

White Paper

# **Module-Based Production in the Process Industry – Effects on Automation in the “Industrie 4.0” Environment**

Recommendations of the  
Modular Automation Working Group  
Following Namur Recommendation NE 148





## Impressum

### **Module-Based Production in the Process Industry – Effects on Automation in the „Industrie 4.0“ Environment**

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# 1. Introduction

## 1.1 Motivation

The subject of “Industrie 4.0” is currently on everyone’s lips. It is often spoken of in connection with “factory automation”. However, cyber physical systems, digitalization, networking and thus new business models are also gaining in importance for process industries and the manufacturers of measurement technology and process automation. Driven by ever shorter product launch times, the chemical/pharmaceutical industry, in particular, is developing modularization concepts for its process plants. In addition to shorter product launch times and more efficient engineering of the process technology, the aim is to considerably increase the flexibility of the process plants<sup>[1]</sup>.

While the chemical and pharmaceutical companies drive modular process design forward, there is the expectation that the automation technology (AT) should provide appropriate support in the process control systems (PCS)<sup>[2]</sup>. This is one of the findings of several case studies, which show that the modularization of processes is a) possible and b) profitable for the chemical and pharmaceutical industry, e.g. through the publicly funded project F3 Factory (flexible, fast, future)<sup>[3]</sup> in the EU’s Seventh Framework program.

Current Namur Recommendations (NE) define the requirements that automation must meet to do justice to the flexibility of modular process plants. In its NE 148<sup>[4]</sup>, Namur working group AK1.12 describes the requirements that must be met by AT manufacturers in order to provide the required functionality.

For batch processing, modular concepts have already been used productively in some application scenarios. NE 33<sup>[5]</sup> (basis for ISA 88) shows how process plants can be structured in levels to obtain the required flexibility. Studies

from AT manufacturers also reveal the advantages of modular automation technology over conventional automation.<sup>[6]</sup>

In 2013, the “Modular Automation” working group was established in the ZVEI specialist area “Measurement Technology and Process Automation of the Automation Division” with the aim of cooperating closely with the Namur working group AK1.12 and formulating a joint response of the working group members to NE 148.

During the working group’s work, it was found to be expedient to create a white paper containing the status of the discussions for further talks with Namur. The presented document focuses on control systems and instrumentation. Predefined standardized electro-mechanical modules for plant engineering are a prerequisite.

## 1.2 The Challenges from NE 148

At its core, NE 148 presents the hypothesis that the architecture of today’s process systems is little suited to the use of modules and formulates a series of requirements for enabling their necessary integration.

The demand for standardized manufacturer-independent interfaces, in particular, requires the cooperation of all manufacturers. This white paper aims to formulate the various requirements, responses and perspectives. However, it also aims to identify the manufacturers’ technical or economic limits.

It must be stressed that this white paper reflects a working state that serves as a basis for discussion with Namur AK1.12. This white paper neither claims to be complete, nor have the discussions with Namur been concluded in their entirety.

## 2 Economic Potential and Markets

Economic potential is estimated in three ways:

- SWOT analysis for evaluation of strategy (see appendix)
- Interviews with experts (section 2.2)
- Market volume estimate based on VCI figures (section 2.3)

The approaches provide well-founded estimates, but cannot offer any guarantees, because actual market development depends on a number of factors that cannot all be recorded sufficiently. The estimates made must be verified taking account of the various interest groups made up of suppliers, integrators and end operators, in order to demonstrate the economic importance of modular plant engineering.

### 2.1 Strategy Options from Module-Based Plants

To estimate the economic potential, the question of who benefits from the new technology, and to what extent, is addressed.

To better estimate the strategic benefit of modular plant engineering, an attempt was made to create a SWOT analysis of a typical market player in the fine chemical and pharmaceutical industry (see appendix).

### 2.2 Interviews with Experts

In their structure, the conducted interviews are very similar. The same, or at least very similar, questions were asked to ensure the comparability of the conversations.

The companies approached, or their representatives, are various stakeholder in the business field of module-based plants and/or their automation. Their business model primarily also influences their expectations and hopes with regard to the new market.

The interview partners to date can be divided into two groups. Interviews were conducted with manufacturers/operators of chemical/pharmaceutical plants, and with carriers of knowledge about module-based plants; this knowledge relates primarily to the design and detailed planning of such plants. The aim of the interviews was to obtain a market estimate from the point of view of decision-makers in various segments of the process industry. The expert opinions show the extent to which the new ideas have arrived in operational practice and, in conjunction with the analyses performed above, form another piece of the puzzle, which will help us to arrive at an enlightening overall picture. (Summary, table 1)

The questions were not formulated in advance word for word, and were instead introduced into the interview in accordance with the particular situation. They can roughly be formulated as follows:

- 1) In which segments of the industry is the use of module-based plants the most likely? Which product groups does this cover, for example?
- 2) What percentage of the plants specified under 1) would most effectively be converted to module-based production plants? Over what time line should this take place? Are there concrete plans?
- 3) What do you regard as the effects of converting production for automation/process automation? What market trends and changes are associated with this?
- 4) What experiences have been made with modularization to date (in Germany and beyond)? How do operators/producers outside Namur AK 1.12 regard the subject of "module-based plants"?

**Table 1: Core statements of interview partners**

<b>I) Planner group</b>
The market is classified as a growth market. There are a few concrete projects and a demand for more (market push – not a demand situation).
Rapid (exponential) growth is not expected. The mindset for modular planning is already established.
A high potential is seen for fine chemicals: 10–30 % of plants could be modularly structured.
Outside of AK1.12, concepts for automation are also regarded as open questions for which a comprehensive solution has not yet been found.
There are concrete ideas for systemizing engineering.
Critical questions still relate to inline analytics and batch consistency.
There will always be batch processes and these will also always be modularized.
<b>II) Manufacturers/operators group</b>
The focus is on both intensifying the processes and modularizing process engineering functions.
The emphasis here is on the transition from batch processes to continuous processes, because this is a more reliable way to ensure a constant level of quality.
Existing assets will not be replaced by modular plants. Instead, new products will be produced with new technology.
It is not clear whether the breakthrough can be achieved this time with module-based plants. At the moment, we are experiencing the second or third wave.
Plant mobility is certainly a required and attractive feature.
Trend: “Why are we measuring pressure and temperature? We’re not interested in that. It’s product and material properties that are of interest.”
Technology maturity is decisive for achieving competitive advantages.
Outside the Namur committees, there are certainly critics of module-based plants (in the process industry). Not infrequently, they are regarded as advocates of an old concept that never became viable.

An interview communicates the market player’s individual insights. Further interviews are being planned. To derive more generally valid statements from the interviews, we would need to poll a representative number of market players.

This does not mean that we cannot derive any general statements at all. Some assessments are not company-specific, and relate instead to the entire industry.

## **2.3 Market Volume Estimate**

Only a very small data basis is available for estimating the market volume for module-based plants. There are no (public) estimates at all from the companies represented by the members of Namur AK 1.12.

The modularization concept described in this document is based on NE 148. The sales figures of the chemical/pharmaceutical industry were therefore used to estimate the market volume. The data can be found in the VCI report<sup>[11]</sup>.

**Table 2: Market volume estimate for automation in modular production**

Year	[mill. EUR.]			
	Sales	Investment rate	Modular	Automation
	Chemical/pharmaceutical industry			
2012	186.830	6,50 %	25 %	3 %
		12.144	3.036	91
2022 Adjusted for inflation	227.746	6,50 %	25 %	6 %
		14.803	3.701	222

Source: <http://publikationen.vci.de/publikationen/CHIZ-2013/blaetterkatalog/>

The calculation is based on a two-percent adjustment for inflation, so total sales for German companies in this industry of approx. € 228 billion is assumed in 2022.

The calculation of the target corridor is based on an average investment rate of 6.5 percent and on the assumption that in 10 years, approx. 25 percent of process plants in these industries will have a modular structure (estimates from interviews). At the moment, automation typically makes up approx. three percent of investments. For module-based plants, the proportion of automation will shift in the future. We assume an average of six percent automation with an average of 25 percent modularly automated plants, so the market volume is estimated at approx. € 222 million. (According to an ARC study from 2013, the total global PCS market can be put at € 11,600 million, € 2,200 million of which in the chemical industry alone.)

#### Closing comments on the market volume estimate

If module-based, standardized plants become established, faster growth would be expected, because this approach promises high cost savings and gains in profitability if the concepts can be implemented successfully.

Within the production of existing and/or new products, module-based technology will replace conventional technology to a certain extent. However, the new technology may create a new type of product and tap into completely new markets (e.g. personalized drugs). These possible developments are not included in the estimate. **The market for modular automation is therefore considered within and outside the Namur companies and is developing.\***

The companies' determination to realize the proposed concepts may prove more important than the investment volume. Interviews with experts in the process industry can provide a snapshot of the discussion, as the next section shows.

## 2.4 Business Model for Module Manufacturers

Changes in the value chain will result from modularization and the standardization that goes with this. The responsibilities in the construction of a plant will be different. The distribution of tasks among operators, module manufacturers and system suppliers must therefore be redefined and clarified.

