. Her expertise covers a wide range of biological, chemical and environmental issues, as well as energy technology. In addition to bioenergy she has previously worked in ecotoxicological and microbiological research. At Elomatic her focus has, among others, been corrosion control and cleantech solutions such as ballast water treatment technologies.

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The new welding symbol standard

– something new, something old

Text: Anna-Mari Hämäläinen

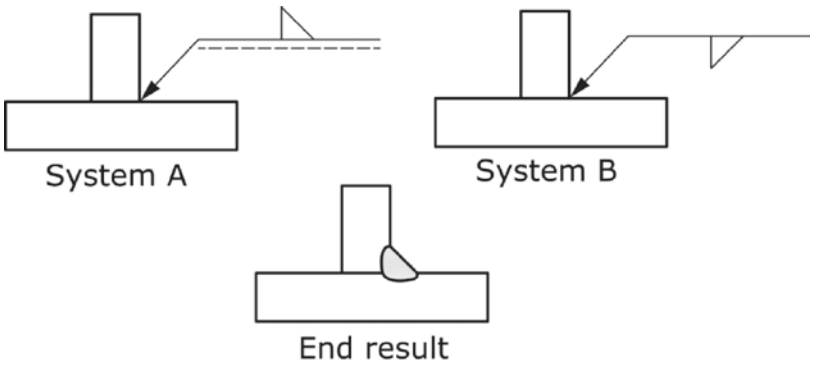
Many years have passed since the SFS-EN 22553 welding symbolic representation was approved in 1994. It has now come to its end of its shelf life and a new symbol standard has been introduced. Approved in 2014, the new welding symbol standard has brought new symbols and methods of indicating welds in more detail.

The basics of welding symbols have not changed. A welding symbol still consists of a reference line and an arrow line, both of which are required elements. The other elements of a welding symbol are the tail, as well as elementary and supplementary symbols. One of the most noteworthy additions in the new standard is that it identifies welding symbols that are used in most Pacific Rim countries.

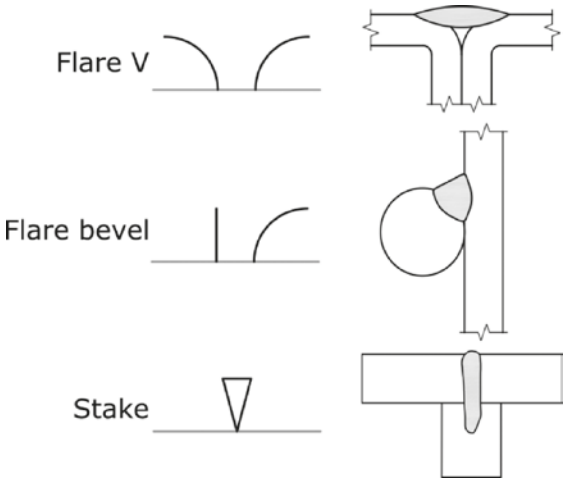
A compromise solution between the European system and Pacific Rim system could not be found in the new standard and as such it includes two different symbolic presentations. This means that there are two different systems to designate the arrow side and the other side. The European system (system A in the standard) uses a dual reference line which includes a continuous line to indicate the arrow side and a dashed line to indicate the other side. The Pacific Rim (AWS) system (system B in the standard) is based on a single reference line where the arrow side is always on the underside of the reference line, as shown in Figure 1.

When using welding symbols these two systems should not to be used alongside each other and there should be a clear indication as to which system is in use. All the new welding symbols are not available in the symbol libraries of all 3D-modeling software programs. Most of the new elementary and supplementary symbols can be found using a different symbol library, such as JIS, but some of the symbols unfortunately need to be handcrafted.

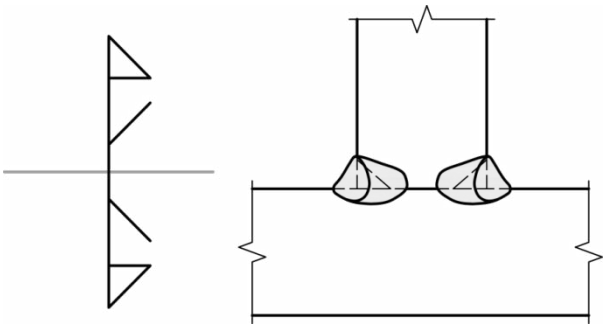
▼ *Figure 1. Systems A and B producing the same outcome*



