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QUALITY ASSURANCE PROGRAM DESCRIPTION

10 CFR 71 Subpart H

NUCLEAR CARGO + SERVICE GMBH

Hanau

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1 INTRODUCTION

The objective of NCS, a company belonging to the DAHER Group is the management of forwarding, freight and storage business and development of packaging conceptions, especially in the field of nuclear- and heavy load logistics.

NCS headquarters with offices, secured parking place for lorries and storage buildings for interim storage of non-fissile radioactive materials (e.g. contaminated packaging and radioactive wastes), as well as maintenance halls, is located within an industrial area at Hanau-Wolfgang.

Infrastructure like

- Plant security
- Radiation protection
- Fire brigade

are either existing at NCS (radiation protection) or are available via a third party contract (plant security and fire brigade of the "Industriepark Wolfgang GmbH" situated on an area close to NCS).

Next to this, NCS has branch offices in Berlin, Darmstadt, Düren, Freiberg and Hagen.

NCS has a staff of employees with a long experience in the field of logistics and transports of dangerous, especially radioactive, and heavy goods.

2 REVISION RECORD

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3 PURPOSE AND SCOPE

This Quality Assurance Program Description identifies how each of the regulations in Subpart H of 10 CFR Part 71 applies to the NCS quality management system and how the requirements are implemented by:

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Germany

The Table 1 shows procedures that demonstrate implementation of a documented QA program.

The purpose of NCS quality management system is to assure a permanent and optimal quality of services. It describes the QM measures which were introduced and which must be permanently observed in order to fulfil the essential objective of avoiding errors and faults. The quality management manual is valid for all organisation units and for all NCS staff members.

These requirements are applicable for purchase orders or contracts that invoke regulatory requirements or specifically require compliance to this program. Each contract will be reviewed to determine regulated activities and the appropriate measures to be implemented

NCS has no packaging hardware production. Packaging products are not manufactured by NCS. Packaging hardware suppliers are required to prove that they have a certified QM system.

The requirements of Subpart H of 10 CFR Part 71 shall be complied with as applicable to the products or services provided. Additionally, the requirements for reporting of defects and noncompliance according 10 CFR Part 21 will be accepted.

Table 1 – QA Program Implementing Procedures

Implementing Document	Title	Regulatory Position	Description
QM, Section 5, Management Responsibility **QM, Attachment 1:** Organization Chart **QM, Attachment 2:** Responsibility Matrix	§71.103 QUALITY ASSURANCE ORGANIZATION	1	Responsibilities for the establishment and implementation of the quality assurance program are defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality are documented. The organization chart provides an outline of the organizational structure. The responsibility matrix describes interfaces within of the organizational structure.
QM, Section 4, Quality Management System	§71.105 QUALITY ASSURANCE PROGRAM	2	Describes how the quality assurance program is planned, implemented, and maintained. Identifies the activities and items to which it applies. The program provides control over activities affecting quality to an extent consistent with their importance. The program includes monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.
QM, Section 7.3, Design and development **VA-V-03-01, Section 5** Development of Packaging Concepts	§71.107 PACKAGE DESIGN CONTROL	3	Design inputs are specified and translated into design documents. Design interfaces are identified and controlled. Individuals other than those who designed the item or computer program verify design adequacy. Design changes are governed by control measures commensurate with those applied to the original design.
QM, Section 7.4, Purchasing **VA-V-03-01, Section 6**, Development of Packaging Concepts, *Fabrication /Acquisition of Packagings*	§71.109 PROCUREMENT DOCUMENT CONTROL	4	Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents require Suppliers to have a quality assurance program consistent with the applicable requirements of the QM.

