Click Here

Skip to main content ISO 28590:2017 provides a general introduction to acceptance sampling by attributes and provides a brief summary of the attribute sampling schemes and plans used in ISO 2859-1, ISO 2859-2, ISO 2859-3, ISO 2859-4 and ISO 2859-5, which describe specific types of attribute sampling systems. It also provides guidance on the selection of the appropriate inspection system for use in a particular situation. : International Standard confirmed [90.93] ISO/TC 69/SC 5 RSS updates Check out our Help and Support In today’s global economy, maintaining product quality is crucial for businesses striving to meet consumer expectations. Whether you're a manufacturer, retailer, or involved in quality assurance, one standard that plays a pivotal role in ensuring product consistency and quality is ISO 2859. This international standard focuses on sampling procedures for inspection by attributes and helps companies make informed decisions about product acceptance.In this blog, we’ll take an in-depth look at ISO 2859, its importance, its key components, and how it is applied in real-world scenarios to maintain quality standards across industries.What is ISO 2859?ISO 2859 is an internationally recognized standard for acceptance sampling in quality control, which outlines the procedures for sampling and inspecting batches of products. The purpose of this standard is to guide companies in determining whether a batch of products should be accepted or rejected based on sampling inspection rather than 100% inspection. The goal is to reduce costs, minimize inspection time, and maintain an acceptable quality level (AQL).ISO 2859 was developed by the International Organization for Standardization (ISO) and is widely used across manufacturing and inspection industries. It primarily applies to attribute-based sampling plans, where products are assessed for conformity or non-conformity (e.g., pass/fail, good/bad). This standard can be customized to suit various industries, including electronics, textiles, automotive, and more.Key Components of ISO 2859To fully understand ISO 2859, it’s essential to explore the components that make up the standard. Below are some key elements:1. Acceptable Quality Level (AQL)A crucial concept within ISO 2859 is the Acceptable Quality Level (AQL). This is the maximum number of defective items (non-conformities) allowed in a batch of products for the batch to be considered acceptable. The AQL is determined by the buyer or regulatory body and varies depending on product type and the industry’s risk tolerance. For example, the AQL for a critical medical device may be much lower than that for consumer goods.Common AQLs include:AQL 1.0%: Suitable for products with low-risk tolerance (e.g., medical supplies).AQL 2.5%: Standard level for general consumer products.AQL 4.0%: Used for non-critical products where minor defects are acceptable.Also read: How to use the free AQL calculator from Testcoo2. Inspection LevelsISO 2859 provides different inspection levels to determine how much of a product batch should be sampled. There are three main general inspection levels (GI, GII, GIII) and four special inspection levels (S1, S2, S3, S4).General Inspection Level I: Applied for reduced inspection rigor.General Inspection Level II: The most commonly used level for standard inspection.General Inspection Level III: Used for stricter inspection protocols.Special Inspection Levels: Applied when the sample size needs to be small but still reliable for high-value items or specialized situations.3. Single, Double, and Multiple Sampling PlansISO 2859 offers three different sampling plans depending on the risk tolerance and cost considerations of the company.Single Sampling Plan: A fixed number of units are inspected. Based on the result, the batch is either accepted or rejected. This is the most straightforward plan.Double Sampling Plan: If the first sample does not provide a clear decision, a second sample is drawn to determine whether the batch should be accepted or rejected.Multiple Sampling Plan: This is a more complex plan where multiple rounds of sampling may be conducted until a decision is reached. It allows for more flexibility but can increase the time required for inspection.4. Lot or Batch SizeThe lot size or batch size is a critical component in determining the sample size. The larger the lot, the more units need to be sampled. ISO 2859 provides sampling tables that help companies calculate the appropriate sample size based on the lot size and desired AQL.Why is ISO 2859 Important?ISO 2859 plays a vital role in helping businesses manage quality control without the need for inspecting every single item in a batch, which can be time-consuming and expensive. Below are some reasons why this standard is essential:1. Cost EfficiencyOne of the primary benefits of using ISO 2859 is that it reduces the cost of quality inspection. Instead of inspecting 100% of a batch, companies can rely on a smaller sample that provides an accurate representation of the entire batch’s quality. This leads to significant savings in labor, time, and resources.2. Informed Decision MakingISO 2859 provides a systematic and statistically sound approach to determining whether a batch meets the desired quality level. By applying this standard, companies can make data-driven decisions about product acceptance, reducing the risk of releasing defective products into the market.3. Improved Customer SatisfactionBy consistently applying ISO 2859 sampling methods, businesses can ensure that their products meet customer expectations for quality. This consistency leads to greater customer satisfaction and brand loyalty, as fewer defective products are released to the market.4. Standardization Across IndustriesAs an internationally recognized standard, ISO 2859 offers a consistent framework that can be applied across different industries and regions. Whether you're dealing with textiles, electronics, or automotive parts, ISO 2859 provides a standardized approach to quality inspection that ensures global compliance and compatibility.How to Apply ISO 2859 in Your BusinessImplementing ISO 2859 in your quality control processes involves several steps. Below is a simple guide to help you apply this standard effectively:1. Determine the AQLThe first step is to define the Acceptable Quality Level (AQL) for your products. This decision should be based on your industry’s regulations, the product type, and your company’s risk tolerance. You may also consult with