

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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CDSA

NPTEL

LEARNING OBJECTIVES
Be aware of what is risk management to medical devices and in vitro diagnostics.

EXPECTED OUTCOME
Able to understand:
• Standards applicable for Quality Risk Management (QRM)
• Scope of the standards
• Definitions related to QRM
• Tools for risk assessment process

TARGET AUDIENCE
Personnel working in the medical device & IVD industries. Innovators or start ups involved in medical device or IVD industry, regulatory affairs personnel, human ethics committee members, clinical trial team members, researchers, academicians, students etc. and for persons generally interested in medical devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

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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The slide features the CDSA logo on the top left and the NPTEL logo on the top right. Below the logos is a decorative bar with four colored squares: blue, grey, light blue, and dark blue. The main title of the slide is "WHAT WILL WE LEARN IN THIS LECTURE". A central white box contains a bulleted list of topics. To the right of the list is a video inset showing a man with glasses and a beard, wearing a dark suit, sitting at a desk with a laptop. At the bottom of the slide, there is a dark blue footer bar with the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

- What is a risk management?
- Risk management process.
- Standards for risk management (RM).
- Key terms and definition.
- General requirements for RM.

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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CDSA IAT IS A RISK MANAGEMENT?

The purpose of 'risk management' is to achieve **SAFETY** (i.e. freedom from unacceptable risk).

In technical term: Identification, assessment, and prioritisation of **RISKS**.

This international standard was developed specifically for medical device/system manufacturers using established principles of 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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CDSA WHAT IS A RISK MANAGEMENT?

For other manufacturers, e.g., in other healthcare industries, this international standard could be used as informative guidance in developing and maintaining a risk management system and process.

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The slide features the CDSA logo on the top left and the NPTEL logo on the top right. A presenter is visible in the bottom right corner of the slide frame.

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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CDSA **WHAT IS A RISK MANAGEMENT?** **NPTEL**

Evolution of ISO 14971:

1 st Edition	:	2000
2 nd Edition	:	2007
EU Harmonised	:	2012

(An European harmonized version of this standard was adopted by **CEN** as EN ISO 14971:2012).

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

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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CDSA **WHAT IS A RISK MANAGEMENT?**

Evolution of ISO 14971:

This version is harmonized with respect to the three European Directives associated with medical devices Active Implantable Medical Device Directive 90/385/EEC, **Medical Devices Directive** 93/42/EEC, and *in vitro* Diagnostic Medical Device Directive 98/79/EC, through the three 'Zed' Annexes (ZA, ZB & ZC).

3rd Edition : 2019

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

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

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CDSA **ISO 14971:2007 Vs ISO 14971:2019**

Clause	ISO 14971:2007	Clause	ISO 14971: 2019
	EN ISO 14971:2012		
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

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

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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 **ISO 14971:2017 Vs ISO 14971:2019** 

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.

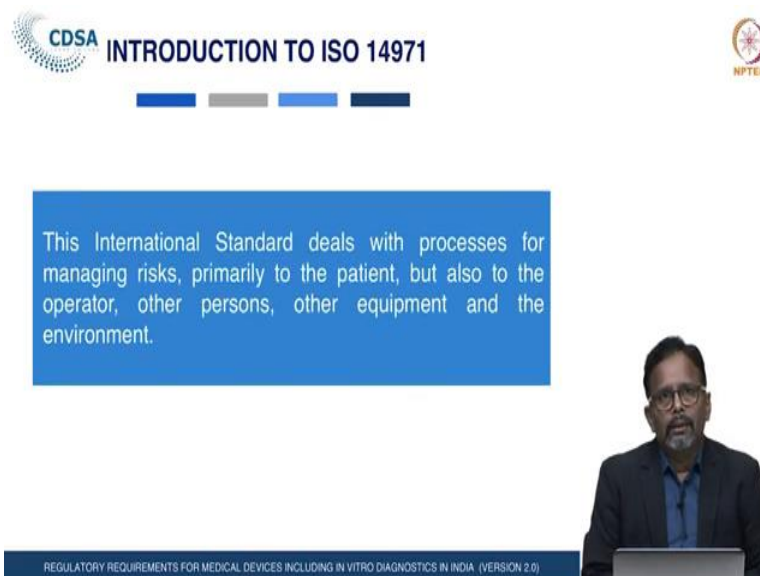
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The slide features the CDSA logo and the title "INTRODUCTION TO ISO 14971" at the top left, and the NPTEL logo at the top right. Below the title is a decorative bar with four colored segments (blue, grey, blue, dark blue). A central blue box contains the text: "This International Standard was developed specifically for medical device and medical system manufacturers using established principles of risk management." On the right side, there is a video inset of a man with glasses and a beard, wearing a dark suit, sitting at a laptop. At the bottom, a dark blue footer bar contains the text: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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.

