Total Quality Management - I
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Lecture – 34
Introduction to ISO 9000

A warm welcome to my friends and dear students, this is the TQM 1 lecture notes or discussions for the under the NPTEL MOOC program, and this is the 34th lecture which I am going to teach and we are doing this course where were discussing about the charts and all the implications and I am Raghunandan Sengupta from IME department IIT Kanpur.

So, continuing the reproductability and all these discussions to introduce some of the basics ideas of measurement system analysis.

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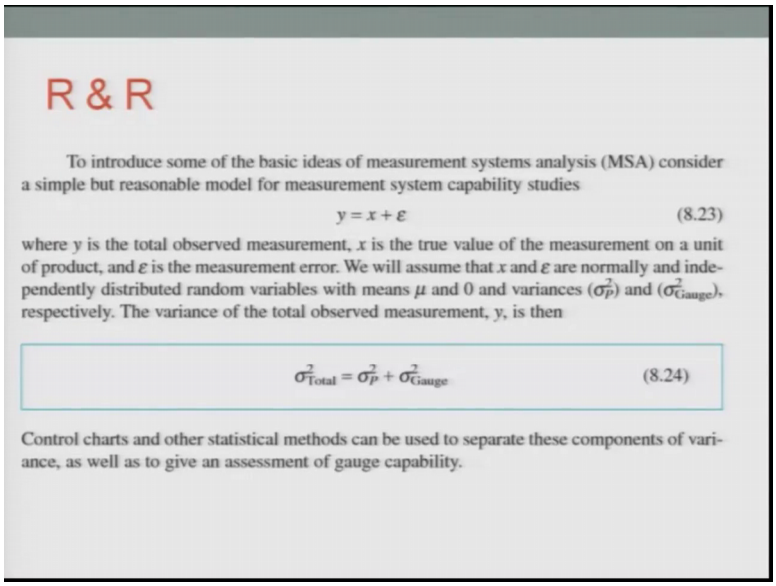

So, consider that a very simple, but reasonable model is given by the so called very simple equation which is y is equal to x plus epsilon. So, the epsilon is the error so; obviously, when your measuring y with respect to x they would be error, which can be both plus and minus. So, where y is the total observed measurement x is the true value of the measurement on a unit of product and epsilon is the measurement error. So obviously, you have to find out that what is and have some assumptions about the errors distribution.

So, we will assume that x and epsilon are normal normally distributed with mean being the values of 0 and 0 for the case of the epsilon and mu being mu or mu x suffix x being the mean value of x, and they are normal normally distributed and independently distributed random variables so obviously, addition have two random variables which are normal would also and in a random distribution which are normal in nature. So, hence y would also be normal distributed.

Now the variance of x is given by sigma square suffix p and the variance of the error is given by sigma square the of the of suffix gauge. So, actually it means the error of measurements which can come from the gauge. So obviously, we will understand they would be plus minus, but in the long run the average value basically comes out to be 0. The variance of the total observed values would definitely be some of them the reason being they are independent. So, any covariances existing between x and epsilon x would be 0.

So, control charts and other statistical methods can be used to separate these components of variability as well as to give an assessment of the gauge capability and take decisions accordingly.

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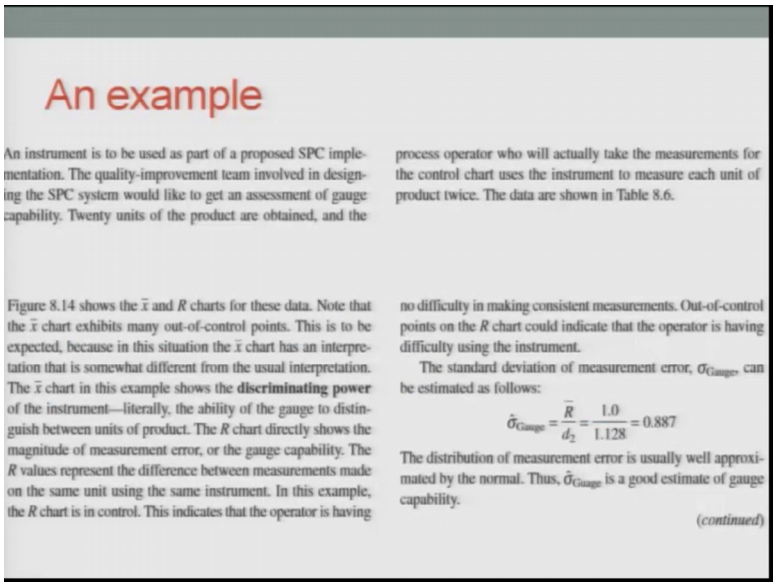

So, let us consider an example; an instrument is to be used as part of the proposed SPC implementation or statistical process quality controlled charts implementation. The quality improvement team involved in designing the SPC system would like to get an

assessment of the of gauge capability, and 20 units of the of the products are obtained and you will have in the book that book which is their visit mount economy, which I mentioned in figure 8.14 shows the x bar and the R charts for these data.