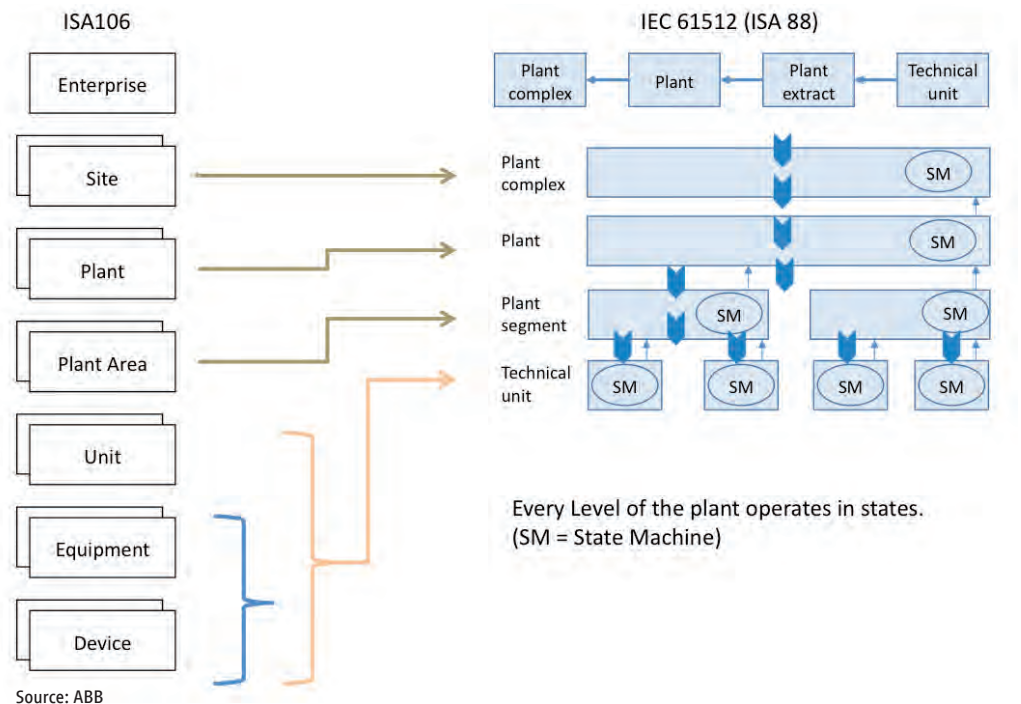
As a result of these changes, the working group has decided to also seek out interviews with module manufacturers.

\* See summary of theses in appendix section 9.5





**Fig. 2: Mapping of physical model ISA 106 to IEC 61512 (ISA 88)**



The aforementioned model can also be applied to a batch-based procedure, because it is compatible with ISA 88<sup>[7]</sup> (NE 33<sup>[5]</sup>). Figure 2 provides the representation of the physical model according to ISA 106 mapped to the model described according to ISA 88 (IEC 61512).

The model according to ISA 106 can be mapped to the requirements of NE 148. It is therefore suggested that the structure according to ISA 106 should be used for the modular AT system.

### 3.3 Modular Automation

(requirements NE 148, section 3.1: automation of a module)

A further question is the automation of the modules themselves. In addition to the required AT hardware (variant A: small control units, variant B: I/O assemblies), the AT functions are particularly important, because they have to be seamlessly integrated into the higher-level PCS and a connection should also be established between the modules.

Communication between the modules themselves, and between them and the higher-level PCS, can be achieved via IEC-Ethernet-based

protocols or standardized fieldbuses (see fig. 3). The control and integration concept described in this white paper can be applied equally for both communication variants.

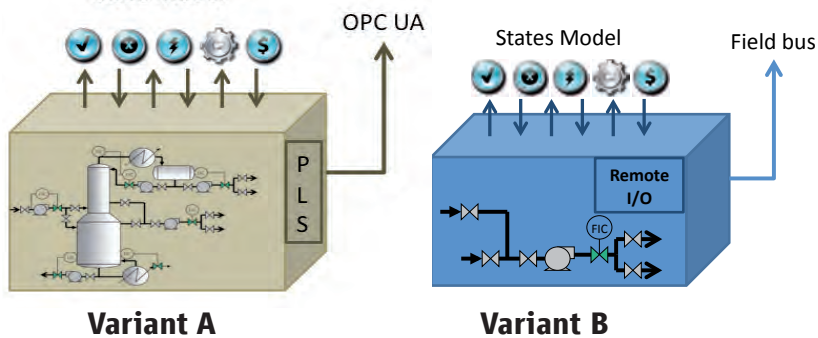
#### 3.3.1 State-Based Control

The control concept is based on a state-based description and state-based operation of the modules. Every module type provides a description of its states. The state model is publicly accessible in the whole system and is used as the sole interface for the logical connection between the modules.

The internal AT logic (such as Interlocks or control loops) is developed separately for each module type and is actuated via public interfaces.

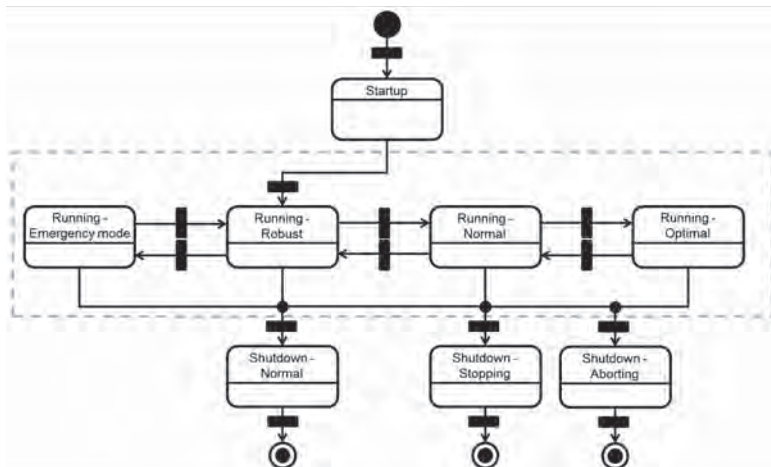
For data encapsulation, object-oriented approaches are used to a) hide the unnecessary module complexity from the engineer and b) ensure knowledge protection for module suppliers. As an example, the automation (or state model) of a distillation tower is shown in figure 4.

**Fig. 3: Interfaces of the module variants**



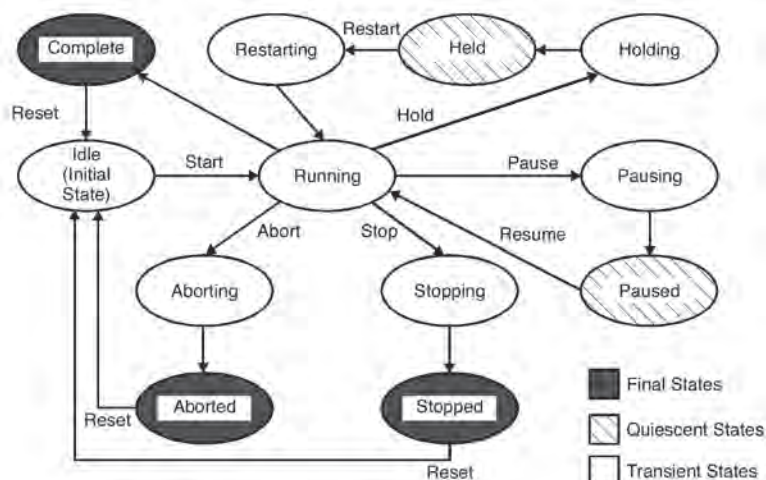
Source: ABB

**Fig. 4: Automation of a distillation tower**



Source: ABB

**Fig. 5: Rigid state model according to ISA 88<sup>[7]</sup>**



Source: ANSI/ISA-88.01-1995 - Formerly ANSI/ISA-S88.01-1995  
Batch Control Part 1: Models and Terminology  
ISBN: 1-55617-562-0

The “state-based control” concept corresponds both to ISA 106 for the continuous procedure and to ISA 88 for the batch-based procedure. While ISA 88 defines a rigid state model for batch operation (an example of which is shown in figure 5), ISA 106 defines a variable state model, which the user can freely design. An example is provided in figure 6. “State-based control” is therefore suitable for both standards.

### 3.3.2 Vertical Communication & Integration

Vertical communication relates to the communication between the modules and the PCS. The modules used must also be integrated into the environment of the PCS, which is why communication is also required for this.

This communication can be achieved via IEC Ethernet-based protocols or standardized fieldbuses.

In addition, the modules of variant A could use an OPC-UA interface (via the fieldbus) to communicate process values to the PCS (see figure 7). The state model of each module type is consumed by the PCS and thereby integrated in the PCS to later identify and integrate the module instances.

Technologies such as FDI are available for describing the modules and access to the modules. Its suitability for module integration still has to be verified in detail.

