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Hilti Nuclear Quality Assurance Manual

Contents

Hilti Corporation
9494 Schaan | Liechtenstein

Objectives

I. ORGANIZATION

1. The senior management of each organization covered under this program is responsible to establish the expectations for effective implementation of this program and obtaining the desired results.

2. The Management Representative assigned by the F&PS Quality Management is responsible for and oversees the overall program and ensures through an audit program that the requirements of the program are being met.

3. Each organization covered under this program will have a NQA manager assigned to assist the management representative in carrying out his responsibilities. These Local NQA Managers are responsible for coordinating NQA-related activities within their organizations. They shall ensure that adequately qualified and trained personnel are available and relevant documentation is maintained. The assignments are as follows:

Location / Organization	**Responsible Person / Role**
BU Anchor Design in Schaan, FL	F&PS Anchor Q Manager (DQD)
Hilti Plant 1 in Schaan, Liechtenstein	Plant 1 Q Manager (P1Q) or assigned deputy
Hilti Plant 8 in Zhanjiang, China	Plant 8 Q Manager (P8Q) or assigned deputy
Hilti Plant 10 in Matamoros, Mexico	Plant 10 Q Manager (P10Q) or assigned deputy
Hilti Plant 18 in Kecskemet, Hungary	Plant 18 Q Manager (P18Q) or assigned deputy
Global Logistics / Warehouses	Local NQA Program Manager
Hilti Marketing Organizations (MO)	MO Q Manager / Local NQA Program Manager

i.e. USA, Canada, Korea, Mexico, China, Spain, Belgium, …

A detailed list of all organizations is provided in Appendix 1 to this manual

4. It is the responsibility of those performing the work to ensure that quality is achieved and maintained.

5. The achievement of product quality must be verified by other than those that perform the work. Each manufacturing plant covered by this program must have processes in place that describe these verification activities and who will perform them. These verification activities would include but not necessarily be limited to inspections, audits and commercial grade dedication.

6. Each organization covered under this program is responsible for ensuring that those performing quality verification activities have been given sufficient authority, direct access to management, organizational freedom and physical access to perform their work. To this end each organization is responsible for maintaining an organizational chart that clearly depicts reporting lines. These organizational charts are to be augmented with verbal descriptions when deemed appropriate and necessary by the organization.

7. Page 4 of this quality manual document provides an overview of the relevant quality program activities assigned to each organization covered by this program.

Q-Program Activity Matrix

A. Program Management F&PS Quality
B. BU Anchor Design in Schaan, Liechtenstein
C. BU Anchor Testing – not applicable anymore due to in concrete testing not required to be qualified under Hilti NQA Program
D. Hilti Plant 1 in Schaan (Liechtenstein), Hilti Plant 8 in Zhanjiang (China), Plant 10 in Matamoros (Mexico) and Plant 18 in Kecskemet (Hungary)
E. Global Logistics and Warehouses
F. Hilti Marketing Organizations (MO)
G. Hilti Marketing Organizations (MO) including Testing Services

Organizational Unit

	Program Element	**A**	**B**	**C**	**D**	**E**	**F**	**G**
1	Organization	x	x	x	x	x	x	x
2	Quality Assurance Program	x						
	Qualification of Personnel	x	x	x	x	x	x	x
3	Design Control		x					
4	Procurement Document Control		x	x	x		x	x
5	Instructions, Procedures and Drawings	x	x	x	x	x	x	x
6	Document Control	x	x	x	x	x	x	x
7	Control of Purchased Items and Materials		x	x	x			x
8	Identification and Control of Items				x			
9	Control of Special Processes							
10	Inspection				x			
11	Test Control		x	x	x			x
12	Control of Measuring and Test Equipment		x	x	x			x
13	Handling, Storage and Shipping				x	x		
14	Inspection, Test and Operating Status				x			
15	Control of Nonconforming Items		x	x	x	x	x	x
16	Corrective Action	x	x	x	x	x	x	x
17	Quality Assurance Records	x	x	x	x	x	x	x
18	Audits	x						

