Deltech Kiln and Furnace Design, LLC

Quality Manual

Deltech Furnace Design and Kiln, LLC
1007 East 75th Avenue, Unit E
Denver CO, 80229

http://www.dkfdllc.com

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1. Company Information

DKFD Kiln and Furnace Design, LLC was founded in 2016 to supply electric laboratory furnaces and related supplies and equipment to the nuclear science, engineering, and technology communities. The decision to form DKFD was made after Deltech, Inc. was approached to act as a subcontractor for the supply of furnaces to a nuclear facility. Designs, processes, and products must meet rigorous nuclear quality assurance requirements, and DKFD is positioned to design and subcontract the most complex custom furnace systems, providing quality assurance oversight and documentation at every step in the design, build, test, delivery, commissioning, and maintenance processes.

The joint owner/manager team of J.J. Stevenson and Mary Stevenson are also principals and owners of Deltech, Inc (www.deltechfurnaces.com). Deltech, Inc. has designed and built custom furnaces for materials science researchers, ceramic engineers, and industrial ceramics manufacturers around the world. Customers include NASA, JPL, LLNL, INEL, Sandia labs, LANL, Brookhaven National Labs, ORNL, Savannah River National Laboratories, and NETL, Albany. Projects have included special designs for waste containment, for use in robotically controlled “hot” rooms, and for operation through gloveboxes.

Deltech Kiln and Furnace Design, LLC pursues contract opportunities for the supply of furnaces and related systems to the nuclear research and industrial communities.

DKFD is contracted to both design the furnace systems and to supply the equipment.

The company in turn subcontracts to Deltech, Inc. (aka Deltech Furnaces) to build and test the equipment following DKFD’s and customer requirements for deliverables.

2. Scope of the Quality Management System

2.1. Scope

Deltech Kiln and Furnace, LLC’s Quality Management System (QMS) applies to the operations conducted at 1007 East 75th Avenue, Unit E, Denver, CO 80229. The QMS has been designed to comply with the requirements of ISO 9001:2015, to ensure consistent quality of products and services. DKFD’s scope includes the physical boundaries as described above and the applicable processes being performed. Management has also considered the internal and external issues, the requirements of relevant interested parties, and the products and services offered to determine the scope of the QMS; all of which are documented in the QMS Overview worksheet of the QMS Planning Tool. The scope of the QMS includes:

Design and supply of electric laboratory and production scale furnaces and related control systems, and the provision of design services.

2.2. Non-Applicable Clauses

ISO 9001:2015 7.1.5.2 Measurement traceability is not applicable. DKFD outsources manufacturing to Deltech, Inc., and has no measurement or test equipment requiring calibration. Any measurements deemed necessary by DKFD for activities performed use equipment provided by the external provider, Deltech, Inc.

3. Leadership and Management Responsibility

3.1. Commitment

3.1.1. Management actively demonstrates its leadership and commitment with respect to the QMS by: taking accountability for the effectiveness of the QMS, ensuring the quality policy and quality objectives are established and are compatible with DKFD's context and strategic direction, ensuring the QMS requirements are integrated into the business processes, promoting the use of the process approach and risk-based thinking, ensuring resources needed are available. communicating the importance of effective quality management and of conforming to QMS requirements, ensuring the QMS achieves its intended results, engaging, directing, and supporting personnel to contribute to the effectiveness of the QMS, promoting improvement, supporting other management roles to demonstrate their leadership as it applies to their area of responsibility, and by participating in QMS planning, internal audits, and management reviews

3.1.2. Management is committed to maintaining and improving the QMS to continually satisfy customers by providing them with products and services that meet our specifications and their requirements and expectations. Management ensures that customer requirements are met with the intention of enhancing customer satisfaction. This commitment is demonstrated by the development and implementation of the QMS, by formulating the quality policy, and by establishing measurable objectives against which QMS performance is evaluated and acted upon to improve internal processes and the resulting products and services. Management ensures that employees understand the importance of meeting requirements, particularly those of our customers. Management also ensures that employees are aware of their contribution to the effectiveness of the QMS, the benefits of improved performance, and the implications of not conforming with the QMS requirements.