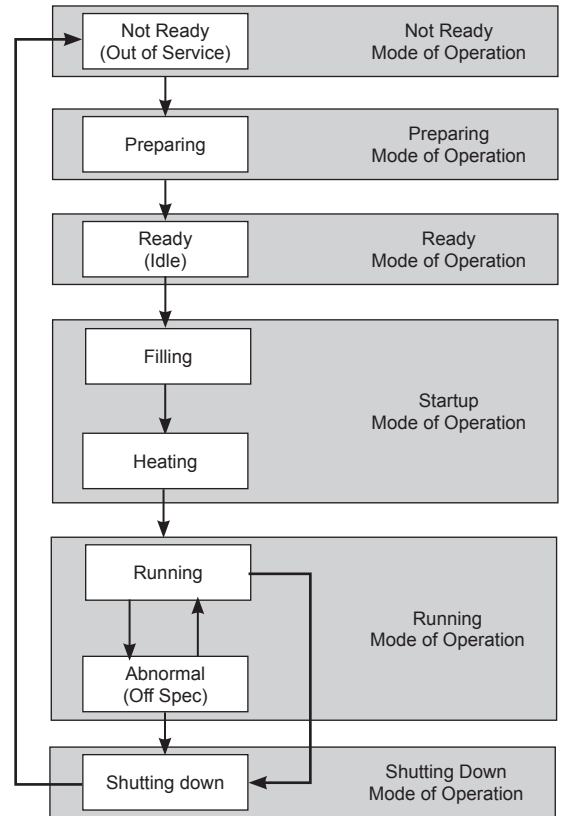
Because the state model maps – from an abstract perspective – the module’s capabilities, control is only possible by the PCS or other modules via state transition requirements. However, within the module, state transitions are controlled by the module’s AT logic. **The modular automation standardizes the interfaces between control level and module.\***

### 3.3.3 Modelling of State Models

As the communication interface between modules and the PCS, state models can be modelled using methods from the current state of the art::

1. Option 1 is the modelling of an SFC using an extended cause & effect (xC&E) matrix. SFCs can be mapped as xC&E, whereby suitable graphical tools considerably facilitate the modelling of SFCs as xC&E. The SFCs are already state models, or can be automatically translated into such, as a result of which these state models can be executed directly on a control unit without further steps. This method should be favored for the modelling of variant B.
2. The SFCs can naturally be modelled in the conventional way using the current editors. This method should be favored for variant A, because in this case, the interim step of the xC&E matrix is not required. Both modelling types a) should be regarded as suggestions and b) may vary depending on the module type. While the xC&E method should be favored for module variant B, both methods can be used equally for module variant A.

**Fig. 6: Example of a self-defined state model according to ISA 106<sup>[8]</sup>**



Source: ISA 106 / Technical Report  
ISA-TR106.00.01-2013 Procedure Automation for  
Continuous Process Operations – Models and Terminology  
ISBN: 978-0-876640-38-8

## 3.4 Central HMI Level

(requirement NE 148, section 3.2.2: operation & monitoring)

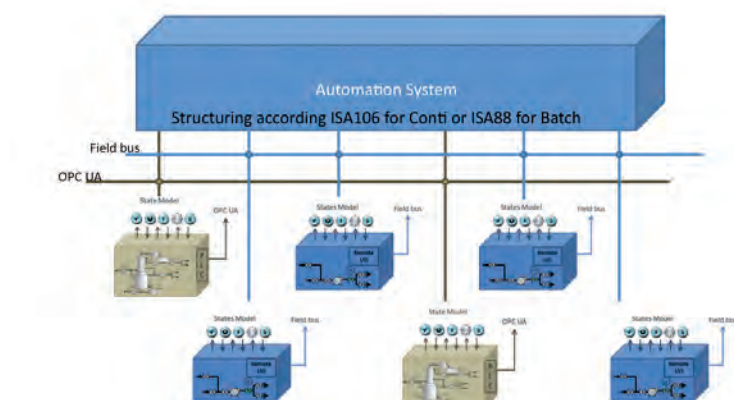
### 3.4.1 Operating Displays

In addition to the AT functions, operating displays are needed to a) manually control individual modules and b) integrate their graph-

ics in the operating screen at a later point in time. The module manufacturer enables parameterization of the modules by means of parameterizing displays.

For the integration of the visualization data, we differentiate between a number of levels.

**Fig. 7: Physical & logical integration of the modules into the PCS**



Source: ABB

\* See summary of theses in appendix section 9.5

### 3.4.2 Semi-Integration into the Control System

In the case of semi-integration, the module provides a standardized description of its interface at levels 1 through 3. For engineering purposes, this description must be available independent of the physically available automation of the module, e.g. in the form of a description file. In the control system engineering, the module description is used to create the relevant alarms, variables etc., so that the graphical representation of the module can be planned there (thus: semi-integration).

The graphical display in the higher-level control system ensures consistency of the representation and, to a large extent, the operating philosophy (with the exception of level 6). Integration at levels 4 and 5 therefore takes place via manual engineering.

Whether data integration at level 6 can also be achieved depends on the individual case. Module manufacturers should therefore avoid high dependency between the logic of the HMI and controller design.

The module description should also contain all data, so that the higher-level control system can access the relevant module automation interface at runtime.

### 3.4.3 Full Integration into the Control System

In contrast to semi-integration, full integration also attempts to automate the design of levels 4 and 5. For this, the module description must also provide a description for levels 4 and 5. Two methods are conceivable for this in principle:

1. The module description provides the actual graphical representation of the module. The operating images of the modules must be provided in a manufacturer-independent, neutral format. The AT system usually uses a system-specific representation of the operating images and provides these in a proprietary format, which is why a manufacturer-independent, easy-to-transform description of the operating image is required here. HTML5<sup>[9]</sup>, for example, is a manufacturer-independent, neutral format.

**Table 3: Levels of visualization data**

	Level	Description
1	Data formats	Real, Bool etc.
2	Data types	Alarms, measured values, statuses, commands etc.
3	Data semantics	Manual operation, automatic operation, temperature measurement at input etc.
4	Data representation	Numeric, bar, curve, button
5	Aggregated representation of data	Faceplates, complex charts etc.
6	Functional integration of data	Controller module and logic of HMI are very bound up with each other. HMI functionality can only be achieved through joint use of HMI and controller modules



HTML5, as an established format in IT and published by W3C as an open language, can be interpreted without knowledge about proprietary operating display formats. If scalable graphics are also needed, these can be embedded in HTML5 code as SVGs (Scalable Vector Graphics), for example. As a result, specific displays and graphics can also be used. The higher-level control system must support the technology for used representation (e.g. ActiveX, HTML5 etc.). The advantage is that these technologies are available and widespread. However, the disadvantage is that this can in no way ensure the consistency of the representation.

2. The module description provides a description of the representation of the module and the higher-level control system decides on the definitive graphical representation. This would ensure consistency of representation. However, in this case, in the module engineering the module manufacturer cannot see the final representation of its module, and it can and will in fact differ from control system to control system.

The fully-integrated approach of HMI demands standardization of the module description up to level 5. The restrictions regarding level 6 also continue to apply for now in this point.

If this point is to be overcome, a technology must be selected that also allows business logic

to be brought from the module description to the HMI of the higher-level control system. These approaches exist in FDI. Assuming that the complete HMI business logic of the module were contained in the description, integration at level 6 could also be achieved.

One compromise between semi- and full integration would be the use of semi-integration for the operator displays and full integration with approach 1 for detailed and diagnostic views. This would simplify the required standardization and technical implementation in the control systems.

### 3.5 Consistency of the Operating Concepts

While approaches 3.4.2 and 3.4.3 ensure a consistent representation of the modules up to a certain degree, this in no way means that a consistent operating concept is therefore automatically a given. It has not been determined which operating options a module can/must have.

From a system point of view, there are only limited means of improving the situation. Standardization is required here, which the operator companies must drive forward with the module suppliers.

**This standardization process changes the operation and monitoring of modularly automated process plants. As a result, the work processes in plant maintenance will also change.\***

\* See summary of theses in appendix section 9.5

## 4 Engineering for Modular Automation

The modularization of plant parts means that for known module specifications, a large part of the engineering work has been, or can be, done in advance. This completed work does not have to be redone as long as the specification stay the same. This saving can lead to a substantial increase in productivity.

### 4.1 Plant Planning Process in Modular Engineering

Figure 8 shows modular engineering in process engineering. For module-based production plants in the process industry, two effects for economic success are of key importance as a result of the modularization of individual process engineering functions:

1. Flexibility of the modules for use with the broadest possible range of process parameters.

As the specific use of the modules in a plant has not yet been defined at the time of module design, a module should be made to be as “general-purpose” as possible.

2. Standardization of the modules to allow the engineering effort per module to be significantly reduced.

For standardized modules, the plant planning process can be simplified to a large

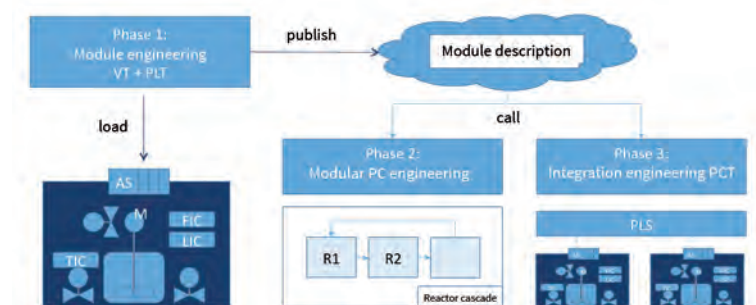
degree, because engineering, qualification and approval have already been carried out in parts.

The planning of the plant and its construction are key factors for the lead time up to production. The time at which the PCS equipper is involved in planning, or is commissioned, differs depending on the underlying conditions of the individual project. It is clear that conclusion of startup requires the work on the PCS, as well as construction work, to have been concluded. If an average degree of standardization is achieved, it can be assumed that the activities in the life cycle of the PCS up to conclusion of the startup do not fall on the critical path of the construction time.

The reduction in construction time  $T$  by using prefabricated modules and the added value possible as a result of reuse are the benefits offered by module-based plants over conventional plants. For a module-based plant to be competitive, both these goals must be achieved to a sufficient degree and scope.