your clients or regulatory bodies to ensure compliance with external standards.Download the AQL Table2. Select the Sampling PlanBased on the desired AQL and the batch size, you can select either a single, double, or multiple sampling plan. Your choice should depend on the criticality of the product and the resources available for inspection.3. Choose the Inspection LevelNext, choose the appropriate inspection level. For standard quality control, most companies use General Inspection Level II, but this can vary depending on the product’s importance and risk factors.4. Draw Samples and InspectOnce the sample size has been determined, draw the necessary samples from the batch and inspect them for defects. Record the number of defective units and compare them to the acceptance and rejection thresholds as outlined by the sampling plan.5. Make Acceptance or Rejection DecisionsBased on the inspection results, make an informed decision about whether to accept or reject the batch. If the number of defective units exceeds the AQL threshold, the batch should be rejected and corrective actions must be taken.Find an interesting read: 5 Things You Probably Didn’t Know About Inspection SamplingBenefits of ISO 2859 for BusinessesISO 2859 offers a multitude of benefits for businesses across various sectors. Some of the most significant advantages include:1. Streamlined Quality Control ProcessesBy following the guidelines set out in ISO 2859, companies can streamline their quality control processes, making them more efficient. Sampling inspections are faster and more cost-effective than full inspections, allowing businesses to focus their resources on improving other areas of the production process.Also read: Quality Control Inspection Companies in China2. Reduced Risk of Product RecallsEffective application of ISO 2859 helps reduce the risk of defective products reaching the market, thereby minimizing costly recalls, legal issues, and reputational damage. Early detection of quality issues ensures that they can be addressed before products are shipped to customers.3. Flexibility Across IndustriesISO 2859 is adaptable to various industries and product types, making it a versatile tool for quality management. Whether your business deals with high-volume consumer goods or specialized industrial components, this standard can be tailored to meet your specific needs.4. Enhanced Supplier RelationshipsBy implementing a standard quality inspection process like ISO 2859, businesses can improve their relationships with suppliers. Clear expectations and consistent quality checks help suppliers align with your quality standards, leading to fewer disputes and better long-term partnerships.Challenges in Applying ISO 2859While ISO 2859 offers numerous benefits, there are some challenges businesses may face when applying the standard:1. Initial Setup ComplexityThe process of defining AQLs, selecting the appropriate sampling plan, and training staff can be complex for companies new to ISO 2859. However, once the process is established, it becomes easier to maintain.2. Risk of Missing DefectsAlthough sampling inspections are efficient, they do carry the risk of missing defects that could be present in unsampled portions of the batch. To mitigate this, companies must ensure that their sampling plans are adequately tailored to the specific risks associated with their products.3. Need for Ongoing TrainingTo effectively implement ISO 2859, companies need to invest in ongoing training for quality control personnel. Inspectors must understand how to select samples, perform inspections, and make accurate acceptance decisions based on the standard.ConclusionISO 2859 is a powerful tool that enables businesses to implement cost-effective, statistically reliable quality control processes. For third-party inspection companies like Testcoo, ISO 2859 provides a solid framework for delivering efficient, accurate, and cost-effective quality control services. By applying this internationally recognized standard, inspection firms help clients ensure that their products meet high-quality standards without the burden of inspecting every single unit.By working with a third-party inspection company like us that uses ISO 2859, businesses can achieve better quality control, faster time-to-market, and improved customer satisfaction. Whether you are in manufacturing, consumer goods, or highly regulated industries, ISO 2859 ensures that your products consistently meet the required standards, safeguarding your brand and minimizing risks. Get in touch with our team today!Request QuotationTESTCOO is a leading third-party quality control inspection company headquartered in China and we are accredited by ISO9001, CNAS, AQSIQ, and IS0 27001. We provide product inspection, factory audit, testing, and certification in every sector around the world. With 500 full-time qualified inspectors and auditors, TESTCOO performs over 100,000 inspections annually and is trusted by more than 5000 global retailers, brands, and suppliers worldwide.Read More Sampling is the foundation of all food analysis procedures. Without proper sampling standards, the most advanced analytical techniques and equipment would be rendered meaningless. Think of it this way: if your sample doesn’t truly represent the entire batch of food product, no amount of sophisticated testing can provide accurate results. This is why understanding sampling standards is crucial for anyone involved in food quality control, safety assessment, or regulatory compliance. Table of Contents Sampling standards serve as the backbone of reliable food analysis. They provide structured guidelines that ensure consistency across different laboratories, regions, and even countries. These standards help minimize variations and biases that could otherwise compromise the integrity of analytical results. In the food industry, where even minor analytical errors can lead to significant consequences such as product recalls, consumer illness, or regulatory penalties, adhering to established sampling standards is not just good practice—it’s essential. These standards provide a systematic approach to collecting, handling, and preparing samples in a way that maintains their representativeness and integrity. Why standardized sampling matters Consider a scenario where a food manufacturer needs to test a batch of spices for potential contaminants. Without following proper sampling standards: Representativeness issues: Samples might only be taken from easily accessible