BS EN ISO 9000 : 1994 Quality System and the Brewing Industry

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ABSTRACT

BS EN ISO 9000 : 1994 Quality System is now renown across the world as being an excellent building block on which to base any company’s drive towards quality improvement.

There are some basic understandings that are required if you are just starting out down the formal quality system route, using this tool. Understanding all the requirements of the twenty sections in the standard are fundamental to ensuring that the correct quality system is put into place in today’s modern breweries and packaging halls.

Not only are the requirements explained, but so are the benefits required for making good beer and the costs and risks associated with making bad beer. A well structured Quality System, based on ISO 9000 is a valuable management tool that will optimize and control quality related to risk, costs and benefits. It will also help satisfy customer needs and expectations whilst protecting the company’s interests.

Quality Improvement does not finish once a company has been registered to ISO 9000, on the contrary, it allows further quality incentives and requirements to be built onto it. For example, HACCP, Self-Assessment through Altruistic Auditing and the needs that produce World Class.

WHAT IS BS EN ISO 9000?

BS EN ISO 9000 is a basic formalized organizational structure, responsibilities, procedures, processes and resources for the implementation of quality management. This is known as the Quality System, which has to be established and implemented to enable the company’s quality policies and objectives to be accomplished.

These have to be well understood and be effective enough to produce beer that satisfies the company’s customers. The 1994 Standard very clearly now puts the emphasis on prevention rather than detection and determining key control points throughout the process.

There are three systems and two sets of guidelines. The most popular systems are 9001 and 9002 which contain twenty sections.

The following is a “quick breeze” through those sections.

SÍNTESIS

El sistema de calidad ISO 9000: 1994 es ahora reconocido en todo el mundo como una excelente base sobre la cual fundamentar la dirección de cualquier compañía para el mejoramiento de la calidad.

Hay algunos conceptos básicos que son requeridos si usted esta recién empezando su ruta sistemática de calidad, usando esta herramienta. Entender todos los requisitos de las veinte secciones en este estándard es fundamental para asegurar que se ponga en marcha el sistema de calidad correcto en las cervecerías y líneas de embotellado modernas.

No solamente se explican los requisitos, sino también los beneficios de implementarlos para elaborar buena cerveza, así como los costos y riesgos asociados con la elaboración de mala cerveza. Un sistema bien estructurado de calidad en base a ISO 9000 es una valiosa herramienta gerencial que optimiza y controla calidad relacionada con riesgo, costos y beneficios. También ayudara a satisfacer las necesidades y expectativas del cliente mientras protege los intereses de la empresa.

Mejoras de calidad no terminan cuando una compañía ha sido registrada en el ISO 9000. Al contrario, permite incorporar incentivos adicionales de calidad. Por ejemplo, “HACCP,” la Auto-Determinación por medio de Auditoria Altruística y las necesidades que producen la Calidad Mundial.

POLICY

ISO 9000 starts with the Chief Executive and the corporate policy on quality.

The interpretation of this policy by management to state the purpose of its quality system is the first important step. The aims and purpose in the policy should be achievable and measurable and express those requirements to meet and satisfy their customer’s needs, including the control of beer spoilage and product safety.

The BS EN ISO 9000 Standard requires that everyone in the company knows and understands the Quality Policy as well as their contribution towards achieving it.

There are basically three main areas to be addressed.

1) The role and responsibilities of management.
2) The operation of the key processes involved.
3) The control of those processes.

RESPONSIBILITIES

The systems that do not progress or even fail are the ones where the Chief Executive Officer delegates the quality responsibilities to others. Senior management cannot delegate quality.
ISO 9000 requires that all the activities that relate to ensuring quality form part of the management system. This system is based on a Quality Plan, either written into the quality manual or demonstrated through written procedures. The key control points in the process should be clearly indicated in this plan. An alternative is to produce a diagrammatic flow chart showing the key control points.

A management representative has to be appointed. This person is responsible for ensuring the system is implemented and maintained and thus becomes the custodian of the system. It is also important to identify the responsibility of individuals working in the system and document them.

ISO 9000 states that the system is the means of ensuring that beer, in either keg or small pack, conforms to specified requirements, but really this is no longer sufficient. The system must be on quantity, delivery, time and price as well as appearance, quality system.