So, note that the x bar charts exhibits many out of control values this is to be expected obviously, because in this situation x bar chart has an interpretation that is somewhat different from the usual interpretation of analysis. The x bar chart is in this example shows the discriminating power of the instruments, which means literally the ability of the gauge to distinguish between the units of products. So, if obviously, they would been error. So, the error is coming from measurement error or from the gauge error has to be basically thought and analyze in depth.

The r values which is the range values represent the difference between the measurements made of on the same unit using the same instrument, in this example the R chart is which should be in control so obviously, because the range values which is happening r do not have that amount of variability they average value can changed, but the range variability r within the midst. So, this indicates that the operator is having a process operator who will actually take the measurements for the control charts, and uses the instrument to measure each unit of the product twice.

So, those information is given in table 8.6 of Montgomery. So, what we need to do is that the it indicates the operator has no difficulty in making consistent measurements, now took of points on the R charts could indicate that the operator is having difficulty using the instrument in measurements. The standard deviation is given as usual by as the sample size is, you find out small d two suffix 2 and divide R bar by d 2 and you find out 0.887. So, the distribution of measurement error is usually well approximated by the normal distribution even though that is technically may not be true because as I mentioned very flittingly long time back in this in lecture series of TQM 1 that the that chi co square distribution with the best fit, when you are trying to measure something and find out the distribution for the standard deviations of the variances.

So, thus we will can conclude in this example speaking this approximation that the sigma hat of the gauge is good estimate of the gauge capability and you can use that gauge accordingly depending on the variability which you have.

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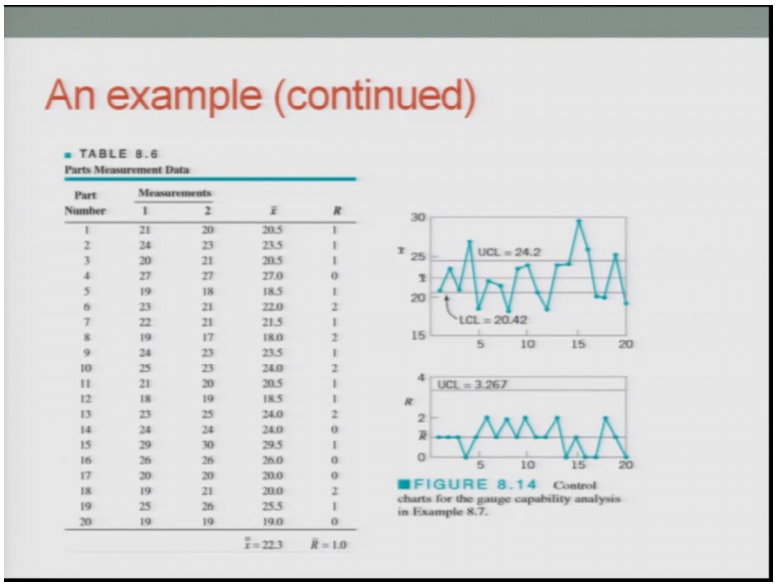

So, the tables which I have just discussed now it will make sense. So, the part numbers are given in the first column, on the measurements are given 1 and 2 which is the second and the third column. So, say for example, for row 1 the measurements are 21 and 20. So, from there you find out x bar which is basically sum of that divide by 2 comes out to be 20.5 and the range is basically 21 minus 20 which is 1.

Similarly, if I go to the twentieth data point which is the last row, the measurements are 1990 in the average is 19 and the range is 0. So, from that when I basically find out and drew the control charts. So, the first chart which I have in front of me sorry I just missed it. So, the first chart which is there which is highlighted yellow. So, I am just trying to highlight it, and this colour yellow being not that distinct you are able to discriminate the chart which is drawn along with the highlighted part.

So, you are trying to machine measure x bar along the y axis along the x axis you have the reading number part number, and the graph shows the UCL values is 24.2 and the all sale value is basically 20.42. So, there are many points which are above and below the control limits. When I do the, but drawing for the R charts of. So, similarly I have the R values and I find out the UCL which is 3.267 and the LCL is 0 based on that when again I draw, again I am trying to highlight our circle this R charts are there and from that you can do the studies accordingly.

