



**Danfoss**

**Supplier Quality Manual**

Revision 1

January 2010

# 1 Index

1 Index.....	1
1 Introduction .....	2
1.1 Danfoss Quality Policy.....	2
1.2 Suppliers Quality Management System development – road map .....	3
1.3 Supplier Quality Manual revision history .....	3
2 Determination of Special characteristics .....	3
2.1 Symbols for Special Characteristics in Danfoss drawings.....	4
2.2 Process requirements.....	4
2.3 Process Flow for determination and control of special characteristics.....	5
3 Quality Plan (QP).....	5
3.1 Quality Plan activities .....	5
3.2 Quality Plan standard table.....	6
4 Part Approval Process (Sample Certificate Approval Process).....	6
4.1 General Requirements for the Part Approval Process.....	7
4.2 Delivery of Part Approval to Danfoss - documentation and samples products .....	7
4.3 Document Control and Records of Part Approval.....	7
4.4 Part Approval Documentation Requirements .....	7
4.5 Quality Plan, Part Approval definitions and instructions.....	9
5 Non-conformities regarding product specifications .....	16
5.1 Deviations found by Danfoss .....	16
5.2 Containment, Corrective and preventive activities .....	16
5.3 Concessions (waiver) Requests.....	17
5.4 Supplier Change Requests .....	17
6 References.....	17
7 Templates.....	18
8 Annex.....	18
8.1 Measuring System Analysis (MSA).....	18
8.2 Process capability calculation .....	21

## 1 Introduction

The purpose of the Danfoss Supplier Quality Manual is to enhance a uniform way for all Danfoss plants and global procurement organizations to communicate requirements and expectations to Danfoss suppliers regarding quality performance.

The Supplier Quality Manual represents Danfoss practices and ways of working. Danfoss suppliers must comply with the requirements by signing a Danfoss Supplier Quality Agreement. Suppliers shall refer to the Supplier Quality Manual to be informed and understand expectations and specified Danfoss requirements regarding quality. The intention is that suppliers together with Danfoss proactively work and embrace a continuous improvement mindset. It is expected that Danfoss suppliers are building a quality culture by using the required disciplines based on the Automotive Technical Specification ISO/TS16949.

Suppliers are expected to perform a detailed review and discuss specifications with Danfoss Purchasing or the Danfoss Supplier Quality Assurance organization to understand specific requirements and to ensure effective business regarding quality, logistics and commercial aspects.

Requirements in the Danfoss Supplier Quality Manual covers all quality matters related to all deliveries from the supplier to any Danfoss plant or Danfoss customer(s).

The supplier recognizes the responsibility to deliver parts and products to Danfoss with 0-defects and with full conformity to specifications. In case of deviations, the supplier is expected to carry out **containment action(s), root-cause analysis, corrective action(s) and evaluating preventive action(s)** as mandatory steps according to the 8D problem solving method.

The supplier is fully responsible for all parts, products and services supported by the supplier's sub-suppliers. The supplier shall ensure that sub-suppliers are fulfilling specified Danfoss requirements for parts, products and services destined for Danfoss.

When relevant, Danfoss will define special characteristics related to the design and the supplier shall identify process related special characteristics in a P-FMEA document. All special characteristics must be documented in a Control Plan. Special characteristics are synonymous with critical, key and/or safety characteristics.

In general all specified Danfoss requirements in this document must be met unless deviations are agreed in writing with the corresponding Danfoss quality responsible party.

### 1.1 Danfoss Quality Policy

Danfoss regards quality in a wider perspective – as we are convinced that high quality in everything we do is a basic competition parameter. This means that Danfoss will:

- Maintain a world class standard on quality management
- Maintain appropriate quality systems in accordance with international quality standards
- Ensure that Danfoss products, services and solutions are among the best in the market
- Measure and evaluate the quality in order to improve our products, services and solutions, and the way we work

## 1.2 Suppliers Quality Management System development – road map

Danfoss will ensure that purchased parts conform to specified purchase requirements. The type, demands and extent of control applied to suppliers (and to the purchased parts) will depend on the effect of the part on subsequent Danfoss products manufacturing.

Danfoss suppliers are requested to develop their Quality Management Systems using Automotive Technical Specification TS16949 as a reference, using the following recommendation:

- Conformity with latest version ISO9001 demonstrated by a third party certification or through an equivalent second party (Danfoss) audit process.
- Gradually develop a quality processes and the tools required by TS16949 including the following:
  - Process flow charts
  - 8D problem solving
  - Design Failure Mode and Effect Analysis (D-FEMA)
  - Process Failure Mode and Effect Analysis (P-FEMA)
  - List of special characteristics
  - Control plan
  - Error proof methods
  - Inspection / control instructions
  - Measuring System Analysis
  - Capability analysis for all special characteristics
  - Statistical Process Control (when relevant)
  - Other Quality Management System additional requirements specified by TS 16949

## 1.3 Supplier Quality Manual revision history

Date	Revision	Change description
March 2009	0	Original version
January 2010	1	Scope is expanded: Drives, Heating and Global Procurement organizations are included. A Supplier Quality Management system development road map is added. Determination and control of special characteristics section is added. Improved descriptions of Part Approval definitions and instructions. An annex to describe detailed calculation formulas is created.

## 2 Determination of Special characteristics

Special characteristics are describing product characteristics and process parameters which have a significant influence on the product performance due to customer specific requirements and product specification(s). Not fulfilling the special characteristics definition could cause extreme and

serious failures that affects the safe and proper use of Danfoss product or could violate statutory and regulatory requirements.




Special Characteristics are marked in the Danfoss specifications. For Special Characteristics identification within the production processes the following criteria should be considered:

- Product performance
- Product reliability
- Product safety (FMEA severity ratings and other safety regulations)
- Statutory compliance (FMEA severity ratings and other regulations)
- Product durability, life time tests (FMEA occurrence ratings and other surveys)
- Other special characteristics based on customer specific requirements

A cross functional team including design, process and quality engineers should identify the Special Characteristics. Classification of Special Characteristics should follow the Danfoss Corporate Standard # 500B0404 ("Classification of requirements in the product basis"), as well as symbols to be used in raw materials and parts drawings:

- Class S** Requirements demanding particular attention because deviation could mean danger to personnel, serious injury, or the non-observance of safety or regulatory compliance.
- Class F** Requirements demanding particular attention because deviation could prevent or hinder form, fit or function of the product.
- Class P** Requirements demanding particular attention because deviation could hinder production, installation, or any other subsequent operations.

