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Lot Sampling

White Paper

Introduction to lot sampling

Lot Sampling in manufacturing is often referred to as Lot Quality Assurance Sampling (LQAS), and Acceptance Sampling. It is a method of taking smaller random samples from a larger lot and testing each sampled item to determine if the samples meet a predetermined standard of quality. The quality of the lot is determined by the random sample. Skip lot sampling is an extension of Lot sampling and means that only a fraction of a lot is submitted for inspection and only 1 out of every X lots needs to be inspected. Standards have been established by ISO and ANSI where they have defined when a lot needs to be inspected and the quantity, or sampling, of that lot to be inspected. These organizations have published a series of tables and mathematical formulas for determining these inspection factors. Skip lot means that each lot will not be inspected, and skip-lot is predisposed through a series of qualifying lot receipts. Once the initial lot receipts meet the qualification standards through passing inspections, the future lots will enter skip-lot. In simple terms, for example, a purchased product will initially enter into a “qualification” mode. During qualification mode each lot will be sampled, and the results will determine if future lots can enter skip-lot mode or remain in qualification mode. When the initial lots meet qualification, they enter skip-lot and are determined “qualified”. Once entering skip-lot the random generators will determine which lots will be flagged for sampling inspection. Based upon these

standards future lots can enter “re-qualification” should the inspection results determine quality issues and failures when sampling. Once entering requalification, future lots will need to once again meet the quality standards to achieve a qualified standard. Skip-lot sampling provides a lower cost solution for inspecting large lots when the economics does not make it feasible to inspect each item from the lot. ISO and ANSI define skip-lot as well as the standards to determine when a sampling from a lot fails or passes through AQL (Acceptable Quality Levels). Another skip-lot standard is NIST. A notable difference with NIST is that in the NIST definition sampling occurs in every lot.

Inspections in TQCM

Sampling in TQCM is performed through inspections and is integrated in Dynamics processes. This simplifies the sampling for inspectors as TQCM sampling flows within the normal processes for Dynamics users. Calculations for Lot Sampling and Skip-lot are based upon actual lot sizes for purchase and production lots within Dynamics. There are no external calculations as TQCM is an integral part of Dynamics 365. So, purchase, production, and sales inspections are calculated at the time these orders are created through a process called Quality Requirements Planning (QRP). QRP sees the lots created and performs projections for the inspectors providing them with dates for inspections, type of inspections, and lot quantities. Should lot quantities change or dates from MRP and/or dates by customers and vendors change; QRP will recalculate

these projections based upon these changes. All upcoming inspections are viewable from standard Dynamics views. One view, as shown below, displays all upcoming inspections including details of the lot and if the plan attached to the product requires inspection or not. Those lots are indicated by a check box called “Marked”. Inspectors can override the projections through buttons to manually override the systems calculated lot inspections to unmark, or, mark the lots for inspection. Any product which has a plan attached for inspection will be displayed. If a lot is in Skip-Lot, the lot is displayed but the check box for Marked will not be checked. An inspector has the option at time of inspection to override the marking and enforce all plans for a specific lot.

properties created for a product. It identifies the properties of upcoming lots and makes the decision as to what plans are in place based upon these calculated factors. In TQCM a product may have multiple plans associated to it, or a single plan. These decisions are user options. In some cases, plans are similar across products. For example, multiple raw materials may have the same material hardness test but different dimensional tests. So, the material hardness test can be setup as a single plan across several products, but the dimensional tests can be setup specific to the item. There might be other plans that could hit an item seasonally. For example, an item could be setup for a once per year full audit that includes more specific details to test

including destructive tests. The end result is that the plan(s) are virtual and adapt in many ways. The plans adapt based upon excellent or bad quality. They adapt based upon seasonal or other timing factors. They adapt based upon

lot size. They adapt when the same material is placed through a new operation on the shop floor or purchased from a new vendor. It adapts based upon qualification methods with Skip-lot. And they adapt through properties based upon levels and switches. QRP controls this and analyzes the properties of each lot and delivers to the inspector the correct plans