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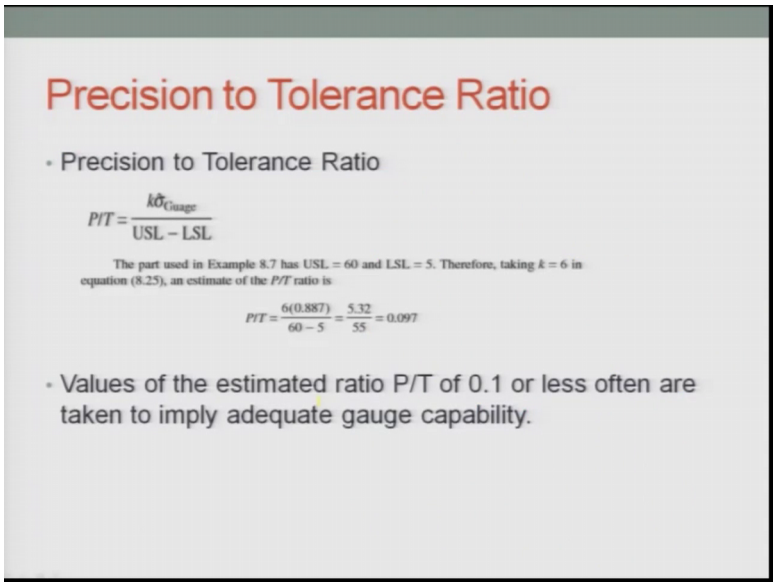

So, now, I want to find out the precision of tolerances. So, that would be if you remember I have consider if I did mention time and again it was basically two sided or one sided for the two sided one I found of the difference between the upper control minus the lower control and divided by 3 sigma, depending on the level of some confidence which is there and the coefficient being 3 because you have want to cover about 99 percent of the area would be the 6 sigma concepts. The coefficient would be 2 depending of on the overall coverage being 95 percentage of the area and similarly you can do the calculations accordingly.

So, the precision how to tolerance ratios which is given P by T is given by the constant k multiplied by the standard deviation estimate, divided by the difference between the upper control and lower control for the both sided parts. So, this this this upper control and the lower control values are given as 60 and 5 from there you find out the value of precision to tolerance ratio as 0.097. So, with the value estimated ratio of 0.1 or less often taken to imply adequate gauge capabilities such that you are aware that the gauge is able to take care of the work for which its being assigned to do the take the readings.

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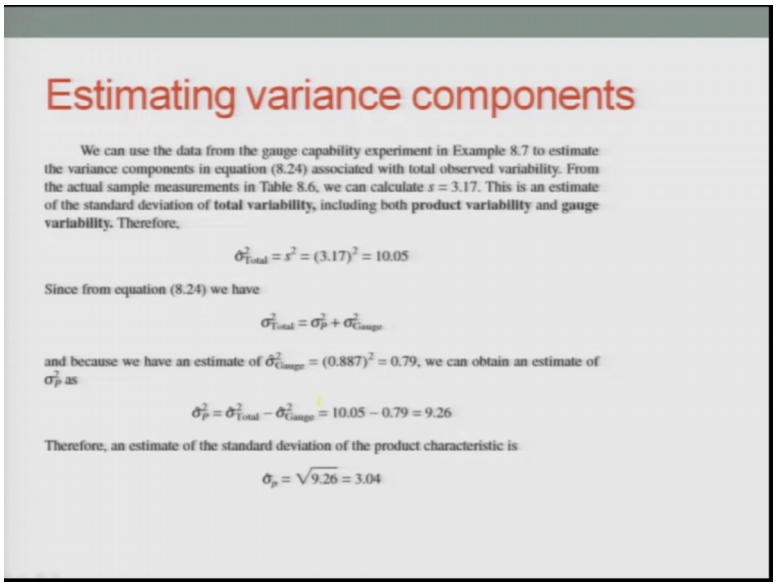

So, further on if you want to estimate the variance components, we can use the data from the gauge capability as shown in the example 8.7 to estimate the variance component and the equation as I mentioned was 8.24 in the book of Montgomery, and which it with it is associated with total observed variability. From the actual sample measurements given in table 8.6 we can calculate the standard error which is for the sample comes out be 3.17.