Table 1 – QA Program Implementing Procedures (continued)

Implementing Document	Title	Regulatory Position	Description
QM, Section 7.3.3 Design and development outputs **VA-V-03-01, Section 5.6** Development of Packaging Concepts **AA-V-89-02**, Preparation of drawings **AA-V-89-04**, Preparation and Examination and Checking of Documentation	§71.111 INSTRUCTIONS, PROCEDURES, AND DRAWINGS	5	Activities affecting quality and services are prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity is described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions are determined based upon complexity of the task, the significance of the item or activity, work environment, and worker and capability (education, training, experience).
QM Section 4.2.2 Control of documents and records **RL-Q-89-01** Creation and Management of Documents **FP-95-01** Archiving of documents	§71.113, DOCUMENT CONTROL	6	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings are controlled to ensure that correct documents are being employed. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.

Table 1 – QA Program Implementing Procedures (continued)

Implementing Document	Title	Regulatory Position	Description
QM, Section 7.5 Production and service provision **VA-V-03-01, Section 6**, Development of Packaging Concepts, *Fabrication /Acquisition of Packagings* **AA-V-89-05** Incoming Inspection **AA-V-89-06** Preparation, Examination and Tests of Approval Documents	§71.115, CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES	7	The procurement of items and services are controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.
QM, Section 8.2.4 Monitoring and measurement of product	§71.117 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS	8	Controls are established to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
QM Section 7.1 Planning of product realisation **Special instructions** (e.g. PA-11-05)	§71.119 CONTROL OF SPECIAL PROCESSES	9	Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements.

Table 1 – QA Program Implementing Procedures (continued)

Implementing Document	Title	Regulatory Position	Description
QM Section 7.4 Purchasing **AA-V-89-05** Incoming Inspection **AA-V-89-06** Preparation, Examination and Tests of Approval Documents, **Special forms** (e.g. FPP) **Special instructions** (e.g. HA-00-03)	§71.121 INTERNAL INSPECTION	10	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service are planned and executed. Characteristics subject to inspection and inspection methods are specified. Inspection results are documented. Qualified persons other than those who performed or directly supervised the work being inspected perform inspections for acceptance.
QM Section 7.1 Planning of product realisation **VA-V-03-01, Sections 5.7, 5.8** Development of Packaging Concepts / *Testing program and Tests*	§71.123 TEST CONTROL	11	Tests required to collect data such as for design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with test requirements and acceptance criteria are evaluated.
QM, Section 7.6 Control of monitoring and measuring devices **RL-Q 89-08** Monitoring Measuring and Testing Equipment	§71.125 CONTROL OF MEASURING AND TEST EQUIPMENT	12	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

Table 1 – QA Program Implementing Procedures (continued)

QM, Section 7.5.3 Customer property **QM, Section 7.5.4** Preservation of product	§71.127 HANDLING, STORAGE, AND SHIPPING CONTROL	13	Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration. These activities are conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.
QM, Section 7.5.3 Identification and traceability	§71.129 INSPECTION, TEST, AND OPERATING STATUS	14	The status of inspection and test activities are identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status is maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means. The authority for application and removal of tags, markings, labels, and stamps are specified. Status indicators shall also provide for indicating the operating status of systems and components of the nuclear facility, such as by tagging valves and switches, to prevent inadvertent operation.
QM, Section 8.3 Control of nonconforming products **AA-V-89-03** Preparation, Examination and Checking of Deviation Reports	§71.131 NON-CONFORMING MATERIALS, PARTS, OR COMPONENTS	15	Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

Table 1 – QA Program Implementing Procedures (continued)

QM, Section 8.5.2 Corrective action **RL-Q-95-01** Planning and Implementation of Corrective Action **RL-Q-95-02** Reporting and Assessment of Errors **AA-V-89-03** Preparation, Examination and Tests of Deviation Reports and Certificates of Change	§71.133 CORRECTIVE ACTION	16	Conditions adverse to quality are identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management. Completion of corrective actions is verified.
QM, Section 4.2.2, Control of documents and records **RL-Q-89-01** Creation and Management of Documents	§71.135 QUALITY ASSURANCE RECORDS	17	The control of quality assurance records is established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records are identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities are documented.
QM, Section 8.2.2 Internal audit **RL-Q-91-01** Planning and Execution of Internal Audits	§71.137 AUDITS	18	Audits are performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. Personnel who do not have direct responsibility for performing the activities being audited perform these audits in accordance with written procedures or checklists. Audit results are documented and reported to and reviewed by responsible management. Follow-up action is taken where indicated.