parts of the batch, missing potential hotspots of contamination. Inconsistency problems: Different technicians might follow different procedures, leading to variable results even from the same batch. Documentation gaps: Without standardized protocols, the sampling process might lack proper documentation, making it difficult to trace back issues if problems arise later. Standardized sampling eliminates these risks by providing clear, replicable procedures that ensure the sample accurately represents the whole. The International Organization for Standardization (ISO) plays a pivotal role in establishing and maintaining sampling standards worldwide. ISO brings together experts from different countries to develop consensus-based standards that can be applied globally, ensuring a level playing field for international trade and consistent consumer protection. For food products specifically, ISO has developed numerous standards that address various aspects of the sampling process. These standards are regularly reviewed and updated to incorporate new scientific findings and technological advancements. Key ISO standards for food sampling Several ISO standards are particularly relevant for food sampling procedures: ISO 2854: This standard provides guidelines for the statistical interpretation of data. It helps analysts determine the appropriate sample size, sampling frequency, and statistical methods to ensure that conclusions drawn from the sample accurately reflect the entire batch. ISO 7002: Specifically designed for agricultural food products, this standard outlines comprehensive sampling procedures that account for the unique characteristics of these products, such as natural variability and uneven distribution of components. ISO 6887 series: These standards focus on the microbial examination of food products, providing specific guidance on sample preparation to ensure accurate microbiological testing. ISO 707: This standard addresses milk and milk products, detailing the specific sampling requirements for these highly perishable items. Each of these standards has been developed with input from scientists, industry experts, and regulatory bodies to ensure they represent best practices in food sampling. Phases of standardized sampling Sampling standards typically address three critical phases of the analytical process, each with its own set of potential errors and challenges. Primary sampling: Getting it right from the start Primary sampling involves the initial collection of material from the larger batch or lot. This is perhaps the most critical step, as errors at this stage cannot be corrected later in the analytical process. ISO standards for primary sampling often specify: Sample size determination: Guidelines for calculating the appropriate amount of material to collect based on batch size, expected variability, and the specific analytes being tested. Sampling patterns: Recommendations for systematic approaches to collecting samples, such as grid, diagonal, or random patterns, to ensure representativeness. Sampling equipment: Specifications for tools and containers that minimize contamination and preserve sample integrity. Environmental considerations: Precautions to take regarding temperature, humidity, and exposure to light or air during sampling. For example, when sampling a storage silo containing rice, ISO standards might recommend collecting multiple samples from different depths and locations using specialized probes, then combining these samples in a specified manner to create a composite that represents the entire silo. Sample preparation: Maintaining integrity during processing Once collected, samples often require preparation before analysis. This might involve grinding, homogenizing, drying, or other treatments to make the sample suitable for the analytical method being used. Sampling standards address this phase by providing guidelines for: Homogenization techniques: Methods to ensure uniform distribution of components throughout the sample. Subsampling procedures: Approaches for dividing the primary sample into laboratory samples and test portions. Preservation methods: Techniques to stabilize the sample and prevent changes that could affect analytical results. Cross-contamination prevention: Protocols to avoid introducing foreign materials or cross-contaminating between samples. For instance, when preparing a fruit sample for pesticide residue analysis, standards might specify the use of stainless steel equipment, particular grinding parameters, and specific storage temperatures to prevent pesticide degradation before analysis. Analysis protocols: Ensuring accurate measurements While the analytical methods themselves are typically covered by separate standards, sampling standards often include provisions for how test portions should be selected from the prepared sample and how results should be interpreted and reported. These provisions might include: Replicate analyses: Requirements for conducting multiple analyses to assess variability and increase confidence in results. Quality control measures: Incorporation of blank samples, spiked samples, or certified reference materials to validate the analytical process. Data handling: Guidelines for statistical treatment of results, including outlier identification and handling of non-detects. Uncertainty estimation: Methods for calculating and reporting the uncertainty associated with the entire sampling and analytical process. Statistical foundations of sampling standards A key aspect of sampling standards is their basis in statistical principles. ISO 2854, in particular, focuses on the statistical underpinnings of sampling design and data interpretation. Determining appropriate sample size Sample size determination is a critical aspect of sampling standards. Too small a sample might not adequately represent the batch, while too large a sample wastes resources without significantly improving representativeness. ISO standards provide statistical formulas and considerations for determining sample size based on: Desired confidence level: The probability that the sample results accurately reflect the entire batch. Expected variability: The anticipated heterogeneity of the product being sampled. Acceptable margin of error: The maximum deviation from the true value that can be tolerated. Critical threshold levels: Regulatory limits or specifications that the analysis aims to assess compliance with. For example, when testing for mycotoxin contamination in a batch of