FlexNet™ Quality Management

A Functional Overview

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APRISO®

Key Idea

Web services applications are essential for automating business solutions.

FlexNet Process Quality Manager is just one example of Apriso's new generation Web services applications available to support collaborative business processes over the Internet.

Executive Overview

By the end of 2002, nearly all of today's enterprise computing platforms will support Web services architectures. Representing the next generation of platform middleware, Web services are essential for automating business solutions that use standard components, utilities and registries. Forward-thinking software vendors are making Web services a strategic part of their software architectures. Apriso® has taken the next step by introducing two FlexNet Web services applications, FlexNet Process Quality Manager and FlexNet Material Quality Manager, using Microsoft® .NET™ tools and middleware.

Evolving from client/server architectures and Internet integration, Web services applications are nonetheless fundamentally different from previous approaches. To help laypeople as well as experts understand this new phenomenon and its potential, this paper provides concise answers to four key questions:

- What is FlexNet Process Quality Manager?
- What business issues does FlexNet Process Quality Manager address?
- What are the important features and benefits of FlexNet Process Quality Manager and Material Quality Manager?

What is FlexNet Quality Management?

FlexNet Process Quality Manager and Material Quality Manager are two of a new generation of business- and device-oriented Web services applications from Apriso that automate and assist workers in their daily activities and quality inspectors and their supervisors in the areas of production and material quality control. FlexNet Quality Management applications are available to any computer screen, touch screen, PDA, telephone or programmable logic controller (PLC), and allow people to:

- Bid for, commit, schedule and dispatch inspection work;
- Deal with the movement of samples and sample containers;
- Find resources — workers, inspectors, test equipment and machines;
- Make sequencing, quality control and rework decisions, and initiate corrective actions on-the-spot;
- Remember and track the execution of inspection tasks, while accessing all relevant test instructions and standard operating procedures;
- Coordinate quality control activity with downstream as well as upstream resources; and
- Respond to out-of-control situations and other emergencies.

FlexNet Quality Management applications form part of an integrated family of Web services applications that address manufacturing and supply chain execution requirements.

What Business Issues Does FlexNet Quality Management Address?

Nearly all manufacturers need to inspect their work to assure that specifications from product engineering and customers are met. These activities might be minimal for some industries and painstaking for others, depending upon the industry, locale, type of product, customers' tolerance for defects and the degree of government regulation. The issue isn't whether or not to inspect, but what, how much and when.

Traditional quality control methods focus on inspection of inventory. Raw materials get inspected when they arrive at the receiving dock from suppliers. Intermediates, subassemblies and finished goods get inspected when they come off the production line. And, in some industries, inventories get re-inspected before they are used in production or shipped to customers — possibly to manage shelf life issues, or possibly because some customers have tighter or different specifications than others.

All this inspection activity carries a hefty price tag. For example:

- 100% of a manufacturer's cost of sales is already absorbed whenever inspection occurs after manufacture. This translates into maximum scrap and rework expense whenever defects are found.
- In make-to-stock situations, a product's ultimate customer may not be known at the time of manufacture. When some customers have tighter or different specifications than others, manufacturers tend to inspect production according to the lowest common denominator, in order to maximize production yields, then re-inspect before the product is shipped to customers with unique inspection requirements. This

spawns redundant inspection activity in the warehouse, increasing overhead costs, and lengthens fulfillment cycle times. It also might lead to the accumulation of excess inventory that customers won't accept.

- Statistically, the need to inspect production diminishes with the actual defect rate. But many manufacturers lack the flexibility — or confidence — to vary their inspection rates according to quality performance. As a result, they tend to over-inspect which not only spawns redundant inspection activity but also diminishes yields when product is destroyed in the process.
- When inspection occurs after manufacturing is complete, it may be difficult to pinpoint the actual root causes, especially for complex manufacturing processes. This makes it problematic to identify and implement the corrective actions necessary to prevent defects in the future — perpetuating, in effect, the conditions that breed defects and their resulting scrap, rework and inspection costs.
- Many manufacturers must not only undertake strict inspection regimes, they must also be able to prove that the necessary inspections were carried out for each production unit, and conclusively show that they did not deviate from specifications and standard operating procedures when accepting or rejecting production. This imposes change-control and record-keeping costs that inflate overhead costs and lengthen cycle times.

To address issues like this, manufacturers are increasingly pursuing five important business objectives:

- **Improve Productivity by Eliminating Scrap and Rework Costs**. To keep such expenses at minimum, it would be better to undertake inspections at various points in the production process. A defect found upstream is always easier, faster and less expensive to correct than one found downstream.

- **Minimize Re-Inspection and Inventory Obsolescence Costs**. To eliminate redundant re-inspection costs, it would be better to postpone finished goods production until customer orders are in hand, then inspect in-process production according to each customer’s exact specifications. This has the salutary benefit of cutting finished goods inventories, eliminating the possibility accumulating excess inventory that customers won’t accept.

- **Minimize Inspection Costs**. By automatically varying inspection rates statistically according to actual quality performance, manufacturers can assure compliance with all applicable specifications while minimizing inspection activity. Statistical process control (SPC) techniques can also sharply improve yields by keeping the amount of destructive sampling and testing to a minimum.

- **Minimize Record-Keeping Costs While Complying Fully With Quality Control Procedures**. A quality control system that requires workers to follow current standard operating procedures, collects data effortlessly, and automatically remembers every bit of inspection activity, would dramatically reduce record-keeping expenses while guaranteeing that all necessary inspection activity is carried out.

- **Continually Improve Quality and Cost Performance.** A quality control system that instantaneously spotlights where, when and how defects occur would make it possible to identify and implement the necessary corrective actions on the spot. This not only will prevent costly defects in the future, but it will provide a basis for continually raising quality performance standards and measuring progress toward those goals.
- **Implement Flexible Enterprise-wide Quality Control Programs**. Although inexpensive SPC software is widely available, manufacturers are discovering that such “point” solutions are expensive to implement and maintain. That’s because they are difficult to integrate with other quality management and supply chain execution systems. Manufacturers need ways to attach their software solutions together as if with Velcro instead of tediously “gluing” them together using programmer-intensive processes. It would be best to use business-oriented Web services that share a common repository of processes, business rules and historical events, and that adapt easily to different business needs.

What Are the Important Features and Benefits of FlexNet Process Quality Manager?