## 2.1 Symbols for Special Characteristics in Danfoss drawings

Class	Symbol
S	 or < S >
F	 or < F >
P	 or < P >

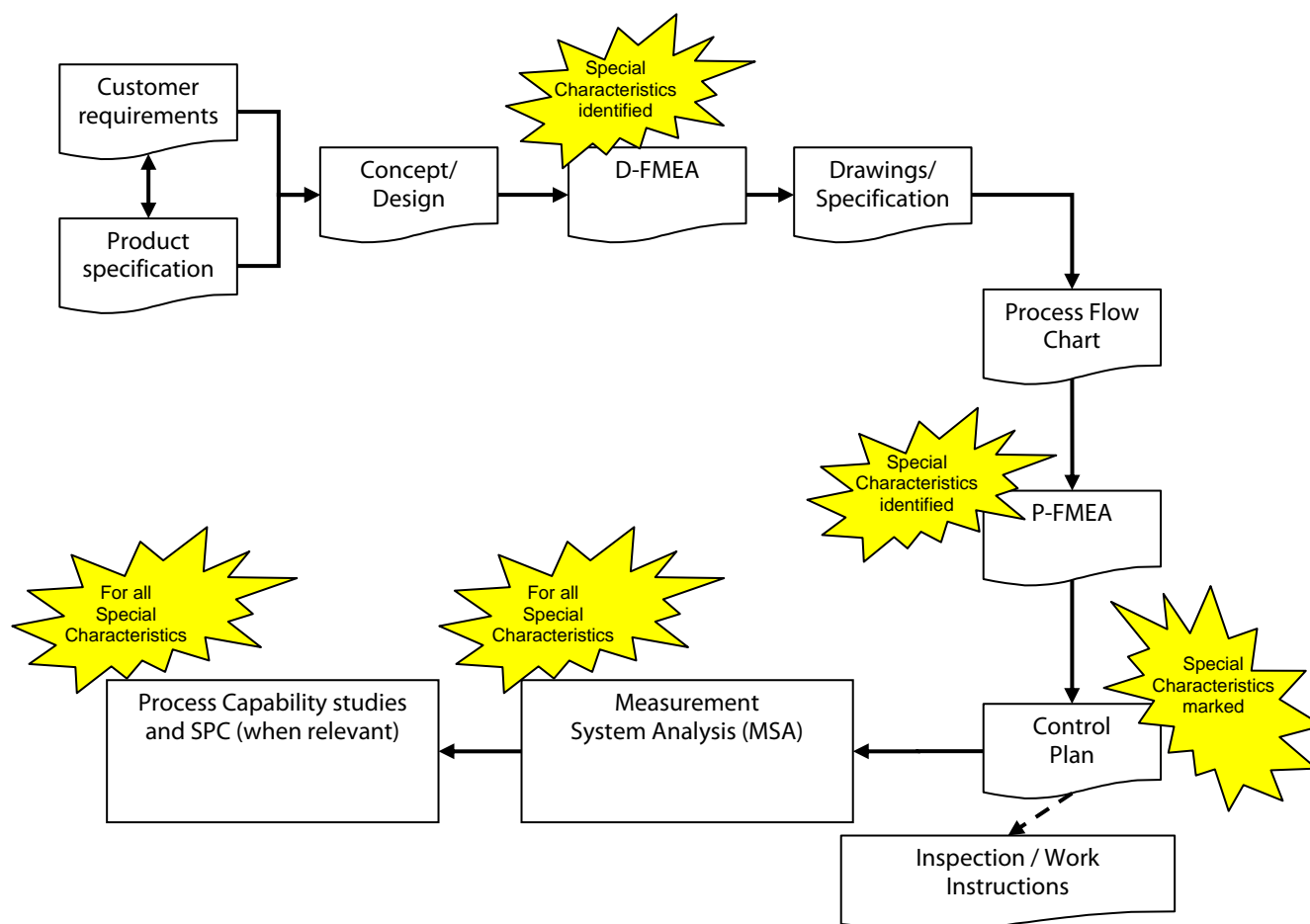
## 2.2 Process requirements

The supplier must assign a reference number to each special characteristic to be used as reference in control plans and measurement reports. The following specified Danfoss requirements must be fulfilled to control the Special Characteristics;

- 1) Process FMEA for identification. In case of design responsibility also the Design FMEA
- 2) List of special characteristics (with reference numbers)
- 3) Control Plan with marking the special characteristics
- 4) Measurement System Analysis (MSA)
- 5) Initial process capability studies (Short term, Cpk)

6) Statistical Process Control (SPC / Long term capability, Ppk)

## 2.3 Process Flow for determination and control of special characteristics



## 3 Quality Plan (QP)

Supplier is obliged to prepare a Quality Plan and carry out the planned activities, when preparing a part for first time approval or re-approval for production. Quality Plan can be done according to APQP (Advanced Product Quality Planning) process or contain below activities in QP standard table (see 3.2). The Quality Plan shall describe the schedule of planned quality assurance activities. The Quality Plan shall be presented to Danfoss upon request.

### 3.1 Quality Plan activities

The Quality Plan shall contain as a minimum, activities according to the QP standard table. In individual cases (depending on product complexity, volume, etc.) specified Danfoss requirements may (in cooperation and partnership with Danfoss) be added, enhanced and/or reduced. The supplier shall submit a complete Quality Plan with timing plan before making parts for qualification for running production.