4 QUALITY ASSURANCE CRITERIA

4.1 Organization

The NCS Management is responsible for the development and realisation, as well as for continuous improvement of the efficiency of the quality management system.

Responsibilities and authorities are presented in the NCS organisation chart and result from the corresponding job descriptions, according to the following pattern:

- Position Title
- Subordinations
- Superseding relations
- Deputy relations
- Objectives
- Special authorisations and duties
- Tasks and duties

Furthermore, the allocation of responsibilities from organisation units to the implementation steps is represented in the form of a matrix for each corresponding main process.

Responsibility for quality assurance within the General Management of NCS is governed by the business distribution plan.

The Managing Directors have entrusted the planning, introduction, maintenance and permanent improvement of the QM system to the head of the Quality Assurance Department.

It is the duty of head of the QA Department to implement the Company's quality management system in the organisation and to make sure that it is understood and followed at all levels. For this, head of the QA Department has the full support of the Managing Directors.

4.2 Quality Assurance Program

NCS keeps up a process oriented QM system based on DIN EN ISO 9001. It contains all QM requirements that must be observed by all organisation units and by all NCS staff members.

Documentation related to the QM system has a step shaped structure, the highest step being the QM manual and the others consisting of procedures, guidelines and work instructions. The ISO 9001 Standard program is a framework that is used to implement the NCS QM system quality program.

In general, the regulations in 10 CFR 71, Subpart H, are included within a Quality Assurance Program complying with ISO 9001. Requirements from German standard KTA 1401 and from IAEA TS-G-1.4 "The Management System for the Safe Transport of Radioactive Material" supplement the ISO 9001 requirements to provide additional detail required by 10 CFR 71, Subpart H.

4.3 Package Design Control

Generally, customers initiate the development of new products. The technical and economical requirements towards the product are assessed and taken into account during development and design. The head of Design/Technology department coordinates development projects. He works out a development plan which appoints the members of the development team, defines their tasks, the development steps and the schedule.

Control steps are planned within the course of the single development projects, in order to make sure that the defined quality requirements are actually achieved. When doing so, preliminary requirements which might have been expressed by exterior inspection instances, customers, etc., will be taken into account.

The degree to which the development objective has been achieved is checked internally through NCS by means of the conditions in the system requirement specifications or in similar documents, and, depending on project conditions, also submitted to external controls (authorities, experts, customers).

Assurance that the product is capable of fulfilling the requirements inherent to the use to which it is foreseen will be, as a rule, verified through cold handling.

Changes of the design and development parameters will take place whenever customer requirements or requirements imposed by the authorities change

during the course of development, or if it should become apparent, when checking development, that the defined objectives cannot be achieved.

Changes of quality related documents (e.g. system requirement specifications, safety reports) will be carried out through the corresponding responsible instance and will only be valid when carrying the corresponding control/release remark.

4.4 Procurement Document Control

All suppliers of safety related products and services are supervised by means of adequate quality assurance measures. These include:

- a first evaluation of the quality capabilities of possible suppliers
- an evaluation of samples
- periodic evaluations of suppliers

Hardware suppliers will as a rule are required to prove that they have a certified QM system.

Purchasing documents for the different fields of business are very different as far as their contents and form are concerned. Corresponding details are regulated in the corresponding procedures.

4.5 Instructions, Procedures, and Drawings

Production drawings will be worked out, based on design drawings, insofar as no definitive production drawings were worked out with the safety report. These production drawings may be worked out by NCS, insofar as they have sufficient knowledge and experience concerning production processes and possibilities. If experience concerning production processes and possibilities is not sufficient, the manufacturer of the packaging may be entrusted with the working out of the production documents.

