Guideline to secure Quality of Supplies

(CeramTec Customer Requirements)

For Suppliers to Manufacture Ceramic Products

Issue 02 (February 2017)

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1 PREAMBLE

Quality of our products and services are essentials guaranteeing our position in the world market. The quality of your supplies is of direct influence to CeramTec´s competiveness. Not just your delivered goods, but also the quality of the logistics and administrative processes are key success factors.

We regard you as being responsible for conformance with specifications of your products and for the capability of your manufacturing, logistical and administrative processes. This also encompasses components, services or finished product you may buy from or subcontract to third companies.

This guideline shall contribute to further optimize the technical quality of your and our products as well as the logistical and administrative processes between our companies. Only by continuously improving of our interface within the scope of a true partnership, will we be successful together. Please regard this guideline as CeramTec´s customer requirements in the sense of a supplement to the requirements of the management systems we refer to under item 2.3.

In addition to process and product related aspects, norms and values are key success factors. CeramTec strives to work up to high ethical standards. We encourage our suppliers to act by the standards listed under item 2.2.

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2 GENERAL REQUIREMENTS

2.1 Scope

As not all materials and services supplied are impacting our products equally, we differentiate between

a) Materials and Services directly influencing the quality of our end products. Those are identified as **product critical**. (Rem.: usually these are raw materials, components which are built into or onto our products as well as subcontracted processes but also, for instance, cleaning of our clean rooms or packaging of low microbiological contamination).

b) Materials indirectly influencing the quality of our end products. Those are identified as **processs critical.** We differentiate between **direct** and **indirect** process critical. This is dependant on the contact between end product or not (Rem.: usually those are process aids).

c) Materials, Buildings, equipment and services belonging to the production environment. These are called **non-critical**.

d) Materials and Services which are only related indirectly to the manufacture of our products. These are identified as standard items (Rem.: among them are MRO materials).

This guideline is valid for all supplies of product critical and process relevant materials and services to CeramTec Group, which are used for the manufacture of our ceramic products. It forms an integral part of the contractual agreements with suppliers, also in case where our purchase orders do not explicitly refer to this document.

2.2 Corporate Governance

2.2.1 Compliance to Code of Conduct

CeramTec reserves the right to prove the compliance to the Code of Conduct for suppliers by adequate appointment. CeramTec encourages its suppliers to introduce own binding standards for ethical behaviour.
The supplier encourages his own suppliers to follow the ethical standards, human rights, working and environmental standards based in this agreement when working with us to fulfill our contractual agreements. The supplier is responsible for his own Supply chain.
Each violation against the commitments in the Code of Conduct will be considered as essential violation of contract by the supplier.
The supplier communicates the baselines of the Code of Conduct to its sub-suppliers and other business partners, who are included in the delivery of products and services. The supplier demands all involved parties to act according to the standards as a common base.

2.3 Management Systems

As a matter of principle: Please demonstrate existing certifications by means of copies of the certificates to our purchasing department. Please also inform our relevant purchasing unit in writing, in case you are denied renewal of your certification, or if yourself decide to discontinue certification.

The norms named hereafter are representative for similar other norms, discussing the respective topics. Should you be certified against a norm not mentioned here, then please let our relevant purchasing unit know. In most cases, we will honor such certificates.

2.3.1 Quality Management Systems

With the exception of small entities, for whom implementation and preservation of complex management systems may not be reasonable, all our suppliers should remain a certified quality management system according to current ISO 9001. In case your company provides analytical services for CeramTec, we require certification per ISO 17025.

Should your supply or services be required for applications in the automotive or medical sector, you will be asked to comply with those requirements coming from CeramTec customer requirements or to assume certification per the norms ISO/TS 16949, ISO 13485 or GMP.
In case this is not possible we will check if customer requests can be acknowledged or implemented.

2.3.2 Environmental Management Systems

As a minimum standard we expect that your company complies with all statutory regulations applicable for the nature of your business in the countries of manufacture and of sales. We would appreciate it if you should strive for being audited respectively certifies per EMAS, responsible care or ISO 14001.

2.3.3 Occupational Health and Safety

As a minimum standard we expect that your company complies with all relevant provisions for occupational health and handling of hazardous goods. Should you decide to become certified per OHSAS 18001, this would be welcome.

2.4 Documentation and Traceability

We are putting emphasis on traceability of the manufacturing processes of supplied material to the greatest possible extent. Please ensure traceability by mean of adequate systems, for example for clear distinction of batches, labeling and retention of your process and analytical data. Raw data, measuring results and interpretations shall be stored for a minimum of 10 years and are to be made available in case of need (search for cause of deviation or in the course of audits).

