Regulatory Requirements for Medical Devices Including In Vitro Diagnostics in India (Version 2.0)

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Lecture – 09
ISO 14971 (Medical Devices – Application of Risk Management to Medical Devices)

Now, welcome to Regulatory Requirement for Medical Devices including In Vitro Diagnostics in India, version 2, lecture 9, that is ISO 14971:2007, that is the Medical Devices Applications of Risk Management of the Medical Devices.

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Learning objective- be aware what is the risk management applicable for the medical devices and in vitro diagnostics.

Expected outcome- We will able to understand the standards applicable for quality risk management of the medical devices, a scope of the standards definitions related to Quality risk and tools for the risk assessment process.

Target audience- the personal working in the medical devices and in vitro diagnostic industry,Innovators or a startup involved in the manufacturing of medical devices or in vitro diagnostics, Regulatory Affairs Personnels, Human Ethics Committee members,

Clinical Trial team (CTT), Researchers, Academicians, A Students and the person generally interested in the field of medical devices and in vitro diagnostics.

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What will we learn in this lecture? We will understand what is the Risk Management, what is the Risk Management Process (RMP), standards for the risk management process, what is the standards available the definitions applicable for risk management and the general risk requirement for the risk management. In this lecture be the though this subject is very important subjects, but we cannot discuss that lecture in details because of time constraint.

So, I will give the overall scope of the standards, what are the component of the standards, what is the Risk Management Process, what is the tools for risk assessment? We will discuss, but the details you can refer the website for having detailed knowledge and information about the Risk Management.

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In this risk management that standards, the purpose of the risk management is to achieve the safety, safety of the devices that is the device should be free from unacceptable risk. Technically the identification assessment and prioritization of risks associated with the device we can evaluate through that Risk Management Process.

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The International Standards which was developed specifically for the medical devices and the system manufacturers using the established risk management principles, the standards which laid down by the ISO 14971. This is standard that is for the

manufacturers of medical devices and in vitro diagnostics. For other manufacturers other than manufacturers, the other Health Care Professionals industries, they can use these standards as a informative guidance in developing and maintaining the risk management system and process.

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History of the standards, the evolution of the ISO 1497 that is the standards for risk management of the medical devices, the first edition of this standard was published in the year 2000 before that there is no specific standards applicable for risk management process of the medical devices or in vitro diagnostics. After publication of this risk management standards in 2000, to most of the country have adopted this standards the manufactured man of the medical devices and in vitro diagnostics.

They have also adopted these standards, the second version of this standard, which standard was revised after 6-7 years and in 2007 2nd edition of the standards was published. Another publication in 2012 that is European Union (EU) harmonized standards with respect to the ISO 14971 that was published in the line of the European Union Harmonizations.

This particular edition that is in 2012 which was published with objective it should be only applicable to the European Union members. Rest of the world the 2007 edition of the standards is only applicable, but for European Union this 2012 version is actually meant for adaptation by their member economy and this 2012 version is harmonized with

the three European directives associated with the medical devices, active implantable devices and in vitro diagnostic devices.

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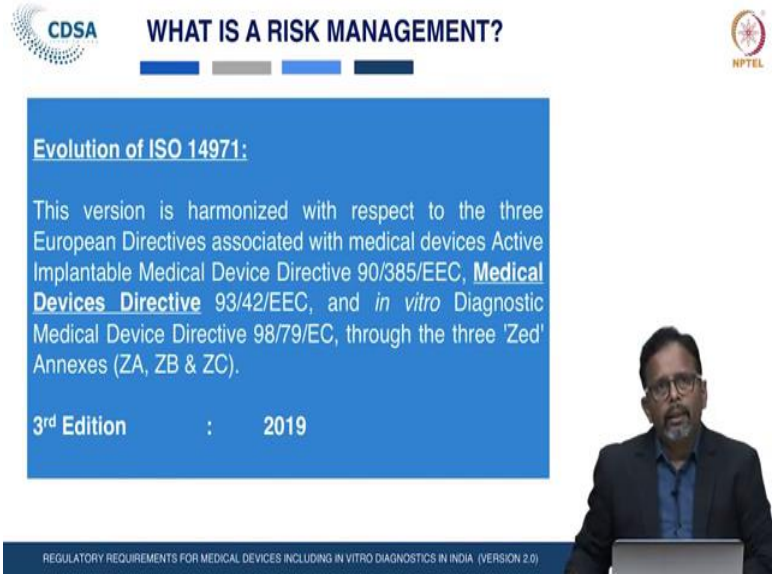

And then recently in 2019, the latest edition of the standards that is the 3rd edition in 2019 was published.