A system is the means for ensuring that customers, right down the supply chain to the ultimate consumer, are “delighted.”

**DOCUMENTATION**

The Standard requires the system to be documented and effectively implemented. There is the need to describe in writing all the various processes and the links between them that collectively make up the system. The control of all documents is equally important and to do this, a comprehensive coding system is required.

**REVIEW SYSTEM EFFECTIVENESS**

ISO 9000 asks for at least an annual review. However, if this is all that management is willing to do and is satisfied with it, then systems improvement will be long in the coming and management will never realize the potential power of the requirement.

If they did, they would realize that continual system review improves the performance of the system as those responsible for it continually improve it and also the product quality, by continually raising the standards.

Management owns the system and is, therefore, responsible for its implementation and improvement which involves foresight, commitment, determination and change.

William Foster once said that “Quality is never an accident, it is always the result of high intention, sincere effort, intelligent direction and skillful execution: it represents the wise choice of many alternatives.”

Introducing ISO 9000 by itself will not improve the quality of your products. It will help ensure that the quality remains constantly uniform. It is the management and those responsible for the processes who will improve the product quality using the quality system.

**CONTACT REVIEW**

This section ensures that there is clarity concerning the requirements of a supplied item, whether it be items purchased by the brewer or items sold to the customer. This means that the items sold must meet the agreed requirements on quantity, delivery, time and price as well as appearance, flavour, presentation and safety.

Raw materials, additives, cleaning agents and packaging components, for example, must be purchased against agreed and written specifications. Authority to vary raw materials like hops and malt or even make process changes where such changes could affect quality, is required.

Thus a high standard of logistics and planning as well as process capability and systems control are required. Process capability studies carried out before starting an ISO 9000 program can be extremely beneficial. Customer feedback via the sales force can also be extremely useful in setting up and agreeing achievable and measurable contracts. Always think of your customers as “suppliers” first, work closely with them so they can “supply you” with the information you need to “supply them” with the right products and services.

**DESIGN and DEVELOPMENT**

The purpose of this section is to ensure that the completed design/development meets and has been verified to meet specified requirements.

This area could be in marketing of new beers, the development of new packaging or the building of a new brewhouse. It is a requirement solely of BS EN ISO 9001:1994 and not in either 9002 or 9003.

The process must ensure a continuing and effective dialogue between the customer, usually represented by Marketing or Sales and Design, Manufacturing and other operations of the company.

The requirements ensure that the design or development process produces designs or develops new products that conform and have been verified to conform to the required specification.

**PURCHASING**

The purpose of this section is to ensure that purchased products that affect quality and are required in the key processes conform to specified requirements.

Here operational parameters and definitions are clearly needed, but mere conformance to specified requirements is not really enough and the system should be used to improve the quality of purchased products. Therefore, due diligence, supplier assessments, partnerships, building better relationships, are all needed to provide for greater understanding of your supplier’s needs and capabilities in providing you with improved quality in both services and product. Inevitably due to the time and financial constraints, this means using fewer but higher calibre suppliers.

Some suppliers of materials to the brewing industry are not quite that easy to influence, particularly where you have almost a single sourced supply and, therefore, a virtual monopoly.

All suppliers, from maltsters to laboratory services and from maintenance equipment to CIP cleaning services, must be involved.

We must not forget, of course, that, in some companies, transport, warehousing and distribution may have been out-sourced and, therefore, will have become service suppliers.

Inherent variations in hops, malt and certainly barley must be accommodated and specifications must encompass the need for any special controls necessary to maintain integrity.
**PRODUCT IDENTIFICATION AND TRACEABILITY**

At this point we must look at the section on identification and traceability, before getting involved with the brewing process. All incoming materials must be identified, as must each process, right the way through production.

Product identification in the brewing industry requires that there be an adequate system of identification and traceability. Therefore, any quality system in the brewing and associated industries must contain documented procedures for product recall and indeed perhaps even crisis management.

The extent to which packaged beer, including contract packaged products, is to be traceable, depends as much on the market requirements, national and international, corporate and consumer expectations and legal requirements, all of which must be stated in the procedures.

When and where it is appropriate, a system that defines the product’s shelf-life, whether small pack or draught, must be included. This also means the use and interpretation of such things like bar coding as well.