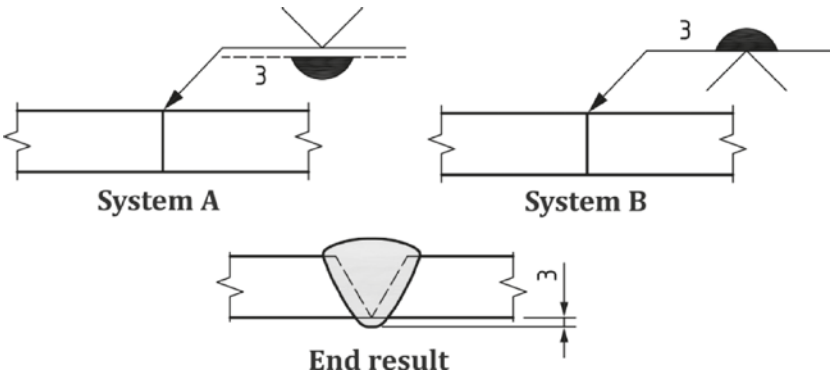
▼ *Figure 2. New elementary symbols*



▼ *Figure 3. Combining filled weld and bevelled preparation*



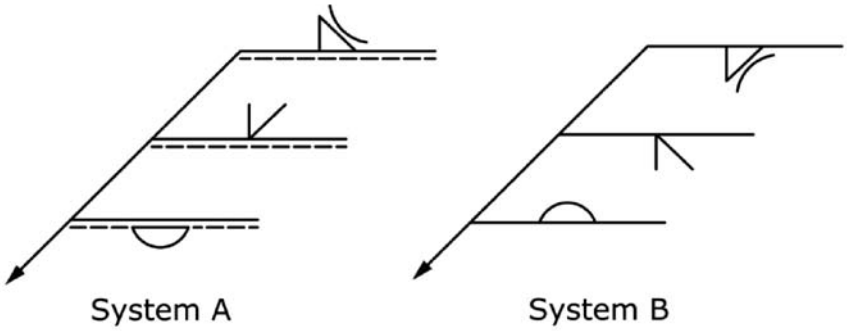
▼ *Figure 4. The same specified root reinforcement shown with both systems*



What's new with elementary and supplementary symbols

In the new standard some old symbols are used alongside new symbols, which have been added to clarify cross sections (see Figure 2). Flare V and flare bevel symbols are used with round corners and the stake symbol can be used with beam welding where the weld is narrow and deep. Older European standards did not recognize filled weld symbols on top of regular elementary symbols, but now this combined marking is possible in European drawings too, not only in AWS drawings (see Figure 3).

▼ *Figure 5. Welding operation order starting from the bottom up*

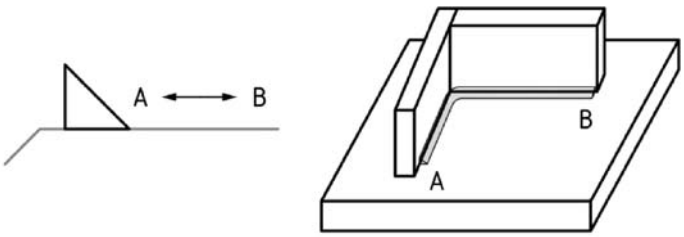


One of the new supplementary symbols is the specified root reinforcement for butt welds welded from one side (see Figure 4). The standard states that the "symbol shall only be used when complete joint penetration plus a specified minimum root reinforcement dimension is required".

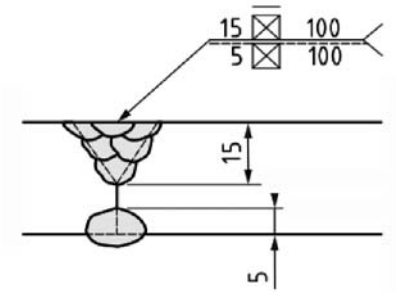
This minimum measure for root reinforcement can contradict the maximum root cap height in the welding quality standard (SFS-EN ISO 5817) if it is not taken into account. In the quality standard there is a maximum measure for the same root cap height. During weld quality inspections these two measurements can be in conflict if the minimum root reinforcement measure is greater than the allowed cap height.

There is a new way to emphasize the welding operation order if necessary. A multiple reference line has been included in the new standard and can be used to indicate the order of subsequent operations. Welding operations are piled up in a line so that the first operation is closest to the arrow.

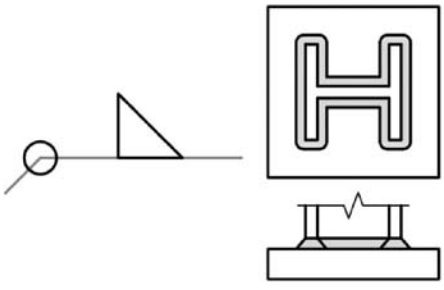
▼ *Figure 6. Weld from point to point*



▼ *Figure 7. Alternative butt weld symbol*



▼ *Figure 8. Weld all-around*



Point-to-point or full length?

The length of the weld has also received a makeover. The usual "non-measured" length is still valid and it is used to indicate that the weld is continuous for the whole length of the joint. If the length of the weld is shorter than the joint the start point of the weld should be marked clearly and the measurement marked on the welding symbol to the left of the elementary symbol. This is nothing new.