3.1.3. Management also demonstrates a commitment to quality by conducting periodic management reviews of the QMS and its processes. Based on data driven information regarding performance and feedback from customers, and in consideration of future customer needs, Management allocates resources and outsources as necessary to ensure conformity of product and service, to improve the QMS, its processes, and resulting products and services, in order to promote customer satisfaction.

3.2. Quality Policy

3.2.1. Management's commitment to meeting requirements, satisfying customers, and improving the QMS, its processes and resulting products is reflected in the following quality policy:

Quality begins with customer expectations and ends with customer satisfaction. We achieve quality and compliance to all requirements by involving our employees, customers, and external providers in a process of continual improvement.

3.2.2. Management reviews the above policy periodically during management review to ensure its continuing suitability, ensuring that it remains appropriate for the company, that it includes a commitment to comply with requirements and to continually improve the QMS, and that it provides a foundation for measurable objectives against which performance can be evaluated. Management also ensures that all employees understand the policy, how it applies in their work, and how their performance relates to the achievement of quality policy objectives. The quality policy is also available to relevant interested parties as deemed appropriate by Management.

3.3. Quality Objectives

3.3.1. Management has established measurable objectives for QMS performance that are derived from the policy. Such objectives serve as a foundation for reviewing performance at both the process and system level. The quality objectives take into account applicable requirements that are relevant to conformity of products and services and the enhancement of customer satisfaction.

3.3.2. The Metrics worksheet in the QMS Planning Tool is used to identify and plan quality objectives and process measurements. Key objectives and measurements are addressed during management review meetings, along with an indication of a timeframe for their achievement, and are used to implement the quality policy.

3.3.3. Along with planning the quality objectives, Management has determined plans on how to achieve them. Such planning includes what will be done, what resources will be required, who will be responsible, when it will be completed and how the results will be evaluated. As necessary, quality objectives and the goals to achieve them are updated as appropriate.

3.3.4. The quality objectives are communicated through posting the metrics in the facility, and/or are reviewed during meetings.

4. QMS Overview

4.1. Overview

4.1.1. DKFD's QMS, like the documentation describing it, is structured around the processes affecting the quality of products and services offered. The QMS has been developed and implemented to promote quality and improvement, and is managed to meet the requirements of ISO 9001, customer requirements, and all applicable regulatory and statutory requirements.

4.1.2. The QMS can be viewed as a system of processes that fall into two general categories: primary processes and support processes. The primary processes involve product and service realization activities intended for customers. These processes include (in general sequence):

Sales -> Design -> Purchasing -> (outsourced receiving, manufacturing, and shipping)

Or

Sales -> Design Services -> Deliverables to Customer

4.1.3. Support processes are those necessary for the successful operation and control of the primary processes and the QMS as a whole. These operate in parallel with primary process, and thus are not sequential: Documented Information, Training and Competence, Internal Audits, Nonconformity and Corrective Action, and Leadership and Management. Overviews of all QMS processes appear in section 5 of this manual.

4.1.4. Outsourced quality management system support to Deltech, Inc. personnel is controlled through the Purchasing and Training and Competence procedure and verified in accordance with the Training and Competency procedure. Outsourced internal audits when used are controlled in accordance with the Internal Audits and Purchasing procedures and the results are verified in accordance with the Internal Audis procedure.

DKFD outsources receiving, production, and shipping to Deltech, Inc. to fulfill accepted orders for furnaces, kilns, and spare parts, etc. This outsourcing is controlled through the Purchasing procedure, the results of which are verified in through direct involvement

and oversight as the processes are being performed. Included in this monitoring, DKFD management ensures the measurement equipment used to test and inspect the product is calibrated and suitable for use.

4.1.5. Management had determined the extent necessary maintain documented information to support the operation of DKFD's processes and to retain documented information to have confidence that the processes are being carried outs as planned.