**PROCESS CONTROL**

The quality system must contain the necessary elements of process control to ensure that specified performance standards are maintained. Added to which in the brewing industry, the avoidance of contamination, flavor and odor variability and also taints, are all key issues.

Brewing and packaging processes must be controlled by the use of work instructions and planned arrangements. There are no definitive instructions as to how the work instructions should be derived, nor how the planning should be carried out, but the processes and responsibilities must be described in detail in the written system. All those involved must know what they are responsible for and how the tasks and jobs should be carried out.

This does not mean that these tasks cannot be changed and improved. You are actually encouraged to improve them, thus making the processes more effective and efficient as well as improving the level of quality and reducing variations.

The requirement is that changes are documented and everyone works to the new work instruction only, the old ones being removed and no longer available.

There are other considerations that come under this section, for example, environmental aspects in the form of ISO 14000, the new environment standard that fits into the existing ISO systems.

Associated issues concerning buildings, malt storage conditions, personal and site hygiene, CIP, chemical and toxic contamination through the brewing process to packaging as well as quality control on and off line, need to be addressed.

All legal requirements should feature here as well, for example, your national, food safety, labeling and health regulations.

**INSPECTION AND TEST**

The standard lays great emphasis on inspection and testing and requires that all planned tests must have been completed before product is released.

Any beer that fails a test must be identified as such and segregated where possible. As long as non-conforming product is being brewed and packaged, inspection will be necessary. However, we all know that 100% inspection is ineffective let alone impossible.

Most of the brewing industry’s testing is either laboratory or line-based objective analysis. The test methods for which are long standing, well documented and traceable to National Standards. Tests based on visual inspection, flavor, odor and mouth feel must be combined with the following elements: a) holding standard batches, b) having staff trained and qualified in sensory evaluation and analysis, and c) having staff retrained and re-evaluated as required. These elements should be added into the procedures to demonstrate long-term consistency.

In-house tests or modified standards can be used but they must be validated.

It must also be remembered that inspection and testing applies to goods being received, in process, as well as finished products and that all test results must be recorded.

**CALIBRATION**

ISO 9000 requires that measuring equipment be calibrated and the calibration be maintained at all times. There is generally a lot of financial heartache about this part of the standard and the brewing industry is no exception, in that it feels the same about it, too.

The key is to determine which are the items that affect quality and calibrate all those, as an absolute minimum. Then by working through each of the processes and determining where equipment accuracy would be of benefit in process capability and calibrating those other pieces of equipment, you will find the money will have been well spent, not only that but you will be making the longer term ability to improve, easier.

Where process instrumentation is used for monitoring and control on an “indication basis only,” it need not necessarily require calibration. It does require it to be identified as “only for monitoring.” However, where reliance on such equipment is fundamental to the quality of the product, for example, temperature control in pasteurization, then the measuring equipment must be calibrated.

There is an excellent section called “Quality Assurance Requirements for Measuring Equipment (ISO 10012-1 : 1992)” that is of immense help with calibration.

**INSPECTION AND TEST STATUS**

When product has been tested or analyzed, it will be in one of the following phases: Passed, Failed or Held for either re-testing, awaiting results or awaiting a decision. Therefore, whether it conforms or not, whatever the status of the product is, it must be identified as to which of these three categories it falls. This should cover the whole process from goods receipt, through brewing and packaging to dispatch.

Therefore, only product that has passed the required inspection and test, or has been released under an authorized concession, can be dispatched.
CONTROL OF NON-CONFORMING PRODUCT

Non-conforming product, from mash tun to bright beer tanks or from maturation to warehouse that has been rejected, has to be controlled and, therefore, must be clearly identified and segregated until a decision has been made for its disposal. If it resembles or could be mistaken for acceptable product, there must be procedures in place to ensure that it is rendered unusable.

Clear authority must be defined for those responsible to make the decisions and maintain the relevant records.

CORRECTIVE AND PREVENTIVE ACTION

This is one of the most important sections in ISO 9000 and only now are the assessors beginning to pay more attention to it as shown by the 1994 rewrite, providing clarity between correction and prevention and putting much greater emphasis on the latter as a demonstrable requirement.