In particular, it must be noted that it is necessary to plan and to engineer with modules as early as the process engineering phase. Only modules engineered there can be used efficiently in control technology engineering.

**Fig. 8: Modular engineering for process technology/process control technology**



## 4.2 Module Engineering

Module engineering is interlinked with the process technology engineering of the plant via the interfaces of the module plant that need to be specified. Depending on the engineering tools used, the engineering of the module takes a different amount of time. The information below attempts to explain the decisive factors that are important from the automation specialist's perspective in module engineering, taking account of the variety of technologies and philosophies advocated by the committee members.

At the outset, it must be stated that the engineering of a module takes place in the system that the module manufacturer uses. This system may not be the higher-level control system. Integration of module engineering in the engineering system of the control system is not planned.

To be able to make statements independent of a particular technology, a variety of factors will be considered. The topology of the automation system is described in section 3.2. The functional structuring and the methodological approach are described below.

### 4.2.1 Functional Structuring

The structure relates to the software-based realization of module-based automation. This, like the implementation of the process engineering, must be module-based, and is essentially its software equivalent. Implementation decisively affects the following characteristics of the software:

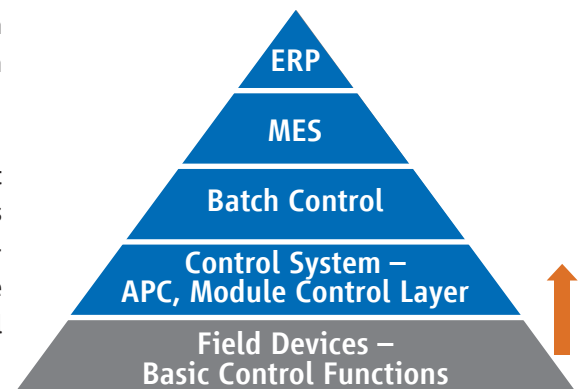
- Reusability
- Maintenance and flexibility in the sense of the fundamental idea of modularization
- Usability of the software in the sense of ISO 25000<sup>1</sup>.

To clarify the importance of the data model, two different versions of the data model are presented below:

- (a) Classic access at field level  
→ Classic plant engineering
- (b) Provision of services  
(enclosing of the module)  
→ module-based production plant

The conceptional move from the conventional chemical plant to the module-based plant implies a transition from concept (a) to (b). This transition results in lower complexity and the encapsulation of functions. The field level does not disappear, but it becomes increasingly invisible to the operator.

**Fig. 9: Rule pyramid for control-relevant IT systems**



#### Example:

We can draw an analogy with the transformation in vehicle technology. Twenty-five years ago, all drivers of a VW Beetle could and wanted to be able to maintain and repair the engine in their vehicle themselves. Today, the engine is an enclosed unit (not just in a Beetle). For a complete diagnosis, the driver usually has to visit a specialist workshop. The modern engine is a modular unit that generates error and status messages, but the detailed diagnosis should be performed by an expert (internal/external).

<sup>1</sup> The international standard ISO/IEC 25000 Software Engineering – Software Product Quality Requirements and Evaluation (SQuaRE) – Guide to SQuaRE, replaced standard ISO/IEC 9126 in 2005 and was drawn up by the standardization committee ISO/IEC JTC 1/SC 07 Software and systems engineering.



The operating concept for module-based plants intends for some responsibilities to be transferred to the module manufacturer. The terminological similarity to the automotive industry and the reference to the aforementioned analogy are not accidental. The shift in the operating concept should not be seen as reducing transparency, but rather as increasing the focus on relevant (process) information, such as:

- Current state of the module
- State monitoring with regard to state-based maintenance
- Focus on product-relevant data: Quality, progress of the production process etc.
- Focus on operation-relevant data: Energy consumption, order situation & scheduling etc.

The shift described above is a consequence of modularization. In addition to the use of dedicated components, this requires, in particular, a shift in the expectations of operators and planners.

#### 4.2.2 Methodological Approach

The method describes the sequence of activities carried out to achieve a goal. Selection of the method includes selection of the tools used (e.g.: Development Kit, CAE tool + MS-Excel etc.), training of employees and other specifications such as internal guidelines and procedures.

The methodological approach within the framework of module-based plant engineering is conducted as a combined approach:

- (a) Top-down and
- (b) Bottom-up

In the top-down approach, the entire plant is structured in accordance with ISA 106. The modules that represent the specific process engineering plants are mapped at plant part level. Approach (a) is used to determine the first modules and to support the standardization of modules.

The top-down approach is supplemented by a bottom-up approach, which ensures that available modules are also used. This again underlines that modular engineering starts starts not in control engineering, but in the process engineering design.

Tool support is particularly important, because it significantly helps to increase productivity. The Development Kits from the various automation specialists are not to be individually assessed here. A comparison of the tools appears hard to achieve. Alternatively, the capability for "integrated engineering" may be a good yardstick for determining efficient tool support. There is now no defined procedure for measuring the integration of various tools. A clear indication of good integration is a more or less closed tool chain that supports the conversion of engineering data from plant engineering to engineering data for the control system. Other criteria could be:

- If possible, no manual input of data
- Few specially adapted solutions, as these have not been proven in use
- Traceability of changes
- Versioning

### 4.2.3 Engineering State-Based Control

The engineering of module types is realized in two ways, as two different module variants are under consideration:

**Engineering variant A:** The first variant contains an autonomous control unit within the module. The control unit is used to control the module independently, as though it were a stand-alone solution. The normal engineering procedures can therefore be used to automate the module types in this variant. The only difference to conventional engineering is that each module must inform the PCS of its state. "State-based control" concepts must therefore be used during engineering.

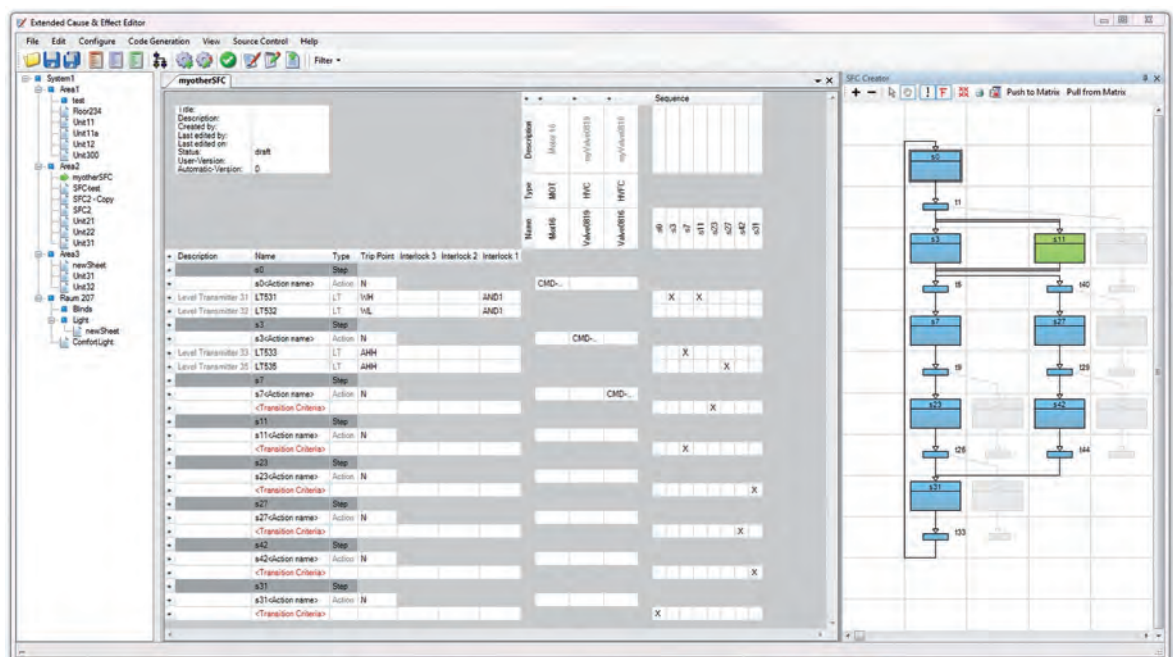
**Engineering variant B:** In variant B, only I/O assemblies are used for control. In this case, the required AT logic is executed in the higher-level PCS system. Module types of variant B should therefore be developed using a method that permits the automatic generation of the code.

For this case, engineering using an extended Cause & Effect (xC&E) matrix was discussed, because it offers the option of modelling SFCs (Sequential Function Charts, IEC61131-3<sup>[10]</sup>) and state models.

The xC&E matrix can later be exported as XML (e.g. based on IEC 62424: CAEX<sup>[11]</sup>) in a manufacturer-neutral manner. The export can be used to automatically generate the AT functions in the PCS (see fig. 10).

The requirement of independence from a specific manufacturer is then met via this XML. Because a generated code generally cannot necessarily be read and maintained by humans, it is necessary to discuss the extent to which this approach would really be accepted by users.

**Fig. 10: xC&E representation of an SFC**



# 5 Requirements for Sensors and Actuators

## 5.1 Miniaturization of Field Devices

The modernization of process engineering plants with the focus on execution on an industrial scale through “numbering-up” goes hand in hand with a scaled module architecture (modules in module ...) and a corresponding reduction in module size and increased module compactness. This tends to result in reduced nominal pipe sizes for the process and auxiliary media, while at the same time, the packing density of the sensors and actuators (field device level) is higher. It is therefore necessary to design the field devices as compactly as possible. As the packing density in the (sub-)module increases, so does the load on the (compact) field devices with regard to ambient conditions – in particular as a result of high temperatures (caused by the process), but also as a result of the heat loss of apparatuses and electrics. A further modularization level may be necessary at field level with the separation of sensor and/or actuator and control unit (e.g. positioner, solenoid valve). Integration of the converter electronics in the housing of the actual sensor is also possible to reduce the volume and size.