To meet these objectives, FlexNet Process Quality Manager combines five mission-critical capabilities into a single application that runs anywhere, on any device:

- Embeds inspection processes into manufacturing routings;
- Automatically chooses and displays the right inspection processes for the job;
- Automatically minimizes inspection rates;
- Collects and analyzes the right quality data, and controls production processes in real time, with minimum effort;
- Automatically tracks actual quality performance, identifies out-of-control production processes, and alerts supervisors to undertake corrective action; and
- Forms part of a complete, fully integrated quality management and supply chain execution system.

Embeds Inspection Processes Into Manufacturing Routings

Before production starts, FlexNet Process Quality Manager automatically detects which inspection processes need to be undertaken at every operation and step of the manufacturing process. These processes are automatically embedded into the manufacturing routing, permitting production workers to self-inspect their work whenever possible. Alternatively, FlexNet Process Quality Manager can be configured to electronically dispatch inspectors to exactly the right place, at exactly the right time, on the basis of actual production reports.

As inspection activities are carried out, FlexNet Process Quality Manager automatically displays the most up-to-date version of all necessary work instructions — in each worker's own language — on personal computers (PCs), kiosks, and portable or handheld computers. Workers can optionally access supplemental information such as standard operating procedures. The entire inspection process is paperless.

Benefits:

- **Minimizes scrap and rework costs** by pinpointing defects and their root causes at specific operations and steps within the production process.
- **Minimizes inspection costs** by allowing production workers, and not quality control personnel, to self-inspect their work whenever possible.
- **Minimizes inspection queues**, and overall production cycle times, by electronically alerting personnel of the need to inspect product on the basis of actual production reports. Personnel are dispatched to exactly the right place, at exactly the right time, as soon as in-process production is available to inspect. Any type of business rule can be implemented to automatically resolve conflicting inspection priorities during the dispatching process.
- **Assures enforcement of the right inspection and quality control procedures**, at all times. FlexNet Process Quality Manager enforces revision control whenever necessary, and assures that only the most recent approved process documentation is available to

production workers and quality control personnel. Process documentation is available in read-only mode only.

Automatically Chooses and Displays the Right Inspection Processes for the Job. FlexNet allows sampling, inspection and material review processes to be defined on the basis of product, product family, product group, customer or customer ship-to location. FlexNet Process Quality Manager automatically chooses the right processes for each production order. This gives you the ability to undertake exactly the right inspections when manufacturing or assembling products to order.

Benefits:

- **Eliminates redundant re-inspection of products in the warehouse** by automatically matching inspection activity to exact customer requirements.
- **Minimizes order fulfillment cycle times** by eliminating the need to re-inspect product before using or shipping it.
- **Minimizes excess inventory buildup**, and maximizes inventory turns, by preventing excess production of substandard goods.

Automatically Minimizes Inspection Rates

Using standard probability functions, FlexNet Process Quality Manager can be configured to dynamically adjust sampling rates according to production order quantities, defect tolerances, confidence levels and the recent quality performance history. Available probability functions include the normal, binomial, hyper geometric, Student-t, Chi-square and Fisher-F distributions. FlexNet Process Quality Manager automatically tracks the quality performance history of a process and can be configured to adjust sample sizes on the basis of the entire history, most-recent history, or historical moving average.

If out-of-tolerance defects occur, FlexNet Process Quality Manager can be configured to automatically trigger second and subsequent dispositions that reflect higher sampling rates. This way, you can focus your inspection efforts spotlighting production processes that are truly suspect.

Dynamic Sample Sizing: An Illustration

Assume that the standard specification for a product allows a defect tolerance of ±3%.

The minimum sample size is **1,067 units** using the normal probability distribution (at 95% confidence) and an unknown production quantity.

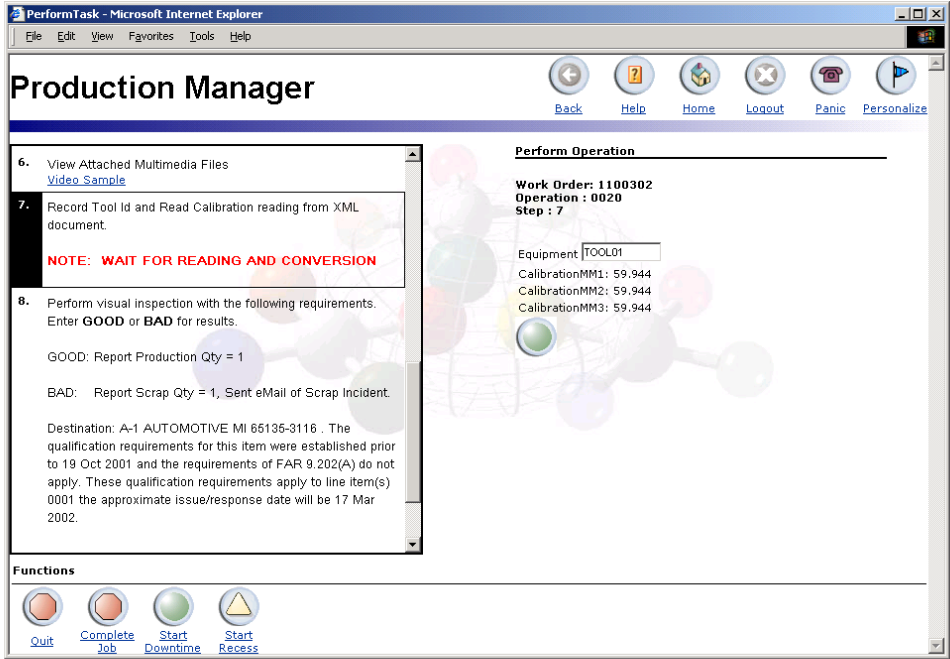
When a specific customer's tolerance is ±6%, then the necessary sample size falls by **75%** to **267 units**.

If recent history reveals a 2% defect rate, then the necessary sample size for the standard specification (±3% tolerance) falls by **92%** to **84 units** (assuming an unknown production quantity), or by over **99%** to **5 units** (assuming a production quantity of 300).

Conclusion: under these circumstances, dynamic sample sizing techniques can reduce inspection quantities and the cost of quality by 95% or more while assuring complete conformance to specification.

Benefits:

- **Minimize inspection activity and cost** by dynamically calculating the absolute minimum sample sizes necessary to satisfy the applicable defect tolerances, according to industry-standard sample sizing theory.
- **Maximize yields and minimizes waste** by minimizing destructive samples.
- **Automatically yield increasing dividends**, as actual quality performance improves due to continuous improvement initiatives.