Now it is simply not enough just to correct activities that have gone wrong. Great attention is now required to prevent non-conformances from occurring.

There are several requirements to this clause therefore:

1) Non-conformance trends analysis.
2) Investigation of the root causes of problems, leading to implementation of corrective actions.
3) Causative investigation into prevention.
4) Implementation of preventive measures.
5) Assurance that all agreed actions have been taken.

It is extremely important to ensure that information leading to corrective action is not misinterpreted. The wrong corrective action can cause more problems than it was intended to solve.

The analysis of all processes including internal and external concessions, customer complaints and quality records, etc. is necessary to help eliminate potential causes of non-conformances.

It is important that as many activities across the company as possible are studied, from people’s attitudes to suppliers and sales data. It is the way information is collated and shows how effective the process systems are.

This is an example of where ISO 9000 provides the essential building blocks for moving forward with quality improvement programs and total quality management initiatives.

Some of the preventive actions may be easy and relatively inexpensive to achieve. Others, for example, redesigning part of the brewery or purchasing a new item of bottling equipment, can run into tens of millions of dollars. That does not mean that they can or should be ignored. They have to be planned and budgeted for, but with a time frame that is acceptable to both company accountants and external assessors.

The action that is required and then taken should be submitted to management and reviewed regularly.

HANDLING, STORAGE, PACKAGING AND DELIVERY

This tends not to be a problem for the brewing industry, as there are well tried and tested methods of storing, packaging and transporting beers that have been used for many years and the very nature of the product helps preserve it.

Having said that, stock rotation and shelf-life are still important issues as, of course, is storage temperature.

Product safety as well as the maintenance of product quality is vital. One does not really exist without the other, of course, but a system called Hazard Analysis by Critical Control Point (HACCP) used as part of your quality system will indicate the potential hazards in your process and demand that you design them out or continuously check to make sure hazards are not created.

Correct and adequate packaging must be used that will keep the product in perfect condition, for example, to prevent ingress of air or to minimize staling by sunlight.

Reducing waste by reducing out of specification product and brewing under the right process conditions is obviously the correct approach, so perhaps the logic should be extended to determine how much stock is required to meet the customer’s needs.

QUALITY RECORDS

Retention periods for all quality records must be specified and reflect both the statutory regulations and product shelf-life. Basically, records must be kept for at least three years to demonstrate the effective management of the system.

INTERNAL QUALITY AUDITS

ISO 9000 requires that audits be undertaken and aimed at establishing whether processes are being run in the way described in the written procedures. The audits, therefore, should check if procedures are in place and are being used, that they are adequate and that training is also adequate and appropriate.

It invites auditors to comment on the effectiveness of the processes. Auditing carried out correctly using trained and qualified Lead Assessors (using ISO 10011-1/2/3: : 1991) is a powerful tool that helps establish the desire and drive for improvement within the management system.

Objective, intrinsic auditing and self-assessment, where blame and fear for non-conformances are removed, will reduce the barriers and allow people to provide for corrective action. Most problems in a process are due to the system rather than to individuals and, therefore, require management to work on improving the system to resolve them.

Audits have to be planned and prepared for and the more time spent on doing this, the better the corrective action will be.

TRAINING

The company has to ensure that people are trained to undertake the tasks to which they are assigned. A system is required that identifies the staff training needs. Legislative needs like hygiene and food safety must be included.

Having identified the needs the agreed training has to be provided. Training must be planned to provide the company and the individuals, with the skills to do the job now and in the future.

STATISTICAL TECHNIQUES

Finally, the area that tends to get forgotten. It is not mandatory to include statistics and, therefore, there is some confusion regarding its meaning.
Statistical techniques, statistical process control (SPC), sampling regimes, capability studies are all part of analyzing the performance of the system and its processes.

Although it is not mandatory, I know there are very big benefits from doing such work and I would strongly advise that you put some effort into this area.

**WHAT ARE THE BENEFITS OF ISO 9000 FOR BREWERS?**

There are two areas of consideration, one as brewers and one as consumers that we should look at. These are:

1) **Benefits** required for making good beer
2) **Costs and Risks** of making bad beer

**Benefit Considerations**

If a brewery is making good beer than it would expect to see an increase in profitability and market share.

