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ANALYSIS AND IDENTIFICATION OF NONCONFORMING PRODUCTS BY 5W2H METHOD

Abstract: *The process of controlling products which do not conform to product requirements can make use of a wide range of procedures designed to detect nonconformities in the production process and to prevent their occurrence. Chapter 8.3. EN ISO 9001:2008 dealing with requirements on quality management systems states that the organization is obliged to identify and control nonconforming product to prevent its unintended use or shipment to the customer. However, the nonconformity control system is essentially a defensive process, where effective and user-friendly methods of control of nonconforming product are relatively rare. One of them is the 5W2H method aimed at clarifying the problem (defect, nonconformity), which is used not only when dealing with complaints, but with any issues which could directly or indirectly endanger the customer. This paper shows the use of the 5W2H method in analysing the causes of nonconformity in the production of energy drink, in which there occurred damage to both packaging material and the product contained in it.*

Keywords: *process, nonconformity, corrective action*

1. CONTROL OF NONCONFORMING PRODUCT ACCORDING TO EN ISO 9001: 2008

The product is defined in the EN ISO 9000:2005 standard as “result of a process”, while the term product denotes a material, good, service, information etc. [15]. In the process of nonconforming product control, it is not enough to identify the nonconformity, label it properly and separate or discard the product. It is also necessary to apply carefully selected corrective and preventive actions, to prevent future occurrence of the given nonconformity. Failure to provide a reliable system for the identification of nonconforming product may lead to the identification of nonconformity by end-consumers, which may result in economic loss, damage to reputation, or the impairment of supplier-customer relations. Facilitation of this system is particularly important if the product undergoes various stages of production having various subcontractors that enter the process to participate in the creation of the product. ISO 9001 requirement 4.1 states explicitly that where an organization chooses to outsource any

process that affects product conformity, the organization shall ensure control over such processes. This means that the system of effective control of nonconforming product should (also in case of outsourced processes) include the following activities [2]:

✓ **Identification of nonconforming product**

The technical inspection of the product or conformity verification of a shipment from a supplier may reveal that the product does not meet the pre-specified requirements and expectations. If nonconformity is identified, it is necessary to implement a number of additional steps, which identify the cause of this nonconformity,

✓ **Labelling and separation of nonconforming product**

In accordance with Article 7.5.3, labelling is one of the basic requirements of a quality management system. The organization has to clearly identify all materials, tools, instruments, information, documentation etc. Identification and traceability removes anonymity from all major elements of the process. Labelling nonconforming products as elements that should in no case reach the next process cycle

or customer is an absolute necessity. The organization determines its own labelling methods with respect to the nature of their processes; labelling can take many forms, each having a unique purpose, e.g.:

- keywords, signs, stickers placed on the product,
- labelled bins, boxes, bags, ribbons and tags,
- notes or descriptions written directly on the product,
- coloured product identification signs,
- electronic identification with a barcode,
- placement of the product in a designated place.

✓ **Collecting data on nonconforming product and defining the causes of nonconformity**

Data collection is the main tool for further control of nonconforming product and identification of the cause of nonconformity. If possible, data collection is carried out directly on site where the nonconformity occurred. It consists of various measurements, analyses, examinations, tests, etc., aimed at identifying the cause of nonconformity.

✓ **Determination of corrective and preventive actions and their implementation**

Upon finding the causes of nonconformity supported by relevant evidence, the quality management system requires the determination of corrective and preventive actions. It is a logical step whose aim is not only to solve a particular nonconformity or complaint but to prevent its recurrence in general, and thus ensure continuous quality improvement.

✓ **Documentation**

Documentation of the control of nonconforming product is one of further activities required by EN ISO 9001: 2008. The documentation includes the aims and procedures and systematizes activities. Its use contributes to [3]:

- achieving conformity,
- staff training,
- repeatability and flow of work,
- provision of objective evidence,
- evaluation of the effectiveness and sustained suitability of nonconforming product control.

✓ **Assessment of damage**

If nonconformity is identified during the production process, or on the premises of the organization, the financial costs are much lower than if it is identified by the customer.

Organisations should therefore pay more attention to output control and thus minimize the risk of releasing and shipping nonconforming product to the customer.