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Clause	ISO 14971:2007 EN ISO 14971:2012	Clause	ISO 14971: 2019
1	Scope	1	Scope
2	Term & Definition	2	Normative Reference
3	General Requirement for Risk Management	3	Term & Definition
4	Risk Analysis	4	General Requirement for Risk Management
5	Risk Evaluation	5	Risk Analysis
6	Risk Control	6	Risk Evaluation
7	Evaluation of Overall Residual Risk Acceptability	7	Risk Control
8	Risk Management Report	8	Evaluation of Overall Residual Risk
9	Production and Post Production information	9	Risk Management Review
		10	Production and Post Production Activities

If you compare the old version of the standards that is ISO 14971:2007 and the recent one that is ISO 14971:2019 what are the difference? What is the major difference between these two standards. in that there is no major difference. As per as the clauses of

the standards is applicable only one new clauses, one new clause that normative reference that has been included in the new version. in the earlier version of 2007 the normative reference is not there, but the other clauses that is the clause 1 is scope, that means same terms and definition that becomes 3rd clause in the 2019 editions.

The general requirement for risk management that is clause 3 that is also same in the new version of the standards, the risk analysis clause 4 that becomes clause 5 in the new versions, the clause 6, clause 5 that is risk evolution that becomes clause 6 in the new versions, clause 6 that is the risk control of the old version becomes clause 7 of the new version of the standards.

Clause 7 of the old version that is the evolution of overall residual risk acceptability, with the slightly modification in the title of the clauses that has been changed to clause 8 of the new version and that is renamed as the evolution of the overall residual risk. acceptability has been removed in the new standards and the clause 9 that is the last clause of the old version that is production and post production information that becomes clause 10 in the latest version of the standards and it has been renamed as production and post production activities information has been replaced with the activities.

And the risk management report that is clause 8 of the old version that becomes clause 9 of the new version and that risk management report has been renamed as the risk management review. Only these minor changes in the clauses,This new version of the 2019 has come up the major changes what they have incorporated in the new standards.

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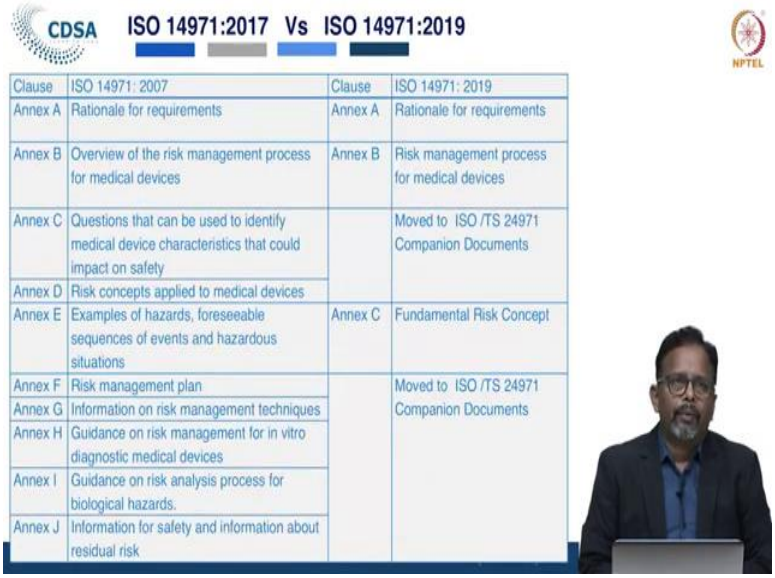

Clause	ISO 14971: 2007	Clause	ISO 14971: 2019
Annex A	Rationale for requirements	Annex A	Rationale for requirements
Annex B	Overview of the risk management process for medical devices	Annex B	Risk management process for medical devices
Annex C	Questions that can be used to identify medical device characteristics that could impact on safety		Moved to ISO /TS 24971 Companion Documents
Annex D	Risk concepts applied to medical devices		
Annex E	Examples of hazards, foreseeable sequences of events and hazardous situations	Annex C	Fundamental Risk Concept
Annex F	Risk management plan		Moved to ISO /TS 24971 Companion Documents
Annex G	Information on risk management techniques		
Annex H	Guidance on risk management for in vitro diagnostic medical devices		
Annex I	Guidance on risk analysis process for biological hazards.		
Annex J	Information for safety and information about residual risk		