4.6 Document Control

This quality management element describes the decisions made to assure a correct flow of information. It is thus assured that the correct and valid versions of all required documents are available at all places within the Company and to the customers and suppliers.

As a general rule, every organisation unit (department, group) will prepare the documents necessary for its activity, being thus responsible for these documents. In case of documents that cover more than one organisation unit, a responsible organisation unit is appointed.

4.7 Control of Purchased Material, Equipment, and Services

NCS does not produce packagings by themselves. This is assured by manufacturers selected by NCS, who are in the list of qualified suppliers or who were entered into this list before the order was placed.

The manufacturer's specification, drawings and the instructions mentioned in the manufacturer's specification are part of the acquisition documents.

4.8 Identification and Control of Materials, Parts, and Components

The inspection status of hardware and documents is identified by means of stamps, labels, accompanying cards, control reports, signatures or other adequate means indicating that requirements are fulfilled or not, based on the quality controls which were carried out. The verification of the inspection status is maintained throughout the service performance process.

4.9 Control of Special Processes

Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements.

4.10 Internal Inspection

The manufacturer will work out the preliminary checking documents, based on the manufacturer's specification and the drawings of the packaging:

- List of materials,
- Fabrication and control follow-up plan (in part also named construction control follow-up plan, according to the manufacturer's choice),
- Welding plan,

- If applicable, completion drawings (e.g. forging drawings).

The supervision of fabrication through NCS is settled in the preliminary checking documents. The checking steps are carried out under the responsibility of the person responsible for acceptance appointed by NCS. Implementation of the supervising steps is documented in the preliminary checking documents and, insofar as necessary, in the corresponding records.

4.11 Test Control

Testing programs are set up for the development projects, for which technical safety characteristics must be verified by means of practical tests. This may be due to technical causes (non existent or not sufficiently validated analytic procedures) or to economical reasons (the costs for application of analytic processes are higher than verifications by empirical tests).

4.12 Control of Measuring and Test Equipment

All monitoring/measuring devices used to evaluate safety relevant quality characteristics (e.g. for radiation protection), are kept locally by the corresponding instances in a file, and are subject to permanent monitoring.

Those responsible for the corresponding monitoring/measuring devices will make sure that inspections/calibrations are carried out in due time. When a monitoring/measuring device appears to be nonconforming, it will be identified by means of a blocking sticker and the blocking will be recorded in the file.

4.13 Handling, Storage, and Shipping Control

Proceedings are taken to avoid damages of packages during handling, storage and transport.

4.14 Inspection, Test, and Operating Status

Recordings concerning quality are gathered and assembled by the corresponding project manager or, if no such person has been appointed, by the instance responsible for documentation in the concerned case.

The documents are examined according to documentation criteria for

- Completeness

- Unambiguous allocation
- Legibility
- Traceability
- Actualisation

4.15 Nonconforming Materials, Parts, or Components

If a product (e.g. packaging, study or preliminary drafts for this) does not fulfil quality requirements, it is marked and/or segregated in order to make sure it will not be used by mistake. The corresponding processes have been defined in such a way that identification, documentation, evaluation and measures for further treatment are given in advance.

Corrective actions will be carried out at once by the responsible instances, inasmuch as they are known, in order to allow for the continuation or finishing of the service performance process.

4.16 Corrective Action

The QM system can only be effective if identified faults are permanently eliminated (avoiding of repetition of faults, etc.) and the system is continuously adapted to internal/external changes (optimisation).

Corrective action will be carried out, especially in order to effectively eliminate systematic faults.

The reasons for triggering corrective action are the evaluation of quality data, of audits and the evaluation of single nonconformities.

4.17 Quality Assurance Records

This quality management element describes the decisions made to assure a correct flow of information. It is thus assured that the correct and valid versions of all required documents are available at all places within the Company and to the customers and suppliers.

4.18 Audits

Planning of internal audits will be oriented according to the necessity of periodical controls of the effectiveness of the QM system. It shall be foreseen that all organisation units involved in the QM system will be audited annually. The intensity of the audits will depend on the safety relevance of the concerned processes.