## 5.2 Sizes

When the modules with apparatuses, sensors and actuators are made smaller and more condensed, the structure is compact, which when operated manually on site, requires mobile, wireless maintenance devices, rather than operating elements on the instrument. As a result, in some cases, local display and operating components may be omitted, and the free volume can be used to the benefit of the production apparatuses.

To free up further volume, the data and signals can be transmitted via fieldbuses or similar.

Both sensors and actuators should be optimized for lower flows and pipe diameters, a consequence of the smaller sizes. Higher pressures could also occur if the process is intensified further.

In the case of mechanical connections between individual modules and/or infrastructures that rarely (< once a month) need to be separated, sensors, actuators and conduits can be screwed on. In general, coupling elements with minimal dead space should be favored because of the small volumes.

## 5.3 Diagnosis Requirements

(requirement NE 148, section 3.2.4: diagnosis)

To ensure and, where applicable, optimize operation of the modules over the life cycle, it is essential to process additional information as well as the actual process value in the control and regulation tasks.

The standardization of the modules – associated with the fact that these units can be multiplied – facilitates the evaluation of diagnostic information. In addition, the market also demands greater use of available information. This means, in particular, that asset information from the field will increasingly be used at module level to evaluate the performance of the process engineering process.

From the module operator’s perspective, the benefits of the individual assets, the modules and the plant as a whole increase with the consistently standardized integration of diagnostic information coming directly from the field instruments.

To include existing plant components in maintenance measures more efficiently, it is essential for the asset operator to manage and evaluate the health of the assets using the resulting diagnostic information.

With NE 107, Namur has already laid a solid foundation, which helps to categorize diagnostic information into four filter categories, so that later, it is easier for the user to understand. These categories are defined as follows:

Maintenance required



Out of specification



Check function



Failure



These four classification areas and their accompanying symbols make it much easier for the operating personnel to evaluate errors and carry out corrective measures on the basis of this evaluation. The information of the underlying field level can be linked at module level, so that the overall state of the module can be portrayed.

It must be stated that only the diagnostic information provided by the modules (no direct access to field devices) is available in the higher-level control system. Operators and module manufacturers must reach a reasonable compromise here between the need for information and IP protection.

This is a paradigm shift from the current procedure.

## 6 Standards and Norms

### 6.1 Explosion Protection

The key standards on the subject are (list not exclusive):

- Explosive atmospheres - Explosion prevention and protection - Part 1: Basic concepts and methodology; German version EN 1127-1:2011
- TRBS 2152 Part 1–4: Hazardous, potentially explosive atmosphere – avoiding the ignition of hazardous, potentially explosive atmosphere
- IEC/EN 60079-xy: Description of ignition protection categories for electrical explosion prevention as well as design and checking

#### 6.1.1 Schematic Plan of a Production Plant

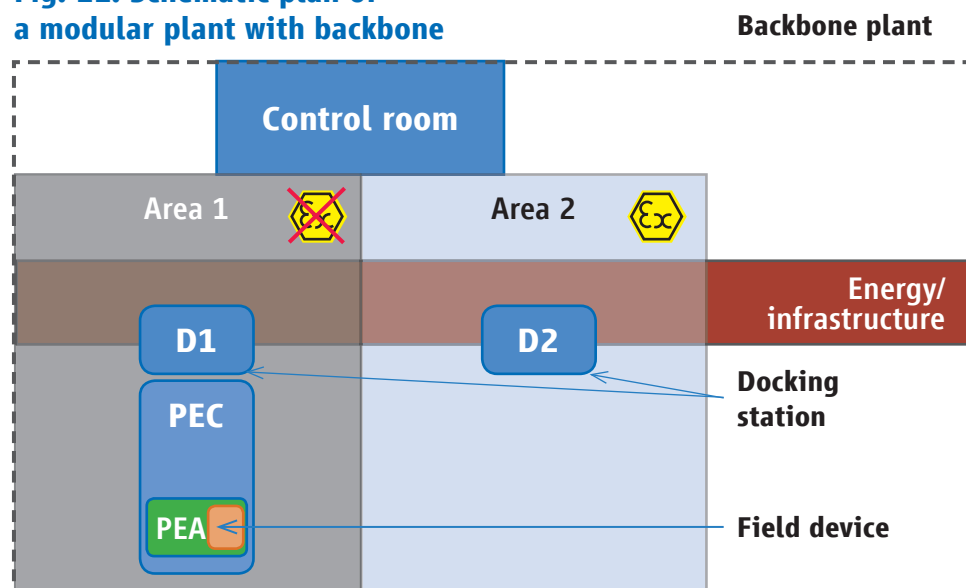
Figure 11 shows the schematic design of a backbone plant. For considerations relating to explosion protection, the particular structure of the plant is important, because different concepts for achieving explosion protection can be implemented.

The backbone plant enables the process equipment container (PEC, unit in the sense of ISA 106) to be docked and thus supplied with the necessary energies, such as current, data net-

work, steam, compressed air, gas, waste water and so on. The PEC is a collection of process equipment assemblies (PEA, equipment in the sense of ISA 106), which in turn contain field devices (actuators and sensors), apparatuses, pipes and so on. The various processes are observed, monitored and controlled from a control room.

The company Invite GmbH, for example, provides an area for the operation of transportable modular process plants. Here, the container-based plants (PECs) can be connected to the company's infrastructure via the backbone. The PEC forms the framework for installing the modules (PEA). For reasons of explosion protection, all PEAs are designed for zone 1. An alternative approach is to have two areas within the backbone plant. One area is not classified as an explosion zone, and the other is classified as zone 2 or zone 1, whereby subareas can also be classified as zone 0. A production plant can be subdivided into modules with and without explosion protection. The plant parts are mounted as PEC, are accommodated in the areas set up for this and are connected accordingly. At the moment, it is not clear whether such an approach is cost-effective.

**Fig. 11: Schematic plan of a modular plant with backbone**



**Table 4: Particular features that characterize a module-based plant with regard to explosion protection**

EX-	Feature	Explanation
A	High installation density	The components and modules are (relatively) close together. There is almost no way of installing devices outside the hazardous area. Natural ventilation is restricted as a result of the high installation density. This effect is partially cancelled out by low material quantities.
B	Modularity	The modular structure allows spatial separation as shown in figure 11. A high modularity requires the integration of functions that could previously be installed outside the hazardous areas. Because of the high number of flanges, there are additional sources for a risk of explosion.
C	Standardization	The desired uniformity of the modules also requires standardized solutions for explosion protection. The choice of protection concept also affects the engineering of the components and their usability/flexibility.
D	Electrical operating resources without approval	Devices such as process control systems, SPS or frequency converters, i.e. devices that are not designed with explosion protection, should be used in hazardous areas.
E	Zone classification and selection of operating resources	The high installation density makes classification into explosion zones difficult. A different sequence of modules can therefore lead to a different subdivision. The measures for making devices suitable for use in the respective explosion zone are very diverse.
F	Approval/acceptance	As far as possible, approval and acceptance should already exist for a module. The startup of a plant consisting of several modules will make a separate approval necessary.

### 6.1.2 Particular Features of Module-Based Plants

With regard to explosion classification and handling, module-based plants have some particular features that do not apply for conventional plants (table 4).

Because it should be possible to deploy the modules variably and flexibly, their potential use in the hazardous area must be taken into consideration. Because of the compactness of the plants and their poorer ventilation it is difficult to classify a plant into different zones. It is therefore advisable to design the modules for zone 1.

### 6.1.3 Explosion Protection and Module-Based Plants

The explosion protection document forms the basis for selecting the electrical operating resources for hazardous areas. This document

contains all the required information for selecting the electrical operating resources and the type of installation, such as zone classification, explosion group and temperature class. The plant operator is responsible for creating and maintaining this document. In practice, the plant operator will need the assistance of the designer of the plant/production module. A few comments on the features listed in table 4 are provided below.

#### A) High installation density

The high installation density of the production modules means that if they are used to process mixtures that are potentially explosive, it is highly likely that a zone-1 environment must be assumed. This means that a potentially explosive atmosphere occurs often. In some cases, technical ventilation may be possible to downgrade the area from zone 1 to zone 2. It follows from this that:

- During the processing of flammable gases or flammable liquids above the flash point, atmospheres that are potentially explosive can be created. As a result, the entire production module becomes a hazardous area. In the case of containers that are installed spatially very close together, the potentially explosive atmosphere can spread from one container to another. According to the German ordinance on operational safety, the interaction between the containers must be taken into consideration.
- In modular plants, the number of plant parts and devices operated in hazardous areas is greater than in non-modular plants
- For an optimum setup, a mix of ignition protection categories is used)
- There are different electrical powers on site (in the module)
- Regulation on site (smart field devices): The controls and regulators – previously not usually designed with explosion protection – are now installed in the hazardous area

Use of the Intrinsic Safety ignition protection category requires compliance with the installation rules specified for this in accordance with EN 60079-14/DIN VDE 0165-1. These rules require, among other things, that the installation is carried out in such a way that there is no power input from outside. For this reason, intrinsically safe lines are usually laid separately from non-intrinsically-safe lines.