Should the application of our end product, e.g. in the automotive or medical product sector, require longer retention periods, this will be constituted in separate agreements.

2.5 Information

2.5.1 Communication

We prefer an open relationship. Especially in case of identified risks or deviations from agreed upon or from herein mentioned standards. Please approach us promptly in such a situation.

2.5.2 Confidentiality

Your information will always be treated confidential. Vice versa the same is expected. With sensitive projects, or prior to insight into your manufacturing processes (e.g. during audits) we are ready to conclude on a non-disclosure agreement (NDA).

3 PRODUCT ENGINEERING PROCESS

During design or change of products, you are involved in our engineering processes as a new or as an already approved supplier. As a new supplier, you are passing through all stages of this chapter. Already approved suppliers are just checked to make sure their capabilities would match the requirements of a new application.

In accordance with the requirements resulting from the application of our products, we are expecting implementation, and adherence to an organized advanced product and process planning process which, if needed, encompasses the process and services of your sub-suppliers.

3.1 Registration of (new) Suppliers

As a base for the approval as a new supplier, we at first compose a verifiable dossier. Thereto we invite you to let us have essential information about your company, your products which are of interest to us and to your quality- and environmental management system by means of completing check-lists. A further important element is your competiveness regarding costs which we check by sending inquiries. In the course of this process, we expect your support in the form of rapid and complete information respectively documented proof.

3.2 Approval of (new) Suppliers

As a function of our requirements and on the nature of your products, approval as supplier for series deliveries can encompass:

1. only the aforementioned dossier,
2. the dossier and successful production runs with your products, or
3. both elements (items 1 and 2) together with an initial audit

3.3 Qualification of Material

3.3.1 Requirements (PPAP)

Depending on the requirements resulting from the application or from our customers´ needs, we may require different levels of support from you doing during qualification of your materials (laboratory and production tests). This may result in a request to perform PPAP or a formal validation of your analytical and production equipment and processes per current GMP.

We are well aware of the fact that sometimes these requirements may represent an extraordinary challenge for your organization if you should not yet supply to automotive or medical products markets. However, compliance to these requirements are crucial prerequisites for our success in those markets. That´s why we expect their best efforts from our suppliers to support us. Please contact the buyer in charge for assistance in case you are facing problems with the regulations required.

We will detail our requirements for the individual cases.

3.3.2 Supply of Samples

Please care for correct labeling and complete documentation per the attached instruction when you supply samples.

3.3.3 Environmental Sustainability of your Materials

Already in the phase of product design it is our goal to avoid environmental risk originating from our products. We therefore expect from you to inform us by your own accord about ingredients and eventual risks – also for marketability – of your materials. Please thereby, among other legal requirements, take following regulations into consideration:

- **REACH** (Registration, Evaluation and Authorization of Chemicals, EG 1907/2006)
- **RoHS** (Restriction of Hazardous Substances, 2002/95/EG)

3.4 Contractual Agreements

Dependent on material, application and risk of supplies we create the contractual foundations for serial delivery in the form of:

- Supply contracts
- SAP-Contractual Data
- Quality Assurance Agreements
- Technical Material Specifications

3.4.1 Supply Contract

Regulates all commercial, logistical and legal aspects within our relationship.

3.4.2 SAP-Contract

Fixes agreed prices for a certain quantity for a defined period and shall support your production planning.

3.4.3 Quality Assurance Agreement

Regulates all quality relevant aspects within our relationship.

3.4.4 Technical Material Specification

Defines all quality relevant attributes of a material such as quality characteristics, tolerances, analytical procedures, packaging and usability. In absence of a quality assurance agreement, it may also contain regulations like obligation to announce process changes.

Please notice that we usually expect several supplements to the technical material specification. These are detailed in the specification. We ask you to provide these supplements together with the signed technical material specification.

3.5 Supplier Status

The life-cycle of a supplier is being structured by means of following status:

- Approved Supplier
- Restricted Approved Supplier (e.g. for a certain time period or quantity)
- To be Phased out Supplier
- Blocked Supplier

In the following, please find the definitions for these status. Please notice that we do not issue a separate status for preferred suppliers although we are interested in keeping the portfolio of your suppliers neatly arranged. As we would like to work with the best suppliers in the market, we expect that these prevail, due to their strength with product quality, on time delivery, service, competence and also with cost effectiveness, against the competition.