Collects and Analyzes the Right Quality Data, and Controls Production Processes in Real Time, with Minimum Effort. FlexNet Process Quality Manager can be configured to collect and validate any amount of quality data from people, machines and equipment at specific operations and steps within a manufacturing routing:

- Manual data entry, using a keyboard (or a virtual keyboard for touch-screen or stylus devices);
- Point-and-release data entry, using a mouse, touch-screen actions or stylus. FlexNet Process Quality Manager supports drop-down lists, combo boxes, check boxes and radio buttons;
- Bar code scan (one- or two-dimensional);
- Voice recognition (speech-to-text); and
- Direct electronic integration with machines or test equipment.

You can configure FlexNet Process Quality Manager to automatically perform calculations that convert one or more test readings to test results after data collection, and before quality analysis.

FlexNet Process Quality Manager performs quality analysis on the spot by comparing test results to the characteristics comprising a specification. You can configure FlexNet Process Quality Manager to analyze:

- Variable characteristics, using upper and lower specification or control limits; and
- Attributes, identifying conforming as well as nonconforming results.

Nonconforming results can be classified as critical, major or minor for purposes of alerting people to emergencies and prioritizing corrective actions.

For graded products, FlexNet Process Quality Manager can be configured to assign the right grade to individual production lots or serial-numbered units when their test results conform to the grade characteristic.

You can configure FlexNet Process Quality Manager to automatically divert the manufacturing work flow to an alternate sequence of operations and steps — for re-work, disposal, grading or re-inspection purposes — if the quality analysis reveals a nonconforming result, or a result that exceeds specification or control limits. If different workers perform the alternate sequence of events, personnel are dispatched to exactly the right place, at exactly the right time, as soon as the quality analysis is complete. Any type of business rule can be implemented to automatically resolve conflicting inspection priorities during the dispatching process.

FlexNet Process Quality Manager completely automates material review board (MRB) decision-making processes. Inspection processes are tracked according to unique disposition numbers. The creation, labeling, movement, replacement and scrapping of sample quantities can be tracked by disposition number and by container serial number. FlexNet Process Quality Manager automatically keeps a complete audit trail of all test readings and results obtained for each disposition, sample and container, as well as the resulting grades, passes, and failures by reason code, defect code and corrective action code. Because every audit trail entry identifies the responsible production worker or inspector, FlexNet Process Quality Manager complies fully with user identification and authentication requirements such as the U.S. Food and Drug Administration (FDA) 21 CFR, Part 11.

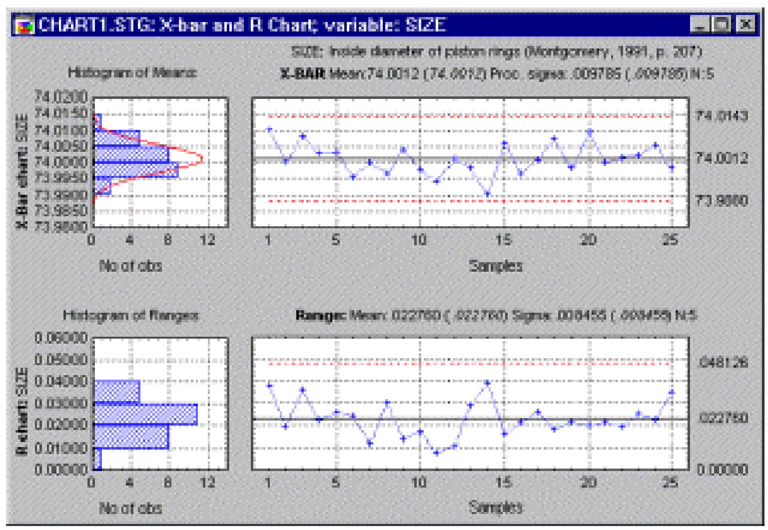
Benefits:

- **Dramatically reduces data collection expense** by eliminating paper reports, and by providing automatic or hands-free data entry methods;
- **Significantly improves data accuracy** and the cost of checking and re-checking data for accuracy;
- **Minimizes scrap and rework costs** by alerting supervisory personnel of production processes that are trending out of control — and possibly shutting them down automatically — before defective products are actually made;
- **Eliminates inspection and material review queues and lead times** by providing immediate quality analysis, automatic material review and decision-making, automatic grading and dispatching of non-conforming products in real-time; and
- **Assures quality and regulatory compliance** by tracking dispositions and all their related samples, containers, test readings, test results, grades, passes, failures, reason codes, defect codes and corrective action codes — with conclusive identification of all responsible personnel.

Automatically Tracks Actual Quality Performance, facilitating on-line quality control and continuous quality improvement initiatives. You can configure FlexNet Process Quality Manager to automatically alert supervisory personnel as soon as quality performance begins to trend out of control, but before defective products are actually made. Any type of business rule can be implemented to govern who is alerted, how long the system waits for a response, escalation procedures, and whether or not to shut the production process down automatically.

The general approach to on-line quality control is straightforward. FlexNet Process Quality Manager extracts samples from the ongoing production process history. It then produces line charts of the variability in those samples, and considers their closeness to target specifications. If a trend emerges in those lines, or if samples fall outside pre-specified limits, FlexNet Process Quality Manager declares the process to be out of control and takes action to find the cause of the problem.

The most standard display actually contains two charts; one is called



an *X-bar chart*, the other is called an *R chart*.

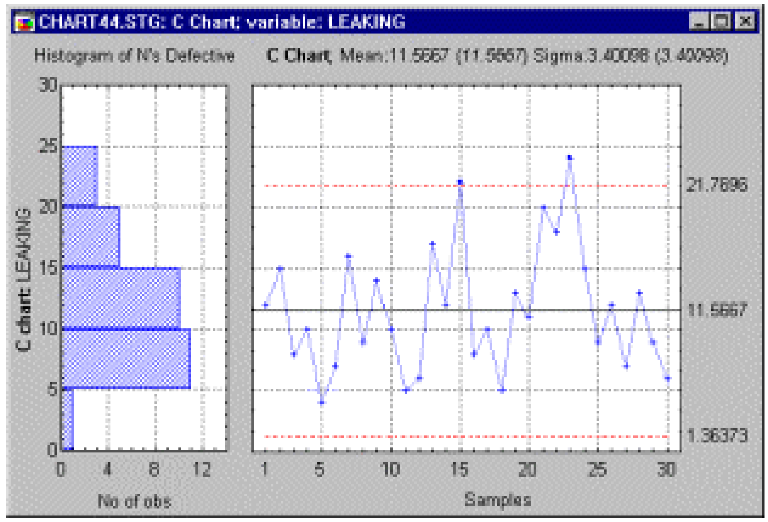
In both line charts, the horizontal axis represents the different samples; the vertical axis for the X-bar chart represents the means for the characteristic of interest; the vertical axis for the R chart represents the ranges. For example, suppose you want to control the diameter of piston rings. The center line in the X-bar chart would represent the desired standard size (e.g., diameter in millimeters) of the rings, while the center line in the R chart would represent the acceptable (within-specification) range of the rings within samples; thus, the R chart tracks the variability of the process (the larger the variability, the larger the range). Two additional horizontal lines represent the upper and lower control limits (*UCL, LCL*, respectively). A line, representing the samples, connects the individual points in the chart. If this line moves outside the upper or lower control limits or exhibits systematic patterns across consecutive samples, then a quality problem may potentially exist.