### 3.2 Quality Plan standard table

Quality Plan activities	Required
<b>Design activities (only when the supplier is Design Responsible)</b>	
Design FMEA	X
Design Review	X
Danfoss Approval of Design Records (if required)	X
<b>Pre-production Activities</b>	
Feasibility study	X
Process Flow Chart	X
Process FMEA	X
Control Plan (Prototypes, sample testing and series production) marking special characteristics	X
Planning of Production, Tooling, Measuring and Testing Equipment	X
Working, Inspection, Test and Packing Instructions	X
Training of Operators	X
Preventive Maintenance Plan	X
Traceability Preparation (if required)	X
Measurement Systems Analysis (for special characteristics)	X
<b>Sub-Supplier Activities</b>	
Sub-Supplier Assessment	X
Sub-Supplier Quality Plan	X
Part Approval (Sub-Supplier)	X
<b>Verification and Approval Activities</b>	
External Approvals (if required)	X
Part Approval for series production	X
Part Approval Process (PPAP-documentation)	X
Initial Process Capability assessments (Cpk and Ppk)	X

### 4 Part Approval Process (Sample Certificate Approval Process)

Purpose of working out Part Approval Process (or Sample Certificate) is to document that quality is ensured and delivered parts fulfill agreed specifications. Before the supplier starts deliveries to production, all parts and materials must be approved according to the specified Danfoss requirements described in this document and will result in a Sample Certificate using a Part Submission Warrant (PSW see 4.4).

For part approval process, the supplier is responsible to submit requested parts and documentation. If any document or result does not comply with specifications the supplier is not allowed to supply parts to Danfoss without a written exemption (clarification / waiver form).

Situations where the supplier always shall obtain a Part approval from Danfoss
Supplier shall always notify Danfoss by use of Supplier Change Request and is responsible for obtaining a part approval from Danfoss in the following situations:
<b>1. New part or product not previously supplied to Danfoss.</b>
<b>2. Modified part, for instance by an engineering change to design, specification or materials impacting form, fit and function.</b>
<b>3. When a wholesaler is changing his sub supplier of Danfoss items</b>

<b>Situations where the supplier always shall notify Danfoss</b>
Supplier shall always notify Danfoss by use of Supplier Change Request form of any planned design or process changes as indicated in the following table. Subsequently, Danfoss will decide whether a new part approval is required based on impact to form, fit and function.
<b>1. Changes in current process flow or production location.</b>
<b>2. Change of sub suppliers for parts, non-equivalent materials or services (e.g. heat-treating, painting etc.) that may effect specified Danfoss requirements</b>
<b>3. Product produced after the tooling has been inactive for 12 month or more</b>
<b>4. Production from new or modified tool (for new/modified drawings)</b>
<b>5. Production from equipment transferred to a different location or from an additional plant</b>

#### **4.1 General Requirements for the Part Approval Process**

All measuring, testing and verifying that are included in the Part Approval shall by performed with part samples produced in the production run for part approval parts. Parts from each unique production process i.e. each production cell, line, tool or cavity, shall be separately measured, tested and verified. The Supplier shall always give Danfoss the opportunity to participate at the production run for part approval parts.

#### **4.2 Delivery of Part Approval to Danfoss - documentation and samples products**

Part Approval sample products must always be delivered separately from production shipments and other samples. Part Approval samples must be labeled and sent to Danfoss according to agreed upon instructions. Requested documentation shall be sent electronically by e-mail or CD-ROM to Danfoss quality responsible or according to given instructions.

#### **4.3 Document Control and Records of Part Approval**

Part Approval documentation including enclosed measuring and test results shall be retained as long as the product is being produced and at least 3 years after the production has stopped. If the product specification contains external product approval e.g. UL approval, ATEX approval, IECEx approval etc. or other safety requirements the documentation shall be retained as long as the product is being produced and at least 10 years after the production has stopped. Documentation on previously approved (and produced) products may be requested by Danfoss on a case by case basis.

#### **4.4 Part Approval Documentation Requirements**

Suppliers shall use level 3 as the default level for all submissions unless otherwise specified by the authorized Danfoss representative. Depending upon supplier development level, FMEAs Risk Analysis Table and/or parts impact (financial, strategically, etc), the authorized Danfoss representative may require only a submission "starting level", which means some of the items are not required for initial part approval, however an action plan must be agreed on with a quality roadmap to develop such tools and/or records.

Part Approval Documentation	Level 1 (Self certify)	Level 2 (Reduced approval)	Level 3 (Default Approval)	Starting Level (Interim approval)
<b>Quality assurance documentation (When the supplier is Design Responsible)</b>				
Design FMEA	R	R	R	R
Danfoss Approval of Design Records (if required)	R	S	S	S
<b>Quality assurance documentation</b>				
Process Flow diagram	R	R	S	R
Process FMEA	R	R	R	R
Control Plans	R	S	S	P
Traceability Preparation (if required)	R	R	S	P
External laboratory accreditation certification (if required)	R	S	S	P
<b>Test Results documentation</b>				
Dimensional results	R	S	S	S
Material, Performance results (Material Certificate)	R	S	S	S
Checking aids (drawings and measurements for special gauges, self made devices etc.)	R	R	R	R
External approval certificates (if required)	R	S	S	P
Appearance results	S	S	S	S
Sample Products (According to Purchasing Order)	R	S	S	S
Measurement System Analysis (MSA) for special characteristics	R	R	S	P
Initial Process Capability Study (Ppk) for special characteristics	R	R	S	P
<b>Other required documentation</b>				
Part Submission Warrant (PSW)	S	S	S	S
Danfoss Negative list conformity (including ROHS and REACH requirements)	S	S	S	S
Specific requirements of European Community Directives, product safety approvals (i.e. UL) and other local legal requirements when applicable	R	R	R	R

S = Shall be included in the Part Approval documentation **submitted** to Danfoss

R = Shall be **retained** by the supplier and submitted/available to Danfoss upon request

P = Shall be **planned** with Danfoss depending on risk assessment (RPNs) and/or supplier development level

## Part Submission (Sample Certificate) Warrant dispositions

### Approved

“Approved” indicates that the part or material, including all sub-components, meets all specified Danfoss requirements. The supplier is therefore authorized to ship production quantities of that part.

### Interim approval

“Interim approval” permits shipment of material for production requirements on a limited time or piece quantity basis. Interim approval will only be granted when supplier has:

- Only fulfilled “Starting Level” evidence for Part Approval requirements
- Clearly defined the non-compliances preventing approval; and
- Prepared an action plan agreed upon by Danfoss.