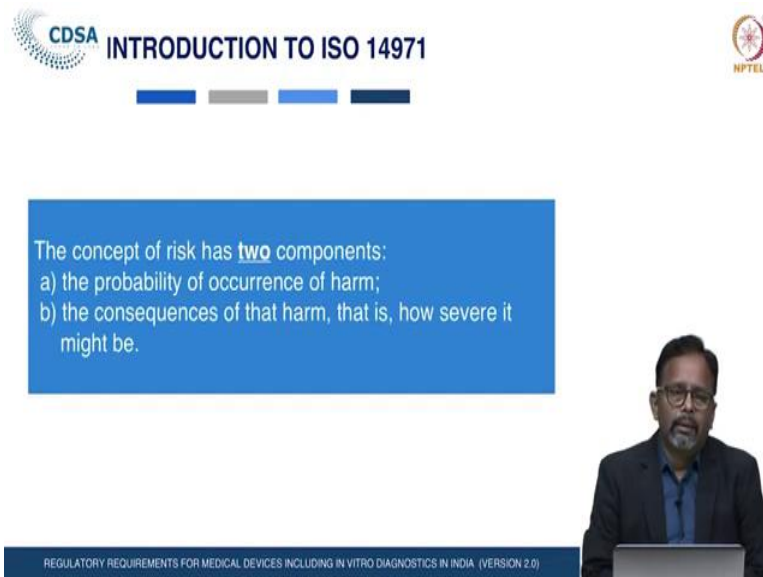
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The slide features the CDSA logo and the title "INTRODUCTION TO ISO 14971" at the top left, and the NPTEL logo at the top right. Below the title is a decorative bar with four colored segments (blue, grey, blue, dark blue). A central blue box contains the text: "This International Standard deals with processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment and the environment." On the right side, there is a video inset of the same man from the previous slide, sitting at a laptop. At the bottom, a dark blue footer bar contains the text: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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 slide features the CDSA logo and the title 'INTRODUCTION TO ISO 14971' at the top left, and the NPTEL logo at the top right. Below the title are four horizontal bars in blue, grey, blue, and dark blue. A central blue box contains the text: 'The concept of risk has two components: a) the probability of occurrence of harm; b) the consequences of that harm, that is, how severe it might be.' On the right side, there is a video inset of a man with glasses and a beard, wearing a dark suit, sitting at a laptop. At the bottom, a dark blue footer bar contains the text: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'.

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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The slide features the CDSA logo and the title 'INTRODUCTION TO ISO 14971' at the top left, and the NPTEL logo at the top right. Below the title are four horizontal bars in blue, grey, blue, and dark blue. A central blue box contains the text: 'This International Standard specifies a process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the risks associated with these hazards, control these risks, and monitor the effectiveness of that control.' On the right side, there is a video inset of the same man as in the previous slide, sitting at a laptop. At the bottom, a dark blue footer bar contains the text: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'.

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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CDSA **SCOPE OF ISO 14971** **NPTEL**

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.

This International Standard does not apply to clinical decision making.

This International Standard does not specify acceptable risk levels.

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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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CDSA **SCOPE OF ISO 14971** **NPTEL**

This International Standard does not require that the manufacturer have a quality management system in place.

However, risk management can be an integral part of a quality management system.

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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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The slide features the CDSA logo on the left and the NPTEL logo on the right. The title 'KEY TERMS AND DEFINITIONS' is centered at the top. Below the title, there are four colored bars (blue, grey, blue, dark blue). The main content is a blue box containing the following text:

- 2.2 Harm**
physical injury or damage to the health of people, or damage to property or the environment
- 2.3 Hazard**
potential source of harm
- 2.4 Hazardous situation**
circumstance in which people, property, or the environment are exposed to one or more hazard(s)

At the bottom of the slide, there is a dark blue bar with the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'. A small inset image of a man in a suit is visible on the right side of the slide.