This is in estimate of the standard deviation of the total variability including both product variability and the gauge variability. So, that you want to basically find out if you remember I did mentioned adding up the standard deviation or adding up the variances is allowed not adding of the standard deviations or not for the variances allowed not for the standard deviations. So, the total variability is given as 10.05, we already know that there is the sum of the process for the gauge, the gauge comes out to be 0.79 from there we find out 9.26 is the process one, and thus we estimate the standard deviation of the product characteristics out from based on which we are trying to for which we are trying to measure that comes be about 3.04.

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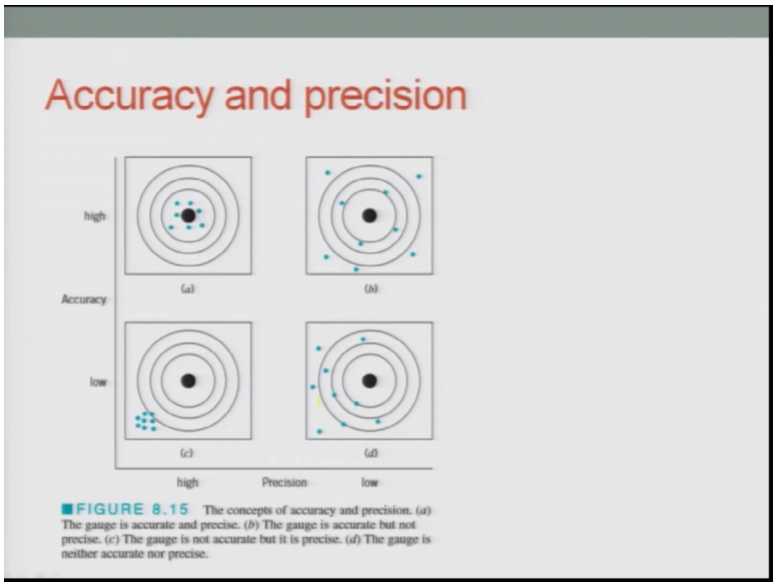

So, if you want to understand in a pictorial way the accuracy in the precision. So, it gives you the as the figure mentions it gives you the concept of accuracy and precision in figure a the gauge is accurate and precise in b the gauge is accurate, but not precise in figure c the gauge is not accurate, but it is precise and gauge d it is neither accurate not precise. So, if you concentrate on the diagrams it will give you.

So, it may be wrong, but if you keep repeating taking the wrong estimate on wrong reading; obviously, it means that my actual gauge calibration has been done very wrongly, but still it is accurate because able to find out precision values is very high because is able to basically find out the values which are actually concentrated in around the value which is being calculated. So, that value may be wrong. So, that is the secondary question.

So, if you concentrate on figure one. So, they are actually write because they are in around the actual value which is the red dot shown quite big here and they are all concentrated in around the black dot which means that they are quite precise in their estimation. In the second case the gauge is estimate accurate because all the values are concentrated in and around the black dot, they are scattered the scattered part is very high which means the precision is low.

In a second case the precision is very high because again they are concentrate in around some actual value, but that actual value by itself is wrong. So, which is the third diagram

and in the fourth one they are actually all scatted in such a direction that if I want to find out the average also some central value for that, that is actually totally remove from what the actual value would be. So, again repeating first one is accurate and precise b is basically accurate, but not precise c is basically not accurate, but precise and d is none of them; that means, it is neither accurate not precise.

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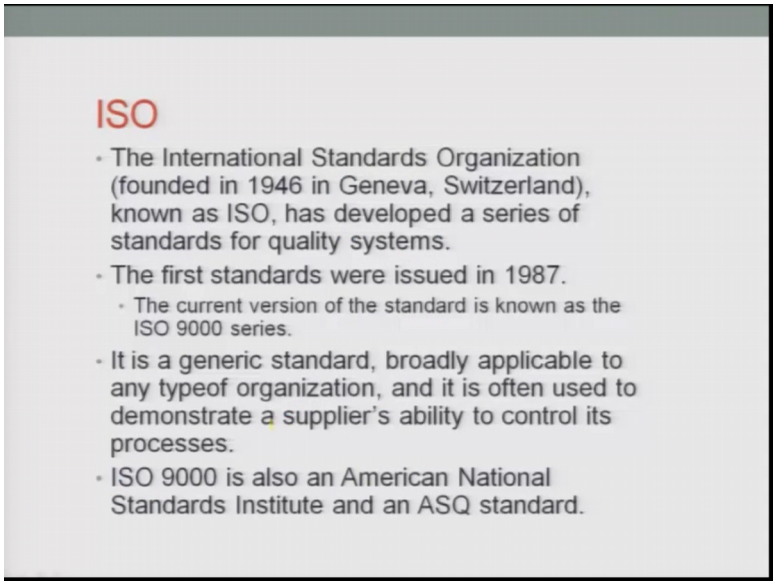

Now, we will consider something and I am go into some little bit in depth about ISO. So, which is the international standard organization data and the relevance of that. So, it was founded in 1946 in Geneva in Switzerland and is known as the ISO and it is developed a series of standards for quality systems. The first standards were issued in 1987 and the current version of standard is also known as ISO 9000 series.