4.1.6. To support the operation of our processes, a documented procedure has been established, implemented, and maintained for each QMS process, regardless of whether it is a primary or a support process. Each procedure identifies the inputs to and outputs of the process, and describes how those inputs are transformed into their respective outputs under controlled conditions. Each procedure also identifies responsibilities and authorities of personnel performing the process, as well as those responsible for measuring or monitoring process performance against established objectives, and for reacting appropriately to ensure the quality of the product and to promote improvement. Retained process outputs (records of completed activities) demonstrate the processes are achieving their intended results.

4.2. Roles, Responsibilities, and Authorities

4.2.1. Management ensures that roles, responsibilities, and authorities are defined and communicated to all employees. Management is ultimately responsible for the quality of DKFD's processes, products, and services.

4.2.2. Roles, responsibilities, and authorities for QMS activities are defined in Job Descriptions (see the Training and Competence procedure) and process operating procedures.

4.2.3. The President and Deltech, Inc.'s Mechanical Engineer share the responsibilities of the Management Representative. As such, they are responsible for ensuring that the QMS conforms to the requirements of ISO 9001, ensuring that the processes are delivering their intended outputs, for reporting/reviewing performance information and improvement opportunities during management review, for promoting awareness of customer focus throughout the company, and for ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

4.2.4. Though responsibilities and authorities ultimately reside with Management, they are delegated to competent personnel as necessary. All personnel who perform, manage, and/or verify work are responsible for the quality of products and services provided. All employees are responsible for complying with documented procedures and the direction of Management. All employees are authorized to identify and record problems relating to products, processes, and the quality system as a whole, and to provide suggestions for improvement or recommendations for solving problems by initiating actions according to the Nonconformity and Corrective Action procedure. All employees are also responsible for cooperating fully with internal audits.

4.2.5. Production and service personnel are responsible for ensuring control over their activities and to complete work in a responsible and safe manner. All employees are responsible for maintaining the premises in a state of order, cleanliness, and repair consistent with product and processing needs. They are also responsible for identifying nonconforming product, stopping builds as necessary, and controlling further processing until Management has been promptly notified and the problem has been corrected.

4.3. Quality Planning

4.3.1. Management ensures that QMS planning occurs and is carried out in order to meet the requirements of our customers as well as our own internal requirements. QMS planning occurs at two levels: the process level and the system level.

4.3.2. Planning at the process level focuses on order fulfillment to ensure designed furnaces and kilns are supplied to customers while ensuring conformity of the product to applicable requirements of internal specifications, customer requirements, statutory and regulatory requirements, and acceptance criteria.

Planning at the process level for Design Services focuses on providing required consulting services for furnace or kiln designs and providing the associated deliverables.

This planning is to establish processes and documentation specific to the product or service, and to identify outsourced resource requirements. This level of planning results in accepted orders supported by design outputs, which identify required verifications to ensure conformity of the product, records demonstrating conformity, and methods for reacting when planned arrangements are not achieved, or outputs supported by documented reports or other deliverables demonstrating service conformity.

4.3.3. Planning at the system level involves establishing the QMS processes and infrastructure necessary to meet general requirements of customers, focusing on the ability of the system to effectively and efficiently meet all requirements. This planning is conducted with a multidisciplinary approach, and takes into consideration facility and equipment plans, plant layout to optimize project build flow, handling, and value-added use of floor space. This planning results in system-level processes and procedures that represent the planned arrangements described by QMS documentation.

4.3.4. The QMS Planning Tool ensures that Management identifies important considerations of the organization that are necessary to optimize the QMS' performance and thereby enhancing customer satisfaction. The QMS Planning Tool address the following:

a) the purpose of the organization,

b) DKFD's strategic plan and direction,

c) relevant external and internal issues impacting the performance of the QMS and DKFD's products and services,

d) recognition of interested parties and their requirements that have an effect or have the potential to affect DKFD's ability to consistently supply products and provide services that meet customer and applicable statutory and regulatory requirements,

e) opportunities to enhance desirable effects and contribute to achieving improvement,

f) the organizational knowledge necessary to ensure conformity to requirements and for the operation of DKFD's processes, and the means to maintain and upgrade organizational knowledge, and

g) a communications plan that includes internal and external communications that are relevant to the QMS.