II. QUALITY ASSURANCE PROGRAM

1. This NQA manual, along with the associated implementing procedures of the facilities covered under this program, has been developed to meet the requirements of ASME NQA-1-2000 and 10CFR50 appendix B. Additionally it has been assessed to meet the applicable requirements of ASME NQA-1 2008 / 1-a-2009 and be compliant with the respective requirements of the following standards: ANSI N45.2-1971, ANSI N45.2-1977, ASME NQA-1-1994, HAF-003, KEPIC QAP-1, KTA 1401, NSQ-100 and NP-090-11. Hilti has implemented an effective integrated management system that fosters a strong safety culture and meets the intentions of the IAEA GS-R-3 standard. Furthermore, Hilti will apply the reporting requirements of 10CFR21 to product sold as nuclear "safety related" when specifically requested by customer purchase order. The organizational units covered under this program will comply with the posting requirements of 10CFR21 for US-based units and have alternate posting requirements for non-US-based units that effectively address reporting procedures.

2. This manual applies to the design, manufacture, inspection, testing and supply of the following Hilti products. A detailed list of items is provided in Appendix 1 to this manual:

- specific anchoring products (see Appendix 1 for a list of specific items included):

  KB-, KB-TZ- and HST- expansion anchors. HSL- heavy duty expansion anchors and HDA undercut anchors.

It is not a total reflection of all quality programs applied to other Hilti products or all other quality programs applied to above listed products. The allocation of product families to manufacturing plants is shown below:

Manufacturing	City	Country / Region	Type of Anchors	Product Families
Hilti Plant 1	Schaan	Principality of Liechtenstein	Expansion Anchors	KB/KB-TZ and HST
Hilti Plant 8	Zhanjiang	China	Expansion Anchors	HSL, HST, HDA
Hilti Plant 10	Matamoros	Mexico	Expansion Anchors	KB/KB-TZ
Hilti Plant 18	Kecskemet	Hungary	Undercut Anchors	HDA

With regards to sales and distribution of above listed product families to nuclear customers this manual applies to the Hilti Market Organizations (MO's) and Warehouses qualified under this program.

3. The senior management of each organization covered under this program is responsible to ensure that adequate resources including indoctrinated / qualified / trained personnel (as appropriate with

the scope and complexity of the activities to be performed) are provided to carry out the activities required by the quality program.

4. Each organization covered under the quality program is responsible to identify initial qualification requirements for inspection, test and commercial grade dedication personnel, to evaluate candidate qualifications to the established requirements and to review job performance at least once every three years. If during these evaluations, it is determined that an individual is no longer qualified to perform inspections, tests and / or commercial grade dedication, that person shall be removed from performing that activity until such time that the required capability has been demonstrated.

5. Each organization covered by this program is responsible for ensuring that personnel that performs quality system audits and / or commercial grade surveys of the activities covered by this program has been appropriately qualified to perform these audits / surveys. Overall responsibility for ensuring the qualification of auditors and surveyors under this nuclear quality program lies with the Management Representative utilizing an auditor / surveyor skill verification document.

6. The qualification of inspection, test, auditor and commercial grade dedication personnel shall be documented.

7. The Hilti F&PS Quality Management in Schaan, Liechtenstein has assigned the responsibility to the Management Representative to monitor the overall effectiveness of the program and keep pertinent management levels throughout the organization informed. Program management is responsible for establishing, maintaining and coordinating communication between the involved organizations (Business Units including test fields, Manufacturing Facilities, Warehouses and Market Organizations) under this program.

8. Any changes or revisions to this document or other program documents described herein must pass through the same adequacy review, approval, routing and distribution as the original document.

9. Whenever this manual is revised, the previous revision is deemed a quality assurance record and will be retained for a minimum of 5 years by the F&PS Quality Management department.

III. DESIGN CONTROL

1. Design control for items covered under this Quality Program is located at the Hilti design facilities in Schaan, Liechtenstein.

2. The Hilti “duty description” generated by the Product Management function shall be used as the primary design input document. This may be augmented, as appropriate, with code and regulatory approval requirements, etc.

3. The design process shall document the design activities and result in the creation of a documented design. This documented design includes such items as drawings and test plans.