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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The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the title, there are four colored bars (blue, grey, blue, dark blue). The main content is in a blue box with two items:

- 2.7 Life-cycle**
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal
- 2.10 Objective evidence**
data supporting the existence or verity of something.

A man in a suit is visible in the bottom right corner, and a dark blue footer bar at the bottom contains the text: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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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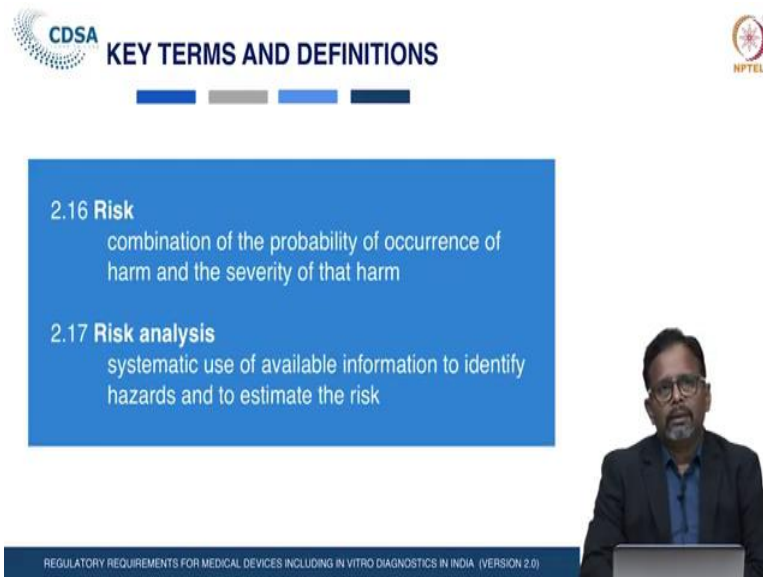


The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the title, there are four colored bars (blue, grey, blue, dark blue). The main content is in a blue box with two items:

- 2.11 Post-production**
part of the life-cycle of the product after the design has been completed and the medical device has been manufactured
- 2.15 Residual risk**
risk remaining after risk control measures have been taken

A man in a suit is visible in the bottom right corner, and a dark blue footer bar at the bottom contains the text: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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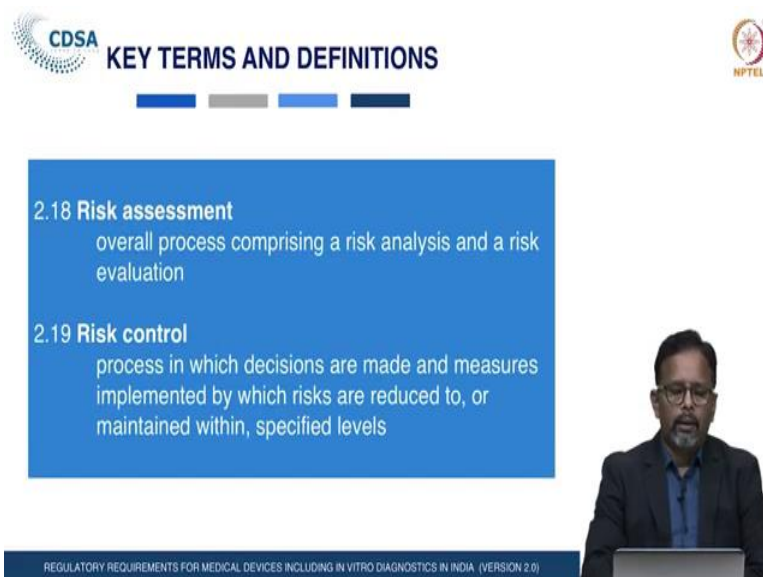
The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the title, there are four colored bars (blue, grey, blue, black). The main content is in a blue box with two items:

- 2.16 Risk**
combination of the probability of occurrence of harm and the severity of that harm
- 2.17 Risk analysis**
systematic use of available information to identify hazards and to estimate the risk

A presenter is visible in the bottom right corner, and a footer at the bottom reads: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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

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The slide features the CDSA logo on the left and the NPTEL logo on the right. Below the title, there are four colored bars (blue, grey, blue, black). The main content is in a blue box with two items:

- 2.18 Risk assessment**
overall process comprising a risk analysis and a risk evaluation
- 2.19 Risk control**
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

A presenter is visible in the bottom right corner, and a footer at the bottom reads: "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)".