So, it is a generic standard broadly applicable to any type of organization is often used to demonstrate a suppliers ability to control its processes. So obviously, if I have an ISO standard certification which means that and if I show it to my customers who are trying to basically buy some product from me so; obviously, it will give the level of confidence to the capability of workmanship I have with its services products whatever it is. ISO 9000 is also an American national standards institute is equivalent form and is known as the a and has a standard which is known as the ASQ standard.

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So, three standards for ISO 9000 are ISO 9000 2 semi colon 2000 which basically deals with quality management systems and fundamentals and vocabularies are basically del there.

Then ISO 9001 2000 basically gives you the quality management system and its requirements, and the last one ISO 9004 2000 basically gives you the quality management systems guidance and how to basically perform and try to being improvement in the whole system.

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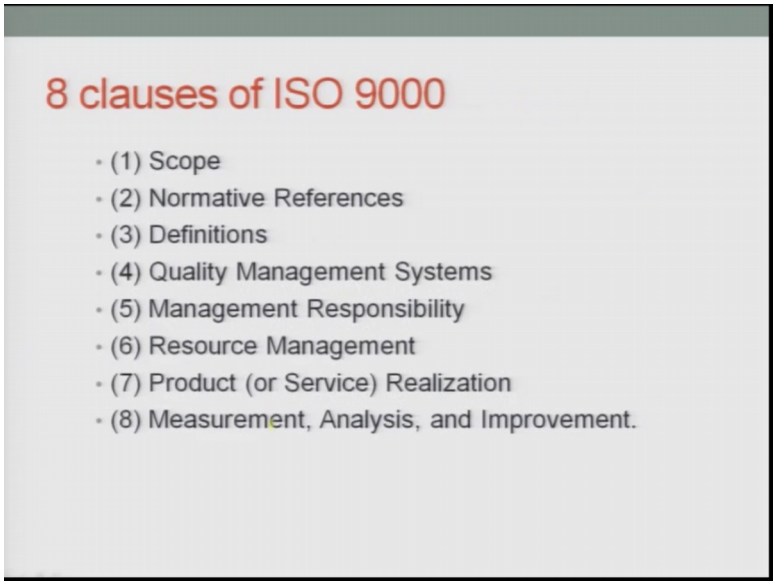

So, now they are basically eight clauses of ISO 9000. So, one is basically the scope, second is the normative references, other is the definitions. So, you basically have to define your actual work which you are trying to do, the quality management systems are to be discussed the management responsibility have to be defined and basically laid out in very clear terms. The resources management based on which the work could be done this also need to be specified product and services realization when what we want to achieve and based on what from where you are proceeding should definitely be made in in made aware to both the customer and the supplier. That means, supplier and customer I means one is giving some product or services and always be acquiring it being some money.

So, it also be related to the class would be measurements and analysis and how the improvement should be made in the ISO system, that should basically be a clause there in ISO 9000 set of nomenclature.

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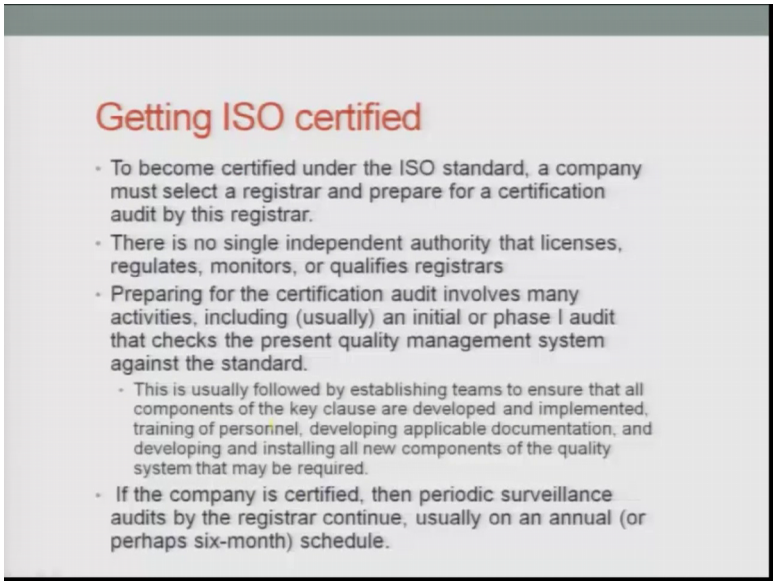

So, getting the ISO certificates the general things and the and the schematic we how you proceed is that to become a certified a user under the ISO standard system a company must select a registrar and prepare for a certification audit by that particular registrar.