Part Approval (Sample Certificate) re-submission is required to obtain status of “approved”.

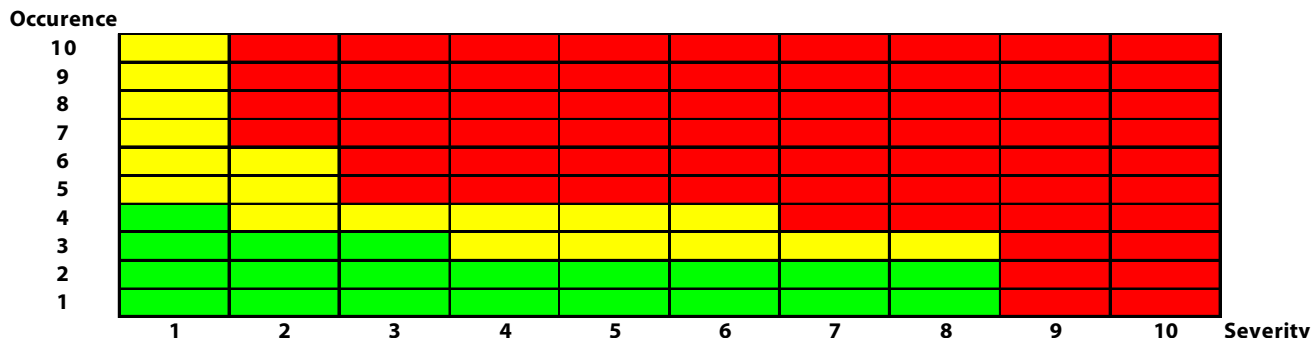
### Rejected

This means that the Part Submission (Sample Certificate) Warrant does not meet specified Danfoss requirements, based on the production lot from which it was taken and/or accompanying documentation. In such cases, the submission and/or process shall be corrected to meet specified Danfoss requirements.

## 4.5 Quality Plan, Part Approval definitions and instructions

### 4.5.1 D-FMEA – Design Failure Mode and Effect Analysis

The D-FMEA shall identify and evaluate the risk of failure concerning the design of the product. If nothing else is agreed between Danfoss and the supplier, the D-FMEA should be completed for all products where the supplier is design responsible. The D-FMEA shall be available in connection with the part approval and presented upon request, and the completed document shall be according to Automotive Industry Action Group (AIAG) recommendations. An action plan must be done according to **Risk Analysis Table** shown below:



Green area - no actions needed

Yellow area - no mandatory actions required, but corrective and preventative actions should be defined and communicated to Danfoss to reduce the risk to both parties

Red area - mandatory corrective and preventative actions are required and shall be communicated to Danfoss to reduce the risk to both parties to reduce the risk

A Design as well as Process FMEA must be used as a guideline for Special Characteristics determination. In the cases where the severity  $S > 8$  and the product of the risk factor multiplied by the factor of probability for occurrence  $S * O \geq 40$  a characteristic is recommended to be defined as a Special Characteristics.

#### **4.5.2 Design and processes review**

The supplier shall carry out formal and systematic design reviews in the product development project to identify and anticipate possible problems and defects. The supplier shall always give Danfoss the opportunity to participate in the Product Development Project. Depending on the actual phase of the project, the design reviews must contain a review of the basis/engineering specification, the design and the selected processes.

The review of basis/engineering specification shall as minimum contain:

- An evaluation proving that all specified Danfoss requirements are met

In case of incomplete, unclear or contradictory requirements in the basis-/engineering specification, this must be reported to Danfoss quality responsible or the responsible Danfoss purchaser

The review of design shall as minimum contain:

- An evaluation proving that the requirements, in the form of drawings and specifications, are unambiguous and meet specified Danfoss requirements.
- An evaluation of the biggest risk in the construction documented in D-FMEA.
- An evaluation of permissible tolerances and comparison with the capability of selected processes.
- An evaluation of the possibility of choosing alternative sub-suppliers.
- An evaluation of the product regarding how easy it is to install, maintain and service; storage need, storage time and removal possibilities.
- An evaluation of the user safety of the product.
- An evaluation of the statutory compliance of the product.
- A determination of specifications and acceptance criteria concerning the visual requirements.
- An evaluation of requirements to labeling, warnings, identification, production coding, and operating and assembly instructions.

The review of processes shall as a minimum contain:

- An evaluation proving that a supplier process is able to produce according to drawings and specification.
- An evaluation of the specified Danfoss requirements for special processes, automation and assembling systems.
- An evaluation of the needs and specified Danfoss requirements to inspect and test
- An evaluation of the specified Danfoss requirements for packaging, handling, storage, and storage time.
- An evaluation of the specified Danfoss requirements for equipment and measuring devices

If the supplier finds any deviations from the specified Danfoss requirements, the supplier must contact Danfoss immediately.

#### **4.5.3 Danfoss approval of design records**

Danfoss shall always approve design records (drawings, etc.) created by the supplier specifically according to Danfoss specifications, before the part approval.

#### **4.5.4 Feasibility study**

The supplier should carry out formal review of drawing and specifications (for example a Design for Manufacturing review, DFM) previous to defining processes and flow. In case of incomplete, unclear or contradictory requirements or specifications, this must be clarified through Danfoss quality responsible or Danfoss purchaser. Additional requirements/checklist/signoff may be required depending on agreements done with Danfoss.

#### **4.5.5 Process flow diagram**

The supplier shall have an overall process flow diagram that clearly describes the full production process steps and locations.

#### **4.5.6 P-FMEA – “Process Failure Mode and Effect Analysis”**

The Process-FMEA shall identify and evaluate the risk of failure during the production processes. If nothing else is agreed between Danfoss and the supplier, the P-FMEA should be completed for processes. The P-FMEA shall be available in connection with the Part Approval Process (Sample Certificate) and completed according to the AIAG recommendations. A corrective action plan with responsible person and completion date must be established with the same Risk Analysis Table as described in the D-FMEA section.

The Design and Process FMEA must be used as guideline for Special Characteristics determination. In the cases where the severity  $S > 8$  and the product of the risk factor multiplied by the factor of probability for occurrence  $S * O \geq 40$  a characteristic is recommended to be defined as a Special Characteristics.