4.3.5. Risked-based thinking is applied to the QMS through the consideration of the internal and external issues and the requirements of relevant interested parties. The Risk Management Report identifies typical risks requiring mitigation to give assurance that the QMS can achieve its intended results, to prevent or reduce undesired effects, and achieve improvement. Risk-based thinking is also applied to opportunities and the planning to implement them if deemed of value to DKFD. See the Leadership and

Management procedure, and primary process procedures for on-going risk management.

4.3.6. The above system level planning has already been implemented and the resulting arrangements are currently adequate to meet the requirements of our customers and demonstrate the QMS is operating as planned. In general, the quality plan for processing customers' orders is to process them in a manner consistent with the existing arrangements described by QMS procedures. Where requested orders, products or projects containing significantly new or modified requirements are to be pursued, Management will ensure that quality planning is conducted, and that such planning is implemented and appropriately documented before promising to supply new or significantly modified products. See the Leadership and Management procedure.

4.3.7. Where changes to the QMS are planned, due to changes in technology or in the market, changes caused by suppliers, changes to processes, procedures, or product requirements, introduction of new processes or products, etc., Management will ensure that the integrity of the QMS is maintained to ensure conformity of product and services to requirements. The full impact of such changes will be determined, as appropriate. Any such changes will be verified and validated to ensure conformity to internal specifications and customer requirements before implementation. Such QMS planning and change Management is conducted during management review, or more frequently as circumstances dictate. See the Leadership and Management procedure.

4.4. Resource Management

4.4.1. Management ensures that resource requirements are determined and met to effectively operate and control QMS processes, to maintain and improve the QMS, and to achieve customer satisfaction by meeting their requirements.

4.4.2. Resource requirements comprise human resources (including personnel and training needs), infrastructure resources (including the building, workspaces, equipment, operating supplies, documentation, and supporting services and utilities), and work environment resources (including safety, ergonomic and human/physical aspects of work being performed).

4.4.3. Resource needs may be identified within any QMS process, or they may arise from management reviews, corrective actions, internal audits, employee observations, etc. Resource needs are fulfilled according to the Purchasing procedure, and hired or subcontracted personnel are trained for competency per the Training and Competence procedure.

4.5. Monitoring, Measurement, Evaluation, and Analysis

4.5.1. Monitoring and measurement methods to evaluate performance against established objectives have been identified, where suitable and applicable, to improve performance. Management review meeting minutes and/or the Metrics worksheet in the QMS Planning Tool describe each objective, the monitoring and/or measurement(s) applied, and the frequency of measurement analysis. The Leadership and Management procedure provides details regarding responsibilities and authorities for reviewing the resulting performance information, for analyzing it, for reacting appropriately, and for reporting QMS performance to employees.

4.5.2. The application of performance monitoring and measurement reflects the original quality planning that resulted in the development of the QMS in two levels: the process level and the system level. (See section 4.3 above, Quality Planning.)

4.5.3. Process Level

4.5.3.1. At the process level, attention is focused on ensuring conformity of the product and services to requirements, and to assure the effectiveness and efficiency of primary processes.

4.5.3.2. DKFD ensures Deltech, Inc. uses suitable verification and/or measurements to demonstrate that product conformity has been achieved before releasing it to subsequent processing or to the customer. Evidence of conformity with acceptance criteria is retained and these records indicate the person(s) authorizing release. This verification or measurement is not only an indication of product conformity, but also an indication of the effectiveness of the process to produce planned results. Controls relating to nonconforming outputs appear in procedures where nonconforming output is encountered.

4.5.3.3. Suitable monitoring and/or measurement is also applied to each process itself, where applicable. At a minimum, each QMS process is monitored by internal audits, corrective action, and management review meetings. Management determines further monitoring and measurement that is suitable and applicable for process effectiveness and/or efficiency. Monitoring or measurement indicators will be identified in the Metrics worksheet and management review meeting minutes and will be reported, evaluated, analyzed, and acted upon accordingly.