4. As part of the design process the responsible design engineer shall designate those characteristics and features that cause the item to perform its intended function in the expected manner. These features shall be documented as the product “design basis” (Ref. 10CFR50, app. B, § 50.2).

5. The design process, design analysis and design verification shall culminate with either the performance of functional product testing in accordance with documented test plans and a documented review of the test results confirming the criteria established in the design input phase have been met, or calculations that have been independently verified by a qualified expert other than the originator of the calculation. The test reports and calculations shall provide sufficient detail that a technically qualified person can review the results and independent of the originator can verify the adequacy of the results.

6. For commercial grade items their critical characteristics and critical acceptance characteristics (those characteristics that must be verified to provide reasonable assurance that the item will perform its intended function) are identified and documented in design basis documents.

7. Design changes that affect the established design basis of an item shall require testing and a review of the test report by the assigned product engineer prior to approval and release of the change.

8. In-process design information available to those other than the identified designer shall show evidence of the design status.

9. Design documentation and records from design input through the final released design documents (drawings and specifications) shall be maintained.

IV. PROCUREMENT DOCUMENT CONTROL

1. Procurement documents for items, raw materials, component parts and services shall include, as appropriate and applicable:

    - Technical requirements by reference to specific drawings (including drawing revision) and specifications
    - Test, inspection and acceptance criteria
    - QA program requirements
    - Right of access to supplier and sub-tier supplier facilities as appropriate
    - Documentation requirements
    - Reporting of nonconformance requirements (Ref. 10 CFR Part 21)

2. Procurement documents shall be reviewed and approved prior to release of the documents. This review shall be documented, including release date and who performed the review. Such a release may take place in the electronic system (SAP) and is documented in the system log.

3. Changes to procurement documents shall go through the same review and approval process, and with the same degree of control as the original document.

4. It is the responsibility of Hilti Marketing Organizations (MO) to review customer procurement specifications, requests for quotations and purchase orders for safety-related applications in accordance with documented procedures. Contract / purchase order review and fulfillment, including issuance of certification documents, must be performed by qualified personnel and records of these activities must be created and maintained.

V. INSTRUCTIONS, PROCEDURES AND DRAWINGS

1. Activities affecting quality will be described and performed in accordance with documented instructions and procedures.

2. Quality activities described by written documents shall include, but not be limited to the following and shall include qualitative and quantitative acceptance criteria when appropriate:

    - Receiving inspection
    - Machine line inspection
    - Fracture load testing (when required)
    - Plating inspection
    - Heat treat inspection
    - Assembly and packaging inspection
    - Rework inspection
    - Preparation of inspection and CGD plans and work instructions
    - IMTE guideline for anchor test fields
    - Documentation requirements NQA (development)

- Guideline for audits / surveys under the NQA program
- CGD-Guidelines
- Dedication plans
- Development of PO texts

3. Inspection and test plans, commercial grade dedication plans, procedures and work instructions shall be available to those performing the activities.

4. The ultimate controlling document for generating or guiding inspection instructions shall be the part drawing, referenced specifications and/or design basis documents.

5. Dedication plans and/or receiving inspection plans shall contain specific requirements for the detection of counterfeit, fraudulent, suspect materials (CFSI) wherever appropriate.

VI. DOCUMENT CONTROL

1. Documents used in the purchase, manufacture, inspection and test of production items shall have sufficient controls to ensure adequacy.

2. Sufficient controls include the following:
   - Identification of controlled documents
   - Specified distribution
   - Identification of the individual(s) / organization responsible for the preparation, review, approval, issuance and distribution of the documents
   - Measures to ensure that the correct documents are being used

3. Changes to these documents shall go through the same review and approval processes as the original documents.

4. This quality manual (SCM-3 NQA Nuclear Quality Assurance Manual) is treated as a controlled document and as such it is the responsibility of the assigned Management Representative to fulfill the requirements described in paragraphs 2 and 3 above. Program Management is responsible for the preparation, review, approval, issuance, distribution and training of all program management documents in accordance with paragraphs 2 and 3 above.

5. This quality manual (SCM-3 NQA Nuclear Quality Assurance Manual) shall carry a revision date and bear evidence of an annual review by the Management Representative of the original copy “only for information”.