So, now registrar will come have we setup procedures based on which the analysis of the company and its facilities and the product should be done and based on that the next step of action whether that ISO certificate should be given or not or whatever the

improvement should be done should be analyzed. There is no single independent authority that gives you the licenses regular or regular some monitors or qualifies as the registrar. So, it may be the area of manufacturing, it can be area of services, it can be for the doctors, for the hospitals, nurses whatever it is. So, then it becomes preparing for the certification audit involves many activities which includes and initial or phase one audit that checks the present quality management system and basically finds out what were the improvements need to be done and how things can be improved.

This is usually followed by establishing teams to ensure that all components or the key clause have been developed and they have been implemented, and training of the person have been done and developing applicable document should also be ready. So, they if we if we have a set of document which is basically theory right theoretically right and if you doing a problem formulation of trying to solve it practically, if there is huge amount of difference in trying to basically do that work then; obviously, it becomes a problem or maybe say for example, theoretically the procedure which you have set may not be actually attainable theoretically not possible, but he still you are doing the your caller improvements right so; obviously, they should be some dichotomy they are which needs to be basically bridged and actions should be taken such that actual practical concept comes into the picture.

So, let me read it and continue reading it. So, this is usually followed by establishing teams to ensure that all components of the key clauses are developed, and the implementation part is taken care of, training of personnel have been taken care of developing applicable documents and developing and installing all new documents and components of the quality systems that we did that may be required is to be done. If the company satisfied or about the policies that means, the registers who come and do the work and in the company certified then the periodic surveillances is done.

So, say for example, if I am a manufacturer I am producing gas kits, and I have a set policies of ISO 9000 whatever the improvement scheme is based on their standards and may companies following it. So, now obviously, registered will come do analysis check with there is variability what are the overall scheme based on which the work is been done, the work can be related to quality of product, can be related to quality of say for example, the shop floor maybe how safety equipments are being kept how safety issues are taken care of, what is the overall humidity like environment in which people are

working on environment which the products are being produced, how they are towards standard they are being met, it they may also deal with the level of say for comfort the workmanship have with respect to the facilities which has been giving it may be mess it can be water it can be food whatever it is, because there is a collective things which has to be analyzed.

So, if the government company gets the go ahead that certificate should be given then they certified, then the periodic surveillance needs to be done because if the company has got the certificate and the workmanship they some aberrations. Obviously, in that case the ISO certificate is not being fulfilled or not being implemented to the maximum core concept based on which it has been issued. So obviously, it has to be studied some corrective actions needs to be taken. So, which means that these periodic surveillances should be done audit should be done by the registrar and it should continue usually on an annual or perhaps 6 months basis depending on the frequency of a level of which has been planned.

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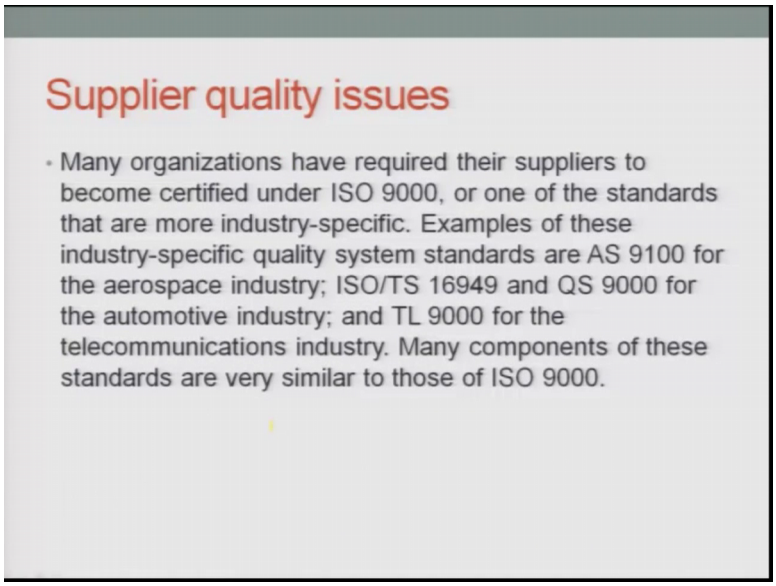