3.5.1 Approved Supplier

The release according to the supplier dossier has been made. The supplier is a potential source of supply. This status is not referring to an authorization.
Approved suppliers will be treated as described under point 4. Series production. Materials which are considered as product critical or process critical will be under surveillance through a supplier rating regarding supplier performance and if needed by audits.

3.5.2 Restricted Approved Supplier

The supplier has been issued a preliminary approval to be used within the scope of R&D projects up to the pilot production scale. Before the end of the conceptional phase (product and process design freeze), we will define those materials and suppliers, with whom we will continue the further qualification process (product engineering process).

3.5.3 To be Phased Out

Suppliers, whose performance does not meet our requirements, respectively who are not improving their performance to the necessary extent, are receiving this status. Parallel to the change of status we would start a project to substitute the supplier.

3.5.4 Blocked Supplier

After a successful project to substitute a supplier, or if the supplied material is no longer required, the supplier receives this status. A later resumption of the relationship is possible.

4 SERIES PRODUCTION

In order to be safely supplied, we expect faultless supplies and shipping documents with respect to their quality and timely delivery. In case of failure we expect dedicated search for root causes, corrective and preventive actions against reoccurrence of the deviations.

4.1 Competiveness

CeramTec often supplies to markets which are characterized by decreasing prices but at the same time by high expectations for product and service quality. We compete internationally successful with vendors also from low cost countries. Only continuous optimization of our productivity puts us into the position. For materials supplied to our series processes, we expect your dedicated and concentrated assistance in optimizing our costs in addition to your performance with regards to product quality, logistics and technical competence.

On the occasion of inquiries and annual meetings we will monitor your advancement and evaluate your contribution to our competiveness.

4.2 Purchase Order Processing

4.2.1 Purchase Order / Contract

You shall receive purchase orders in the form of

- Individual orders, or
- Call-off orders for agreed upon SAP-contracts

Call-off orders always refer to the related contract number.

4.2.2 Order Confirmation

We require your order confirmation for all purchase orders. Please direct these to the contact named in the header of the purchase orders and notify the corresponding purchase order number.

4.2.3 Dispatch Notification

Should you ship from outside of the European Union, we ask for your dispatch notification at the time of shipment. Please also direct this information to the contact named in the header of the corresponding purchase order.

4.2.4 Shipping Address

The shipping address is the CeramTec site using your material. You will find the relevant address for each individual purchase order in the header of the purchase order under the title “Please deliver to:”.

4.3 Packaging

Please use adequate packaging for transportation and secure that the packaged units can be stacked without damage to the lowest layer. Please pay attention to the agreed upon packaging which is detailed in the technical material specifications.

4.4 Selecting and Assignment of Forwarder

In case CeramTec is paying for the freight costs, we determine forwarder/freight carrier and parcel services. Exception is only possible when justified reasons occur and need to be agreed in written form with CeramTec contact person in advance.
In case the supplier is covering the freight costs, the choice of forwarder needs to be done either having a forwarder with AEO status or needs to prepare actions to ensure a secure delivery chain.

4.5 Shipping Documents and Labelling

4.5.1 Delivery Note

Please attach your delivery note to each shipment. Fix the document visible in a pouch to the outside of a package. The pouch has to be secured against loss during transportation. Please ensure that the delivery note shows our purchase order number.

4.5.2 Certificate of Analysis / Specific Test Report

Please attach your certificate of analysis to each delivered batch. Please also put it into a visible pouch attached to the outside of the corresponding packages. The pouch has to be secured against loss during transportation.

Optional, the certificate of analysis can be sent per e-mail to: h.poehlmann@ceramtec.de

Please ensure that the certificate of analysis complies with the following minimum standard:

- The values have to be measured at the current delivered batch
- The certificate has to contain all parameters which are required in the technical material specification. In cases where no technical material specification has been agreed upon, the certificate has to show all parameters listed in your product data sheet.

In addition, the certificate has to contain:

- The production lot number
- Our purchase order number
- The date of the analysis and the name of the responsible person who has taken the measurements

4.5.3 Bill of Lading and Airbill

For clearance of customs please send us the Bill of Lading respectively Airwaybill in good time prior to the arrival of the consignment. Please send these documents to the contact person shown in the header of our purchase order.

4.5.4 Labelling

Please mark each package with a clearly legible label following minimum information:

- Name of company of supplier
- Product designation
- Quantity per individual package (net weight)
- Number of production lot
- Production date

4.6 Receipt of Goods

4.6.1 Incoming Goods

We only accept shipments which are undamaged and furnished with documents meeting the above mentioned standards.