FlexNet Process Quality Manager produces 8 types of charts for different types of quality characteristics. Some of these charts control variables while others control attributes:

- **X-bar chart.** In this chart the sample means are plotted in order to control the mean value of a variable (e.g., size of piston rings, strength of materials, etc.).
- **R chart.** In this chart, the sample ranges are plotted in order to control the variability of a variable.
- **S chart.** In this chart, the sample standard deviations are plotted in order to control the variability of a variable.
- **S**2 chart.** In this chart, the sample variances are plotted in order to control the variability of a variable.

For controlling quality characteristics that represent attributes of the product, the following charts are commonly constructed:

- **C chart.** In this chart (see example below), FlexNet Process Quality Manager plots the number of defectives (per batch, per day, per machine, per 100 feet of pipe, etc.). This chart assumes that defects of the quality attribute are rare, and the control limits in this chart are computed based on the Poisson distribution).



- **U chart.** In this chart FlexNet Process Quality Manager plots the rate of defectives, that is, the number of defectives divided by the number of units inspected. Unlike the C chart, this chart does not require a constant number of units, and it can be used, for example, when the batches (samples) are of different sizes.

- **Np chart.** In this chart, FlexNet Process Quality Manager plots the number of defectives (per batch, per day, per machine) as in the C chart. However, the control limits in this chart are not based on the distribution of rare events, but rather on the binomial distribution. Therefore, this chart should be used if the occurrence of defectives is not rare (e.g., they occur in more than 5% of the units inspected). For example, you could use this chart to control the number of units produced with minor flaws.

- **P chart.** In this chart, FlexNet Process Quality Manager plots the percent of defectives (per batch, per day, per machine, etc.) as in the U chart. However, the control limits in this chart are not based on the distribution of rare events but rather on the binomial distribution (of proportions). Therefore, this chart is most applicable to situations where the occurrence of defectives is not rare (e.g., we expect the percent of defectives to be more than 5% of the total number of units produced).

FlexNet Process Quality Manager also produces short run control charts for short production runs. These plot observations of variables or attributes for multiple parts on the same chart, addressing the requirement that several dozen measurements of a process must be collected before control limits are calculated. Meeting this requirement is often difficult for operations that produce a limited number of a particular part during a production run.

For example, a paper mill may produce only three or four (huge) rolls of a particular kind of paper and then shift production to another kind of paper. But if variables, such as paper thickness, or attributes, such as blemishes, are monitored for several dozen rolls of paper of, say, a dozen different kinds, control limits for thickness and blemishes could be calculated for the transformed variable values of interest. Specifically, these transformations will rescale the variable values of interest such that they are of compatible magnitudes across the different short production runs (or parts). The transformed values can then be applied in monitoring thickness, and blemishes, regardless of the types of paper being produced. Statistical process control procedures can be used to determine if the production process is in control, to monitor continuing production, and to establish procedures for continuous quality improvement.

FlexNet Process Quality Manager produces several different types of short run charts. The most basic are the nominal and target short run charts. In these charts, the measurements for each part are transformed by subtracting a part-specific constant. These constants can either be the nominal values for the respective parts (nominal short run chart), or they can be target values computed from the (historical) means for each part (Target X-bar and R chart). For example, the diameters of piston bores for different engine blocks produced in a factory can only be meaningfully compared (for determining the consistency of bore sizes) if the mean differences between bore diameters for different sized engines are first removed. The nominal or target short run chart makes such comparisons possible.

If the variability of the process for different parts cannot be assumed to be identical, then a further transformation is necessary before the sample means for different parts can be plotted in the same chart. Specifically, in the standardized short run chart the plot points are further transformed by dividing the deviations of sample means from part means (or nominal or target values for parts) by part-specific constants that are proportional to the variability for the respective parts. For example, for the short run X-bar and R chart, the plot points (that are shown in the X-bar chart) are computed by first subtracting from each sample mean a part specific constant (e.g., the respective part mean, or nominal value for the respective part), and then dividing the difference by another constant, for example, by the average range for the respective chart. These transformations will result in comparable scales for the sample means for different parts.

For attribute control charts, the estimate of the variability of the process (proportion, rate, etc.) is a function of the process average. Hence, only standardized short run charts are available for attributes. For example, in the short run P chart, the plot points are computed by first subtracting from the respective sample *p* values the average part *p*'s, and then dividing by the standard deviation of the average *p*'s.

FlexNet Process Quality Manager can be configured to plot group control charts showing multiple streams of observations or attributes on the same chart. This simplifies interpretation when monitoring many process streams or characteristics. Process streams may be different machines, assembly lines, operators, or the like. All of these may be plotted on a single group chart.

For a group X-bar chart, two points are plotted for each of the samples for which measurements are collected, producing two plotted lines across samples. The upper line is a plot of the highest mean values from the multiple streams or attributes measured for each of the samples, and the lower line is a plot of the lowest mean values from the multiple streams or attributes for each of the samples. These upper and lower plotted points represent the maximum and minimum mean values across the multiple streams or attributes for each sample, and if these extreme values are within the specified control limits, then obviously all other mean values are also within the control limits. The group X-bar chart, therefore, allows you to quickly determine whether many process streams or characteristics are under control without necessarily inspecting each and every measurement.