#### **4.5.7 Control Plan**

The supplier shall prepare a Control Plan based on D-FMEA and P-FMEA for the complete process and method describing which control and inspection activities that have been implemented to ensure conformity to the specification. Special characteristics shall be marked with their reference number.

#### **4.5.8 Planning of production, tooling, measuring and test equipment**

The supplier shall ensure that new Production, Tooling, Measuring and Test equipment is delivered in time and capable to fulfill the required Danfoss specifications. Production, Tooling, Measuring and Test equipment owned by Danfoss, shall be clearly identified by a permanent marking as Danfoss' property. Production measurement equipment and method has to be aligned with Danfoss.

#### **4.5.9 Working-, inspection-, testing- and packing-instructions**

To ensure that the supplier can produce and deliver products that fulfill the specified Danfoss requirements, the Supplier must develop and implement necessary working, inspection, testing and packing instructions. These instructions must clearly describe the criteria for a satisfactory performance of each manufacturing process, be related to the specifications of the finished product, and describe the inspection and test procedure.

#### **4.5.10 Training of operators**

The supplier shall ensure and document that employees have relevant training for competence to be able to manage the process and follow related instructions. Appropriate competences detection must be done by each supplier to ensure corrective and preventative actions can be executed.

#### **4.5.11 Traceability documentation**

If there are any traceability requirements about the supplier shall be able to present documentation describing how the specified Danfoss requirements will be met. Danfoss will specify what degree of traceability is needed: raw materials, work in progress and/or finish goods.

#### **4.5.12 Preventive maintenance plan**

The supplier shall carry out and implement a preventive maintenance plan.

#### **4.5.13 Sub-Supplier assessment**

The supplier is responsible to ensure that sub-suppliers are capable of fulfilling all relevant specified Danfoss requirements. Danfoss may also request to assess/audit sub-suppliers.

#### **4.5.14 Sub-Supplier Quality Plan**

The supplier is responsible to ensure that sub-suppliers are planning and completing necessary quality assurance activities to ensure parts and product delivered fulfill the specified Danfoss requirements.

#### **4.5.15 Part Approval (Sub-Supplier)**

The supplier is responsible to approve all products supplied by sub-suppliers to ensure parts and products delivered fulfill the specified Danfoss requirements. The supplier should use Danfoss Part Approval Process or an equivalent process.

#### **4.5.16 External approvals**

In case of external approval requirements (e.g. ATEX or UL-approval), specific information will be provided to the supplier from the Danfoss quality responsible or responsible Danfoss purchaser.

#### **4.5.17 Part approval for serial production**

Three (3) phases shall be done prior to serial production at suppliers:

Phase 1: Purchasing project preparation where all necessary tasks have to be fulfilled to select the supplier and get the release for the purchasing project.

Phase 2: Production process development. All process applicable requirements stated in the Supplier Quality Manual shall be implemented in addition to the sample planning for necessary tests. The amount of samples must be defined together with Purchaser, Quality, Product Development and Operations of the Danfoss Business Unit.

Phase 3: Approval of serial production. During this phase the supplier applies for the approval of his serial production. Danfoss may conduct a process, product or system audit during the production trial / pilot series production in order to confirm and approve the production is ready for series supply and specified Danfoss requirements are fulfilled.

Supplier must carry out a series production for Part Approval to make sure that a newly developed part can be produced as expected, before the part is approved for production. The production of Part Approval Parts shall be manufactured at the same production site as where production will take place. The parts shall be manufactured using the same equipment from the production environment as for future deliveries. Production shall be performed in the same way, by using the same material,

and under the same conditions (including operators/competences) as for future serial production runs.

The production run for part approval shall be a significant production run that will ensure relevant variation sources (e.g. change of operators and material) will have an impact on the process variation. The Danfoss Purchasing Order shall always confirm the size of the production for Part Approval. Parts produced in the production for Part Approval shall be used for evaluation according to Danfoss Part Approval Process.

The production for Part Approval must confirm:

- The inspection and test methods (and the approval criteria) which must be used to evaluate the product (or the processes) during the production phase have been determined and can objectively prove whether the product (or process) meets the specified Danfoss requirements.
- The capability and capacity of the production equipment meet the specified Danfoss requirements under production-like conditions.
- The product meets the specified Danfoss requirements for packaging and labeling.
- The production and material systems are suited for the purpose.
- The operators have the necessary qualifications and competences.

If deviations from the specified Danfoss requirements are found when implementing the production for Part Approval, the supplier must carry out the necessary corrective action improvements and have them confirmed before Danfoss can approve the part for serial production.

#### **4.5.18 Dimensional results**

The supplier shall report all of the dimensional results of the measurements stated on drawings. When requested, these dimensional results (measurement equipment, nominal measurements and tolerances) shall be detailed in the measurement report. Any measurement that falls outside the tolerances shall be clearly indicated, and must be approved by Danfoss prior to dispatch. Number of parts to be measured must be agreed on in advance with the Danfoss quality responsible person.

The supplier shall present results for parts from each unique production process (i.e. each production cell, line, tool or cavity) including complete measurement of all product dimensions shown in the design record. The parts used for evaluation of the dimensional results shall be picked with equal distribution among the parts produced in the production run for part approval parts. When requested by Danfoss dimensional results must be presented.

#### **4.5.19 Material, Performance Result**

All material and performance requirements according to Danfoss specification shall be verified. It shall appear in the record document whether verification and testing have been performed with approved result.

Specific test results must be presented. General statements such as conformity to specifications (e.g. "OK", "Approved", etc.) are not acceptable. Material properties shall be verified by using material certificates according to the European standard EN10204. Certificates (at minimum) shall be EN10204-2.2, written in English and signed by the drawer unless other requirements are specified.

#### 4.5.20 Appearance Results

For parts with appearance requirements in the design record, the supplier shall verify that the specified Danfoss requirements have been met by submitting a test report to Danfoss. Parts used for evaluation of the appearance requirements shall be picked among the parts produced in the production run for part approval parts. The acceptance criteria and verification method shall be agreed between Danfoss and the supplier before the approval (e.g. reference parts) process begins.