They would be quality supplier issues also. So, many organizations have required the suppliers to become certified ISO 9000 keep set of companies, which means that if I am sure that my supplier of the vendor to whom I am suppling based on these mutual understanding. So, if there are ISO 9000 certified companies which means the level of confidence based on the quality level on different aspects, services, then products been

produced raw materials, vendors, financial systems are all in place. So, there is a big normal field normal stage based on which the analysis can be done. So, both the supplier both the vendors and the companies everybody satisfied to the level of qualities methodology which everybody is following.

So, many organizations have required their suppliers to become certified under ISO 9000 or one of the standards that are more industry specific. So, for manufacturing sectors or set of ISO certification should be used for service sectors are different set of service ISO 9000 certification should be used. Examples of these industry specific quality system standards is AS 9001for aerospace industry ISO TS 16949 and QS 9000 for automotive industry then TL 9000 for the telecommunication industry, many components of this standard are very similar to the ISO 9000 which is the base set of rules and regulations based on which the quality improvements and the quality structure is analyzed or some plan is made based on which the companies can follow that accordingly.

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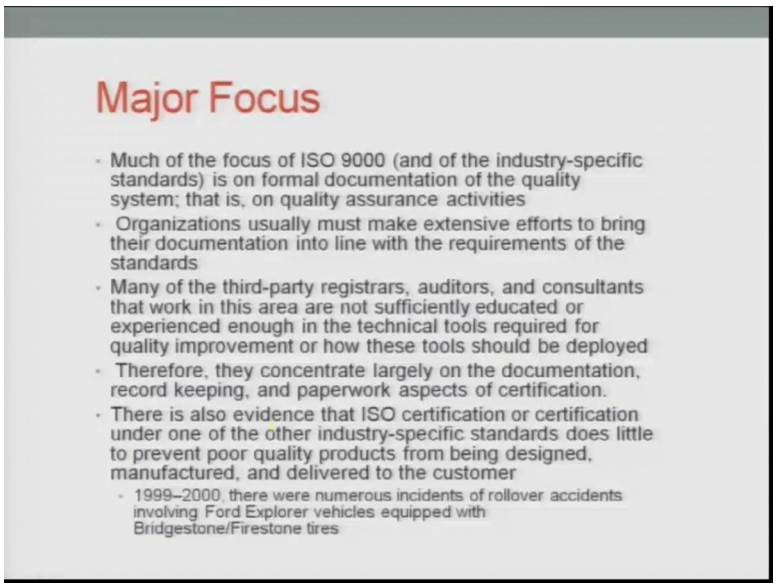

So, main major focus of the ISO 9000 are and of the industry which are basically let me continue reading it and or the industry specific standards are is on a formal documentation of the quality system, that is on quality assurance and then the activities. Organizations usually must make extensive efforts to bring their documentation in line with the requirements of the standards, many of the third party registrars auditors and consultants that work in this area are not sufficiently educated or experienced, enough in

this technical tools required for quality improvements on how or how this tools should be deployed.

Therefore they concentrate largely on documentation, record keeping and paper works aspects of the certification. So, rather than actually looking into the quality aspects which is the actual core issue, people are more interested trying to basically check whether the eating space of the of the workman or the employees are proper or whether cleanliness is there or whether the paper documents have been maintained properly without going to the actual core issues, which should be analyzed and studied in depth in order to dare to the basic philosophy and the properties of ISO 2000.

So, as it mentions therefore, they concentrate more on the documentation part record keeping and the paper work aspect of certification rather than doing the actual work. There is also evidence that ISO certification or certification processes under one of the under one of the other industries specific standards does little to prevent poor quality products from being designed, because in that case it may be possible that the ISO certifications concept have been implemented in such a way that the poor quality has become a part and parcel of the company as such.

So, considering given an example in 1999 to 2000 there were numerous incidents on rollover accidents involving ford explorer vehicles equipped with Bridgestone and firestone tires, even if for both of them or all the companies ISO certifications have been tempted and they as for the norms were working or on the manufacturing of the surface is about being delivered according to the ISO 9000 standards.