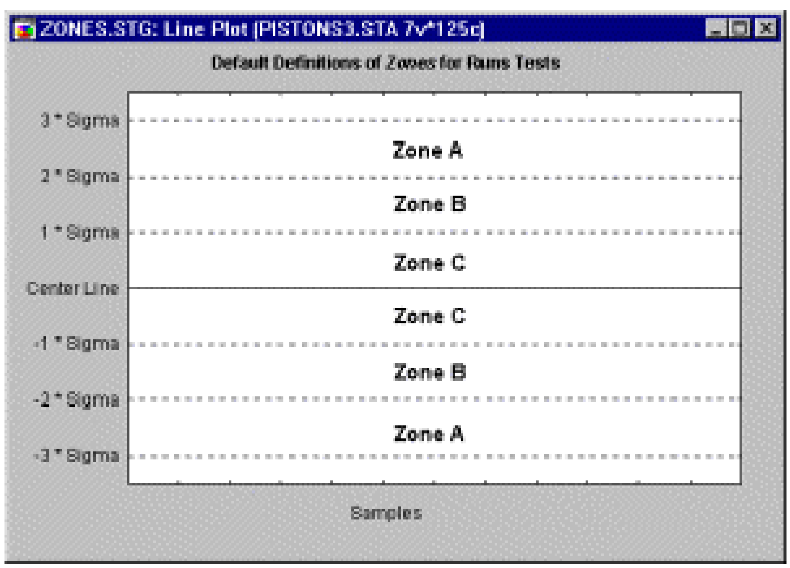
For group R-bar, S, or S**2 charts for variables, or for group C, U, Np, or P charts for attributes, the two points that are plotted for each sample are the respective maximum and minimum ranges and standard deviations from the multiple streams or attributes measured for each sample. As with the group X-bar chart, comparison of these extreme values with the specified control limits allows you to quickly determine whether the multiple process streams or characteristics are under control.

FlexNet Process Quality Manager uses configurable business rules reflecting best quality control practices to determine when a process is no longer in control. The application employed by AT&T runs rules and tests for special causes. This is an example of how FlexNet Process Quality Manager uses configurable business rules to distinguish special or assignable causes from chance or common causes.

The rules within a run are based on statistical reasoning. For example, the probability of any sample mean in an X-bar control chart falling above the center line is equal to 0.5, provided (1) that the process is in control (i.e., that the center line value is equal to the population mean), (2) that consecutive sample means are independent (i.e., not auto-correlated), and (3) that the distribution of means follows the normal distribution. Simply stated, under those conditions there is a 50-50 chance that a mean will fall above or below the centerline. Thus, the probability that two consecutive means will fall above the centerline is equal to 0.5 times 0.5 = 0.25.

Accordingly, the probability that 9 consecutive samples (or a run of 9 samples) will fall on the same side of the centerline is equal to 0.5^9 = .00195. This is approximately the probability with which a sample mean can be expected to fall outside the 3- times sigma limits (given the normal distribution, and a process in control). Therefore, business rules could look for 9 consecutive sample means on the same side of the centerline as another indication of an out-of-control condition.

Zone A, B, C. Customarily, to define the runs tests, the area above and below the chart centerline is divided into three "zones."



By default, Zone A is defined as the area between 2 and 3 times sigma above and below the center line; Zone B is defined as the area between 1 and 2 times sigma, and Zone C is defined as the area between the center line and 1 times sigma.

- **9 points in Zone C or beyond (on one side of central line).** If this test is positive (i.e., if this pattern is detected), then the process average has probably changed. Note that it is assumed that the distribution of the respective quality characteristic in the plot is symmetrical around the mean. This is, for example, not the case for R charts, S charts, or most attribute charts. However, this is still a useful test to alert the people to potential shifts in the process. For example, successive samples with less-than-average variability may be worth investigating, since they may provide hints on how to decrease the variation in the process.

- **6 points in a row steadily increasing or decreasing.** This test signals a drift in the process average. Often, such drift can result from causes such as tool wear, deteriorating maintenance or skill improvements.

- **14 points in a row alternating up and down.** If this test is positive, it indicates that two systematically alternating causes are producing different results. For example, you may be monitoring the quality for two different (alternating) shifts.

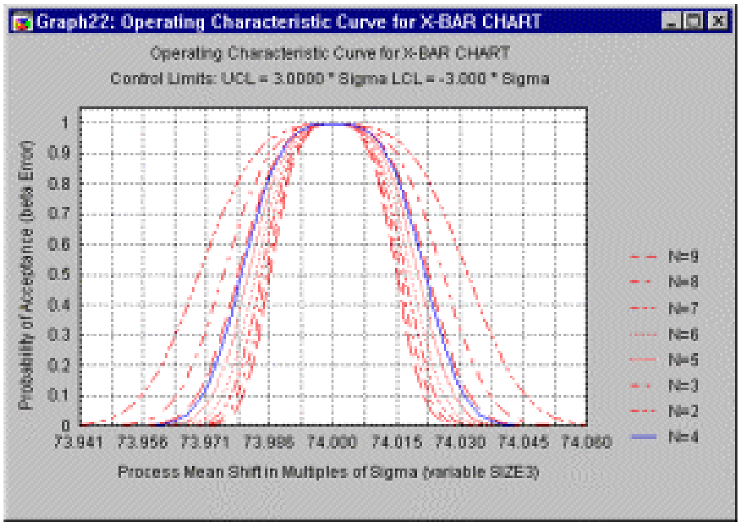
- **2 out of 3 points in a row in Zone A or beyond.** This test provides an early warning of a process shift. Note that the probability of a false-positive error is approximately 2%.

- **4 out of 5 points in a row in Zone B or beyond.** Like the previous test, this test may be considered to be an early warning indicator of a potential process shift. The false-positive error rate for this test is also about 2%.

- **15 points in a row in Zone C (above and below the centerline).** This test indicates a smaller variability than is expected, based on the current control limits.

- **8 points in a row in Zone B, A, or beyond, on either side of the center line (without points in Zone C).** This test indicates that different samples are affected by different factors, resulting in a bimodal distribution of means. This may happen, for example, if different samples in an X-bar chart where produced by one of two different machines, where one produces above average parts, and the other below average parts.

FlexNet Process Quality Manager also provides operating characteristic (OC) plots. These address measure the sensitivity of current quality control procedures. Put in more specific terms, they measure the likelihood that you will not find a sample (e.g., mean in an X-bar chart) outside the control limits (i.e., *accept* the production process as in control), when, in fact, the process has shifted by a certain amount. This probability is usually referred to as the β(beta) error probability, that is, the probability of erroneously accepting a process (mean, mean proportion, mean rate defectives, etc.) as being in control. Operating characteristic curves pertain to the false-acceptance probability using the sample-outside-of- control-limits criterion only, and not the runs tests described earlier.



Operating characteristic curves are extremely useful for exploring the power of your quality control procedure. The actual decision concerning sample sizes should depend not only on the cost of implementing the plan (e.g., cost per item sampled), but also on the costs resulting from not detecting quality problems. The OC curve allows you to estimate the probabilities of not detecting shifts of certain sizes in the production quality.

For variable control charts, FlexNet Process Quality Manager includes process capability indices in the summary graph. In short, process capability indices express (as a ratio) the proportion of parts or items produced by the current process that fall within user-specified limits (e.g., engineering tolerances).