A customer of that brewery would expect a reduction in the cost of a glass of its beer, an improved fitness for use (a more consistent quality) that would increase his satisfaction in the product and increase his confidence in the brewery.

**Cost Considerations**

If a brewery makes bad beer, then there are bound to be cost implications, which come from financial losses due to perhaps unsatisfactory raw materials and components, having to rework and reprocess beer, replacing kegs, bottles or cans and obviously a loss in production.

From a customer’s viewpoint, deficient products cost the brewery money, in the costs associated with returning and replacing products. These could be internal between, for example, warehouse and packaging or distribution and warehousing as they are internal customers.

There are costs if draught dispense systems do not function correctly and the costs of disposing of substandard beer in the bars and pubs and the costs of having no stock and finally, there are the costs of losing sales.

**Risk Considerations**

If a brewery makes bad beer there is a risk of getting more complaints, maybe having liability action taken and losing market share. These lead to a loss of image and a further loss of market share.

The waste of human and financial resources are also possible. From a consumer viewpoint, there is the possible risk to health and safety. Consumers become dissatisfied with the beer, returning more product as their confidence is lost with a subsequent increase in claims for compensation.

**The Requirement**

Surely the intention of a well run and competent business is to meet both the customer needs and the company needs. From a brewery’s perception, that is to attain and then maintain the right beer quality at optimum cost and to do this by planned, efficient use of technology, human and material resources.

The consumer has to have confidence in the brewer’s ability to deliver the desired quality, consistently.

**Policy**

Management should develop a quality system to control all aspects of quality. It should be developed and implemented to accomplish the corporate strategy and objectives laid down in the Quality Policy and be right for the specific business the brewery is operating in.

To do these things requires the senior management team to be responsible for committing to managing quality, starting with an achievable and measurable quality policy that they can implement. They must make sure that it is understood, implemented and maintained.

**Success**

In order to be successful, beers for our customers must meet a well defined consumer need and satisfy their expectations as well as comply with brewery standards and laid down specifications. Our beers must comply with legal and statutory requirements and be competitively priced, always available and, last, but not least, yield a small but acceptable profit at the end.

**Conclusion**

A well structured Quality System based on ISO 9000 is a valuable management resource that will optimize and control quality related to risk, costs and benefits.

An effective Quality Management System satisfies customer needs and expectations whilst protecting the company’s interests.

**LIFE AFTER REGISTRATION - THE WAY AHEAD**

Having described what BS EN ISO 9000 is and perhaps what some of the benefits of a successful quality system are, you can see perhaps some of the opportunities that it provides after you have been registered. It is rather like passing your driving test. Once you have your license and you are on your own, you start to really learn to drive.

Having complied with the requirements of ISO 9000, a company has already achieved:

- A documented quality system.
- Procedures and work instructions that help standardize processes producing more consistent outputs.
- A start on measuring performance to identify and implement improvement.
- A start to corrective and preventive action.
- Regular review meetings, carried out by management which can lead to improving the system and making more effective use of the process.

Senior management need to understand that it owns its system and for it to improve they have to lead and drive change through “Best Practice” to “World Class.”

Once the brewery or packaging hall has been registered, senior management should extend the ISO 9000 system into other areas up and down the supply chain, from Marketing to Sales, from Project Engineering to Warehousing and from Technical Services to Personnel.

The measurement of process performance must be extended and a culture of continual improvement established. All employees must be encouraged to participate in improving their own processes. Waste elimination, supplier development through
business process re-engineering, all can be developed.

Activity Based Costings is one such development as is Self-Assessment, where the visions, goals and strategies of the company are measured and benchmarked, the improvement gaps determined and the appropriate action to close the gaps put in place.

Within Guinness Brewing Worldwide, we are just beginning to apply the basics of a self-assessment system using Altruistic Auditing (figure 1). This looks at the business as a whole, but in seven distinct areas. As the number of areas being audited increases so we can measure more of the company’s performance as a whole.

ISO 9000 helps us control the Level 1 audits, that is legislation, hygiene, process control, quality systems and HACCP. We are already auditing to Level 2, which encompasses all these and have started on Level 3 audits involving suppliers and understanding customer requirements and how to satisfy them.

We will see where the future takes us, but we certainly wouldn’t be where we are today without having ISO 9000 as our quality keystone.