wheat, the standard might recommend larger sample sizes due to the typically uneven distribution of these contaminants, compared to testing for moisture content, which tends to be more uniformly distributed. Accounting for the sampling distribution Sampling standards recognize that the distribution of analytes within a food product can vary significantly. Some contaminants, like aflatoxins in nuts, tend to be highly localized, while others, like salt in a well-mixed sauce, are more evenly distributed. Standards account for these differences by specifying: Stratified sampling approaches: Methods for dividing heterogeneous batches into more homogeneous strata before sampling. Composite sampling strategies: Guidelines for combining multiple incremental samples to create a more representative composite. Sequential sampling plans: Approaches that adjust sampling intensity based on initial findings. Application of ISO 7002 for agricultural food products ISO 7002, specifically designed for agricultural food products, addresses the unique challenges associated with sampling these naturally variable materials. Accounting for natural variability Agricultural products inherently have greater variability than manufactured foods. A single field of wheat can have different moisture levels, protein content, or contaminant concentrations depending on soil conditions, microclimate, and other factors. ISO 7002 accounts for this variability by recommending: Increased sampling points: Taking more incremental samples from different locations within a batch. Consideration of visible heterogeneity: Stratifying sampling based on observable differences, such as color variations or damage. Timing considerations: Guidelines for when to sample agricultural products, recognizing that characteristics can change during storage or ripening. For instance, when sampling a truckload of mangoes, the standard might recommend selecting fruit from different positions in the load, including from the center where temperature and ripening conditions might differ from the exterior. Many agricultural products are handled and transported in bulk, presenting unique sampling challenges. ISO 7002 provides specific guidance for sampling bulk commodities such as grains, oilseeds, and legumes. This guidance includes: Dynamic sampling techniques: Methods for collecting samples from moving streams, such as during loading or unloading operations. Static sampling approaches: Procedures for sampling stationary bulks, including the use of specialized equipment like grain probes. Lot identification and traceability: Requirements for documenting the origin and handling history of bulk lots to facilitate traceability. Ensuring accuracy and precision through sampling standards Two fundamental concepts in analytical chemistry—accuracy and precision—are heavily influenced by sampling procedures. Sampling standards aim to maximize both of these critical quality parameters. Minimizing systematic errors Accuracy refers to how close a measurement is to the true value. Systematic errors in sampling can lead to consistently biased results, undermining accuracy. Sampling standards help minimize systematic errors through: Representative sampling design: Ensuring that all parts of a batch have an equal probability of being included in the sample. Proper equipment selection: Specifying tools and containers that won’t introduce bias, such as using non-reactive materials that won’t absorb analytes. Validated procedures: Recommending sampling methods that have been proven to produce unbiased results. Training requirements: Outlining the necessary skills and knowledge for personnel conducting sampling to prevent procedural errors. Reducing random variation Precision refers to the reproducibility of measurements—how consistent results are when repeated. Random variation in sampling can reduce precision. Standards address this by: Standardizing procedures: Providing detailed, step-by-step protocols that reduce variability between different samplers or different sampling events. Specifying environmental controls: Recommending measures to minimize the impact of environmental factors on samples. Defining sample handling parameters: Detailing how samples should be transported, stored, and prepared to maintain consistency. Requiring documentation: Mandating comprehensive records of all sampling conditions and procedures to identify potential sources of variation. Practical implementation of sampling standards While understanding sampling standards is essential, implementing them effectively in real-world situations is equally important. Developing a sampling plan A well-designed sampling plan is the practical application of sampling standards. It translates the general principles into specific actions tailored to a particular food product and analytical objective. An effective sampling plan based on ISO standards typically includes: Clear objectives: Specific statements of what the sampling aims to determine. Lot definition: Precise description of the batch or lot being sampled, including size, packaging, and production information. Sampling method: Detailed procedures for how, when, and where samples will be collected. Sample size and number: Specifications for how much material will be collected and how many incremental samples will be taken. Equipment list: Inventory of all tools and containers needed for sampling. Handling instructions: Protocols for sample identification, transport, and storage. Documentation requirements: Forms and records to be completed during the sampling process. Training sampling personnel Even the most comprehensive standards and plans are only effective when implemented correctly. Proper training of sampling personnel is essential and often addressed within the standards themselves. Training requirements might include: Understanding of basic statistical concepts: Ensuring personnel grasp why random sampling is important and how bias can be introduced. Equipment proficiency: Practical training in the use of sampling tools and devices. Contamination prevention: Techniques for avoiding sample contamination during collection and handling. Documentation practices: Training on proper record-keeping and chain-of-custody procedures. Problem-solving skills: Preparing personnel to adapt procedures when faced with unexpected circumstances while maintaining compliance with standards. The future of sampling standards in food analysis As food supply chains become increasingly global and complex, and