What is new, however, is that the weld is done from point to point. A continuous weld with the same weld type and dimensions, which does

(Figures 1–8 source: SFS-EN ISO 2553 Welding and allied processes)

The new standard has brought many useful improvements and additions to weld indications.

not start and stop at the same point can be marked with this new point-to-point symbol. The weld can continue around the corner and cover more than one joint. The start and end points have to be clearly indicated in the drawing.

Beneath the surface

As with weld lengths butt welds are full penetrating unless otherwise dimensioned or if other information, such as WPS, is referred to. The designer dimensions the required minimum penetration after strength calculation without assuming that the penetration will exceed the minimum measure. Manufacturers can then produce joint welding in the most practical way to attain the minimum demand for weld quality and sizing.

The new standard contains guidelines for the marking of dimensions for joint preparations, but implementation requires knowledge of the manufacturer and its WPS-documents. In cases where the preparations are dimensioned it cannot be assumed that another manufacturer would have the same dimensions in their WPS-documents, and therefore the same penetration with exactly the same preparation.

The same outcome can be achieved with different preparations. Small differences in dimensioning are not crucial when manufacturers have approved their WPS-documents with destructive testing and the penetration is confirmed.

There is a new useful welding symbol that can be used if the manufacturers are not known when welding drawings are being prepared (see Figure 7). The symbol contains only the weld quality and the required penetrating depth, which means that the manufacturer can decide what preparation to use to gain the desired quality and dimensions. This symbol is very new and it should not be assumed that everyone is familiar with it. It is recommended that designers ensure that the manufacturer knows the meaning of the symbol.

Small circle, big meaning

A supplementary symbol that has had many interpretations over the years is the all-around symbol. It is intended for use in cases where the weld starts and ends at the same point and during the weld the dimensions and joint type do not change (see Figure 8). This doesn't include circumferences of circular sections, holes or slots as they naturally start and end at the same point. In other words, all-around symbols can be used with profiles that have corners that need to be welded all around.

Sometimes the all-around symbol is used incorrectly. One of the most common situations is when the weld type is changed for a small part. The designer might not even notice this or just feel that it does not need a dedicated welding symbol. An example of this is when a joint is marked with an all-around filled weld and some part of the joint is a bevelled weld. This may cause confusion regarding how bevelled welds with fillet dimensions should be produced and how inspectors will deal with this.

This all-around symbol is not the symbol for "weld everywhere". When planning welds every welded joint should be checked individually, not only for weld markings, but also for the welding order and accessibility.

The new standard has brought many useful improvements and additions to weld indications. The new elementary symbols are an especially welcome addition. As manufacturing continues becoming increasingly international the need for an international symbol standard has likewise grown. The new standard will ensure that there are no longer diverging interpretations and misunderstandings between designers and manufacturers.

About the author

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Anna-Mari Hämäläinen has been working as a Special Designer at Elomatic since 2012. She is specialized in welding and has an IWS qualification (International Welding Specialist). She has consulted on welding issues and provided welding training to designers. She has also conducted mechanical design on a wide range of customer projects.

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Investing in technology and personnel development bears fruit

– *Case Cadmatic*

Investing in developing operations and personnel most often has long-term positive business effects. A good example of this is a project that was started in the early 1980s at Elomatic to take advantage of 3D technology to improve the design, visualization, distribution and total cost efficiency of engineering projects. The spin-off from this development, Cadmatic, is today an independent company and 3D design software used in marine and plant design projects all over the world.

All development projects naturally do not end in similar productized and commercial success stories. Case Cadmatic is, however, a reminder that when a knowledgeable and dedicated development team set their minds to improving their way of working, the results can be far-reaching and add value even beyond initial expectations.

Early days of plastic modelling

For the young, so-called digital native generation, it may seem unfathomable that engineering and design offices used to build large-scale plastic models of process plants and vessels. In the 1970s and early 1980s this was however state-of-the-art and skilled work, which was highly appreciated by customers. Plastic ship model technology was, in fact, instrumental in gaining Elomatic's first ship design contracts.

The advent of laser scanning technology at the end of the 1970s opened the door to visualising such plastic models on computers and led to ideas of designing plants digitally.

In 1983 a project was launched to develop a 3D plant design program and by 1985 the first pilot project using the new 3D technology was completed. The new technology proved to be much more efficient than traditional ways of working and competing systems available on the market at the time. As such it was decided in the early 1990s not only to make use of the software in engineering projects, but also to start marketing the software independently under the Cadmatic brand name.

It was at this time that Cadmatic also started its co-operation with Dutch partners Numeriek Centrum Groningen B.V. (NCG) to develop comprehensive 3D design solutions for ship design under the Nupas-Cadmatic brand name while continuing with plant design software development under the original Cadmatic name.