In earlier edition of the ISO 14971:2007 the standard have annexure A- J that is almost 10 different annexures was incorporated in the earlier version of the standards, however in the new version in 2019 only 3 annexures are there. Annexure 1 and annexure B that remains same which is already in the earlier version that is 2007 version of the standards annexure C, annexure D and annexure F, G, H, I, J that has been replaced with ISO TS 24971 that is the companion document separate documents have been incorporated in the new version by merging of these annexures and annexure C of the new version that is the Fundamental risk concept.

This is the only 3 annexures are there, remaining Annexures have been replaced with the guidance document of the companion document that is ISO TS 24971. These are the major changes of the latest version of this ISO 14971.

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Now, the objective of this 14971 this International Standards was developed specifically for the medical devices and medical system manufacturers using the established principles of risk management.

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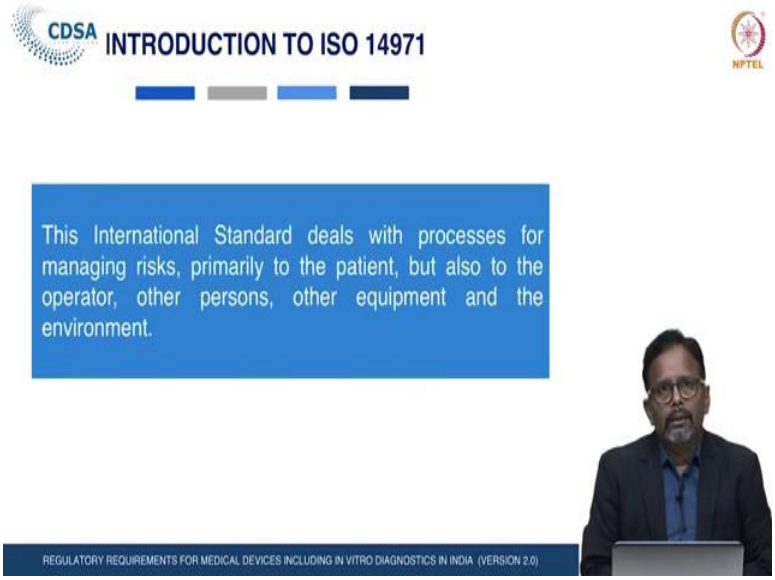

The main objective of this is standards is that and also this international standards deals with the processes for the managing risk primarily to the patient, but also to the operator, other persons, other equipments and the environment. It is not restricted only to the particular devices or the manufactures.

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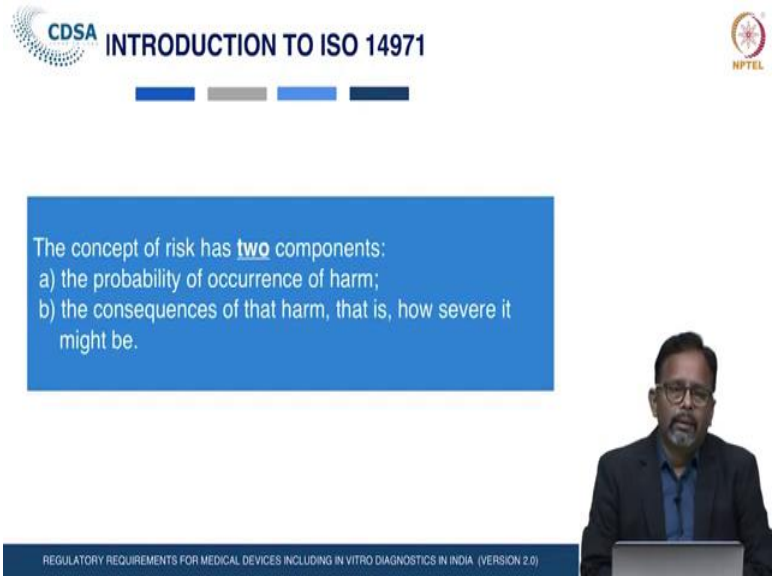

The concept of the risk has two components as per this standard. The one component, first component is the probability of the occurrence of the harm and the another component is the consequences of that harm that is how severe it might be. This is the major component of this standard and based on the probability of the occurrence of harm and the consequences of harm, the risk assessment of the devices can be done by the manufacture of the medical devices.