4.5.3.4. Whenever planned results are not achieved according to the results of monitoring or measurement, either at the process or at system level, correction and corrective actions are taken, as appropriate, to ensure conformity of the product or service. Process level information is analyzed and acted upon as it arises or becomes available, and periodically according to the discretion of Management. Results are recorded as required. Product release does not proceed until all planned arrangements have been satisfactorily completed, unless otherwise approved by Management

4.5.4. System Level

4.5.4.1. At the system level, attention is focused on general performance—performance of the system of processes in aggregate.

4.5.4.2. Suitable measurements are applied to the QMS as a whole to evaluate its performance against the quality policy objectives established in management review meeting minutes. Internal and external measurements are applied, where feasible. For example, objectives derived from the quality policy have been established for customer satisfaction (see below). Appropriate system level information is analyzed and acted upon periodically as required by the management review process, and more frequently as circumstances demand. Results of system level review appear in meeting minutes.

4.5.4.3. As one measure of QMS performance, customer satisfaction is perhaps the most important. Accordingly, information regarding our customers' perception of our performance is determined via various indicators and/or soliciting data according to the Sales process. Unsolicited feedback, including complaints and product returns or field failures, is also received, reviewed, and acted upon according to the Sales procedure using the Nonconformity and Corrective Action procedure.

4.6. Continual Improvement

4.6.1. Through use of the quality policy, process and system level quality objectives and performance information, audit results, external provider performance analysis,

corrective action, and management review, DKFD will continually improve QMS effectiveness and efficiency. See the Leadership and Management procedure.

4.6.2. Improvement is achieved anytime an increased ability to fulfill requirements is demonstrated by measurable results or quantifiable benefits (or estimates thereof).

4.6.3. When opportunities for improvement present themselves by whatever means, Management takes advantage of these opportunities. Improvement efforts are recorded on the Action Item Matrix in the QMS Planning Tool, and some improvements are processed simultaneously with associated corrective actions, according to the Nonconformity and Corrective Action procedure. Improvement efforts may also be initiated and tracked according to the Leadership and Management procedure, or during other planning activities.

5. QMS Processes

5.1. Primary Processes

5.1.1. Sales

5.1.1.1. Generally, the objective of the Sales process is to pursue business opportunities and provide products or design services that will satisfy customers. Inputs include DKFD's furnace designs that may be customized to meet customer requirements or design services that provide consulting for customers' designs. Customer requirements are reviewed to ensure they are clear and complete, and that DKFD has the ability to meet them prior to their acceptance. Applicable statutory and regulatory requirements are also reviewed to ensure compliance can be achieved.

5.1.1.2. Sales activities transform the above inputs into their respective outputs: approved quotations and order confirmations. Before their approval or acceptance, the customer's requirements for the product and its timely delivery are verified to be clear and complete, including any requirements that might not have been stated by the customer but are necessary for the proper or safe functioning of the product. Sales personnel verify the ability to meet such requirements before orders are accepted and supply is promised.

5.1.1.3. Based on accepted orders and current capacity, the process triggers the initiation of Design process activities or Design Services activities. Another output from Sales is purchasing information relating to infrastructure/resources needed to meet orders' requirements.

5.1.1.4. Any relevant statutory or regulatory requirements or special customer requirements relating to handling, preservation, packaging, delivery, and post-delivery support, are also identified and recorded.

5.1.1.5. The Sales procedure also contains provisions for handling inquiries, for reviewing received orders against any previously agreed requirements or quotations, as well as for reacting to change orders from customers and questions regarding order status.

5.1.2. Design

5.1.2.1. The objective of the Design process is to design and develop kilns and furnaces that meet customer specifications and needs. More specifically, the objective of the Design process is to identify design inputs, develop design outputs used by Purchasing and Production to build the product, perform design reviews to verify and validate the design outputs and ensure a successful product is delivered.

Another objective is to control changes to the project and to the actual design configuration. See the Design procedure.

5.1.2.2. Design projects are controlled using the Design Project Template as a guide to ensure a thorough assessment of requirements and results. The template ensures the project is planned, including the identification of milestone deliverables and appropriate reviews. Design inputs, reviews, necessary changes to the design project, and the design outputs are documented and appropriately approved.