VII. CONTROL OF PURCHASED ITEMS AND MATERIALS

1. Suppliers of direct production materials and services shall be selected and evaluated through a direct on-site audit of the potential supplier's facilities, resources and quality system or through the performance of a commercial grade survey (CGS). Additionally, periodic re-audits / re-evaluations (commercial grade surveys) of these suppliers shall take place at an interval not to exceed thirty-six months. These audits / surveys shall be performed by an auditor / surveyor qualified under Hilti's Nuclear Quality program.

2. Criteria for extending supplier audit or supplier commercial grade survey frequencies:

   A. A maximum extension not to exceed 25% of the specified thirty-six months frequency (up to forty-five months maximum) is allowed as long as the requirements described in B and C below are also observed.

   B. When an audit/CGS interval extension is used, the next audit/CGS for that supplier must be scheduled from the original audit/CGS anniversary month rather than from the month that the extended audit was performed.

   C. When an audit/CGS interval extension has been used. The total combined time interval between three consecutive audits shall not exceed 3.25 times the specified thirty-six months interval. (i.e. 36 months times 3.25 = 117 months maximum).

3. Non-direct production material suppliers such as third-party calibration services and independent testing agencies shall be selected based on an assessment of the potential supplier's ability to perform the required service. Official accreditation of a calibration or testing service supplier is an allowed method for qualification, based on the rules defined in ILAC NEI 14-05A, but only when used in conjunction with the commercial grade dedication process. For other calibration services and independent testing agencies not covered by ILAC NEI 14-05A, this assessment is performed as a commercial grade dedication activity and requires a commercial grade survey, which includes in-house evaluation performed at the time the service is provided at Hilti facilities. In all cases, the activities performed to qualify third party calibration service suppliers and independent testing agencies form a part of a commercial grade dedication process and are to be supplemented with additional dedication activities to the extent necessary to meet the requirements of EPRI Guideline 3002002982.

4. When suppliers are required by contract (purchase order or such) to provide quality related documentation (i.e. inspection reports, certification) provisions shall be in place to ensure that the required documents are reviewed for conformance to the requirements. This review shall be incorporated into the receipt inspection function and / or commercial grade dedication function for direct production materials and services and done in accordance with documented processes to ensure compliance.

5. Acceptance of materials and services shall be accomplished in accordance with documented receiving inspection plans and / or commercial grade dedication plans, and describe activities required to be performed upon receipt to determine acceptance. These activities will include the above mentioned review of supplier generated documentation, receiving inspection or a combination of both.

6. In cases that the acceptance of a material or service is accomplished in all or in part via submittal of certification documents, these certificates shall include as a minimum:

- The identity of the material or service covered by the certificate, i.e. ref. to the purchase order
- Reference to the specific requirements met such as codes, standards, specifications, drawings, purchase order provisions
- Identification of any requirements that have not been met
- Identification of sample size for test results documented in CMTR / 3.1 certificates
- A signature of someone authorized by the supplier's quality program to sign such a document

Additionally, as part of the supplier audit or commercial grade survey and approval process it must be verified that the supplier has in place an effective system for providing the certification.

7. Acceptance of services such as third party calibration and outside testing shall be based on a dedication plan and accomplished via a technical verification through review of the reports provided by the supplier. This review shall verify that the services provided met requirements and expectations.

8. In cases that upon receipt inspection it is determined that items provided by supplier's are determined to be non-conforming the material shall be segregated and handled in accordance with documented non-conformance procedures.

9. Commercial Grade Dedication (CDG) is applied to provide reasonable assurance that a commercial grade item, material or service will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program.

- A CGD-procedure identifies the steps necessary to dedicate commercial grade items for use in nuclear safety related applications.
- This assurance is achieved by identifying the critical acceptance characteristics and verifying their acceptability by document review, inspections, tests, or analysis performed by the dedicating entity after delivery, as delineated in commercial grade dedication plans.
- The critical characteristics and the critical acceptance characteristics are identified in a Design Basis Document.
- Commercial Grade Surveys (CGS) are performed as a supplementary method to verify and document the adequacy of suppliers processes and quality controls.
- Sample sizes for the inspection and testing of critical acceptance characteristics are documented in Sample Size Determination Documents (SSDD), following the procedures and principles defined in the Guideline for Sample Size Determination
- The Dedication Plans describe the selection, performance, and documentation of the methods that are necessary to perform the dedication process.
- The results of a CGD are documented in a dedication report.
- The Commercial Grade Dedication Program is designed to meet ASME NQA-1-2008 Subpart 2.14, 10 CFR 50 appendix B, 10 CFR part 21 and EPRI Guideline 3002002982.