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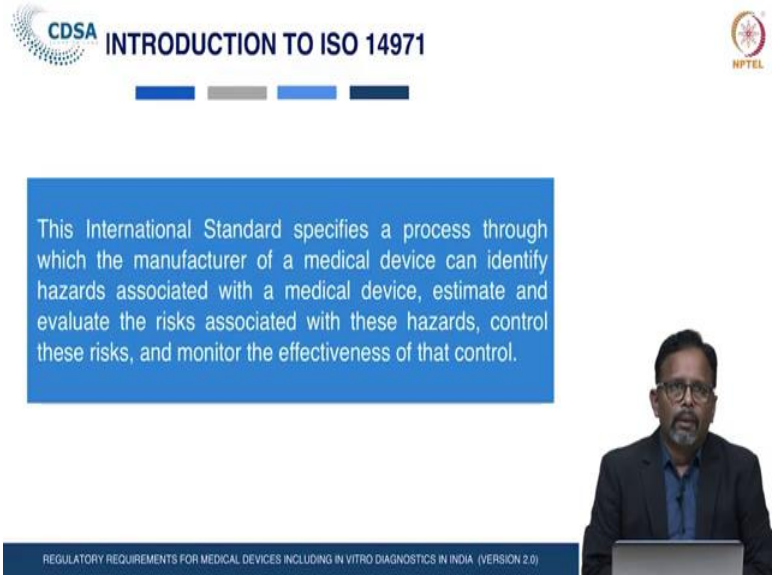

This International Standards also specify a process through which the manufacturer of the medical devices can identify the hazards associated with their medical devices, the estimate and evaluate the risk associated with these hazards. They will control this risk and monitor the effectiveness of that control.

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This Standard is applicable to all the stages of the life cycle of the medical devices and it does not apply to the clinical decision making and this is International standard does not specify the acceptable risk level. This is the limitations of this risk ISO standard 14971.

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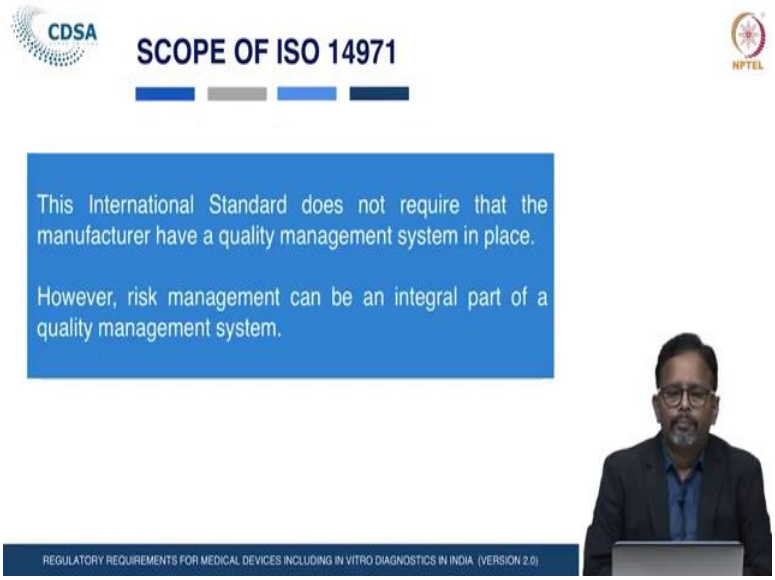

Though this standard does not require that the manufacturer should have the quality management system in place, however the risk management is the integral part of the Quality Management System(QMS).

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Certain terms and definitions that class 2 of the standards where in several definitions related to the risk management has been mentioned. certain definition like harm. What is harm? As per this standard, harm is defined as the physical injury or damage to the health of the people or damage to the property or the environment that is called as harm.

Hazards that has been defined as the potential source of harm. Hazards situation the circumstances in which the people, property or environment are exposed to one or more hazards that is called as the hazardous situation.