Because of the high installation density, a higher risk of a thermal or chemical influence on the installed lines must be assumed. This point must be taken into consideration during installation.

### **B+C) Modularity and standardization**

A module or “package unit” is a subplant that must be integrated into the explosion protection concept of the entire production plant. Consequently, both the production module

itself and the expected environment must be taken into consideration for the explosion protection requirement. This situation is another reason for designing a production module for use in zone 1, because this provides a higher degree of flexibility.

### **D) Electrical operating resources without approval**

Switchboxes and switch cabinets in Ex p or Ex d can be used to make the power electronics and control devices suitable for explosion zones. Control devices and e.g. inverters can therefore be installed directly in the modules.

The ignition protection categories Flameproof Ex d and Pressurized Ex p enable electrical operating resources, particularly those with higher electrical power, to be made suitable for installation in hazardous areas. Both ignition protection categories have advantages and disadvantages, which must be weighed up.

The pressurized enclosure makes it possible to construct a relatively large housing through to a complete container, in which the automation system and power electronics such as motor controls can be housed. The required housings are only slightly heavier than comparable industrial housings without explosion protection requirements. However, the explosion protection category requires compressed air from the non-hazardous area.

Inerting can be used as a means of prevention. When the plant is started, the installed systems cannot be put into operation until there has been sufficient rinsing with compressed air/nitrogen. In the event of pressure loss, the electrical devices are shut down immediately.

Explosion protection category Ex d is based on a housing in which the effects of an explosion are limited to the interior of the housing, i.e. a potentially explosive mixture in the environment is not ignited. To withstand the



pressure of the explosion, the walls of these housings are often very thick. As in the pressurized enclosure, the installed devices cannot heat the outer surface of the enclosing housing to such an extent that the surrounding potentially explosive atmosphere can be ignited. Compared to the pressurized enclosure, the flameproof enclosure is not dependent on the supply of compressed air, and does not require any time-consuming rinsing prior to startup.

The ignition protection category should be chosen taking account of the function and the expected maintenance effort for the operating resources that are to be enclosed. In most cases, an appropriate combination of explosion protections will be the best solution.

#### **E) Zone classification and selection of operating resources**

With the exception of Ex m, all the explosion protection categories can be applied, depending on device, module and zone classification: Ex i, Ex ic, Ex p, Ex d, Ex e, Ex q or Ex o for power electronics, frequency converters or motor controls. Ex-o measures also solve the heating problems of the converters.

#### **F) Approval**

The plant operator must create an explosion protection document in accordance with the German ordinance on operational safety. The manufacturer of a PEC/modular production unit will have to provide the required information about the PEC as the basis for this document.

The manufacturer of the PEC has two options for market placement. The first option is to declare the PEC as a process plant or part of a process plant. Classification as a process plant means that the PEC is permanently installed at the manufacturer's site and is part of a higher-level production process. In this case, the declaration of conformity and the CE mark are not applicable for the PEC. However, the disadvantage of this procedure is that the setup of the

PEC must be adapted to the requirements of the particular country – a free movement of goods within the EU is therefore not necessarily guaranteed.

The alternative procedure is to classify the PEC as a machine and to apply the machinery directive. This procedure offers the advantage of the free movement of goods within the EU and suits the mobile use and desired replaceability of these PECs. If the PEC is an incomplete machine, i.e. the manufacturer cannot evaluate all the risks of the PEC at the place of installation, the CE mark and declaration of conformity are not required and the PEC is given a declaration of incorporation. If it is considered as a complete machine, the manufacturer of the PEC can estimate the risks, and in this case, the CE mark and declaration of conformity are awarded in accordance with 2006/42/EC (machinery directive) and 94/9/EC (explosive atmospheres directive/ATEX 95).

In practice it makes sense to combine these two options. Consideration of the machinery directive is combined with the particular features of the ATEX directive. In this case, the risks of the PEC can also be taken into consideration more effectively (see 6.2 Functional Safety, p. 25). When looking at functional safety, the effects of machine damage are lower than those of process engineering plant damage.

It is necessary to investigate whether the machinery directive has to be applied. There is the tendency to treat plant parts or compact plants as concatenated machines. This means that the complete container (PEC) or module (PEA) would have to bear the CE mark. Up to now, it has been the case that individual, homogenous subplants can fall under the machinery directive, but the whole plant does not have to; however, complete biogas plants have already been marked in accordance with the machinery directive.



Initial startup must be approved by a ZÜS<sup>2</sup>. The module supplier must provide the required documentation such as test reports. The exchange of modules must be evaluated by an expert, but a qualified person is not required.

The effort for documentation should be reduced as far as possible through the provision of suitable documents and templates.

Table 5 shows the translation of some requirements relating to explosion protection for module plants into corresponding solution approaches.

## 6.2 Functional Safety

The key standards on the subject are (list not exclusive):

- Functional safety of electrical/electronic/programmable electronic safety-related systems – part 1: General requirements (IEC 61508-1:2010); German version EN 61508-1:2010
- Functional safety – Safety instrumented systems for the process industry sector – Part 1: Framework, definitions, system, hardware and software requirements (IEC 61511-1:2003 + Corrigendum 2004); German version EN 61511-1:2004

**Table 5: Translation of requirements into a solution approach for explosion protection**

General requirement	Preferred use of ignition protection categories with low space requirement	Solution approach
Miniaturization of electrical operating resources	Installation of systems such as an SPS in zone 1 usually requires these components to be enclosed	Use of ignition protection category Intrinsic Safety Ex i for field devices such as measuring transducers or magnetic valves
Installation of automation systems in the module	Installation usually requires these components to be enclosed	Enclosure by means of housing systems for Flameproof Ex d or Pressurized Ex p, current circuits of higher capacities in Ex e, signal circuits in Ex i
Installation of power distribution in the module	Installation usually requires these components to be enclosed	Installation usually requires these components to be enclosed Enclosure by means of housing systems for Flameproof Ex d in combination with Ex or by means of Pressurized Ex p, current circuits of higher capacities in Ex e, signal circuits in Ex i
Installation of the motor control (e.g. FC) in the module	Electrical plug-in connections or plug-and-socket devices for supplying auxiliary power	Enclosure by means of housing systems for Flameproof Ex d or Pressurized Ex p, current circuits in Ex e
Fast installation and deinstallation of modules	Electrical plug-in connections for signal connections	Use of plug-in connections or plug-and-socket devices with ignition protection category Ex e Use of ignition protection category Intrinsic Safety Ex i
At the time of module design, the overall design of the plant does not need to be known..	BM with high degree of coverage in relation to EPL (Equipment Protection Level), explosion group and temperature class	The design makes economic sense for EPL Gb (zone 1), explosion group IIB and temperature class T4.
Wide-ranging use of the modules for different processes	High degree of coverage in relation to EPL, explosion group and temperature class	The design makes economic sense for EPL Gb (zone 1), explosion group IIB and temperature class T4.
Global use	International approvals	Use of explosion protection categories recognized in all regions. Type examination certificates in accordance with IECEx may therefore be useful. On the other hand, Ex e installations could be out of the question (e.g. in the USA, where the conduit method is common). Zone classification may differ.

<sup>2</sup> ZÜS (Zugelassene Überwachungsstellen, authorized monitoring bodies) were introduced as part of the liberalization of testing procedures in German, and since January 1, 2006 they have been conducting tests that were previously carried out by the officially recognized experts of the monitoring organizations.

**Table 6: Particular features that characterize a module-based plant with regard to functional safety**

FS-	Feature	Explanation
A	Explosion protection classification/	The subject of explosion protection can play a role in considerations about functional safety. The separation of the plant into areas with different explosion zones, in particular, has a significant impact on the assessment of the functional safety of a plant.
B	Modularity/hierarchy	The modular structure allows spatial separation as shown in figure 11. This must be regarded as a separate concept. Modularity also means that modules can initially be assessed for their functional safety separately from and independently of adjacent modules.
C	Standardization	The uniformity of the modules also requires standardized solutions for functional safety. The choice of protection concept also affects the engineering of the components and their usability/flexibility.
D	Approval/acceptance	Approval/acceptance requires all documents to be complete, consistent and traceable.
E	Plant size/numbering-up	The plant size is relatively small. The quantities of hazardous materials are therefore correspondingly lower than for world-scale plants. Instead of one large plant, several small plants are used: Numbering-up rather than scale-up..

### 6.2.1 Particular Features of Module-Based Plants

With regard to the assessment of risks, module-based plants have a number of particular features that result from the structure and operation of the plants. Some of the most important features, and an explanation, are provided in table 6.

In all cases, the module-based plant must be regarded as a whole. This overall view is the operator's responsibility. This responsibility cannot be delegated.

### 6.2.2 Functional Safety and Module-Based Plants

The principle task definition is the same as that for a conventional plant. However, there are some differences in the details. The features listed in table 6 are described in more detail in the sections below.

#### FS-A) Explosion protection classification/risk assessment

On the one hand, the extent of damage for a subplant is lower, because we can assume that the processed quantity of hazardous materials per module is lower. On the other hand, the constricted space means that the hazard zones cannot be easily separated and may adversely affect each other.