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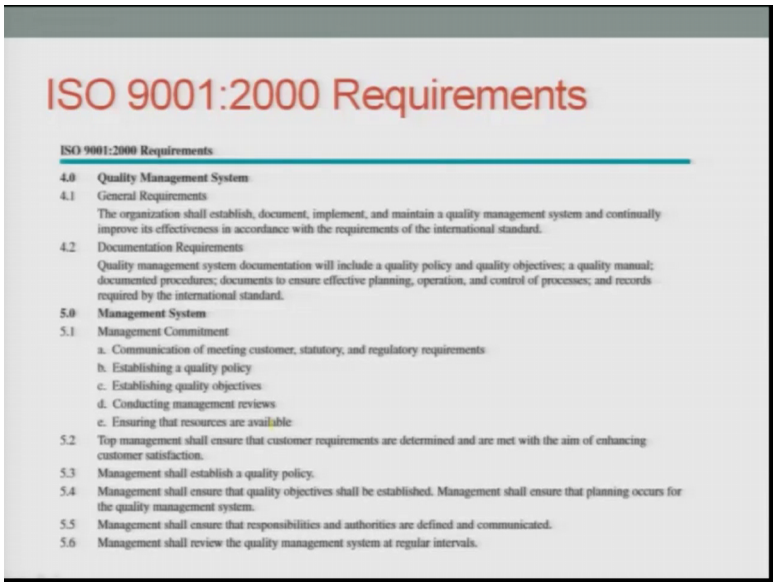

So, ISO 9001 and 2000 requirements are quality management system should be deployed and it should be implemented, general requirements are the organization shall establish documents implement and maintain a quality management system and continued improve on it or make a conscious decision how this can be maintained the overall philosophy can be maintained or improved further on. So, improve is effectiveness in accordance with the requirement of the international standards, documentation requirements would be done in such a way that quality management system documentations will include a quality policy and quality objectives, a quality manual or of documentation should be there such that documents ensure effective planning, effective operations, effective control of processes and records required by international standards.

They should be a management systems also which should include management management commitment level communication of meeting the customers which is basically statutory and regulatory requirements are as are there as per the ISO 9001 2000 series, they should be establishing a policy for quality policies and policy implementation should be there establishing quality objective. So, what you want to achieve that should also be clearly available. Ensuring that the resources are available in order to implement the quality improvement aspects which are being planned top management should ensure the customer requirements are determined and are met with the enhancing customer satisfaction.

So; obviously, the concept of quality should rather than going from the bottom should come up from the top such that if the co or the company owner or the chairman are actually require a very quality conscious, and they want to implement that then basically trying to implement that on the shop floor and actually in the service sector, actually in the accounts, actually in the raw materials and purchase, actually in the marketing area that becomes much more easier.

So, management shall establish a quality policies and the system, management shall ensure that the quality objective should be established, management shall ensure that planning occurs for the quality management systems and people are aware of that management should ensure that responsibility and authorities are defined accordingly such that there is no overlap and obviously, the work can done in accordance to the quality improvement policy which has been followed by the company and as per the ISO 9001 concept of trying to improve the quality.

Management shall review the quality management system on a regular basis and corrective actions should be taken as required. So obviously, if things as I said the registered does the work and then after 6 months or one year the rechecking is done, rather than alloying the system to falter if it is best, if the management themselves do the analysis in such a way that when the registrar comes people we thinks are put up in a much better prospective considering the overall quality principles or philosophies the company has.

To further consider the points mentioned on ISO 9001 you have the resources of management. So, they would be basically organizations shall determine and provide resources the need as they are required for the quality implementation, the workers will be provided necessary education trainings skills and experience to basically maintain the level of quality, the organization shall determine provide maintain the infrastructure needed to achieve the conformity to product requirements.

The organization shall determine the and manage the work environment needed to achieve conformity and for continuing further on they would be product a service realizations, which would basically consider the organization shall plan and develop process and methods, they shall plan and method determine requirements as specified customers, they should basically have design and development of it product or services,

there purchase materials of product conformity should be there as per the standards, then the they should be a monitoring a measurement of the to be undertaken or a regular basis, measurement analysis and improvement should be there which should basically implement and monitor and measure the existing process how they are being implemented.

The organization shall monitor the information related to the customer preparedness proceptions and how they are basically been implemented. The organization shall determine collect and analyze customer satisfaction, customer data, conformation data trend data and how things can be done in the proper way as per the ISO 9001.

So, with this I will end this lecture and continue discussion about ISO in very brief, and basically solve some major problems in the last few lectures of the course of TQM. Have a nice day.

Thank you very much.