2. USE OF 5W2H METHOD IN NONCONFORMITY ANALYSIS

5W2H method (5 Wh-questions, 2 How) is an introductory method of clarifying the problem (error, nonconformity). The aim of its application is to determine *the root cause* of system failure or occurring problem.

The method was originally developed by Sakichi Toyoda and was used by the Toyota Motor Corporation in the development of manufacturing methodologies. This method is an essential item of training in problem solving and it is part of the initial TPS (Toyota Production System) training. The TPS creator Taichii Ohno described it as the basis of Toyota Company's scientific approach. The five Wh-questions make the cause of the problem clearer in search of corrective and preventive actions. The tool has been extended outside of Toyota and it is commonly applied in the automotive industry.

2.1 The principles of 5W2H method

- The evaluation team responds to a series of questions, "What? Why? Where? Who? When? and How?" (Table 1).
- No special questioning technique is required.
- There is no limit in how deep to proceed.

Table 1. Principle of 5W2H methods

	5W2H	Response
5W	What is the problem? Describe it in a single sentence, so that others will be able to understand what you mean.	The problem is...
	Why is it a problem?	This problem has occurred because...
	Where do we encounter the	We encounter the problem at

	5W2H	Response
	problem?	(location) (Time) when (Specific circumstance)...
	Who is impacted?	This impacts: (Staff) by..., (Customers) by..., (Other providers) by ... (others) by...
	When did we first encounter the problem?	We first encountered this problem...
2H	How did we know there was a problem?	The symptoms of this problem are...
	How often do we encounter this problem?	We encounter this problem (x) times and each encounter is (this big). The problem is getting (better/worse).

2.2 The objective of 5W2H method

The objective of 5W2H is not only to identify the cause of a failure, but also to facilitate the implementation of effective corrective and preventive actions. If the organization removes the cause of the failure, it will thus prevent the recurrence of the same failures and problems.

3. CASE STUDY – PROCEDURE FOR THE IDENTIFICATION OF NONCONFORMING PRODUCT USING THE 5W2H METHOD

This study describes the particular steps related to the identification of nonconformity in drinks packaging in a company selling energy drinks. Since the claim procedures are still pending, this paper does not provide the names of the manufacturing companies, only of their final products.

The organization operating in Slovakia is a company established in August 2012 aimed at manufacturing and distributing its own brand energy drink 1Energy on the European market. The product is packed in 330 ml aluminium

cans of the company’s own design. The can consists of two parts: the lid and the body of the can. Both parts are manufactured by separate processes on high-speed automated lines. The production takes place in the manufacturing plants of a Dutch supplier. The cans are then transported to a subcontracting organization operating in Poland, which is responsible for filling. Drinks packed by 24 pieces are palletised; one pallet contains 100 such packages and their durability is set at 24 months.

Each consignment (product), received at the warehouse of the Slovak company is subject to the entry inspection. In this case, it is a simple visual inspection of all pallets that are delivered to the warehouse and random inspection of several unpacked pallets and particular cans. The purpose of this inspection is to reveal any nonconformity. The most commonly found nonconformity is mechanical damage caused during transport (damaged packaging, mechanically damaged/ visibly destroyed cans). This type of nonconformity is considered as part of the product transporting process. The transfer of risk – damage caused during transport – is done by carrier’s insurance. The worker who is in charge of the inspection and collection of the goods not only performs the entry inspection, but also to creates the necessary photo documentation. The photo documentation and goods receipts are chronologically archived and searchable. The received goods are subsequently stored in a warehouse with appropriate temperature, low humidity and no direct sunlight.

3.1 The use of 5W2H method and proposal for immediate action

Not all nonconformities are or may be revealed by a simple entry inspection of the supplied products. Some arise over time in specific conditions or during certain activities. The Slovak company also revealed nonconformity some time after receiving the consignment. About three weeks from the receipt of the consignment (of 62,400 1Energy beverage cans), damp or wet packaging (cartons) were observed in the warehouse. This phenomenon was noticed by a worker responsible for the warehouse and immediately reported to employees in charge, who started to deal with the issue.

The Slovak company uses a variety of tools and methods that help to clearly identify

nonconformities. In this case, it opted for the 5W2H method.