#### 4.5.21 Sample Products

Measured parts stated in "Dimensional results" shall be submitted to Danfoss separated from the Part Approval Order.

#### 4.5.22 Measurement System Analysis (MSA)

The purpose of carrying out a Measurement System Analysis is to evaluate the capacity of measuring capability correctly under the influence of all conditions that might affect the measuring accuracy. The measurement capability study must be performed in order to make a proper evaluation of the measurement method.

Acceptance criteria for MSA Study (Average and Range method)		
Number of Distinct Categories (ndc)	Gage R&R	Status
$ndc \geq 5$	$GR\&R \leq 10\%$	The measurement system can be approved.
$2 \leq ndc < 5$	$10\% < GR\&R \leq 30\%$	The measurement system can be approved, if Danfoss accepts the measuring uncertainty. Corrective actions can be required and the supplier must contact Danfoss responsible SQA (Supplier Quality Assurance) or the responsible Danfoss purchaser)
$ndc < 2$	$GR\&R > 30\%$	The measurement system cannot be approved.

Measurement capability study must always be made for special characteristics and other parameters requested by Danfoss. Therefore the capability of the measurement system must be established prior to any statistical surveys ( $C_p$ ,  $C_{pk}$ ,  $P_p$ ,  $P_{pk}$ ) and calculations must be made to understand the nature of the process. The measurement capability study should always be carried out under actual working conditions. It is recommended that the analysis is carried out at the same location where the measuring equipment will be used during production and under the same environmental conditions that will be anticipated in production.

The analysis of the measurement system must be done by the routine production operators. The measurement capability study should always be carried out using parts from the actual process and cover the entire tolerance. BIAS must always be found and minimized in relation to a traceable and controlled master. The measurement capability study will follow different tracks (including MSA Type I-III) depending on whether the measurement is influenced by the operator or is carried out by automatic measurement system. See **Annex 8.1** for MSA calculation methods.

#### 4.5.23 Process Capability Study

The purpose of the process capability study is to predict the capability of a process to produce parts in accordance with the specified Danfoss requirements. The preliminary process capability Study shall be according to the AIAG SPC Manual and shall include Control chart(s), standard deviation(s), Cp-values and Cpk-values.

For all special characteristics a process must be selected and maintained to perform a specified Process capability for running production according the specification. Special characteristics are marked on the drawing according to Danfoss Corporate Standard #500B0404, and all special characteristics shall be considered input to the Control Plan. The supplier shall perform a process capability Study and the results must be documented in the Part Approval Documentation.

<b>General acceptance criteria for the preliminary process capability CpK (short term) study for special characteristics:</b>	
<b>CpK &gt;= 1.67</b>	Approved result for the preliminary process capability study
1.67 > cpK >= 1.33	Danfoss can in some cases accept the result. Acceptance must be in writing. Corrective actions will be required from the supplier and the supplier must contact Danfoss quality responsible or Danfoss purchaser
Cpk < 1.33	Not acceptable 100 % inspection must be carried out, or alternatively the inspection frequency shall be considerably increased to ensure that the specified Danfoss requirements are always met. The supplier must contact Danfoss quality responsible or the responsible Danfoss purchaser
<b>General criteria for process capability Ppk (long term) for running production:</b>	
All production processes must be selected and controlled to maintain a Process Capability (Ppk) of <b>at least 1.33</b> . The Ppk levels of special characteristics must be documented and reported upon request.	
For special characteristics/parameters or properties the requirements can be different compared to the general requirements.	

Parts used for evaluation of the preliminary process capability study shall be produced and randomly sampled in the production run for part approval parts. The process capability study shall contain a minimum of 30 parts in total. The samples shall be collected in production when the process is stable (i.e. no adjustments are allowed) during the production run. Parts from each unique production process (i.e. each production cell, line, tool or cavity) shall be evaluated separately.

The number of parts used for preliminary process capability study depends on the number of cavities. In case of parts used for high volume production Danfoss quality responsible or Purchaser may require one hundred twenty five (125) pieces to be used for the preliminary process capability.

<b>No. Cavities</b>	<b>Random size (n)</b>
= 1	n ≥ 30 pieces
≥2 ≤3	n ≥ 25 pieces / cavity
≥4 ≤50	n ≥ 50 pieces (cavity x cycles => 50) but minimum 5 cycles
> 50	n = minimum 5 cycles

If the required process capability has not been obtained, an action plan with corrective actions shall be prepared describing the activities to be implemented to ensure compliance with the specified Danfoss requirements. See **Annex 8.2** for process capability calculation methods.

#### **4.5.24 Statistical Process Control (SPC)**

Suppliers approved for running production shall establish and maintain, where relevant, a system where special characteristics are under statistical process control (SPC), according to AIAG or equivalent. Data shall be retained (at minimum) twelve (12) months from last production and shall be documented upon request within five (5) working days. Where agreed and specified, SPC documentation must be included for each delivery. The supplier shall reduce variation through continuous improvements in long term process capability.

#### **4.5.25 Part Submission Warrant (PSW)**

A Part Submission Warrant is an industry-standard document required for all newly-tooled or revised products in which the supplier confirms that inspections and tests on production parts show conformance to customer requirements. Status of a PSW can be: "Approved", "Interim approved" or "Rejected".

## **5 Non-conformities regarding product specifications**

Danfoss reserves the right to make a claim on any products with deviation from agreed specifications.

### **5.1 Deviations found by Danfoss**

In case of deviations from agreed specifications, Danfoss will in cooperation with the supplier, make one of the following decisions:

1. The supplier will inspect and sort parts with uncertain status at Danfoss' premises.
2. The complete batch is returned to the supplier
3. Danfoss will inspect and sort parts with uncertain status at the suppliers' expense.
4. Danfoss will re-work products at the suppliers' expense.
5. Danfoss will grant waiver (concession) for the delivered parts.
6. All costs related to the import and export of products and parts with a confirmed deviation will be at the supplier's expense.