10. Records for the above described activities shall be maintained.

VIII. IDENTIFICATION AND CONTROL OF ITEMS

1. Throughout the manufacturing or dedication processes a system shall be in place to ensure that items maintain proper identification. This identification may include but is not limited to; batch number, lot number, component description, part number, CFSI.

2. This identification requirement begins upon receipt of material and carries through to the assembly and packaging of the product. Upon packaging of the product, a product label fulfilling the above described identification requirement must be affixed to the individual sales units. (i.e. box)

3. Storage of raw materials, component parts and in-process materials shall take place in an inside environment to ensure that no degradation to the materials or items takes place during extended periods of storage.

IX. CONTROL OF SPECIAL PROCESSES

1. Hilti does not treat any internally (Hilti Plant) performed process as a “special” process. Rather than relying on the monitoring of “process controls” for processes such as hardening or plating actual product inspection methods have been developed and are carried out to ensure product quality.

2. Products that are containing welding seams manufactured with automatic welding equipment are inspected with non-destructive and / or destructive test methods, and for these processes the provisions of paragraph 1 do apply accordingly.

X. INSPECTION

1. Product inspection shall be carried out in accordance with documented inspection plans.

2. These documented inspection plans shall include receiving inspection plans, in-process inspection plans (i.e. machining and hardening operations), outside service inspection plans (i.e. plating), rework inspection plans, and assembly / packaging inspection plans.

3. There are two (2) defined levels of internal inspection covered under this program:

    - “Self-inspection”….The ongoing inspections performed by the person doing the work to control the process and the products conformance to specification.

    - “Verification”…. The independent examination activity conducted to verify that the “self-inspection” process is being properly executed. This verification of product quality shall be performed by persons other than those directly responsible for the specific work being examined.

4. Any given batch of material will require self-inspection and verification during the manufacturing process. As a minimum the verification points shall include:

- receiving inspection (commercial grade dedication)
- machining / forming
- plating /coating (when provided by external suppliers – commercial grade dedication)
- rework

Each manufacturing location covered by this program is responsible to define when these verification processes are carried out during the process. For example, the machining verification could take place at completion of the machining process(es) or it could take place in combination with the plating verification.

5. The above described inspections shall be recorded and the records must include as a minimum:

- item inspected
- date of inspection
- person performing the inspection
- type of observation
- results of inspection
- reference to actions taken in connection with identification of non-conformances

6. The above described inspections may be augmented with “work station audits” at the discretion of the manufacturing location.

Note: The requirements for performing commercial grade dedication of an item are described in section 7 of this manual.

XI. TEST CONTROL

1. Tests required to verify design, develop published performance specifications, meet regulatory and code requirements, and verify conformance to specifications, shall be performed in accordance with documented plans and procedures. These plans shall include test configuration and test objectives as appropriate.

2. Prerequisites to these plans must be ensured as following: calibrated instrumentation, appropriate equipment, trained personnel, condition of the test equipment and the item to be tested, suitable environmental conditions, and provisions for data collection.

3. Alternatively to the above described requirements tests may be conducted with reference to appropriate sections of related documents such as recognized test standards (i.e. ASTM, ISO, EN), supplier manuals, equipment instructions, etc.

4. It is the responsibility of the engineering and / or quality function to identify and approve the test plan(s).

5. Tests shall be controlled in a manner and environment with tools and equipment that ensures test result accuracy.

6. Test requirements and acceptance criteria shall be based upon specified requirements contained in design documents, established codes and \ or other pertinent technical requirements.

7. Results of required tests shall be documented.

XII. CONTROL OF MEASURING AND TEST EQUIPMENT

1. Documented program(s) shall be in place to ensure the calibration and control of inspection, measuring and test equipment (IMTE) used for activities affecting quality.