#### FS-B) Modularity/hierarchy

A view of the whole plant is extremely important for safety considerations in accordance with IEC 61511. Submodules or modules can be considered separately at the beginning, this cannot replace a view of the whole plant. The operator must take account of the process engineering interactions between the modules in the safety analysis. The concept for the documentation must build on the documents for the individual modules.

Coupling to the backbone is also extremely important, and may not be extensively standardized. Leakage detectors for the docking sites could be necessary.

If the modules have SIS, these must be integrated in a control technology solution in an appropriate way. Safety-related fieldbus systems appear to be advisable. How can the desired compatibility of the SIS be achieved in the various modules?

After the whole plant has been considered, it may be possible for the SIS to be fitted without significant time delay, because the instrumentation for the SIS can be defined after the whole plant has been considered. Otherwise, an SSPS is to be provided for every module if SIS are required.

#### **FS-C) Standardization**

In the case of standardized modules, the uniformity of the plant may mean that the proof of functional safety is easier to provide. From a safety point of view, PEAs can be certified as a unit. A higher degree of standardization is undoubtedly required for this.

#### **FS-D) Approval/acceptance**

To avoid unnecessary additional work, the documents that look at one module should be integrated in other outline documents as seamlessly as possible and with the need for as few changes as possible. An unclear documentation concept results in cost-intensive follow-on work. The documentation must be traceable and consistent at all times.

As in the case of explosion protection, the module supplier must provide an accurate description for the module – in principle a

“safety manual” for the module that describes to the end user exactly how the module is to be deployed.

#### **FS-E) Plant size/numbering-up**

Numbering-up results in the individual risks becoming a higher overall risk, measured against a world-scale plant with the same product volume, because the risk analysis must be performed at module level. With 10 modules, the overall risk is 10 times the individual risk that would be assumed for both the module and the world-scale plant. However, if a module fails, the extent of the damage can be lower than that for a world-scale plant.

### **6.3 GAMP Factors**

Adherence to the GAMP 5<sup>3</sup> directive or the procedures recorded by the PAT initiative<sup>4</sup> are a prerequisite for processing projects in the regulated market (e.g. pharmaceutical industry). In terms of work processes, the type of processing by module-based plants and their automation does not differ from that for conventional plants. Validation is decisive for the operator, because without this, the plant is not allowed to be operated. Validation also constitutes a significant portion of the overall costs.

For conventional plants, documentation starts at field level (actuators, sensors etc.). When considering module-based plants with standardized modules as technical equipment, this is already documented in full. Only the documentation of the interfaces and composition of modules is missing individually for each configuration of module-based plants.

<sup>3</sup> <http://www.ispe.org/gamp-5>

<sup>4</sup> <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm088828.htm>

### 6.3.1 Documentation Simplification

The goal for the engineering of module-based plants should be to raise the description of the plants to a higher level, to simplify the resultant documentation and therefore provide a direct added value for the operator. This requires the existence of complete descriptions of the corresponding plant parts in an appropriate form.

“Appropriate form” here means the complete description of the plant parts to the extent required and in a form that is consistent for the project in question. Both these points are a prerequisite for successful approval of the process by the authority responsible (EMA or FDA).

### 6.3.2 Documentation Requirements

The documentation for validation of the PCS must be comprehensible for the auditors and completely and consistently describe the implementation of the automation system. For the sake of economic efficiency, it should be formulated concisely and precisely.

In addition to the technical content, compliance with standard ISO 9000<sup>5</sup> (quality management) is required; this standard defines the document structures with regard to traceability and responsibility. All relevant points must also be described. As the concrete form of the documents differs from project to project, it is necessary to focus on the document content when developing the documents. If possible, they should be saved in a tool-independent manner (e.g.: XML).

From case to case, auditors insist on going into the details of the individual modules and checking these. In a concrete case, this may mean that the details of a module, e.g. field level direction, have to be disclosed. This is done to ensure that all the necessary information is available in the event that devices do not function correctly. Alternatively, the supplier itself may be audited to evaluate the supplier’s ability to react in a timely manner. In this case, the module contents do not need to be disclosed.

<sup>5</sup> [http://www.iso.org/iso/iso\\_9000](http://www.iso.org/iso/iso_9000)

## 7 Closing Remarks

The modular concepts for automation are still in the pre-competitive research phase. This white paper presents a concept for developing modular AT systems that ultimately meet the requirements according to NE 148. **The current status of work indicates that modular automation is possible.\***

An essential factor for this is that state modules are used for the abstract description and execution of the AT functions and object-oriented approaches from software are used to encapsulate data and allow seamless integration of the modules into the higher-level PCS.

Approaches for the engineering of modular plants were also discussed. Reference is made here in particular to the relationship between module engineering and the engineering of the control system. The decisive role of the early engineering phases was also discussed. **Modular automation follows module-based plant engineering and makes this more economical.\***

The areas of "Security" and "Life Cycle of Modular Plants" were intentionally omitted from the white paper because of the probable scope. They should be analyzed in more detail in a subsequent step.

The sections on sensors/actuators and standardization and norms dealt with the particular features of modular plants.

If the described approaches are applied in plant planning, engineering and automation systems, there is the opportunity to leverage the potentials identified by Namur. For modular plant engineering to break through, a critical mass of plants is required, as well as a successful paradigm shift. The operators' strength of purpose will be decisive here. Such an approach can only be implemented step by step, and should be tackled in pilot projects.

\* See summary of theses in appendix section 9.5

## 8 Literature

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## 9 Appendix

### 9.1 Internal analysis (company analysis)

S – Strength, W – Weakness

	<b>Company (speciality chemicals &amp; pharmaceuticals in Europe)</b> <b>Goal: What internal incentives and structures do the customers (automation specialists) have that favor/hamper the use of module-based plants.</b> <b>Assumption: Restriction to two industries, products with relatively low annual volume.</b>
<b>W-1</b>	Successful products are lacking (the reduced income as a result of patent expiry is not compensated for by new products) → patent problem
<b>S-1</b>	A significant proportion of pharmaceutical products worldwide are manufactured in Europe because of the large customer base (large potential that can be exploited)
<b>W-2</b>	High development costs for new products. The reduction in the construction time for production plants therefore becomes very important.
<b>W-3</b>	Specialist departments disappear in the large corporate groups
<b>W-4</b>	(reasons: Outsourcing + brain drain)
<b>S-2</b>	Too few staff for current projects
<b>W-5</b>	(dependency on external companies, keyword: knowledge transfer)
<b>W-6</b>	Tendency to focus on core business. Manufacturer has product knowledge and focuses on quality and yield. Focus on topics such as product stability increases → more automation.
<b>W-7</b>	Tendency to focus on core business. Manufacturer has product knowledge but loses the ability to maintain the plants itself. These activities are transferred to the market.
<b>W-8</b>	Question of "make or buy" is frequently a consideration. Production is often outsourced to other companies. Process knowledge is concentrated at the manufacturer. Product knowledge remains with the ordering company. (Protect knowledge)
<b>W-9</b>	Scale-up is just as important as scale-down – both are costly problems with conventional plants. In addition, scale-up is also a process engineering task.
<b>W-10</b>	The plants are not automated to the same degree as is common in other industries (including large parts of the process industry). "The plants look more like big laboratory plants."

## 9.2 External analysis (environmental analysis)

O – Opportunity, T – Threat

<b>Company (speciality chemicals &amp; pharmaceuticals in Europe)</b> <b>Goal: What external incentives and market mechanisms are there that favor/promote/hinder the use of module-based plants?</b> <b>Assumptions and restrictions: see above + European market</b>	
<b>O-1</b>	Demographic change (mega-trend: lack of skilled workers)
<b>O-2</b>	Demographic change (mega-trend: growing need for drugs as a result of higher average age)
<b>O-3</b>	Globalization (mega-trend: emerging markets e.g. BRICS create wealth and thus demand for drugs or the possibility of financing them)
<b>T-1</b>	Globalization (mega-trend: emerging markets product generic drugs and constitute serious competition)
<b>O-4</b>	Wellness generation (mega-trend: Demand for “functional foods” is increasing – which creates demand for substances/products that are not active ingredients in the medical sense but come close to being pharmaceutical active ingredients)
<b>T-2</b>	Change in energy policy (rising energy costs cause companies to move production abroad) – less relevant for the pharmaceutical industry This leads to a market distortion to the detriment of Europe, because in the USA for example, the boom in shale gas is causing a drastic fall in energy prices.
<b>T-3</b>	High raw material prices (production of certain products is therefore postponed or prevented)
<b>O-5</b>	Large liquid sales market in Europe (will it also be there in the future?) – time scale much longer
<b>O-6</b>	Growing numbers of qualified staff needed, and are an important European location factor.
<b>T-4</b>	Worsening of market conditions as a result of Amnog legislation (act on the restructuring of the medicines market) → <a href="http://www.bmg.bund.de/glossarbegriffe/a/das-gesetz-zur-neuordnung-des-arzneimittelmarktes-amnog.html">http://www.bmg.bund.de/glossarbegriffe/a/das-gesetz-zur-neuordnung-des-arzneimittelmarktes-amnog.html</a>
<b>T-5</b>	Patent problem: Many successful products (blockbusters) have recently lost or will soon lose patent protection, without being replaced by similarly successful products.
<b>T-6</b>	Existing product types or active ingredients appear to be “exhausted”. To significantly improve the effect of drugs, experts assume that new products need to be found. Problem of developing new products. Innovation blockade
<b>O-7</b>	Module-based plants present themselves as a solution to existing problems. Initial experiences with the new technology are promising.
<b>T-7</b>	Module-based plants are not a completely new topic. In the past, attempts to realize such plants failed (with high losses)