Strong growth

Over the years the software solution has developed into a top of the range engineering design solution for plant and marine design with a proven track record of optimizing its customer's resources around the world. More than 700 customer organisations are using Cadmatic software in 55 countries and since 1995 it has on average grown by 12,5% year on year.

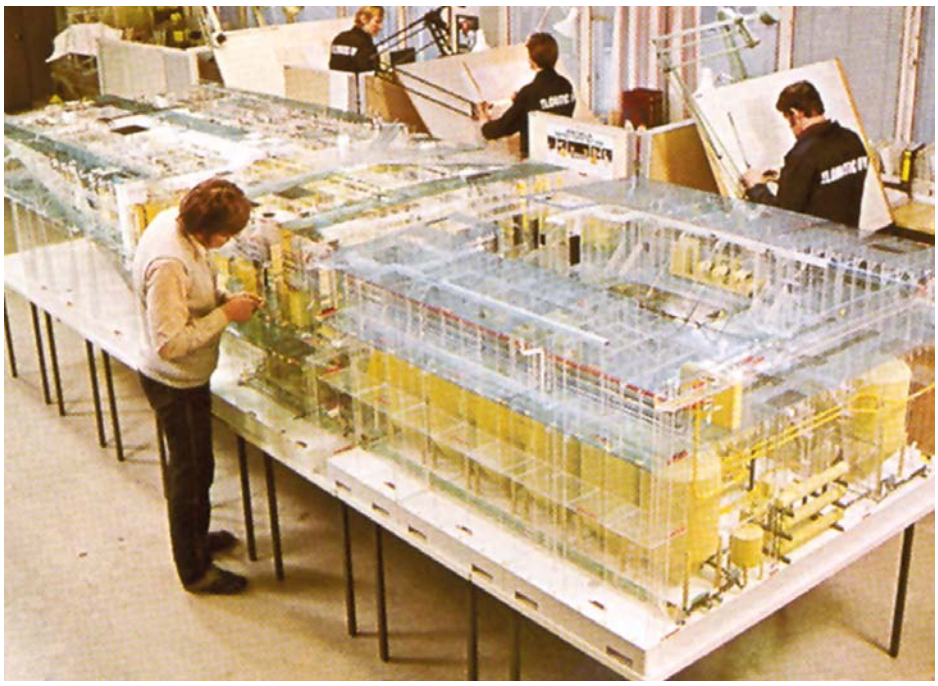
In case Cadmatic an investment in technology and personnel development has born significant fruits. This particular investment's story continues. One can naturally not foresee how each development project will end, but at the very least they have a very good chance of improving ways working and/or creating new skills and know-how that increase competitiveness.

Cadmatic and NCG combine business operations

A recent development has seen Cadmatic acquire all the shares and business operations of its long-term ship design software development partner, NCG, in September 2015. The strategic acquisition sealed the 23 year long cooperation between the companies and formed a leading international design and engineering software development vendor, which is widely used by marine and plant designers, builders and owners worldwide.

After the acquisition, Cadmatic's ship design software, formerly known as Nupas-Cadmatic has been rebranded under the Cadmatic name. Both the company's plant and marine design software solutions continue to show strong growth.

Text: Martin Brink



The roots of Cadmatic lie in the most tangible 3D engineering one can imagine – Elomatic designer at work at the end of the 1970s.

Cadmatic built its own user interface in the 1980s – a long time before windowing technologies were developed.

When Cadmatic acquired Numeriek Centrum Groningen B.V. in September 2015 it rebranded all products under the Cadmatic company and product name.

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Scientia vires est

At Elomatic we believe that our human capital is our most precious asset. With knowledge comes the power to shape the future.

We continuously develop our employees' know-how and strive to be leaders in our respective technical fields. We focus on packaging and delivering this know-how to ensure that our customers stay ahead of their competition.

The Top Engineer magazine offers our experts the opportunity to share their expertise and knowledge and to engage other technical experts with their writing. It is a publication by engineers, for engineers, and other technically-minded readers.

www.elomatic.com

New Elomatic premises at Innopoli in Otaniemi, Espoo

From the end of December 2015 Elomatic's personnel in Helsinki will have a new home in Otaniemi. The 770 m² premises are located in Building A at Innopoli 3 (Technopolis) on Vaisalantie 2–8, Espoo.

Innopoli is the largest and best known campus in the capital region. There are about 2500 employees and over 300 companies from start-ups to multinationals that operate from the campus. Having Aalto University and a high-tech cluster as neighbors bodes well for future product development networking and cooperation.

The campus lies right next to Ring 1 and is easily accessible by bus, car or bicycle. In addition a new metro line to Otaniemi will start operating by the autumn of 2016, which will further improve accessibility.