5.1.2.3. The Design process ensures that customer, regulatory and statutory requirements are captured as inputs before engineering activities commence. Inputs may also include information derived from previous similar designs. Inputs are reviewed prior to approving the customer's purchase order to verify all inputs are identified and to ensure that requirements are complete, unambiguous, and not in conflict with each other.

5.1.2.4. Verification of the designed system is performed during production builds and testing in the Production process and validation is completed through customer acceptance.

5.1.2.5. Outputs from the Design process include the New Furnace Specification Sheet, drawings, wiring diagrams, etc. necessary for Purchasing and Production activities, records of completed reviews and records of design changes.

5.1.3. Purchasing

5.1.3.1. Generally, the objective of the Purchasing process is to procure outsourced services and/or materials needed to build quality products. More specifically, the objective of the Purchasing process is to ensure that purchasing information describes needed products and services in requisite detail, approved orders are submitted to reliable external providers, and that purchased product is verified to conform to requirements (including customer and/or any regulatory requirements). Inputs to the Purchasing process include purchasing needs arising in connection with customers' Purchase Orders, as well as those arising from any QMS process, including management review, where resource needs are identified at both the process and system level. See the Purchasing procedure.

5.1.3.2. Potential external providers (partners, suppliers, vendors, distributors, etc.,) may also be viewed as an input to the Purchasing process. External providers are evaluated and selected as necessary according to their ability to meet purchasing requirements, and their impact on processing activities and the quality of finished product. Records of external provider approval status appear in the current accounting system; external provider performance is reviewed during management review. Records of external provider and resulting actions are kept accordingly and are reflected in the status of suppliers in the current accounting system.

5.1.3.3. External provider performance is monitored via records of supplier incidents. Such records include problems associated with quality, and delivery.

5.1.3.4. The Purchasing process transforms identified purchasing needs into approved Purchase Orders, Manufacturing Service Agreements, or other documented communications which appropriately describe the needed products or services. This information also includes requirements for approval or acceptance of the product, as well as any required verification on the suppliers' premises, or any requirements for the suppliers' QMS, personnel, procedures, processes or equipment (which are not common). Approved purchasing documents are

submitted to reliable suppliers. Received items are verified against the purchasing documentation.

5.1.3.5. DKFD controls outsourced manufacturing, receiving, and shipping to Deltech, Inc. by describing requirements in purchasing documentation which may be a Purchase Order or Manufacturing Service Agreement. The information provided includes requirements to:

- Maintain a quality management system that is registered to or conforms to ISO 9001:2015.
- Accurately verify materials, products, and services purchased by DKFD and received at Deltech, Inc. Report any discrepancies in quantities, or items received to DKFD management. Report any nonconforming product to DKFD management for disposition. Retain records of material test reports, certificates of conformity, etc., received from the external providers.
- Manufacture the products identified per the New Furnace Specification Sheet, drawings, wiring diagrams, and other specifications provided. Report any nonconforming product to DKFD management for disposition.
- Tests and measurements used to verify conformity to requirements must be calibrated and traceable to a national (NIST) or international standard.
- Prepare products for shipment per DKFD specifications once authorization to ship by DKFD management has occurred.

5.1.3.6. Outsourced special processes or the purchase of products manufactured with special processing (those with outputs that cannot be fully verified internally) are subcontracted to approved suppliers. Requirements for suppliers to provide process validation or provide certifications of conformance are contained within the Purchasing procedure. Product resulting from outsourced production or processing is received and verified by the receiving activities performed by Deltech, Inc. before being released for use. Verification includes confirmation that supplied certificates demonstrate conformity to specified purchasing requirements. Suppliers providing outsourced special process services are verified for continued conformance to ISO 9001 7.5.1 f) Validation of processes during the management review. See the Purchasing and Leadership and Management procedures.