## 9.3 SWOT analysis

SWOT analysis		Internal analysis (company analysis)	
		Strengths	Weaknesses
Externe Analyse (Umweltanalyse)	Opportunities	<b>I. MATCHING STRATEGY</b> (S-2+O-6) It is possible to focus on core business, and staff can be streamlined because the suppliers provide staff that can fill this gap while at the same time, responsibilities are transferred (better controlling e.g. of availability).	<b>II. TRANSFORMATION STRATEGY</b> (W-9+O-7) Initial experiences indicate that module-based plants can shorten the construction time by up to 50 %. As a result, investment risks can be reduced and market entry brought forward. (W-7+O-7) Scale-up and scale-down are inherently very possible with module-based plants. The added value is particularly high if scale-up can be achieved in a single step from the laboratory to a plant the size of module-based plants. (W-2+O-7) High development costs also result from the relatively high costs of conventional plants (distributed across the life cycle) that are also built especially for a product. The reusability of modules can help to reduce these development costs. (W-10+O-7) Investment risks fall if the time of construction start can be moved closer to the date of approval as a result of shorter construction times. The opportunities of a new active ingredient can then be evaluated more accurately.
	Risks	<b>III. NEUTRALIZATION STRATEGY</b> (S-1+T-3) Rising raw material prices can be compensated for through the relative low price sensitivity of the European market. The area of marketing must systematically ensure that the products are present in the customers' awareness.	<b>IV. DEFENSE STRATEGY</b> (W-3+T-6) The number of company-internal researchers is too low. Open platforms (internet) can be used to increase the knowledge pool and, thus, achieve new, innovative solutions faster.



### 9.3.1 Evaluation of the Results of the SWOT Analysis

Not all the points in the analysis are directly related to module-based plants. These points were not removed from the list, because all the points together provide an overall impression, which must be taken into consideration.

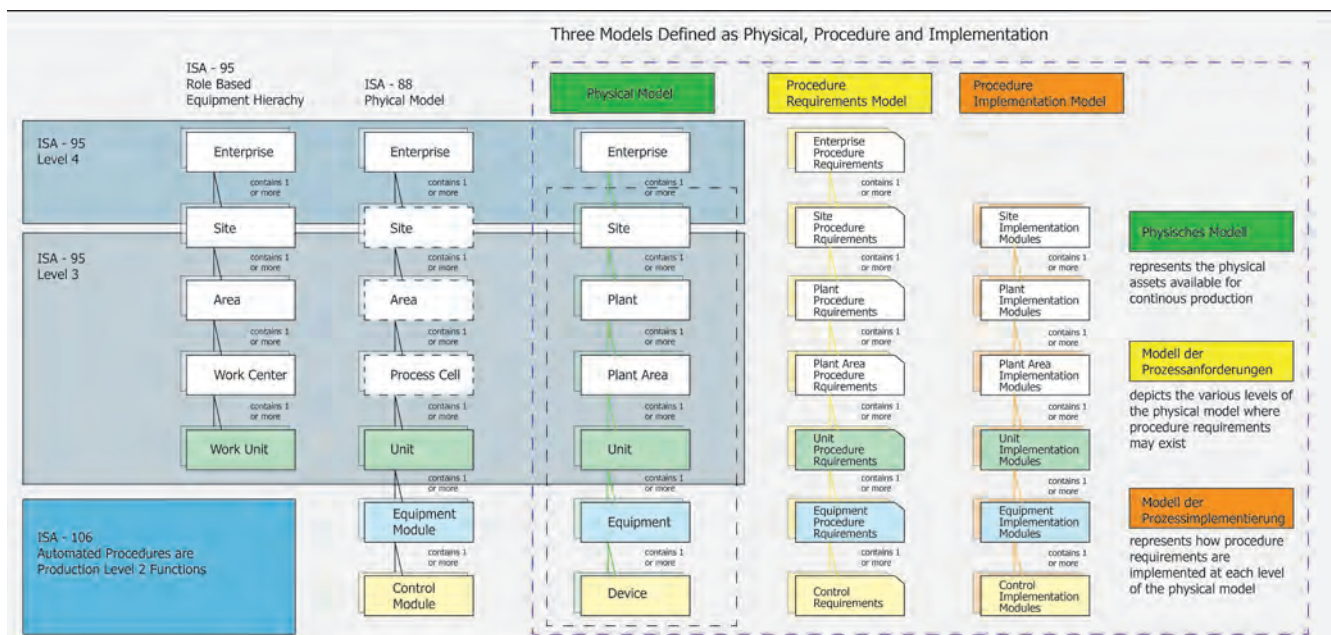
The result matrix clearly shows an emphasis on strategy options in sector II (transformation strategy). This can be interpreted to mean that existing and identified problems in the companies can be solved by module-based plants.

The construction of module-based plants will therefore be the strategy of choice in companies that are convinced they can thus react appropriately to new market requirements.

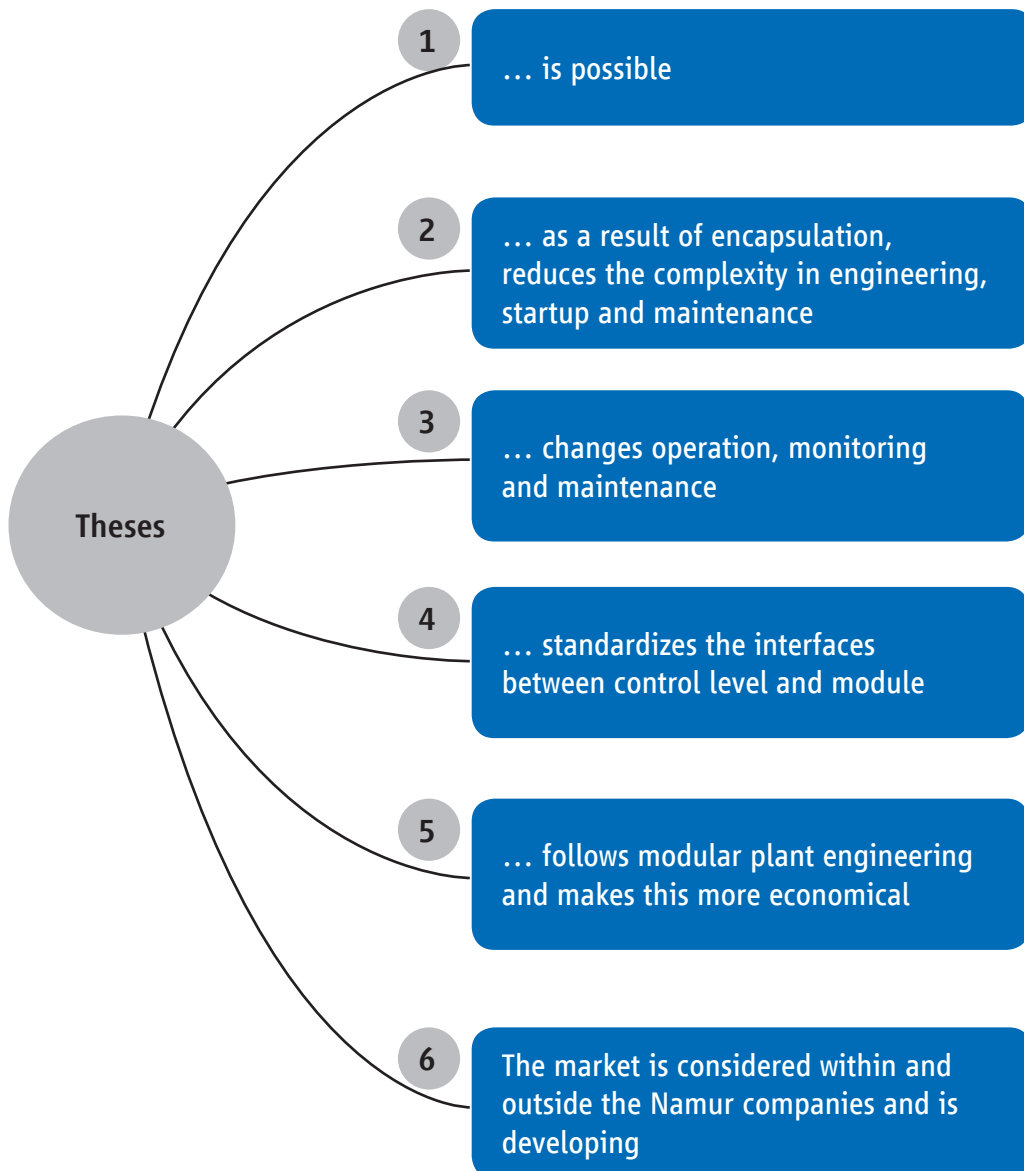
Discussions have shown that this situation is most applicable in the fine chemical/pharmaceutical industry, in particular in places where it seems possible to replace batches by modular continuous plants. Based on this estimate, modular automation will only be relevant for part of the process industry.

Critics (including those in the Namur companies) point out that attempts to realize the technology have already failed in the past or did not produce the desired added value. The market entry barriers to the new technology could be so high that if demand is too low, the critical mass needed to establish standardized process engineering modules as a real alternative to conventional plants on the market cannot be achieved.

## 9.4 Hierarchies for continuous and discontinuous process automation



## Central Theses of ZVEI-AK "Modular Automation"







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