as analytical capabilities continue to advance, sampling standards are evolving to meet new challenges. Emerging trends in sampling standardization Several trends are shaping the future of sampling standards: Integration with risk-based approaches: Newer standards are increasingly incorporating risk assessment principles, allowing for more targeted and efficient sampling based on identified hazards. Adaptation for novel foods: As new food types enter the market, such as plant-based alternatives, cell-cultured proteins, and novel ingredients, standards are being developed or adapted to address their unique characteristics. Incorporation of automation: Standards are beginning to accommodate automated sampling technologies that can reduce human error and increase efficiency. Harmonization efforts: There is growing emphasis on aligning sampling standards across different regulatory regions to facilitate international trade and ensure consistent consumer protection globally. Technological advances in sampling Technology is transforming how sampling is conducted, and standards are evolving to incorporate these innovations: Real-time monitoring systems: Continuous sampling and analysis technologies that can provide immediate feedback on food quality parameters. Non-destructive sampling methods: Techniques like near-infrared spectroscopy that can assess food properties without damaging the product. Digital documentation tools: Electronic systems for recording sampling information that improve traceability and reduce paperwork. Predictive modeling: Statistical approaches that can optimize sampling designs based on historical data and product characteristics. Conclusion Sampling standards are the unsung heroes of food analysis. They provide the foundation upon which reliable analytical results are built, ensuring that the food we consume meets safety and quality requirements. From the initial collection of material to the final interpretation of results, these standards guide every step of the process, minimizing errors and maximizing confidence in the conclusions drawn. ISO standards, particularly ISO 2854 for statistical interpretation and ISO 7002 for agricultural products, offer comprehensive frameworks that balance scientific rigor with practical applicability. By following these standards, food industry professionals can ensure their sampling procedures are both effective and defensible. As the food industry continues to evolve, sampling standards will adapt to new challenges and technologies, maintaining their essential role in protecting consumers and supporting fair trade practices. What do you think? How might advances in technology change the way we approach food sampling in the future? Have you considered how proper sampling procedures impact the reliability of the food quality data you encounter in your studies or professional life? This document establishes single sampling plans for conformance testing, i.e., for assessing whether the quality level of a relevant audit population (lot, process, inventory, file etc) conforms to a declared value. Sampling plans are provided corresponding to four levels of discriminatory ability. The limiting quality ratio (LQR) (see Clause 4) of each sampling plan is given for reference. For levels I-III, the sampling plans have been devised so as to obtain a risk no more than 5 % of contradicting a correct declared quality level. The risk of failing to contradict an incorrectly declared quality level which is related to the LQR is no more than 10 %. The sample sizes for level 0 are designed in a way that the LQR factors of the sampling plans are compatible with the LQR factors for level I. In contrast to the procedures in the other parts of the ISO 2859 series, the procedures in this document are not applicable to acceptance assessment of lots. Generally, this document mainly focuses on controlling type I error, which differs from the balancing of the risks in the procedures for acceptance sampling. This document can be used for various forms of quality inspection in situations where objective evidence of conformity to some declared quality level is to be provided by means of inspection of a sample. The procedures are applicable to entities such as lots, process output, etc. that allow random samples of individual items to be taken from the entity. The sampling plans provided in this document are applicable, but not limited, to the inspection of a variety of targets such as: — end items; — components and raw materials; — operations; — materials in process; — supplies in storage; — maintenance operations; — data or records; — administrative procedures; — accounting procedures or accounting entries; — internal control procedures. This document considers two types of quality models for discrete items and populations, as follows. i) The conforming-nonconforming model, where each item is classified as conforming or nonconforming, and where the quality indicator of a population of items is the proportion p of nonconforming items, or, equivalently, the percentage 100 p of nonconforming items. ii) The nonconformities model, where the number of nonconformities is counted on each item, and where the quality indicator of a population of items is the average number λ of nonconformities found on items in the population, or, equivalently, the percentage 100 λ of nonconformities on items in the population. Over the course of time, the ISO 2859 standard has established itself as an indispensable tool, not only for medical device manufacturers, but also for a wide range of manufacturing companies that rely on effective sampling methods grounded in statistical principles to enhance their operational processes.ISO 2859, commonly referred to as the ISO 2859 series, encompasses a set of international standards developed by the International Organization for Standardization (ISO) for sampling procedures and acceptance sampling plans for inspection by attributes. These standards provide guidelines for establishing sampling plans to ensure the quality of products and materials. ISO 2859 is widely utilized across industries to determine the acceptability of product batches based on statistical sampling methods, helping organizations maintain consistent quality levels while managing inspection costs. Its principles are integral to quality management systems, facilitating efficient and standardized approaches to product inspection and acceptance.In our previous discussions, we have extensively explored the