The applied procedure consisted of answering seven basic questions (Tab. 2). Based on the responses, it was possible to identify the cause of nonconformity as follows:

Table 2. A case study of using the 5W2H method

5W2H		Response
5W	What is the problem?	The problem is wet cardboard and moisture discovered in individual packs, or among cans.
	Why is it a problem?	It poses a problem because the deteriorated product is no longer tradable. Items with no visible damage are not tradable either, until the cause of the moisture is revealed.
	Where do we encounter the problem?	The problem was discovered on 25 th August 2013.
	Who is impacted?	The problem was revealed in the company's own warehouse.
	When did we first encounter the problem?	The problem was discovered by a warehouse worker.
2H	How did we know there was a problem?	The problem was discovered visually when handling the goods.
	How often do we encounter this problem?	Initially about 34 wet cardboard packs were detected (each containing 24 beverage cans).

Although the seven simple questions did not clarify the cause of the moisture, immediate measures were taken on the basis of the findings to prevent further damage. Above all, it was necessary to prevent the nonconforming product from reaching the customer; this could result in complaints and potentially damage the brand's reputation, thus leading to financial loss.

Immediate actions were carried out:

- separation and disposal of damp goods,
- temporary ban on the distribution of goods,
- regular checks of the remaining goods in stock,
- checking the state of goods at key customers',
- contacting the supplier with a request for an urgent meeting with the technical staff and quality department staff.

4. POSSIBLE CAUSES OF NONCONFORMITY IN CAN PACKAGING AND PRODUCTS

Although the release of the product to the customer was suspended immediately, it was necessary to determine the cause of nonconformity. Some of the aspects influencing the occurrence of nonconforming product include the human factor, systemic or random errors, poor prevention, and low frequency of inspections between operations. It was therefore necessary to perform a thorough analysis and identify the cause of nonconformity.

4.1 Nonconformities in the stage of aluminium sheet manufacturing

Nonconformities could arise from the mere fact that can is a metal product. Rolled sheets of special aluminium alloy must meet strict requirements. The final thickness of the can is only 0.13 mm, so any flaws in the semi-finished product may result in nonconformities. Nonconformities of aluminium sheets may include:

- chemical properties of the material (contained impurities, low content of alloying elements),
- material structure,
- material surface quality (roughness),
- strength properties of the material,
- mechanical properties of the material,
- their shapes and sizes.

4.2 Nonconformities in the stage of can lid production

The can lid is not a difficult part to produce, so it is necessary to consider only three possible nonconformities:

- dimensional nonconformity in cutting

- blanks of the sheet metal,
- dimensional nonconformity in bending the edges of the lid,
- insufficient lifetime of the sealing element – silicone.

4.3 Nonconformities in the stage of can body production

The process that gives the can its typical shape is called deep-drawing. The basic prerequisite for the process is the quality of the material to be drawn, while the important variables in the process of deep-drawing, which may affect the conformity of the final product are [17]:

- the ratio of the diameter of the blank and the punch,
- sheet thickness,
- clearance between the punch and the die,
- radii of curvature of the punch and the die,
- holding force,
- friction and lubrication,
- speed of the punch.

In the manufacture of the can body, nonconformities may arise also while it is being imprinted. Layers of paint are applied at high speed to form the required designs, ranging from simple to most complex ones. In the initial optimization of the coating matrix, approximately 20 to 30 thousand cans are discarded before the machine is set so that the final can matches the pattern (i.e. the customer's requirements). Possible nonconformities of the imprint include:

- inaccuracy of colours in comparison to the pattern,
- inaccuracy in design – blurred edges, blurred letters in the information for consumers,
- insufficient paint drying period to increase production speed.

The decorative printing is followed by protective coating. The protective coating is applied from the outside and from the inside of the can. The inside of the can is coated to prevent any contact of the beverage with metal. It also serves as a protection against corrosion. External coating also protects the can against corrosion. Primary corrosion (internal, after the contact of beverage with metal) or secondary corrosion (external, caused by the ambient humidity) in 0.13 mm thick cans results in leaks of the beverage. Nonconformity at this stage could be caused by insufficient internal and

external protective coating.