For example, the so-called Cp index is computed as:

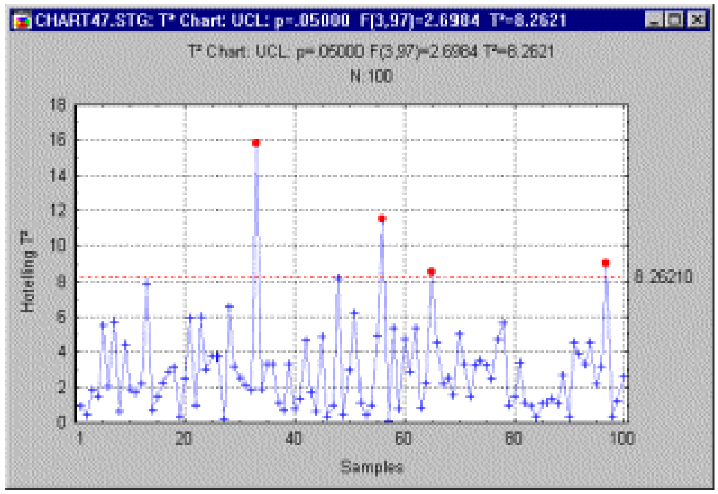
$C_p = (USL-LSL) \div (6 \times sigma)$

Here sigma is the estimated process standard deviation, and USL and LSL are the upper and lower specification (engineering) limits, respectively. If the distribution of the respective quality characteristic or variable (e.g., size of piston rings) is normal, and the process is perfectly centered (i.e., the mean is equal to the design center), then this index can be interpreted as the proportion of the range of the standard normal curve (the process width) that falls within the engineering specification limits. If the process is not centered, an adjusted index C_{pk} is used instead. For a “capable” process, the C_p index should be greater than 1, that is, the specification limits would be larger than 6 times the sigma limits, so that over 99% of all items or parts produced could be expected to fall inside the acceptable engineering specifications.

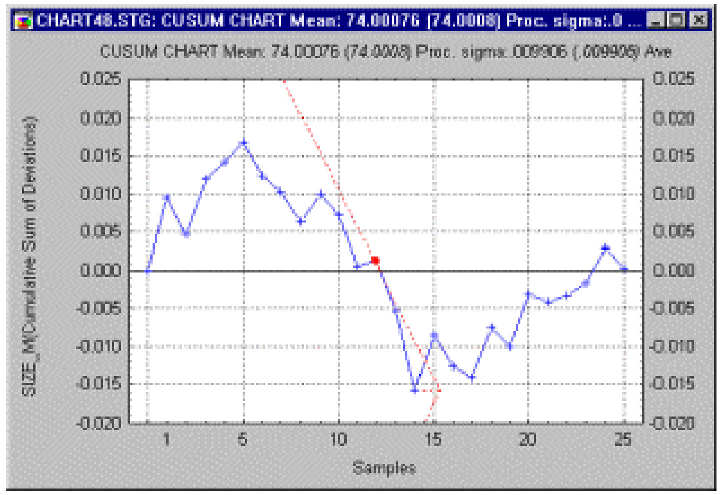
FlexNet Process Quality Manager also produces the following specialized control charts:

- **X-bar Charts For Non-Normal Data.** The control limits for standard X-bar charts are constructed based on the assumption that the sample means are approximately normally distributed. Thus, the underlying individual observations do not have to be normally distributed, since, as the sample size increases, the distribution of the means will become approximately normal. However, when the distribution of observations is highly skewed and the sample sizes are small, then the resulting standard control limits may produce a large number of false alarms (increased alpha error rate), as well as a larger number of false negative (“process-is-in-control”) readings (increased beta-error rate). You can establish control limits (as well as process capability indices) for X-bar charts based on Johnson curves, which allow you to approximate the skewness and kurtosis for a range of non-normal distributions. These non-normal X-bar charts are useful when the distribution of means across the samples is clearly skewed, or otherwise non-normal.

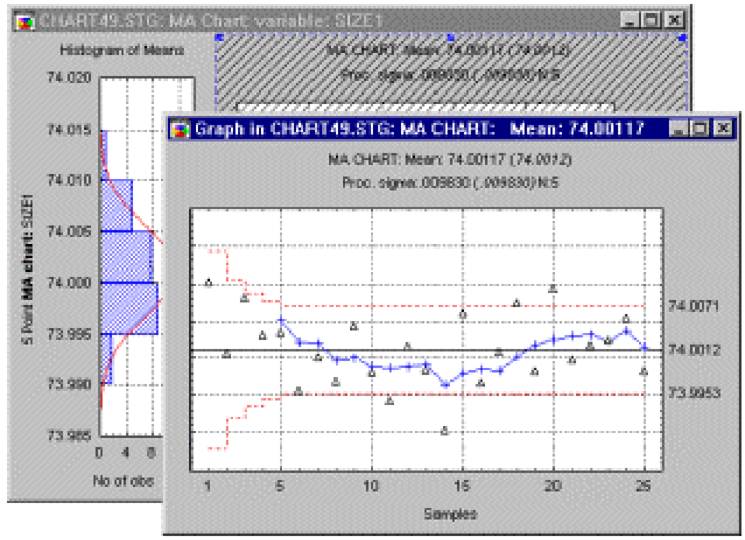
- **Hotelling T**2 Chart.** When there are multiple related quality characteristics (recorded in several variables), we can produce a simultaneous plot (see example below) for all means based on Hotelling multivariate *T**2* statistic.