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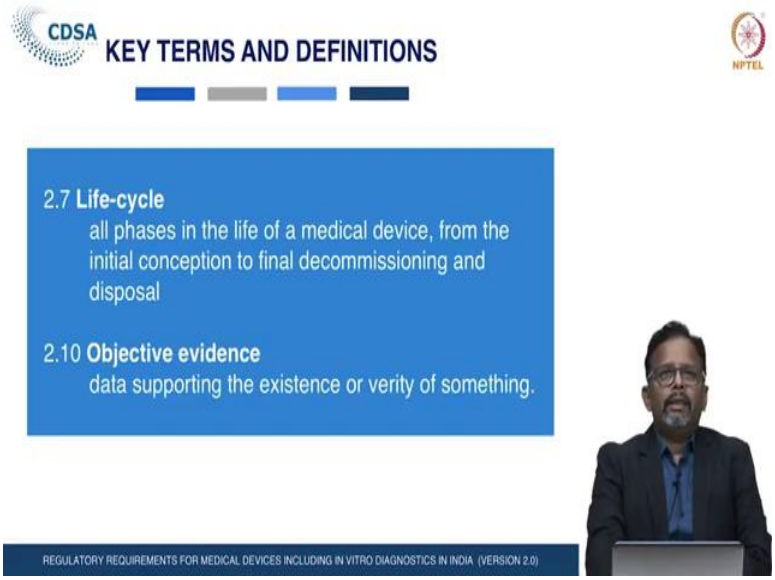

Like that there are so many other definitions which is related to the Risk Management that is like life cycle? What is the life cycle of the medical devices? What is objective evidence, post-production? What is the residual risk?

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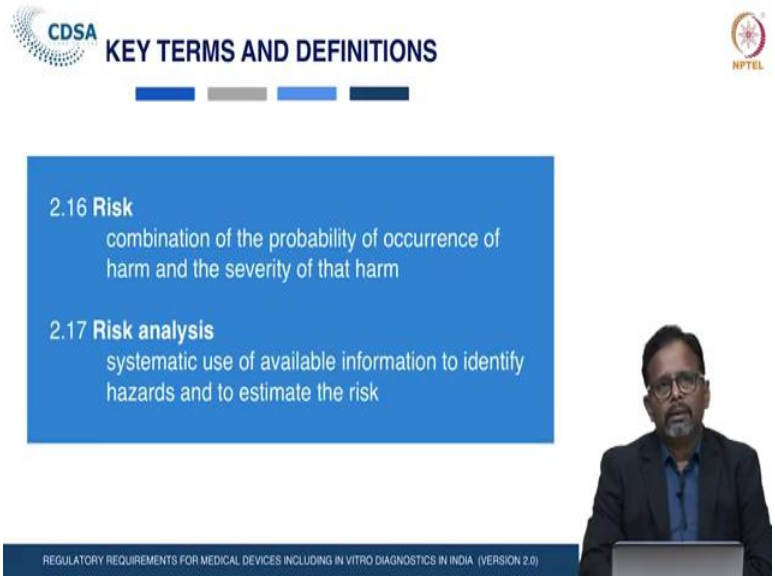

Risk Analysis (RA), Risk Assessment (RA*), Risk Control(RC), Risk Estimate (RE).

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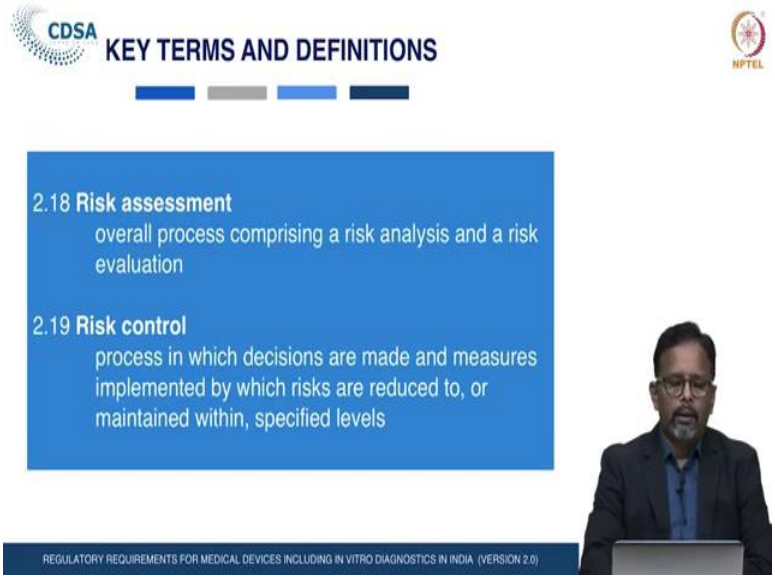

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Risk Management(RM), Safety, Severity, all those definition have been included and you can refer that standard, you will have details of the definitions and the terms which is used in the ISO 14971.