5.1.4. Design Services

5.1.4.1. Generally, the objective of the Design Services process is to provide consulting services for customers' kiln or furnace designs, or in some cases provide trouble-shooting assistance. More specifically, the objective of the Design Services process is to perform these services in a controlled manner to ensure that the resulting service is effective in meeting requirements. Inputs to the Design Services process include customers' designs. Outputs include delivered reports or other types of documented information that meets all customer requirements and include regulatory requirement considerations.

5.1.4.2. The Design Services procedure describes methods for identifying customer-provided documented information and the resulting documented deliverables. The Design Services procedure also addresses the treatment and use of customer and external provider property, as well as preservation methods used during handling their proprietary information.

5.1.4.3. Nonconforming service is properly identified, documented on the Nonconforming Product/Service Log worksheet in the Quality Log evaluated and dispositioned. All nonconforming service is corrected (a.k.a., reworked). (Any corrected service is

re-verified against the criteria against which it originally failed.) Records of nonconforming service and its disposition are retained.

5.1.4.4. Due to the nature of the consulting services provided, the outputs of the Design Services process are not considered processes where the resulting outputs cannot be verified by subsequent monitoring or measurement. The outputs are reviewed for accuracy against the intended results which does not include the actual build of the furnace or kiln.

5.2. Support Processes

5.2.1. Training and Competence

5.2.1.1. Training supports all QMS processes (both primary and support). As a support process, the objective of the Training and Competence process is to ensure that competent personnel perform the tasks required by the QMS processes. The Training and Competence process ensures that competency requirements are identified and that personnel are evaluated and selected based upon the appropriate education, skills, experience, and training required for each position affecting the performance and effectiveness of the QMS.

5.2.1.2. Training is provided as needed, the effectiveness of which is evaluated to verify competence before assigning work. A training record exists for each employee to demonstrate that employee's competence to perform assigned work. Training records also identify where further training needs have been identified for employees, as applicable. See the Training and Competence procedure.

5.2.2. Documented Information

5.2.2.1. The Documented Information process supports all QMS processes. The objective of document control is to ensure that legible, approved documentation is available to employees when and where it is needed in order to perform process activities correctly. The procedure describes how such documentation is initially approved and how it is re-approved after being updated, and how the most current version of any QMS documentation is determined. The procedure also describes treatment of documents originating externally.

5.2.2.2. Controlling documents ensures that only approved, current, controlled documentation is used, and that obsolete documentation is removed from use.

5.2.2.3. The objective of retained records is to ensure that records of processing activities are retained as long as they are useful. Such records demonstrate the effective operation of the QMS and conformity to applicable requirements (including any specified by customers and/or by regulatory agencies). Management establishes retention periods. Records control ensures that quality records are appropriately stored so to be protected from loss, damage, and deterioration, that they are readily identifiable and retrievable when they are needed. Records are also disposed of properly once their usefulness has expired. The Record Retention Matrix identifies the types of records generated as process outputs, their storage and protection, their retrieval or filing method, their retention periods, and their method of disposal. Where customers specify retention requirements, associated records are retained accordingly.

5.2.2.4. The Documented Information procedure also identifies methods for protecting electronic data, documents and records from unauthorized access and changes.

5.2.3. Nonconformity and Corrective Action

5.2.3.1. Nonconformity and Corrective Action supports all QMS processes and improvement activities. Actions taken to improve performance generally result in a corrective action. (However, improvements may be identified and acted upon independently of corrective actions.)

5.2.3.2. As a support process, the objective of the Nonconformity and Corrective Action process is to identify and correct process nonconformities, to identify systemic or process-related problems or undesirable trends, to determine the cause(s) of nonconformities, and to act to address those causes so that they do not recur or occur elsewhere.

5.2.3.3. Requests and needs for corrective action are processed using various methods depending on the process identifying the need. Once closed, completed records provide evidence of actions taken and verification of their effectiveness.

5.2.3.4. Corrective actions are taken in response to information arising from audit results, customer feedback or complaints, external provider performance data, performance information regarding product or service nonconformity, process monitoring and measurement results, etc. Actions also arise in connection with improvement efforts associated with any QMS process or source of information.