4.4 Nonconformities in the stage of can filling

Empty cans are automatically removed from pallets and move along the conveyor belts of the line. The first problem related to the protective coating of the cans may occur there. Older or cheaper filling lines are equipped with stainless steel guard rails along the conveyor belts, which gradually rub the protective coating off the cans. Similarly, the conveyor belt itself can be made of cheaper materials and when the cans stop moving, its constant movement rubs off the protective coating at the lower rim of the can. To prevent this phenomenon, modern lines are equipped with the rails and belts made of materials with a low coefficient of friction, usually silicone.

Nonconformity in the stage of filling may also be caused by an unwanted object in the can – a hair, a speck of dirt etc. This can be prevented by a sensitive sensor that rejects such cans, and they automatically fall off the line. Another nonconformity which is removed off the line by operation inspection is inaccurate filling. Cans that are out of tolerance are rejected automatically.

The most important phase in the filling process is closing of the can lid. The lid is joined with the body of the can in their predetermined shape, by a contact force of the press and silicone seal of the lid. All this is performed data production rate of 2,000 pieces per minute. Nonconformity that may arise at this stage is insufficient tightness caused by inappropriate setting of the press for the type of cans, which may result in leakage of beverage from cans.

The last important phase is the pasteurization – an anti-bacterial heat treatment. It has to take place at the exact temperature for a predetermined time. The pasteurisation temperature is 72°C, so it is a high energy-demanding process. It is controlled by a probe inserted inside the can, which collects data throughout the whole pasteurization cycle. This stage cannot cause leakage of the beverage from the can.

4.5 Nonconformity in the stage of packaging, transport and storage

The filled cans are traditionally packed by 24 pieces in cardboard trays. These are then wrapped in foil. Such packs are then palletized

according to the type of cans. 330ml cans are usually packed 10x10. When packing, it must be borne in mind that the cans take a long way until they reach the end customer. Sometimes it may last a month in the shipping container in saltwater environments.

Possible nonconformities in the packaging include:

- unfitting cardboard trays causing movement of cans = damage to the protective coating, mechanical damage (Fig. 1).
- thin packaging film – also poor stability,
- uneven distribution on the pallet - poorly distributed weight, deformation of cans.



Figure 1 - Mechanically damaged can

There are no special requirements concerning shipment and storage, as long as the packing process is performed well. It is important to avoid freezing temperatures, in which the volume of the beverage changes; it expands, which mechanically destroys the can. On the other hand, it is recommended to avoid direct sunlight and high temperatures.

The last –6th option can be a combination of some or all the above types of nonconformities.

4.6 Determining the cause of nonconformity

Moisture, which caused damage to the cans and packaging comes directly from the drink itself, since the storage conditions comply with the requirements of the supplier. It is caused by leaks from beverage cans. Considering the technical features of the can and a method of its manufacture, there are only three possible causes of beverage leakage, namely:

- mechanical damage (at manufacturing,

transportation, freezing temperatures, etc.),

- leakage from poorly sealed can lid,
- leakage right through the can body.

The cans that were mechanically damaged during transport are rejected at the entry inspection when receiving the shipment. If the nonconformities were caused by insufficient sealing of the cap, it would be possible to identify the cause by vertical strips of dried beverage residues, starting below the edge of the rim. After a thorough analysis, both possibilities were rejected. However, the third type of leak was identified after inspecting a large number of randomly selected cans. To clarify the causes, it should be added that the leak of the beverage through the body of the can may be caused only by two reasons, namely:

- primary corrosion
- secondary corrosion.

Primary corrosion occurs when the inner surface of the aluminium can is not sufficiently protected by the protective coating applied during the manufacturing process, as described in the previous chapter. The beverage, which contains citric acid, reacts with the thin material of the exposed can and consequently causes a leak. The secondary corrosion occurs when the can is not well protected from the outside – the thickness of the outer coating is insufficient. Corrosion then arises from external moisture. It passes through the thin layer of the can from the outside, resulting in microscopic cracks in the structure of the can body and it causes leakage of the beverage. The secondary corrosion was observed on a large number of randomly selected samples (Fig. 2).



Figure 2 - Secondary corrosion

This type of corrosion was observed on all samples in almost identical areas, indicating a systemic error. Moisture which caused the secondary corrosion came from some randomly mechanically damaged cans. These had been removed during the initial inspection. The period lasting three weeks before the problem was noticed indicates the fast rate of the reaction. Had the whole batch not been immediately resorted, the chain reaction could have deteriorated the entire consignment.