Article	Marked	Delivery date	Status	Batch number	Quantity	Sample lot id	Item number	Inspection type
rml	<input checked="" type="checkbox"/>	6/25/2019	Created	190625-000261	70,000.00	SL-00045	TH1001	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created		100.00	SL-00055	A0001	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created		10.00	SL-00055	A0001	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created		10.00	SL-00055	A0001	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created		10.00	SL-00055	A0001	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created	190510-000106	2.00	SL-00007	TransSpacer	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	6/4/2019	Created	190510-000106	2.00	SL-00008	TransSpacer	Purchase incoming inspection
rml	<input checked="" type="checkbox"/>	12/18/2016	Created		21.00	SL-00053	D0001	Production in process inspection
rml	<input checked="" type="checkbox"/>	12/19/2016	Created		12.00	SL-00053	D0001	Production in process inspection
rml	<input checked="" type="checkbox"/>	11/23/2016	Created		184.00	SL-00053	D0001	Production in process inspection
rml	<input checked="" type="checkbox"/>	6/7/2019	Created		5.00	SL-00053	D0001	Production in process inspection

Creating inspection plans in TQCM

The inspection plan in TQCM is virtual and unlimited. It uses a highly sophisticated engine to adapt to lot sizes, previous inspection results, and other factors based upon the plan design. The engine called QRP is a series of calculations based upon