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The clause 3 of this standard which is the general requirement in that clauses, the risk management processes is there. The risk management process which includes the certain elements based on that the manufacture can access the risk of the devices. The one of the important elements are the Risk Analysis. whatever the devices the manufacturer is

manufacturing, they have to analyze the risk associated with their devices, risk analysis as per this standards. It is defined as the systematic use of the available information of the devices to identify the hazards and estimate the risk that is called as the Risk Analysis (RA).

So, this Risk Analysis has to be performed by the manufacturer on their devices. There after the Risk Evolution they have to carry out the risk evolution. The risk evolution that is the process for comparing the estimated risk against the given risk criteria to determine the acceptability of the risk. After doing the risk analysis and risk evaluation, the risk is to be controlled. Risk Control is the process in which the decisions are made and measures implemented by which the risk are reduced and maintained within the specified labels.

So, based on the evolution, the risk control the manufacturer has to control the risk of the devices and after that the production and post production information, they have to inform to the concerned stakeholders.

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The general requirement for the risk management, other components are there or the what is the Risk Management Process (RMP), Management Responsibility, Qualification of the personnel, Management Risk Plan(MRP), Management Risk(MR), Management File(MF), that is the risk management report of that devices all those thing that manufacture has to maintain.

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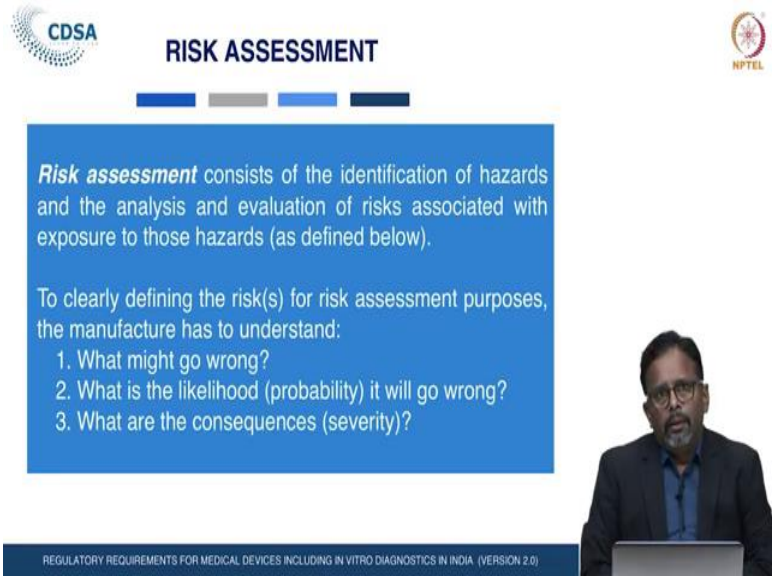

The Risk Assessment is consists of the identification of the hazards and the analysis and evolution of the risk associated with the exposure of those hazards. The risk assessment clearly defines that the manufacturer has to understand what might go wrong with the devices which they are going to manufacture or which are being manufactured. What is the probability if it will go wrong, the intended use or the device go wrong, what is what would be the probability they have to understand and what are the consequences of that probability which they have identified.

These three things we have to understand while maintaining this risk management, while doing the risk management analysis of the particular medical devices which they are going to manufacture or they are manufacturing.

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The general requirement the Risk Assessment Process (RAP), what is the process, the overview of the risk management process that is the slide you can see that.