5. VERIFICATION OF NONCONFORMITY BY METROLOGY

Initial analyses revealing secondary corrosion on the surface of the cans lead to a presumption that the protective coating on the outside is not sufficient and there are various causes of incorrect parameters (nonconformities). It was necessary to confirm or reject this assumption on the basis of measurements of the thickness of protective coating.

The object of measurement consisted of 12 samples of empty unused can bodies that were randomly selected from the inventory of the Dutch supplier of cans. The prescribed thickness of the coating is the internal know-how of the can supplier and it is not featured in any particular standard or other technical documentation. Therefore, besides the samples of 1Energy cans, also 12 sample cans of competing brand Control, which are produced by the same Dutch factory, were used. Samples of both types of cans were individually labelled by numbers 1 to 12 to ensure repeatability of the measurements. The measurements were carried out in precisely identified sectors of the cans. Specifically, in the three different sectors in a horizontal direction (circumferentially) and three different sectors in the vertical direction, designated A1 – C3 see Fig.3. There were 9 measurements on each individual sample in total.



Figure 3 - Selected measurement sectors

It was obvious after the measurement of the first samples that the assumption of nonconforming protective coating would be confirmed. The Control brand reference sample cans contained about 3g of protective coating per m², while in the sample cans of 1Energy, the amount of protective coating was lower, slightly below 1g/m², or even absent. Low values or zero was measured in those areas where the secondary corrosion was present in the stored filled cans.

5.1 Complaint procedure and design of corrective and preventive actions

The results of measurements of the protective coating confirm the nonconformity of a measurable and quantifiable technological parameter. The first immediate action after this finding was separating the damaged cartons from the undamaged ones. The results of the analysis showed that the primary cause of nonconformity was the insufficient surface treatment of the can body, or the outer protective coating. This process is a part of canim printing. Decorating is an automatic process of imprinting cans and applying the protective coating at a speed of 2000 cans per minute. The Dutch factory uses a Stolle Concord decorator. The decorating works on the principle of offset printing. Each colour has a precise numerical designation and precise ratio for mixing various hues, which is important e.g. when printing logotypes and accurate designs, where it is necessary to use the same colours consistently [19].

Besides colours, also protective coating is applied in this manner. Such technology is fast and precise, if the machine is in proper working order. The decorator contains many rotating parts, precision of which is related to the condition of the bearings. The bearings, as elements transferring the rotary motion, may affect the precision of the machine and its vibrations. Upon receiving the complaint related to the nonconformity of protective coating, the Dutch producer conducted a comprehensive inspection of its equipment and processes. The inspection revealed that the bearings used in operation were worn, i.e. past their prescribed lifetime. These bearings are located on the shaft of a rubber cylinder which applies protective coating on offset printing transfer elements. The layers of paint are very thin and so even minimum wobbling of the cylinder causes individual deviations (lack of

coating). This is also the reason why the individual low values were always located in the same can sectors.

The technical condition of the supplier's equipment directly affects the quality of the product. The discovery of bearings that are no longer able to fulfil their function was unacceptable. The first corrective action was to exchange all shaft bearings, which exceeded their lifetime. Another corrective action that prevents shipment of nonconforming product is a more thorough final inspection. Each batch of cans produced on a given day has to undergo rigorous metrological processes.

The above corrective actions were made by the supplier. The Slovak customer and contractor had no direct impact on the technical support and could not directly influence the production processes. Nor is it the intention of the organization. However, the company had to insist on the required quality of the product delivered. Therefore, the preventive action involves requiring a quality certificate, which has to be submitted for each new consignment.

6. CONCLUSION

The control of nonconforming product is an important element of the quality management system. The resulting nonconformities may result from organizational as well as individual failures. In search for the causes, an organization should rely on generally accepted practices and methods that can eliminate such situations. However, effective and user-friendly methods for managing nonconforming product are relatively rare. In this particular case, the customer was responsible for proving the nonconformity, even though it arose on the part of the manufacturer. Such system of providing evidence is not favourable in terms of mutual cooperation and maintaining proper relationships. It is necessary to ensure not only the correct setting of nonconforming product control in the organization but also a way to deal with complaints without undermining trust and impairing future cooperation.

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