2. The selection of IMTE shall take into consideration the type, range, accuracy and tolerance needed to accomplish the required measurement.

3. The calibration program(s) for IMTE shall provide for:

    - traceability to a nationally recognized standard or, if no national standard exists, documentation on the basis of the calibration
    - Identification of calibration frequency
    - Method of calibration
    - Required accuracy or identified normal operating allowances (NOA)
    - Provisions and a documented process that describes the actions to be taken if out-of-calibration discovery events take place including, as appropriate; product re-qualification
    - identification method(s) used to indicate calibration status on the IMTE
    - method(s) used to segregate equipment found to be outside of NOA until such time as the IMTE is brought back into NOA
    - identification of as found and/or as left conditions on calibration records
    - repair or replacement of IMTE consistently found to be outside of NOA

4. Measures shall also be in place to ensure appropriate storage and handling of IMTE.

5. Records of IMTE calibration activities shall be maintained.

XIII. HANDLING, STORAGE AND SHIPPING

1. All production materials and packaged products from the point of receipt to the point of shipment shall not be subjected to outside storage.

2. The production processes, finalizing with the assembly / packaging process, includes the boxing, labeling, placement into cartons and palletizing in advance of movement to the warehouse/shipping department. Therefore, the assembly department manufacturing and inspection plans document the principle activities required to assure proper preservation, packing and handling conditions for storage and shipment.

3. Subsequent and consequent pre-shipment preparations to end user customers subordinate to the main packaging process performed in the manufacturing plants will be appropriately monitored and reviewed for adequacy on a case-by-case (as needed) basis.

4. The warehouse has to ensure that in the event of a fire in the storage area, each item known to have been exposed to heat of over 65° C (150 degrees F) or subjected to smoke contamination shall be withheld from delivery until it has been thoroughly examined and a decision on its further use has been reached [ref. to ASME NQA-1-1994, part II, subpart 2.2, paragraph 6.4.3, “post-fire evaluation”].

5. Global Logistics is responsible for the distribution centers and warehouses and the transport within the Hilti supply network. Warehouse personnel is responsible for keeping product in saleable condition, maintaining lot integrity and traceability, checking for any signs of counterfeit, suspect or fraudulent items (CFSI), and adhering to shipping conditions as agreed in the customer purchase order specifications.

XIV. INSPECTION, TEST AND OPERATING STATUS

1. The inspection and test status of raw material, component parts and in-process manufactured or commercially dedicated items shall be maintained at all times.

2. Acceptable methods for identifying the acceptance status include application of tags / stamps and / or physical location of items.

3. Each plant is responsible to document the method(s) it chooses to use in identifying the inspection status.

4. When tags / stamps are used procedures shall describe the authority to apply and remove such tags / stamps.

5. In those cases that the application of a stamp is defined as an acceptable method to indicate inspection status it must be ensured that a documented stamp control procedure is in place.

6. Transfer to a Hilti warehouse from the manufacturing location constitutes the manufacturing location as having confirmed the inspection status of the finished product as acceptable. As such, no additional inspection status indicators are required by those Hilti warehouses receiving the product.

XV. CONTROL OF NONCONFORMING ITEMS

1. Documented process(es) shall be in place at the manufacturing locations that describe how nonconforming product is identified and controlled / segregated.

2. Nonconformance’s effecting product function, performance, published product information or other aspects of customer (end-user) acceptance are not subject to ”use-as-is” or repair dispositions.

Any other nonconforming features are subject to a waiver request by the manufacturing plant to the respective Business Unit Development department and Quality function. Final approval of use-as-is or repair dispositions will be performed by the F&PS Quality Management (DQ).

3. Actions regarding the disposition of nonconforming material shall be guided by documented procedures and describe specific authorization authorities. Decisions regarding the need for a 10 CFR part 21 reporting shall be documented.

4. Technical justification shall be documented for any “use-as-is” and “repair” disposition.

5. Records of the disposition of nonconforming products shall be maintained in the respective manufacturing plant.

6. Nonconforming materials identified in distribution (warehouse) or sales (customer complaints) must be reported to the responsible quality function following the respective reporting procedures.