A permanent corrective action recommendation including "sorting" of a Danfoss part or product designated with a special characteristic is unacceptable. In case of agreement with Danfoss quality responsible or the responsible Danfoss purchaser for a short-term corrective action of "sorting" a special characteristic Danfoss part or product, the sorting criteria must have control limits based on initial capability study or another more strict tolerance.

### **5.2 Containment, Corrective and preventive activities**

**8D Methodology** – There are 8 Disciplines that must be followed to effectively solve and prevent a problem. This methodology may generate 3 different type of reports: 3D report (Team, Problem description and Containment actions), 5D report (include root cause analysis and corrective action plan) and 8D report (includes also validation and preventive actions).

All claims shall be handled according to the 8D method, including following activities:

1. Establish Task Force Team
2. Problem description
3. Containment action (actions to contain the damage, max 2 working days) "3D report"
4. Root cause analysis of the problem
5. Corrective actions plan (max 10 working days) "5D report"
6. Validation of the implemented corrective actions
7. Preventive actions
8. 8D-report is closed and celebration of the success

**Until the 8D-report is closed the supplier shall attach a declaration (label) of conformity on every pallet to certify that all delivered parts and products have been inspected, are without defect and meet all specified Danfoss requirements. Containment actions must include any parts in transport and supplier warehouses.**

### **5.3 Concessions (waiver) Requests**

If the supplier wishes to deliver products to Danfoss in spite of deviations from the specified Danfoss requirements the supplier must contact Danfoss using a Concession (or "waiver") Requisition form to give notice regarding a specific part or product with regard to quantity, cause and corrective action. Before delivery the Concession Requisition form must be approved and signed by Danfoss. Labeling methods and criteria of the conceded product must be agreed on with Danfoss. Danfoss reserves the right to cancel an issued waiver at any time. Any cancellation by Danfoss will be in writing and delivered to the supplier.

### **5.4 Supplier Change Requests**

If the supplier wishes to introduce changes of processes, design or material having impact on product quality (form, fit and function), a Supplier Change Request form must be submitted for approval to the Danfoss quality responsible person. Changes can be introduced when Danfoss has given approval and signed the Supplier Change Request form for implementing the change and communicated the requirements for requalification and Part Approval Process (Sample Certificate) documentation.

## **6 References**

### **Danfoss Standards with information about related issues**

Danfoss standard 500B0404 Classification of requirements in the product basis

Danfoss standard 500B0751 Negative List for Substances and Materials

### **More information about related issues**

AIAG/reference manual APQP "Advanced Product Quality Planning and Control Plan" 2nd Edition

AIAG/reference manual MSA "Measurement System Analysis"

AIAG/reference manual SPC "Statistical Process Control"

AIAG/reference manual FMEA "Potential Failure Effects Analysis"

AIAG/reference manual PPAP "Production Part Approval Process" 4th Edition

## 7 Templates

In order to secure uniform communication through Supply chain Danfoss require depending of the template to be according AIAG or according Danfoss templates, or without any requirement to the form of template

### Templates mandatory according to AIAG, where enclosed Danfoss templates can be used.



DFMEA\_template.xls



PFMEA\_template.xls



ControlPlan.xls



Part Submission  
Warrant.xls

### Templates mandatory according to Danfoss



Supplier Change  
Request form.xls



Waiver requisition  
form.xls

### Templates without requirements to form

Enclosed Danfoss templates can be used when appropriate



8D Suppliers.dot



MSA.XLS



Capability  
calculation.xls



SPC CONTROL  
CHART auto.xls



Feasibility study.xls

## 8 Annex

### 8.1 Measuring System Analysis (MSA)

#### Performing MSA Type I -III

##### **Type I: Apply to all measuring systems for BIAS and capability**

To evaluate and minimize the systematically deviation BIAS in the measuring system, and to estimate the potential capability of the measuring system.

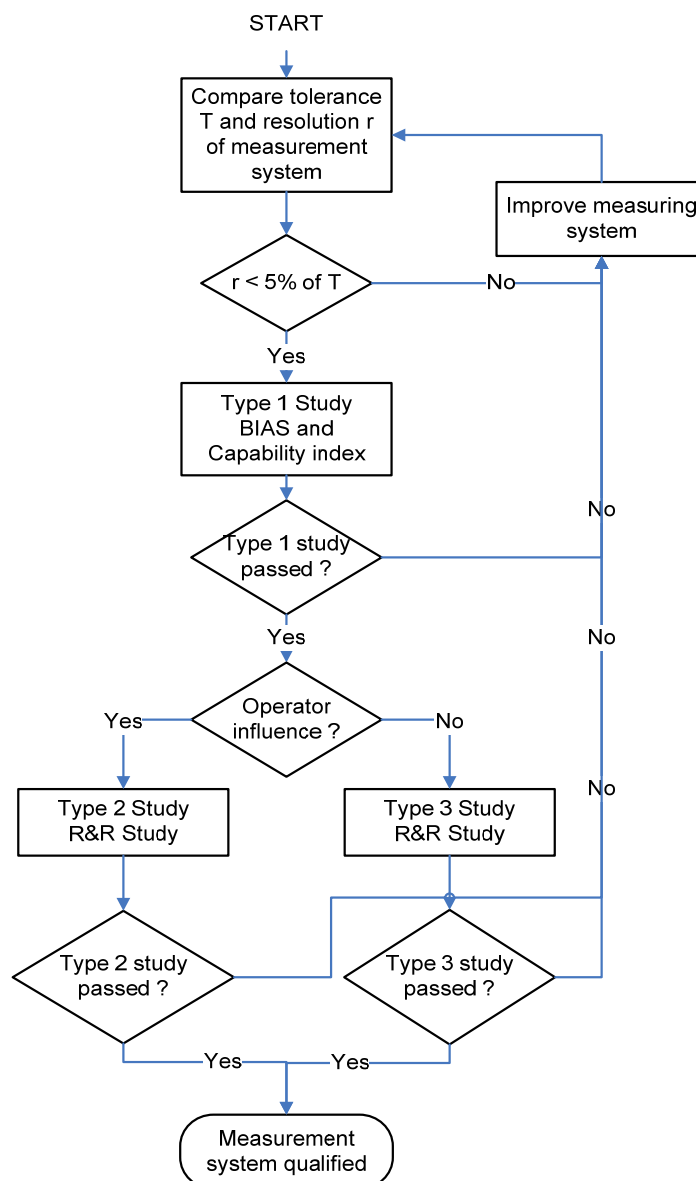
##### **Type II: Apply to measuring systems influenced by operator.**