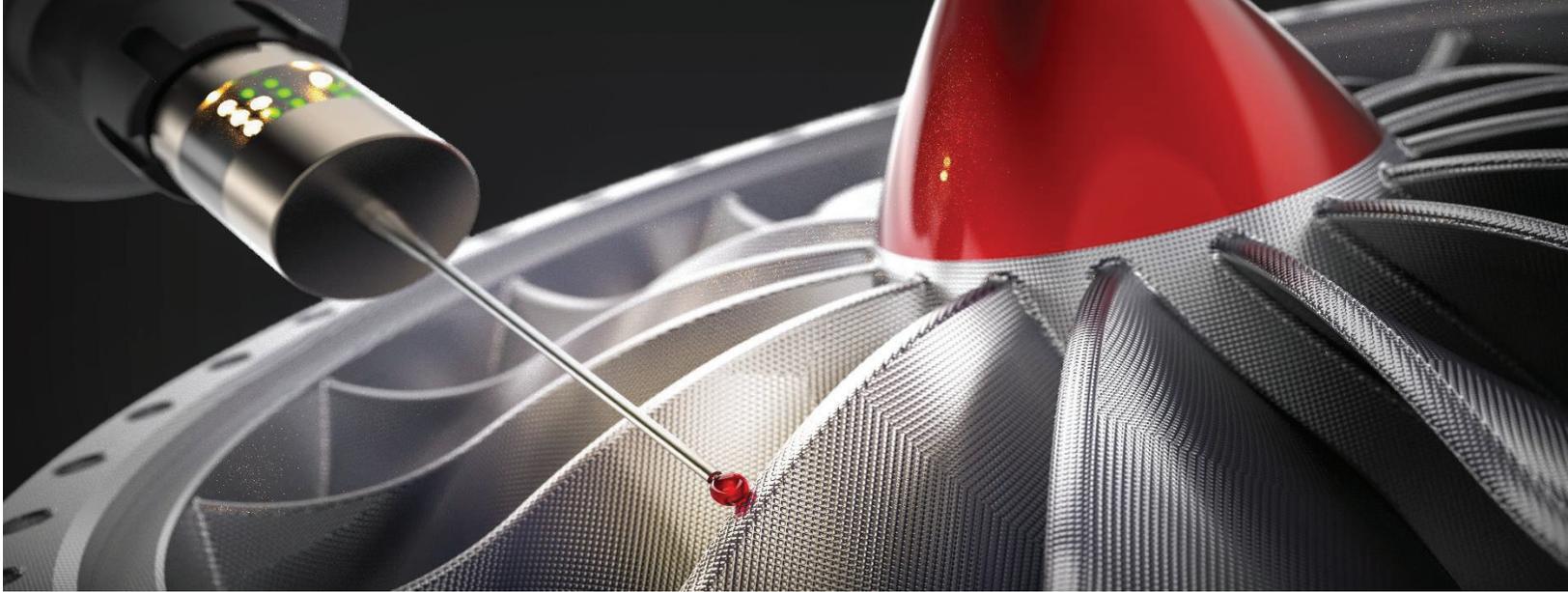


for each lot. QRP performs this analysis automatically in the background. There are no spread sheets to review or hand calculations to be performed. The inspector simply starts the inspection and the correct plan(s) are brought to the screen. The virtual plans that QRP manages is setup through two tables in TQCM to establish the properties. This includes the Lot Acceptance Sampling Plans table and the Sample Lot Table. The following sections provide an overview of these tables.

Lot acceptance sampling plans (LASP)

TQCM provides three industry standards for sampling plans which are ISO2859-1, ANSI Z1.4, and NIST Series 6. TQCM also supports a non-industry type called "Other". Other provides the ability to create sampling plans based upon less complex calculations and are user defined not using the industry standards. For example, a plan can be created to inspect a lot every other week. Size of a company using TQCM does not necessarily dictate the types of plans. However, a plan of the type "Other"

benefits those organizations that need sophisticated inspection plans based upon more simplistic inspection requirements. The plans for the industry standards can be quickly setup to adhere to the published standards. This means that using the "Full Standard" mode will use the tables and calculations based upon each organization's published standards. Full standard still provides the ability to select if the plan type is Single, Double, or Multiple. The plan level can also be designated for Normal levels, Reduced, and Tightened levels for selecting the standards default levels. TQCM also provides the ability to start with an industry standard and use in a "Modified Standard" mode. Through this setup a user would first select the industry standard (ANSI, ISO, or NIST) then select the mode from Full Standard to Modified Standard. In this mode, the user can define exact specifications for the switching rules; Normal to Reduced, Tightened to Normal, Reduced to Normal, Normal to tightened. In the Modified Standard, Skip-lot can be adapted so that user defined factors can be set manually for Qualification and Re-Qualification. Setup for sampling



frequencies and standards are setup in the TQCM Table called Lot Acceptance Sampling Plans (LASP). This area is where the standards for frequency and quantities for inspections are established.

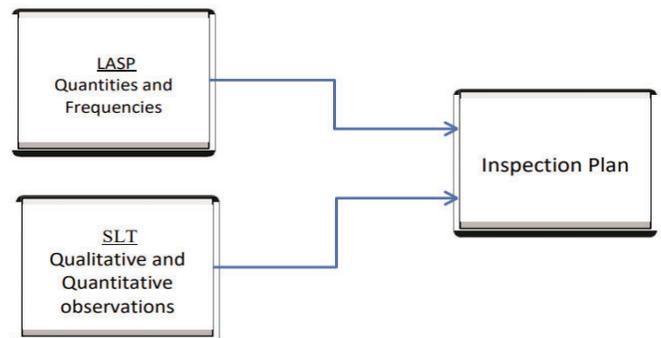
C = Zero

This term is referred to Zero Acceptance Number Sample Plan and means that a sampling inspection must have zero defects to pass. Or, acceptance equals Zero (0) and rejected equals One (1).

Sample lot table (SLT)

The SLT is where the sampling specifications for the product to be sampled are setup. This is the Table specific to the item, or group of items, based upon Qualitative or Quantitative requirements and where the observations are setup for use by the inspector when performing a sampling. Multiple observations can be setup within one SLT with a mixture of both Qualitative and Quantitative observations. An SLT is then associated to an LASP. The LASP provides the quantities and frequency

based upon the setup of the specific LASP and the SLT provides the Qualitative and Quantitative observations that the inspector will use when sampling. So, the setup scenario could result in a company creating just a few LASP's that can be



associated to multiple products through the SLT. An SLT with an LASP associated to it, creates the Inspection Plan.

An LASP (frequency) can also be established at the line level of the inspection steps (observation lines). This is a feature permitting different frequencies by observation line where some lines can be skipped based upon the LASP. However, all lines must have the same AQL as the plan itself.