application of statistical methodologies within the context of a comprehensive Quality Management System. It becomes increasingly evident that the implementation of the Acceptable Quality Level (AQL) sampling methodology is crucial, as it serves as one of the fundamental statistical tools required for ensuring product quality and conformity within the organizational framework.To be more specific, the ISO 2859-1 standard holds a prominent position as the internationally recognized reference for AQL sampling inspections. By following the guidelines outlined in this standard, manufacturers can establish a systematic approach to conducting sampling inspections based on attribute-based criteria.Now, let’s delve deeper into the most significant sections of the ISO 2859-1 standard, which will enable us to gain a comprehensive understanding of its key requirements and their implications for quality control and assurance within various industries.If we consider the ISO 13485:2016 there are specific requirements associated to the verification of purchase products, specifically in the section 7.4.3. Basically the requirements are related to the necessity to have a system for the verification that purchased products are aligned with the specifications defined with the supplier. As usual, a risk based approach shall be applied and thus the extent of the verification activities shall be based on the results of the supplier evaluation and proportionate to the risk associated with the purchased products. If we consider the MDSAP, specific requirements for acceptance activities should also be taken in consideration. For example, Anvisa Regulation requires evidence that sampling plans are based on valid statistical rationale. The organization should also periodically review the sampling methods to ensure they are consistent and suitable for their intended use. The frequency of the review of the sampling plans should be based on the occurrence of nonconforming products, audit results and complaints records. Very similar requirements are mentioned in the US 21 CFR 820 Code of Federal regulation, thus the FDA regulation for Quality Management System. In fact, in the section in the section 21 CFR 820.250(b), it is reported: Verify that the manufacturer establishes and maintains procedures to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed. Before starting with the discussion on the requirements mentioned in the ISO 2859-1, it is important to report some definitions, focusing on the words which are not frequently used and thus the meaning might not be clear to everybody in the framework of Acceptance Quality Limits. These definitions are directly taken from the ISO 2859.Inspection by attributesinspection whereby either the item is classified simply as conforming or nonconforming with respect to a specified requirement or set of specified requirements, or the number of nonconformities in the item is counted. Sampling plancombination of sample size(s) to be used and associated lot acceptability criteria. Sampling systemcollection of sampling plans, or of sampling schemes, each with its own rules for changing plans, together with sampling procedures including criteria by which appropriate plans or schemes may be chosen. Acceptance quality limit (AQL)quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling. In the subsequent sections, as mentioned above, we will discuss the requirements associated to ISO 2859-1 with particular attention to the following topics: Acceptance Quality Limit Lot Acceptance Vs Not Acceptance Type of Inspections Sampling Plans The Acceptance Quality Limit (AQL), in conjunction with the sample size code letter, plays a pivotal role in determining the sampling plans utilized during quality inspections. Essentially, these parameters govern the number of items to be examined and establish the maximum permissible number of non-conforming items that can be present for the entire lot to be accepted.To put it simply, the AQL serves as a critical benchmark that guides the selection of an appropriate sampling scheme tied to a specific AQL value. This scheme ensures that the lot under consideration will be accepted if the observed quality level, represented by the percentage of non-conformities per 100 items, does not exceed the designated AQL value.In practical terms, the AQL value signifies the predetermined quality threshold that delineates acceptable levels of non-conformities within a given lot. By adhering to the specified AQL value, manufacturers can make informed decisions about the acceptability of a batch based on the results obtained from the sampling inspection process. It provides a standardized framework for evaluating the overall quality of the lot while simultaneously taking into account the inherent variability associated with sampling.By utilizing appropriate sampling plans based on the AQL, organizations can establish a robust quality assurance framework that strikes a balance between cost-effective sampling efforts and reliable assessment of product quality. The AQL serves as a crucial tool for decision-making, allowing manufacturers to determine whether a lot meets the predetermined quality standards, thereby ensuring consistent product quality and customer satisfaction. The determination of lot acceptability relies heavily on the chosen sampling plan, as it serves as the foundation for decision-making. If a lot is deemed unacceptable based on the sampling results, it is categorically rejected, rendering it unsuitable for use, particularly in the context of verification activities during incoming inspections.Once a lot is rejected, the next step involves deciding how to handle its disposition. Several options exist, including scrapping the entire lot, subjecting it to rework to rectify any non-conformities, or resubmitting it for further inspection. In some cases, the decision to accept a lot may be reconsidered after conducting a thorough risk assessment of the non-conforming elements.Similarly, when a lot is accepted, it is crucial to address any non-conforming items that may have been identified during the inspection process. These items can be either scrapped, reworked to bring them into compliance, or resubmitted for subsequent inspection. It is important to note that even if an entire lot is accepted, there remains the prerogative to reject individual non-conforming items found within the accepted lot.In situations where a lot is rejected due to a significant number of non-conformities, it is imperative