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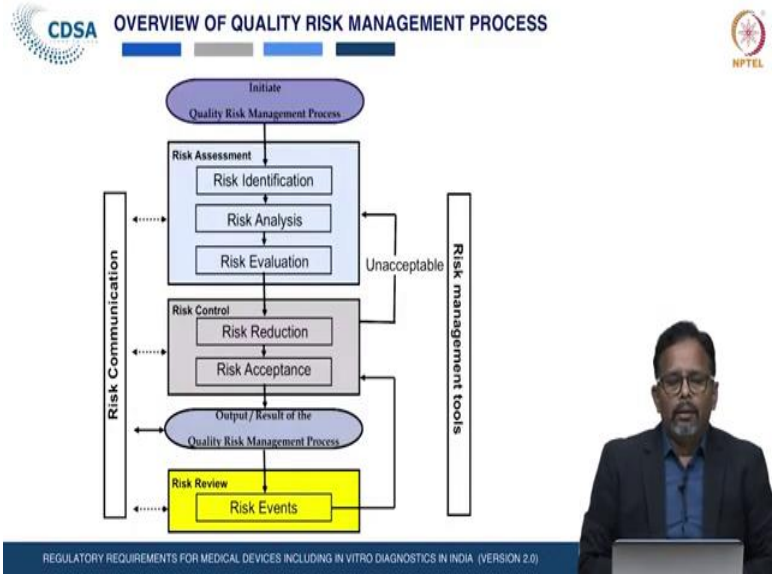

The flow chart is there that is the typical where the first the manufacture they have to carry out the Risk Assessment. The risk assessment process first they have to identify the risk associated with their devices. Once it is identified, they have to analyze the risk. After analyzing they have to evaluate the risk and based on evaluation if the risk is reduced, it is acceptable.

Risk is accepted then the further output they further inform to the concerned for the acceptance of that risk. If it is not accepted again they have to do the Risk Assessment of the devices to identify the acceptable risk. Once the risk is accepted then output or the result of the quality risk process they have to communicate. They have to review and they have to communicate it to the concerned members.

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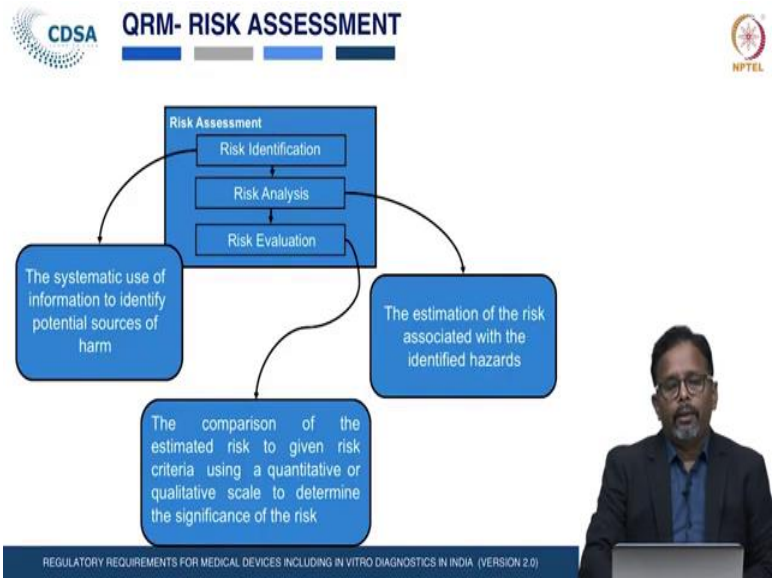

In that table the risk assessment through that assessment that the Risk Identification(RI), Risk Analysis(RA) and Risk Evolution(RE) has to be carried out by the manufacturer. The risk identification that is the systematic use of the information of the devices to identify the potentials source of harm, based on that they have to do the risk analysis that is the estimation of the risk associated with identified hazards.

There after risk analysis, they have to evaluate by comparison the estimated risk to the given risk criteria using the quantitative or the qualitative scale to determine the significance of the risk. After the risk assessment the risk control, the action implementing the risk management decision they have the decision, they have to accept and action taken to lesson the probability of the occurrence of the harm, severity of the harm.

Whatever the action they have taken the decision can be accepted and they will share that information about the risk or the risk management between the decision maker or others and the party can communicate any stage the risk management process. The other clause

that is the Risk Analysis, the detail is given in the standards Risk Evaluation, Risk Control evaluation of the residual risk and finally, the risk management report that risk management file.

They have to maintain and they have to include all those assessment with the manufacturer as carry out during the Risk Management Process of the devices. This is some general idea about this standard that is the ISO 14971 that detail you can refer to the website.