XVI. CORRECTIVE ACTION

1. Management of each organization covered under this quality program has the prime accountability in identifying the need for corrective action when conditions adverse to quality are discovered and for acting promptly.

2. The identification of the need to take corrective action can come from a single adverse condition, a negative trend, customer input, audit results and the like.

3. When management deems an adverse condition significant, processes shall be in place to identify the root cause, identify the corrective action to be taken and verify that the corrective action was carried out and was effective.

4. Corrective actions shall be communicated to the appropriate levels of management commensurate with the significance of the situation.

5. Corrective action records shall be maintained. Decisions regarding the need for a 10 CFR part 21 reporting shall be documented.

XVII. QUALITY ASSURANCE RECORDS

1. Quality Assurance records are those records generated in the course of complying with the policies of this handbook. All quality assurance records are considered non-permanent and therefore retention periods shall be identified.

2. Each organization / facility covered under this quality program shall identify their Quality Assurance records, ensure the records are legible, identify retention periods and identify storage locations.

3. Records shall show evidence of who created the record either through signature, stamping or initials (either electronic or hard copy) and indicate the date the record was created.

4. Records shall be maintained in a manner that allows them to be retrieved and under appropriate environmental conditions to minimize potential damage. Conditions and methods for record retention are detailed in the SCM-2.4 record retention guideline.

XVIII. AUDITS

1. The overall effectiveness of this quality program shall be evaluated via internal quality system audits.

2. The Management Representative shall be responsible to ensure the scheduling and performance of these quality audits at a frequency not to exceed thirty-six months unless the extended frequency requirements described in point 3 below are utilized. Schedules shall be based on the month in which the audit starts. The scheduling of internal audits shall ensure that elements of this quality program are audited every year regardless of the criteria for extending internal audit frequencies.

3. Criteria for extending internal audit frequencies:

    A. A maximum extension not to exceed 25% of the specified thirty-six months frequency (up to forty-five months maximum) is allowed as long as the requirement described in B below is observed.

    B. When an internal audit interval extension is used, the next audit for that particular audit area will be scheduled from the original audit anniversary month rather from the month that the extended audit was performed.

4. These audits are to be performed specific to this NQA-1 / 10CFR50 app. B program and those products produced and supplied under the program.

5. Individual audits shall be planned and include the:

    - Scope of the audit
    - Requirements
    - Audit personnel
    - Activities to be audited
    - Organizations to be notified
    - Schedule
    - Written procedures or checklist

6. Audit team selection shall ensure that team members have sufficient authority to make the audit process meaningful. Nuclear related Internal Audits must be led by a qualified Hilti Nuclear Auditor (Auditor NQA). Audit personnel shall not be assigned to perform audits over areas that they have direct responsibility for.

7. The audit report shall be signed by the Hilti Auditor NQA, issued to the audited organization and include the following:

    - description of the audit scope
    - identify the auditors
    - identify personnel contacted during the audit
    - summarize the audit results
    - include a statement on the effectiveness of the elements audited
    - describe deficiencies

8. Management of the audited organization shall investigate identified deficiencies, schedule corrective / preventive actions and notify the audit team of such so that follow-up verification can take place

9. The responsibility for audit closure must be defined by the assigned leading Auditor. It either remains with the assigned leading auditor or delegation to an auditor from program management or another qualified auditor from the audit team is agreed upon. For all identified deviations, corrective / preventive actions must be completed and the implementation verified. The assigned Auditor for closure is collecting the necessary evidence, files this together with the audit report and confirms closure on the audit report. Audit closure must be done in a timely manner. Timing depends on the kind of identified deviation and corrective / preventive action, but a general expectation is that audit reports get closed within a 3 to 6 months time frame.