to communicate this outcome to all relevant parties involved. As per the guidance provided in ISO 2859-1, it is recommended that rejected lots be subjected to re-inspection until every item has been thoroughly re-examined, ensuring that all non-conforming items have been effectively eliminated or appropriately reworked. In some instances, it may be decided to employ a more stringent inspection approach during the re-inspection of the previously rejected lot.The ISO 2859-1 defines three level of inspections, named: Tighten inspection Normal Inspection Reduced InspectionUsually, at the beginning normal inspection shall be used. Then, it is possible to change the type of inspection performed based on the results of the inspection previously performed, according to the scheme reported below: The switching rules between different levels of inspection are reported in the scheme above. When normal inspection is performed, tightened inspection shall be performed when two out of five consecutive lots have been rejected or considered non-acceptable. Of course, it is possible to switch the level of inspection even before reach the level of five consecutive lots. At the same time, when tightened inspection is performed, it is possible to return to normal inspection level when there are no rejections in 5 consecutive lots. In some circumstances, it is also possible to decrease the level of inspection from normal to reduced. This is typically feasible when reduced inspection is desirable (for example to avoid cost issue on destructive samples) and the production is at steady rate. To switch, usually there might not have been rejections for 10 consecutive lots. When we are at the reduced level, it is necessary to return a normal inspection level in case of: A lot is not accepted Production becomes irregular One of the most significant applications of AQL and ISO 2859 is related to quality control. Do not hesitate to have a look to our WebShop where more the 100 procedures, templates and checklist are available to support your efforts towards regulatory compliance. Incoming Control Procedure There are different tables that need to be taken in considerations to determine the sample size to be inspected and the maximum number of non-conforming items it is possible to have to do not reject the lot under inspection. Firstly, it is necessary to look at the Sample Size Code Letters, as reported in the table mentioned below. As it can be seen, it is necessary to select the appropriate inspection level, which basically, designates the level of inspection. Under standard circumstances, the general inspection shall be considered. Under this category, three level of inspections are considered. As it is mentioned within ISO 2859-1, unless otherwise specified, level II shall be used. Level I and III could be used when less or greater discrimination is needed. Moreover, for additional special levels S1- S4 are defined in the aforementioned table and they can be used with relatively small sample size. When the sample size code letter is found out based on sample size and inspection levels, it shall be used on other tables to find the related sampling plan. The table to be used depends from the level of inspection (normal, tightened or reduced). For example, let’s imagine in the framework of incoming inspection control we have a lot of 1500 items. First, in the sample size code letters table we need to find the related code letter. If we consider we are using Type II General Inspection Level, the code letter is K. Then, if we consider we are using a normal inspection level, we should go to the related table (reported above) and we can find that the sample size code letter K corresponds to a sample size of 125. This number corresponds to the number of items to be checked in the framework of our incoming inspection activity.Then we need to decide the AQL linked to the specific activity. As a reminder, the AQL corresponds to the number of non-conformities for 100 items. Let’s assume that our AQL for the incoming inspection of our lot sample is 2.5. If we check the table above, this AQL corresponds to a limit of acceptance of 7. It means we cannot have more than 7 non-conformities to accept the lot; thus if we have 8 or more non-conformity within the 125 items to be checked, the lot will have to be rejected. In conclusion, we have provided a comprehensive overview of the ISO 2859 standard and its associated Acceptance Quality Limit (AQL) sampling methodology. It is important to note that the value of these concepts extends beyond the realm of medical device manufacturers, finding applicability in various industries.When it comes to verifying purchased products, specific requirements are outlined in standards such as ISO 13485:2016 or in regulations such as the FDA Quality System Regulation and RDC ANVISA 16/2013 (Brazilian Regulation). These requirements often emphasize the necessity of employing a statistically valid methodology to support verification activities related to purchased products. The AQL sampling methodology, as elucidated in ISO 2859, is a widely used statistical tool that fulfills this need.By implementing the AQL sampling methodology, organizations can ensure that their verification activities adhere to recognized statistical principles. This methodology enables them to establish appropriate sampling plans, determine sample sizes, and establish acceptable quality levels for purchased products. The AQL value assigned to a sampling scheme serves as a benchmark, indicating the maximum permissible level of non-conformities per 100 items that can be tolerated while still accepting the lot.Moreover, the AQL sampling methodology promotes consistency and objectivity in the verification process. It provides a structured approach for evaluating the quality of purchased products, helping organizations make informed decisions about lot acceptability and subsequent disposition. This statistical tool is designed to strike a balance between the need for effective quality control and the practical constraints of inspecting every individual item in a lot.In essence, the ISO 2859 standard and its AQL sampling methodology offer a robust framework for conducting verification activities on purchased products. They contribute to the overall quality management system of an organization by ensuring statistically sound and reliable inspections. Regardless of the industry, the utilization of these concepts can enhance the integrity of verification processes, leading