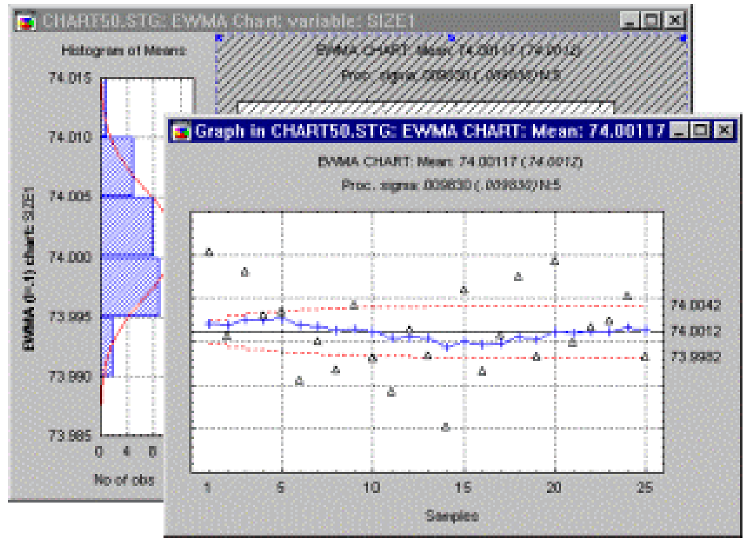
- **Cumulative Sum (CUSUM) Chart.** If you plot the cumulative sum of deviations of successive sample means from a target specification, even minor, permanent shifts in the process mean will eventually lead to a sizable cumulative sum of deviations. Thus, this chart is particularly well suited for detecting such small permanent shifts that may go undetected when using the X-bar chart. For example, if, due to machine wear, a process slowly slides out of control to produce results above target specifications, this plot would show a steadily increasing (or decreasing) cumulative sum of deviations from specification. The V-mask, which is plotted after the last sample (on the right), can be thought of as the upper and lower control limits for the cumulative sums. However, rather than being parallel to the centerline; these lines converge at a particular angle to the right, producing the appearance of a V rotated on its side. If the line representing the cumulative sum crosses either one of the two lines, the process is out of control.



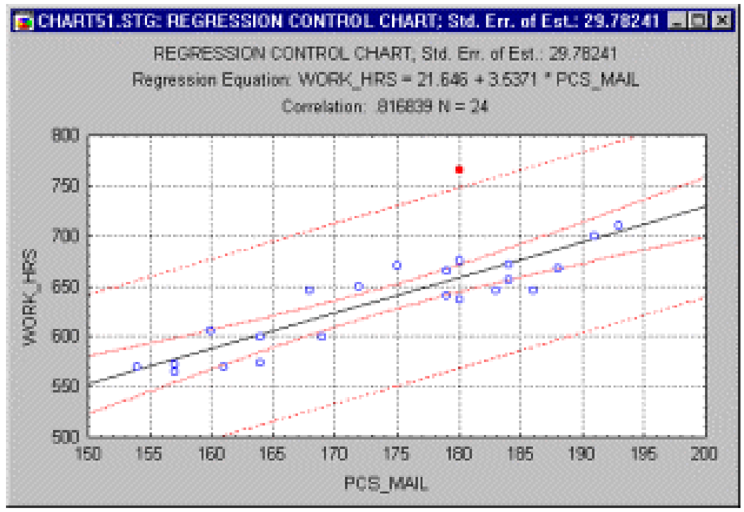
- **Moving Average (MA) Chart.** Returning to the piston ring example, suppose you are mostly interested in detecting small trends across successive sample means. For example, you may be particularly concerned about machine wear, leading to a slow but constant deterioration of quality (i.e., deviation from specification). The CUSUM chart described above is one way to monitor such trends, and to detect small permanent shifts in the process average. Another way is to use some weighting scheme that summarizes the means of several successive samples; moving such a weighted mean across the samples will produce a moving average chart (as shown in the following graph).



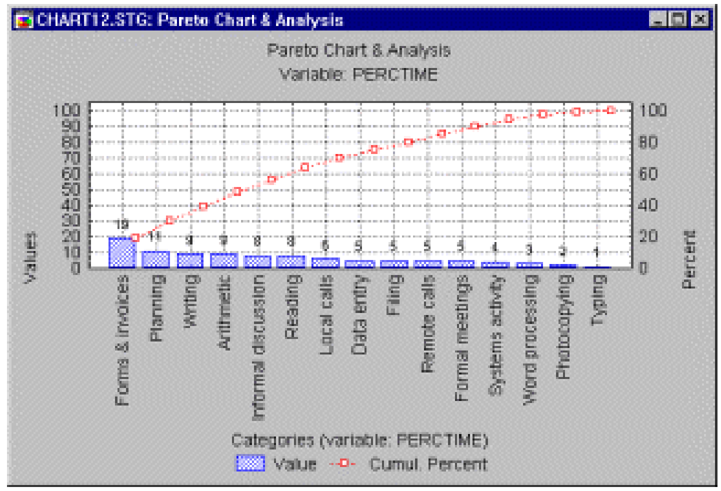
- **Exponentially weighted Moving Average (EWMA) Chart.** The idea of moving averages of successive (adjacent) samples can be generalized. In principle, in order to detect a trend we need to weight successive samples to form a moving average; however, instead of a simple arithmetic moving average, we could compute a geometric moving average. This chart is called a Geometric Moving Average chart. This method of averaging specifies that the weight of historically "old" sample means decreases geometrically as you continue to draw samples. The interpretation of this chart is much like that of the moving average chart, and it allows you to detect small shifts in the means, and, therefore, in the quality of the production process.



- **Regression Control Charts.** Sometimes you want to monitor the relationship between two aspects of our production process. For example, you may want to monitor the number of worker-hours that are spent to make quantities of a particular part. These two variables should roughly be linearly correlated with each other, and the relationship can probably be described in terms of the well-known Pearson product-moment correlation coefficient *r*. The regression control chart contains a regression line that summarizes the linear relationship between the two variables of interest. The individual data points are also shown in the same graph. Around the regression line is a confidence interval within which one would expect a certain proportion (e.g., 95%) of samples to fall. Outliers in this plot may indicate samples where, for some reason, the common relationship between the two variables of interest does not hold.



- **Pareto Chart Analysis.** Quality problems are rarely spread evenly across the different aspects of the production process or different plants. Rather, a few "bad apples" often account for the majority of problems. This principle is known as the Pareto principle, which basically states that quality losses are mal-distributed in such a way that a small percentage of possible causes are responsible for the majority of the quality problems. For example, the majority of losses in most companies result from the failure of only one or two products. To illustrate the "bad apples," FlexNet Process Quality Manager plots the Pareto Chart, which is simply a histogram showing the distribution of the quality loss (e.g., dollar loss) across some meaningful categories; usually, the categories are sorted into descending order of importance (frequency, dollar amounts, etc.). Very often, this chart provides useful guidance as to where to direct quality improvement efforts.



Benefits:

- **Minimizes scrap and rework costs** by alerting supervisory personnel of production processes that are trending out of control — and possibly shutting them down automatically — before defective products are actually made; and
- **Raises quality performance over time** by setting standards and measuring progress toward those goals.

What Are the Important Features and Benefits of FlexNet Material Quality Manager?

FlexNet Material Quality Manager delivers the same capabilities and benefits as Process Quality Manager when inspecting material arrivals, and re-inspecting material in storage or prior to shipment:

- Dynamically creates inspection routings built upon standard inspection processes and operations;
- Automatically chooses and displays the right inspection processes for the job;
- Automatically minimizes inspection rates;
- Collects and analyzes the right quality data with minimum effort;
- Automatically tracks actual quality performance, and alerts supervisors to undertake corrective action; and
- Forms part of a complete, fully integrated quality management and supply chain execution system.