5.2.3.5. According to the Nonconformity and Corrective Action procedure, the following steps are taken for each corrective action initiated: the problem is reviewed and its root cause(s) determined using appropriate problem-solving methods; possible actions to eliminate its root cause to prevent its recurrence are evaluated and an appropriate action is selected and implemented; records of the completed action are maintained; the effectiveness of the action taken is verified.

5.2.3.6. Whenever a corrective action is taken, consideration is given to applying the action to other similar circumstances or areas in order to ensure the problem does not arise in those other areas, wherever possible.

5.2.3.7. Should corrective actions prove ineffective; alternative solutions will be evaluated and applied until the issue is resolved.

5.2.4. Internal Audits

5.2.4.1. Internal Audits support all QMS processes. As a support process, the objective of Internal Audits is to monitor processing activities at planned intervals to ensure their effective implementation and upkeep, and to ensure that they comply with the planned arrangements described by QMS documentation, as well as to confirm their continuing compliance with the requirements of ISO 9001. See the Internal Audits procedure.

5.2.4.2. Internal Audits verify that working practice is conducted in accordance with the quality policy, procedures, and provisions in this manual, ensuring that issues regarding compliance are resolved appropriately. All QMS processes are audited internally by either internal resources or contract auditors. Internal Audits are scheduled according to the importance of the process being audited, changes affecting DKFD, and the results of previous audits. Audits are conducted by trained, impartial Auditors, according to the schedule, instructions, scope, criteria, and any specific methods appearing on Internal Audit Reports.

5.2.4.3. Where working practice fails to conform to planned arrangements, or when problems or opportunities for improvement are discovered, auditors generate findings, which are recorded in the audit report.

5.2.4.4. Upon completion of an audit, auditors summarize their findings and conclusions on the associated Internal Audit Report form and submit the report and findings to Management. Corrective action arising from audits will be processed according to the Nonconformity and Corrective Action procedure to ensure that effective action is taken in a timely manner. Internal audits are conducted, reported and the results acted upon according to the Internal Audits, Nonconformity and Corrective Action and Leadership and Management procedures.

5.2.5. Leadership and Management

5.2.5.1. The Leadership and Management procedure describes Management's responsibilities for overseeing the effectiveness of the QMS, including planning and performance evaluation.

5.2.5.2. The procedure describes how performance data from various sources is analyzed and acted upon, including information relating to customer satisfaction, quality (i.e. conformance to requirements), to process, product, or service performance trends suggesting need for improvement action, and supplier performance. These measurements are analyzed and acted upon to improve performance. The procedure also describes periodic consideration of applying further statistical techniques to control process variability, to control product characteristics, or to further analyze performance data. See the Leadership and Management procedure.

5.2.5.3. Inputs to management review meetings include audit results, customer feedback, information regarding corrective actions and actions decided during previous Management reviews, supplier performance information, internal performance information regarding product and service conformity and process monitoring and measurement, any identified improvement opportunities, and any identified internal or external changes that could impact the QMS. See the Management Review Meeting Minutes form.

5.2.5.4. Management periodically reviews the QMS as a whole to determine its effectiveness in meeting objectives and applicable requirements, including those of our customers and those of ISO 9001. This review also includes evaluation of the cost of poor quality whether detected internally or by customers. Management also determines whether the QMS, the quality policy and quality objectives are still suitable and adequate for the company, according to the management review Meeting Minutes, which when complete, stands as the record of review. Where actions are required based on information from whatever source, corrective actions are initiated, as appropriate, and are processed according to the Nonconformity and Corrective Action procedure.

5.2.5.5. Once performance levels are analyzed and QMS effectiveness has been determined, performance information is communicated to employees, so they understand how their performance affects the achievement of established objectives. Such communication occurs through verbal reporting during meetings or on an individual basis. Performance results may also be posted in a conspicuous location.

6. Change History

Rev Date	Description
10/20/2017	Original issue.

11/21/2017	Revised section 2.2 to correct claim that ISO 9001:2015 section 7.1.5.2 is not applicable and provided justification. Revised section 5.1.3.5 by removing “calibration” from first sentence.