Quality Procedure – Control of nonconformities

Contents

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PA1	2009-09-17	First issue			

1 Objective

Identifying and documenting nonconformities of IMS in all areas.

2 Application

2.1 Identification and treatment of nonconformities

2.1.1 Revealing a nonconformity (NC)

The responsibility to reveal nonconforming products/services/processes and to launch the relative procedure lies with each employee of the area where the nonconformity occurs. He/she should approach the chief of function for further proceedings.

2.1.2 Documenting a NC

The NC shall be documented in the first part of the attached form *LTD-Q-005-01-Nonconformity Report*. Most important data shall be provided here in a synthetic way: a brief description of the NC, area of occurrence, classification of nonconformity and list of enclosed relative reference documents.

2.1.3 Treating a NC

Nonconformity situations are managed by the respective functions (according to cases and specific competences) and may be supervised by the head of company area or QSA.

In particular, the involved chief of function:

- analyses the nature of nonconformity and has the authority to define relative decisions (treatment);
- upon completion of treatment action, has the responsibility to individuate adequate checks to ensure restore of acceptable conformity situation and to become sure that they are carried out properly;
- has the authority to communicate with the outside (clients, suppliers, as the case may be);

while QSA registers the nonconformity in the LTD-Q-005-02-Nonconformity Register, in order to estimate the costs and consider possibilities for improvement by means of Corrective/Preventive Actions.

In case of product nonconformities the treatment for resolution is carried out in cooperation with the chief of function or QSA and the involved operator. It leads to the integration of the product until the acceptable conformity situation is restored (i.e. “the product” is “re-processed” in order to satisfy specified requirements).

In case of nonconformities related to processes (supplies provision, sales, traceability, logistics, etc.) the chief of the involved function has the responsibility to manage the adequate corrective action and the MR or QSA follows it up.

QSA register the complaints by coordinating implementation of agreed remedy actions and verifying that these have taken place as agreed within the agreed time limits and in the proper ways.

2.1.4 Classification of NC’s

Nonconformities are classified as:

- **Major nonconformities** like:
  - Disrespect of valid norms covering the product/service;
  - Failure to close out a minor NC within the agreed timeframe;
  - Everything that may lead to delays of work completion.

- **Minor nonconformities** like:
  - Failure to deliver foreseen documentation;
  - Materials delivered by suppliers is nonconforming.

2.2 Controlling actions for resolving NC’s

Upon completion of resolving actions defined in the Nonconformity Report, QSA launch all the verification activities that were previously foreseen or later filled in the Nonconformity Report.

2.3 Records and analyses of NC's

All Nonconformity Reports issued are recorded in the *LTD-Q-005-02-Nonconformity Register* which is stored in QSA's archive. By means of this register QSA provides for a systematic analysis of quality-related situations of activities implemented in the Company.

Based on the typology and quantity of similar nonconformities occurred, QSA may decide to adopt Corrective/Preventive Actions in order to eliminate causes that have led to nonconformities. Corrective/Preventive Actions are managed as described in the respective procedure.

2.4 Archiving the documents

All the Nonconformity Reports in original and the enclosed documentation is archived by QSA/ESA.

3 Annexes

LTD-Q-005-01-Nonconformity Report

LTD-Q-005-02-Nonconformity Register

LTD-Q-005-03-Complaints Register