10. All documents related to the audit shall become a part of the audit record

XIX. BINDING FOR HILTI

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Issued by:
Quality and Nuclear Program Manager / NQA Program Management, assigned by
Fastening and Protection Systems (F&PS) Quality Management (DQ): DQ / Joachim Wolf

Date	Modifications	Replaces
12-2004	First issue	N/A
02-2018	section 1, pages 3&4, and section 2, page 5: restructuring of table and matrix, discontinuation of Hilti NQA program at BU Direct Fastening and safety related X-BT-items; section 2, page 5, para. 1: inclusion of IAEA GS-R-3 in scope; section 4, page 7, para. 2: clarification of purchasing document review and approval requirements; section 9, page 11, para. 1: removal of obsolete link to AMS-LLC	Rev. 13 from 02-2017
09-2018	Renaming of document: “Hilti Nuclear Quality Assurance Manual”, allocation to new global process management system (GPMS) group “SCM-3 Nuclear Quality Program” section 1, page 3: allocation of responsibility for Anchor testing organizations	Rev. 14 from 02-2018
10-2020	section 1, page 3 and 4: allocation of responsibility for Anchor organizations section 7.2: page 9: clarification of dedication requirements for other calibration services and independent testing agencies not covered by ILAC NEI 14-05A Section 2: page 5 ASME NQA 1 2015 deleted, added clarification regarding which KB-TZ and KH-EZ screw anchors are included in the scope of the program Section 7: page 9 extending supplier audit or supplier commercial grade survey frequencies Section 18: page 15 extending internal audit frequencies	Rev. 15 from 09-2018
12-2020	section 1, page 3 and 4: added Hilti Plant 8 in Zhanjiang, China section 2, page 5: added Hilti Plant 8 in Zhanjiang, China and HSL4/KB-TZ2 item family	Rev. 16 from 10-2020

04-2024	Cover page, page 2: Added Documentation of Annual review (since 09-2023) Section 1, page 4: enable nomination of deputies for Plant Q Manager as Local NQA Program Manager (since 09-2023) Section 1, page 4: Changes in Market Organizations (MO) / Warehouses qualified under Hilti NQA Program see also Appendix 1 Section 2, page 6: Added HST4 item family qualified under Hilti NQA Program see also Appendix 1 (since 01-2024) Section 2, page 6: Screw portfolio (HUS/HUS-HR/KH/KH-EZ) no longer qualified under Hilti NQA Program see also Appendix 1 Section 7, page 10: Change in extended CGS/Internal Audit frequency Criteria B Section 9, page 12: Remove Frigo and Installation as no longer qualified under Hilti NQA Program Section 18, page 17: Change in extended CGS/Internal Audit frequency Criteria B	Rev. 17 from 12-2020
04-2025	Cover page, change to updated Hilti template Section 1, page 2, page 4: Changes in Organizations qualified under Hilti NQA Program. BU Anchor Testing no longer qualified. Section 1, page 2: Changes in Market Organizations (MO) / Warehouses qualified under Hilti NQA Program see also Appendix 1 Section 2, page 5: Wording change “meet applicable requirements of ASME NQA-1 2008 / 1-a-2009" Section 2, page 5: Remove generation from specific anchor products Section 2, page 5: Add HSL/HDA product families being manufactured at Hilti Plant 8 Section 2, page 6: Added HST4-CS item family qualified under Hilti NQA Program see also Appendix 1 (since 01-2025) Section 7, page 10: Change in extended CGS/Internal Audit frequency Criteria B back to wording Revision 17	Rev. 18 from 04-2024

	Section 18, page 17: Change in extended CGS/Internal Audit frequency Criteria B back to wording Revision 17	

❑ **Only for information.** Changes not supplied.	☒ **Registered issue.** Changes supplied.

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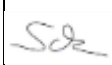
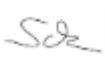
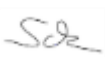
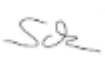
Quality Manager Nuclear Patrick Scholz

Annual Review Date (MM/YY)	12/2021 	12/2022 	09/2023 	04/2024 	04/2025 	xx/2026	xx/2027
By:	DQDsp	DQDsp	DQDsp	DQDsp	DQDsp		

The review of SCM-3 Hilti Nuclear Quality Assurance Manual is done on an annual base and published in new Revisions. In case a new Revision is not required at the review date the documentation of annual review is recorded in Hilti Nuclear Quality Assurance Manual “only for information”, uploaded to GPMS SCM-3 and with that not supplied to controlled distribution list. In case of request the records of annual review the Hilti Quality Assurance Manual “only for information” will be shared with requester.