to improved product quality and customer satisfaction.4EasyReg is an online platform dedicated to Regulatory matters within the medical device, information security and AI-Based business. We offer a wide range of documentation kits to support your compliance efforts towards a wide range of standards and regulations, such as ISO 13485, EU MDR, ISO 27001, ISO 42001 and much more. . Specifically, in our webshop you will find:Within our sister platform QualityMedDev Academy, a wide range of online & self-paced training courses is available, such as for example: As one of the leading online platforms in the medical device sector, 4EasyReg offers extensive support for regulatory compliance. Our services cover a wide range of topics, from EU MDR & IVDR to ISO 13485, encompassing risk management, biocompatibility, usability, software verification and validation, and assistance in preparing technical documentation for MDR compliance.Do not hesitate to subscribe to our Newsletter! Acceptable Quality Limit (AQL)How Do I Determine the Correct Sample Size and Acceptance Number?AQL Sampling SimulatorReady to Simulate Your AQL SamplingMore Resources The Acceptance Quality Limit (AQL) is used in product inspections to determine the maximum acceptable number of defective items in a sample batch. If the number of defective items is higher than the maximum acceptable limit, the batch is rejected. AQL is typically set differently for minor, major, and critical defects. Since critical defects are unacceptable, AQL for critical defects is commonly 0.In sampling inspections, QIMA inspectors follow the ISO 2859 standard, which forms the basis for the Acceptable Quality Limit (AQL) methodology. The standard provides tables to determine sample sizes and defect thresholds, ensuring precise and reliable quality assessments.Our inspectors use pre-defined sampling plans to perform a detailed analysis of production samples, verifying whether they meet the AQL. Our transparent, AQL-based approach to sampling inspections helps you make informed decisions on whether to accept or reject an entire batch.Inspecting a sample of products from a batch in a consistent and systematic way, instead of testing every single item, provides significant benefits:Saves time and reduces costs while still maintaining acceptable quality standards.Helps balance the risk of accepting defective products against the cost and effort of inspection.Allows different AQL levels for different products or defect types, supporting varying quality requirements.Provides clear criteria for accepting or rejecting a batch, simplifying the decision-making process.Our experts will guide you in selecting the inspection level and AQL values that best fit your requirements. Use our AQL sampling calculation tool to simulate product inspections and gain a better understanding of how the process works.For example, if you need to inspect 4,000 face masks using a normal inspection (Level II with an AQL of 2.5), simply enter the relevant data into the designated fields in the AQL calculator below:Quantity: 4000Inspection level: General Inspection IIAQL: 2.5Find the respective Lot Size (quantity) and general inspection level: Code letter L Note: The AQL tables below are based on the ANSI/ASQ Standard Z1.4 – 2008Locate Row L (the required sample size of 200) In compliance with AQL 2.5, no more than 10 units from a sample size of 200 may fail the inspection.Go ahead and simulate your next sampling inspection:Enter your shipment lot quantitySelect General/Special inspection levelSelect AQL for all defects (critical, major, minor)Refer to Tables A and B above to see the impact on inspected quantities and accepted defect limits Back to Background information main pageList of EN and ISO Standards in Sampling:ISO Standards & European Norms are provided for reference where they apply to sampling. However, note that sampling for trade and technical purposes may be more thorough or complex than is required for Customs and Tax purposes.The list of standards on sampling or sampling related matters listed in the tables below is not exhaustive. You may apply other national standards when more relevant in specific cases.The list is divided into three groups. ISO 2859Sampling procedures for inspection by attributesISO 3951 Sampling procedures for inspection by variablesISO 10725Acceptance sampling plans and procedures for the inspection of bulk materialsISO 24153 Random sampling and randomization proceduresISO 28592 Double sampling plans by attributes with minimal sample sizes, indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)EN 133 Respiratory protective devices – ClassificationEN 143Respiratory protective devices - Particle filters - Requirements, testing, markingEN 166Personal eye-protection – SpecificationsEN 397 Industrial safety helmetsEN 1149-5Protective clothing - Electrostatic properties - Part 5: Material performance and design requirementsEN 14387Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, markingEN 80079-36Explosive atmospheres - Part 36: Non-electrical equipment for explosive atmospheres - Basic method and requirementsEN ISO 20345Personal protective equipment - Safety footwearISO 3165Sampling of chemical products for industrial use - Safety in samplingISO 3864Graphical symbols - Safety colours and safety signsISO 13688Protective clothing - General requirementsISO 21420Protective gloves - General requirements and test methodsCEN/TR 15310Characterization of waste – Sampling of waste materialsEN 932-1 Tests for general properties of aggregates - Part 1: Methods for samplingEN 1482-1Sampling of solid fertilizers and liming materials. Sampling and sample preparation. Part 1: SamplingEN 12751Textiles - Sampling of fibres, yarns and fabrics for testingEN 13416Flexible sheets for waterproofing - Bitumen, plastic and rubber sheets for roof waterproofing - Rules for samplingEN 14275 Automotive fuels - Assessment of petrol and diesel fuel quality - Sampling from retail site pumps and commercial site fuel dispensersEN 14899Characterisation of waste – Sampling of waste materials – Framework for the preparation and application of a Sampling PlanEN ISO 542Oilseeds – SamplingEN ISO 707Milk and milk products - Guidance on samplingEN ISO 4257Liquefied petroleum gases - Method of samplingEN ISO 5555Animal and vegetables fats and oils. SamplingEN ISO 10715Natural gas - Sampling guidelinesEN ISO 17604Microbiology of the food chain - Carcass sampling for microbiological analysisEN ISO 24333Cereals and cereal