4.6.2 Incoming Inspection

We perform a qualitative incoming inspection. Prerequisite for this are correct delivery notes and faultless certificates of analysis.

4.7 Invoice / Payment

4.7.1 Invoice

We only accept invoices with clearly legible reference to our corresponding order number.

Please note the shipping and invoicing addresses stated in our purchase order. Please always send your invoices to:

CeramTec GmbH
Department: KF-P
CeramTec-Platz 1-9
73207 Plochingen

or alternative to: kreditoren@ceramtec.de

In case of shipments from outside Germany, your invoice has to state the correct customs tariff number (HS-Number) for the delivered goods.

4.7.2 Automatic Credit Memo Procedure

If we have agreed on a consigned stock, you will receive an automatically generated credit memo at the beginning of each month for the consumed quantity of the finished month. This credit memo is being used as a payment document. Please therefore do not send us invoices for consigned goods.

4.8 Deviations

4.8.1 Deviations from Technical Material Specification

We expect your quality management system to safely secure that only in spec material will be supplied.

Only in cases, where you cannot keep up supplies with in-spec material, it is acceptable that you ask for special release of deviating material in written form. To do so, please inform us immediately using formal "Deviation from Specifications". We expect that you search for the root cause of the deviation in question. If at all possible, please provide your 8D-Report together with the request for special release.

4.8.2 Corrective Action Request

Should we find your material to be defective in our incoming inspection or in our manufacturing process, you will receive a corrective action request. Should we promt you for performing per a 4D- or 8D-Principle, we expect

- On time notification to the steps "Immediate Action", Root Cause/Corrective Action and "Control of Performance"
- Detailed root cause analysis and reasonable corrective actions
- A check of your risk analysis and your operating instructions and specifications to prevent reoccurence

5 IMPROVEMENTS / CHANGES

5.1 Improvement of Technology and Product Quality

We would like to herewith encourage you to initiate programs to improve reliability of your product and to minimize your production cost. Please share those initiatives with us early and notify us about planned changes per the regulations detailed in the next paragraph.

5.2 Changes (Process Changes)

5.2.1 Changes Subject to Approval

Please inform us by means immediately about planned changes of:

- Raw material or purchased components
- Chemical or physical composition of your product
- Appearance of your product
- One or more specified properties of your product
- Your manufacturing technology
- Analytical procedures
- Frequency of incoming, in-process or final controls

As well as of

- Shift of production process to another location
- Shift of machines even within the own location
- Cessation of manufacture of the product

Before putting these changes into effect, we reserve the right to assess the impact of such changes to our process or product. If needed, we will have to perform tests. Appropriate amounts of samples and analytical data, as well as your data from qualification of these changes may be requested.

5.2.2 Changes Subject to Notification Only

Please notify us about planned changes which are not described under item 5.2.1 if you are not absolutely sure that they will not have any adverse effect on our manufacturing processes or final products. Changes for which the possibility of adverse effects can be safely excluded, must not be communicated.

5.3 Audits (Control Audits)

During the phase of supplier qualification, but also during the entire business relationship, we reserve the right to conduct audits at your production site. Audits can be performed as system-, process- or product audits respectively as a mix between those. Prior to an audit, you will be notified in good time.

During an audit, we expect constructive openness and insight into your data, processes, manufacturing sites and laboraties.

Should the audit show potential for optimization, we trust that you will dedicate yourselves to complete the audit actions within the specified due dates.

5.4 Vendor Rating

In cases where we perform an incoming inspection on your material, you will be informed at least once per year about the results of our vendor rating. Requests for improvement will be communicated. Please treat such information in the same manner as a "normal" corrective action request. Search for the root cause, plan trust actions reoccurrence of the deviations and keep us informed about your findings and actions in a timely manner.

6 GLOSSARY

GMP Good Manufacturing Practice (Rem: For CeramTec`s products, part 820 of the Code Federal Regulations applies).

Material Your supplied product. In terms of this guideline, the term "material" is also used for provided services (e.g. analysis in external laboratories).

MRO Materials being used for **M**aintenance, **R**epair and **O**perations. Such materials are ranging from spare parts to letter heads and could also be classifies as "catalogue materials".

PPAP **P**roduction **P**art **A**pproval **P**rocess per DIN ISO/TS (IATF) 16949

NDA **N**on-**D**isclosure **A**greement