- To evaluate Gage R&R under the influence of different operators, machinery and parts, and to demonstrate whether the measuring system can be accepted taking into consideration both GR&R as well as Numbers of Distinct Categories (ndc).
- For Variable gauge study the supplier should utilize 10 parts, 3 operator, 3 trials.
- For Attribute gauge study the supplier should utilize 50 parts, 3 operators, 3 trials
- Minimum required is (numbers of parts) x (number of operators) > 20
- Directions to perform a GR&R study step by step:
  - Calibrate the gauge, or assure that it has been calibrated
  - Have operator #1 measure all samples once in random order
  - Have operator #2 measure all samples once in random order

- Continue until all operators have measured samples once (this is Trial 1)
- Repeat above steps for the required number of trials
- Use a R&R template to determine the statistics of the R&R study
  - Repeatability (%EV)
  - Reproducibility (%AV)
  - Gage RR (%R&R)
  - Part Variation (%PV)
  - Number of distinct categories (ndc)
- Analyze results and determine follow-up action, if any

**Type III: Apply to measuring systems not influenced by the operator.**

To evaluate R&R and to demonstrate whether the measuring system can be accepted taking into consideration both R&R as well as Numbers of Distinct Categories (ndc)



## Measuring System Analysis (MSA) for Attribute or Binary Data

Attribute data (i.e. Gages go/no-go, visual inspections) should be done following below scheme:

Part	True standard (master)	Operator 1	Operator 2	Operator 3	Total
1	Rejected	Rejected 1	Rejected 1	Accepted 0	2
2	Accepted	Rejected 0	Accepted 1	Accepted 1	2
N	Accepted	Rejected 0	Accepted 1	Accepted 1	2
Total hits		1	3	2	

Truth	Operator 1	Operator 2	Operator 3	
Accepted	2	0	0	<- Rejected falsely
Rejected	0	0	1	<-Accepted falsely

Total sample size (N) must always be 20 or more parts.

If only 2 operators are available, then total sample size (N) must be 30 or more parts.

*Inspection capability parameters:*

*Effectiveness (E)* is the ability of an inspector to distinguish between defective and non defective products or parts.

$E = \text{Number of parts identified correctly} / \text{total number of opportunities to be correct}$

*Probability of False Rejects (FR)* is the likelihood of rejecting a good part.

$P(FR) = \text{Number of times good parts are rejected as bad} / \text{total number of opportunities to rate good parts}$

*Probability of False Acceptance (FA)* is the likelihood of accepting a bad part

$P(FA) = \text{Number of times bad parts are accepted as good} / \text{total number of opportunities to rate bad parts}$

Acceptance criteria for Attribute MSA Study			
E	P (FA)	P (FR)	Status
$\geq 0.9$	$\leq 2\%$	$\leq 5\%$	The measurement system can be approved.
$0.9 \geq E \geq 0.7$	$\leq 5\%$	$\leq 10\%$	The measurement system can be approved, if Danfoss accepts the measuring uncertainty. Corrective actions can be required and the supplier must contact Danfoss responsible.
$\leq 0.7$	$> 5\%$	$> 10\%$	The measurement system cannot be approved.

## 8.2 Process capability calculation

$P_p$  and  $P_{pk}$  are based on the overall spread of the measurements.  $s_p = \sqrt{\frac{\sum_{i=1}^{i=n} (\bar{X} - X_i)^2}{n-1}}$

$$P_p = \frac{USL - LSL}{6s_p} \quad P_{pk} = \min\{P_{pu}; P_{pl}\} \quad P_{pu} = \frac{USL - \bar{X}}{3s_p} \quad P_{pl} = \frac{\bar{X} - LSL}{3s_p}$$

$C_p$  and  $C_{pk}$  values can be calculated if the data are taken from a  $\bar{X}$  control chart.

$C_p$  and  $C_{pk}$  are calculated if your spread calculation is based on within sub-group variation from a  $\bar{X}$  control chart.  $s_c = \frac{\bar{R}}{d_2}$  for  $\bar{X}$  R control charts and  $s_c = \frac{\bar{s}}{c_4}$  for  $\bar{X}$  s control charts. The factors  $d_2$  and  $c_4$  are associated with the use of control charts. Reference: AIAG SPC Manual.

$$C_p = \frac{USL - LSL}{6s_c} \quad C_{pk} = \min\{C_{pu}; C_{pl}\} \quad C_{pu} = \frac{USL - \bar{X}}{3s_c} \quad C_{pl} = \frac{\bar{X} - LSL}{3s_c}$$

$C_{pm}$  value can be specified if the responsible engineer regards this parameter is useful.

$C_{pm}$  is based on a special spread calculated with respect to the target.  $s_{Cpm} = \sqrt{\frac{\sum_{i=1}^{i=n} (T - X_i)^2}{n-1}}$

$$C_{pm} = \frac{USL - LSL}{6s_{Cpm}} \quad \text{Assuming bilateral tolerance: } (USL-T)=(T-LSL)$$

Process capability study shall be documented by the supplier for Special Characteristics in Part Approval Process, and the supplier shall be able to present current/latest verification records within five working days.

### Transforming data before Capability studies

Capability studies assume that distribution of data is normal and equal variance over the range of the analysis. If the distribution is non-normal, then the analysis may be misleading or incorrect due to the violation of the normality assumption. A transformation function can be used to convert the data closer to a normal distribution to meet the assumptions and allow valid conclusions.

An Anderson-Darling normality test should be done to confirm non-normality, once this has been determined; a transformation function is used to transform the data. The same test for normality should be then performed on the transformed data before continuing with capability analysis. A transformation function can incorporate any one or combination of the following equations, or may use additional ones not listed:

- Square root:  $\sqrt{X}$
- Logarithmic:  $\log_{10} x$ ,  $\ln x$ , etc.
- Reciprocal of data:  $1/x$
- Square of data:  $x^2$