When dimensional observations are required, much more functionality can be added, at the users' discretion, to improve the capabilities of the tests while simplifying the data entry required by the inspector. One feature includes mistype since there is a difference to the results of an observation where an error in entry has been made versus an observation that fails the tests. Mistype is a feature where an upper and lower tolerance is established that is well out of the range of probability. With mistype enabled the inspector will receive a visual pop-up message that they have mistyped, and the system will force them to re-enter the information. The setup table provides the feature for automatic defect codes. Default defects for both upper and lower tolerances can be setup as well as sub-defect codes if they have been enabled through the parameter settings. This will automatically insert the correct defect code when the data is entered by the inspector and when the observation fails.

Sampling values

Sampling values can be established, shown below, as to the range of the sampling

values. Bounded means that the range is within an upper and lower tolerance. Infinite upper means that the value will have a lower tolerance but no upper tolerance meaning that the sampling will not fail if the value is above the lower tolerance. Infinite lower means that the value will have an upper tolerance but no lower tolerance meaning that the sampling will not fail if the value is under the upper tolerance. And Unbounded means that any value is acceptable, and a pass/fail is not recorded. This may be the case when a temperature is taken at time of inspection. In all cases, an entry of 0 (zero) is acceptable if Zero falls within the range.

Variable control chart setup for X & R (averages and ranges)

Unit	<input type="text" value="in/oz"/>	Starting value	<input type="text" value="100.000"/>
Precision level	<input type="text" value="3"/>	Enable mistype	No <input checked="" type="checkbox"/>
Sampling values	<input type="text" value="Bounded"/>	Data/dimension	<input type="text" value="125.000"/>
	<ul style="list-style-type: none">BoundedD Infinite upperInfinite lowerUnboundedTT	Default upper sub-defective code	<input type="text" value="TL"/>

Instruments

Instruments from the instrument calibration table can also be associated to each observation line. This supports the association of a single, or, multiple instruments to each observation. Or, you may associate no instruments to an observation. Since instrument calibration scheduling is an integrated module of TQCM, the inspector will see the status of the instrument at the time of inspection warning them if the instrument is beyond its calibration date, and/or, if a Risk Instrument Notification is associated to the instrument.

Calculated values

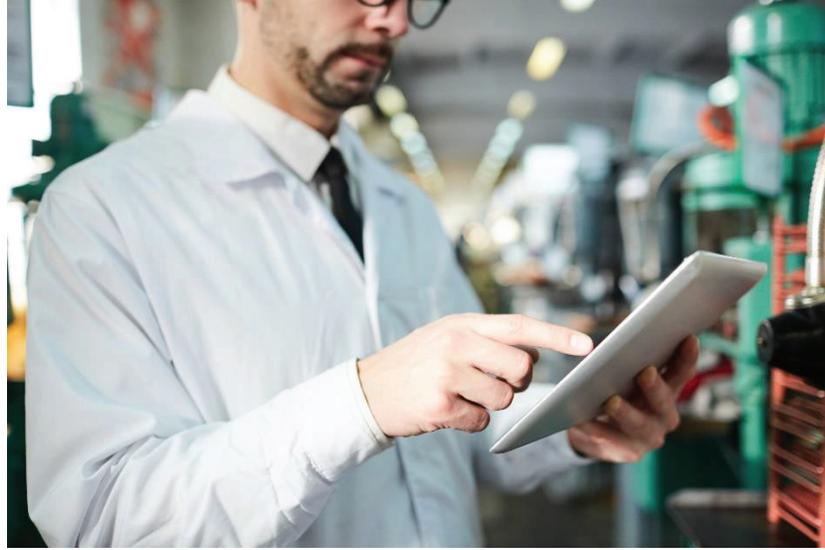
The Sample lot Table also provides an enhanced formula feature for observation lines where the entries made by an inspector require a calculated value. For example, the length, width, and height of dimensional values of these three observations must always fall within a range of volume with upper and lower tolerances. An observation line can be setup with these calculated values.

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