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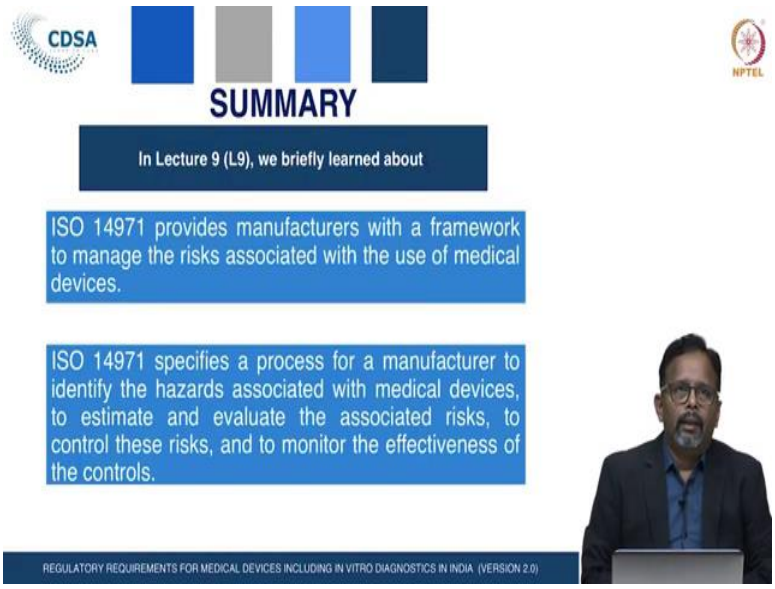

And this is ISO 14971 that provide the manufacture with the framework to manage the risk associated with the use of the medical devices and this also specifies the process for the manufacturer to identify the hazards associated with the medical devices to estimate and evaluate the associated risk to control this risk and to monitor the effectiveness of the controls.

So, this is all about the risk management of the medical devices as per the ISO 14971. You have understand what is the objective of this quality risk management, what is the standard applicable for this risk management and what is the component and tools for the risk management process applicable for the medical devices manufacturers. So, with these this small information we conclude this lecture.

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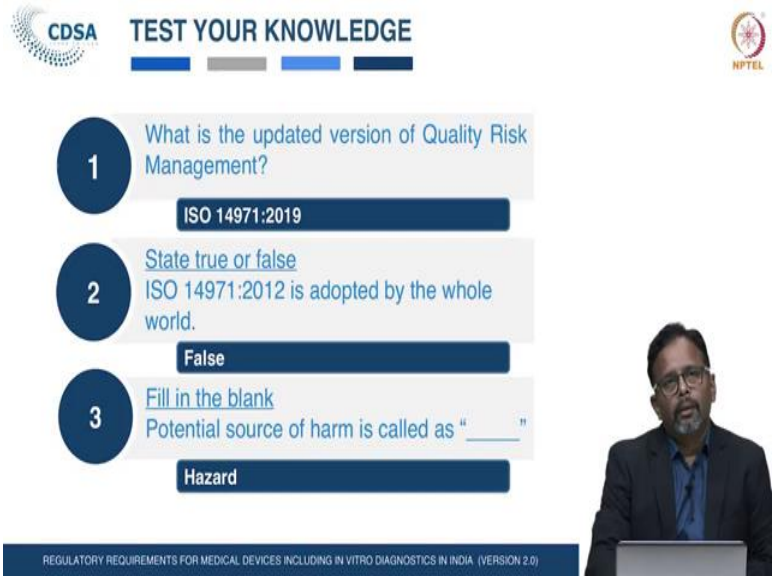

Now, let us have the question answer session. We have discussed about the ISO 14971 that is the risk management of the medical devices. So, we have discuss that what are the classes, what are the publications, where the applicability of this risk management process. Now, can you answer which version of the ISO 14971 is the updated version?

We have discussed that there are four different versions of the standard ISO 14971. So, latest version is ISO 14971 2019 that is the right answer.

Now the following statement whether it is true or false, can you give the answer for that? ISO 14971 2002 that is the 3rd edition of the standards that standard is adopted by whole of the world. This statement is right or wrong?

It is wrong. This standard is applicable only for the European Union members. Rest of the world the ISO 14971:2007 is applicable.

Now the last question.

What is the potential source of harm? The potential source of harm is called as?

It is called as the potential source of harm is called as the hazards. This definition has been defined in the ISO 14971. So, this is all about the quality risk management, what is the standard applicable and what is the scope of these standards. With this we will conclude the lecture.

Thank you very much.