Dynamically creates inspection routings built upon standard inspection processes and operations. FlexNet Material Quality Manager automatically detects which inspection processes need to be undertaken in conjunction with specific logistics and warehousing operations. For example:

- Receiving and dispatch of material from external suppliers;
- Receiving and dispatch of in-process material from outside processors or contract manufacturers;
- Stability testing;

- Re-inspection of perishable or unstable inventory;
- Re-inspection of material prior to shipment; and
- Inspection of material prior to customer shipment, in order to verify that the material meets customer specifications.

These processes are automatically embedded into the inspection routing. FlexNet Material Quality Manager can be configured to electronically dispatch inspectors to exactly the right place, at exactly the right time, on the basis of actual shipping, delivery and re-inspection events.

As inspection activities are carried out, FlexNet Material Quality Manager automatically displays the most up-to-date version of all necessary work instructions — in each worker's own language — on personal computers (PCs), kiosks, and portable or handheld computers. Workers can optionally access supplemental information such as standard operating procedures. The entire inspection process is paperless.

Benefits:

- **Minimizes inspection queues**, and overall fulfillment cycle times, by electronically alerting personnel of the need to inspect product on the basis of actual shipping, delivery and re-inspection events. Personnel are dispatched to exactly the right place, at exactly the right time, as soon as material is available to inspect. Any type of business rule can be implemented to automatically resolve conflicting inspection priorities during the dispatching process.
- **Assures enforcement of the right inspection and quality control procedures**, at all times. FlexNet

Material Quality Manager enforces revision control whenever necessary, and assures that only the most recent approved process documentation is available to production workers and quality control personnel. Process documentation is available in read-only mode only.

- **Automatically Chooses and Displays the Right Inspection Processes For the Job**. FlexNet allows sampling, inspection and material review processes to be defined on the basis of product, product family, product group, customer or customer ship-to location. FlexNet Material Quality Manager automatically chooses the right processes for each material receiver, re-inspection order or delivery order.

- **Automatically Minimizes Inspection Rates**. FlexNet Material Quality Manager allows you to dynamically adjust sampling rates, and automatically trigger second and subsequent dispositions, just like Process Quality Manager.

- **Collects and Analyzes The Right Quality Data With Minimum Effort.** Like Process Quality Manager, FlexNet Material Quality Manager can be configured to collect and validate any amount of material quality data:

You can configure FlexNet Material Quality Manager to automatically perform calculations that convert one or more test readings to test results after data collection, and before quality analysis.

FlexNet Material Quality Manager performs quality analysis on the spot by comparing test results to the characteristics comprising a specification. You can configure FlexNet Material Quality Manager to analyze:

- Variable characteristics, using upper and lower specification or control limits; and
- Attributes, identifying conforming as well as nonconforming results.

Nonconforming results can be classified as critical, major or minor for purposes of alerting people to emergencies and prioritizing corrective actions.

For graded products, FlexNet Material Quality Manager can be configured to assign the right grade to individual material lots or serial-numbered units when their test results conform to the grade characteristic.

FlexNet Material Quality Manager completely automates material review board (MRB) decision-making processes. Inspection processes are tracked according to unique disposition numbers. The creation, labeling, movement, replacement and scrapping of sample quantities can be tracked by disposition number and by container serial number. FlexNet Material Quality Manager automatically keeps a complete audit trail of all test readings and results obtained for each disposition, sample and container, as well as the resulting grades, passes, and failures by reason code, defect code and corrective action code. Because every audit trail entry identifies the responsible production worker or inspector, FlexNet Material Quality Manager complies fully with user identification and authentication requirements such as the U.S. Food and Drug Administration (FDA) 21 CFR, Part 11.

Benefits:

- **Dramatically reduces data collection expense** by eliminating paper reports, and by providing automatic or hands-free data entry methods;

- **Significantly improves data accuracy** and the cost of checking and re-checking data for accuracy;
- **Eliminates inspection and material review queues and lead times** by providing immediate quality analysis, automatic material review and decision-making, automatic grading and dispatching of non-conforming material in real-time; and
- **Assures quality and regulatory compliance** by tracking dispositions and all their related samples, containers, test readings, test results, grades, passes, failures, reason codes, defect codes and corrective action codes — with conclusive identification of all responsible personnel.

Forms Part of a Complete, Fully Integrated Quality Management and Supply Chain Execution System. FlexNet Material Quality Manager interoperates in tandem with Process Quality Manager and the entire FlexNet family of manufacturing execution, warehouse management, logistics execution and plant maintenance solutions. All of these applications share a common database, process definition, business rules, workflow engine and messaging infrastructure.

Processes, business rules, specifications, sampling plans, manufacturing routings and resource details are all stored in the FlexNet database, and are available to all FlexNet applications that require them. This allows you to orchestrate quality control activities in conjunction with quality assurance, receiving, warehousing, manufacturing and shipping processes; to standardize work processes and methods throughout the enterprise whenever possible; and to identify and eliminate non-value-add work from your plants and warehouses.

Likewise, FlexNet Quality Management applications manage inspection and quality control tasks in the same way as all other

FlexNet applications do, providing a single mechanism for dispatching work to employees, sharing resources, and alerting people to events that cut across departments, functional areas and even trading partners. For example, you can implement FlexNet Material Quality Manager and Process Quality Manager not only within your own plants but also at outside processors, giving you the same up-to-the-minute visibility of quality performance and out-of-control processes, as you would have if those operations were done in your own plant. Traditional “point” solutions cannot do this.

Benefits:

- Cuts the time and cost of implementing new production and inspection processes, and switching between processes by sharing a common, re-usable repository of specifications, processes, business rules and messages.
- Facilitates electronic collaboration between enterprises when they manufacture and deliver products jointly.
- Cuts operating expenses and raises productivity throughout the enterprise by simplifying work processes and eliminating non-value-add work.

Conclusion

Apriso stands at the forefront of software vendors who are developing new generation Web services applications to support collaborative business processes over the Internet. FlexNet Quality Management applications are an essential part of an integrated family of Web services applications that enables manufacturers to:

- Improve productivity by eliminating scrap and rework costs;
- Minimize re-inspection and inventory obsolescence costs;
- Minimize inspection costs; and
- Minimize record-keeping costs while complying fully with quality control procedures.
- Continually improve quality and cost performance.

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