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KEY TERMS AND DEFINITIONS



2.20 Risk estimation

process used to assign values to the probability of occurrence of harm and the severity of that harm

2.21 Risk evaluation

process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk



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KEY TERMS AND DEFINITIONS



2.22 Risk management

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

2.23 Risk management file

set of records and other documents that are produced by risk management



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CDSA KEY TERMS AND DEFINITIONS

2.24 Safety
freedom from unacceptable risk

2.25 Severity
measure of the possible consequences of a hazard

2.27 Use error
act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

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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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CDSA GENERAL REQUIREMENTS

3.1 Risk management process

This process shall include the following elements:

- Risk analysis; systematic use of available information to identify hazards and to estimate the risk
- Risk evaluation; process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
- Risk control; process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
- Production and post-production information.

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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 slide displays the following content:

- CDSA** GENERAL REQUIREMENTS FOR RISK MANAGEMENT
- NPTEL**
- 3.1 RISK MANAGEMENT PROCESS
- 3.2 MANAGEMENT RESPONSIBILITIES
- 3.3 QUALIFICATION OF PERSONNEL
- 3.4 RISK MANAGEMENT PLAN
- 3.5 RISK MANAGEMENT FILE

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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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RISK ASSESSMENT

Risk assessment consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards (as defined below).

To clearly defining the risk(s) for risk assessment purposes, the manufacture has to understand:

1. What might go wrong?
2. What is the likelihood (probability) it will go wrong?
3. What are the consequences (severity)?

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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.

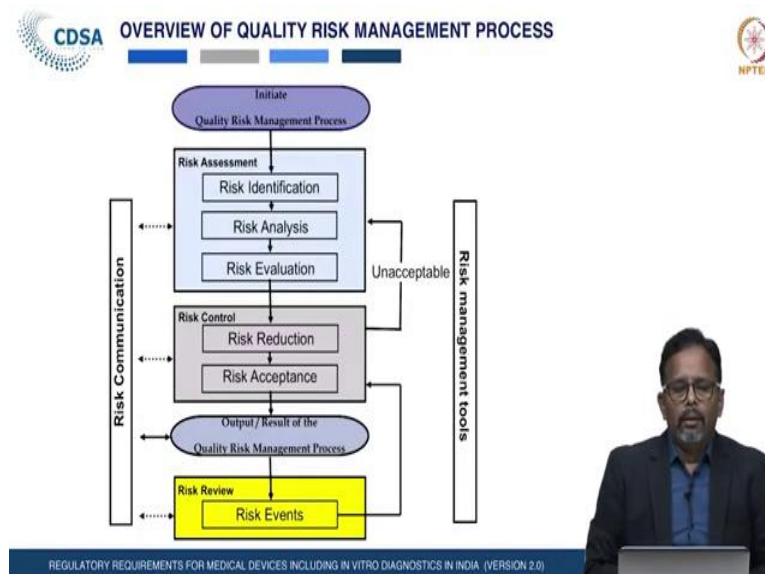
These three things we have to understand while maintaining this risk management, while doing the risk management analysis of the particular medical devices which they are going to manufacture or they are manufacturing.

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The slide features the CDSA logo on the left and the NPTEL logo on the right. The title 'GENERAL REQUIREMENT' is centered at the top. Below the title is a decorative bar with four colored segments (blue, grey, blue, dark blue). A text box in the center states: 'A schematic representation of the risk management process is shown next.' A large blue arrow points downwards from this text box. On the right side of the slide, there is a video inset of a man with glasses and a beard, wearing a dark suit, sitting at a desk with a laptop. At the bottom of the slide, a footer reads: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'. The NPTEL logo is also present in the top right corner.

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.

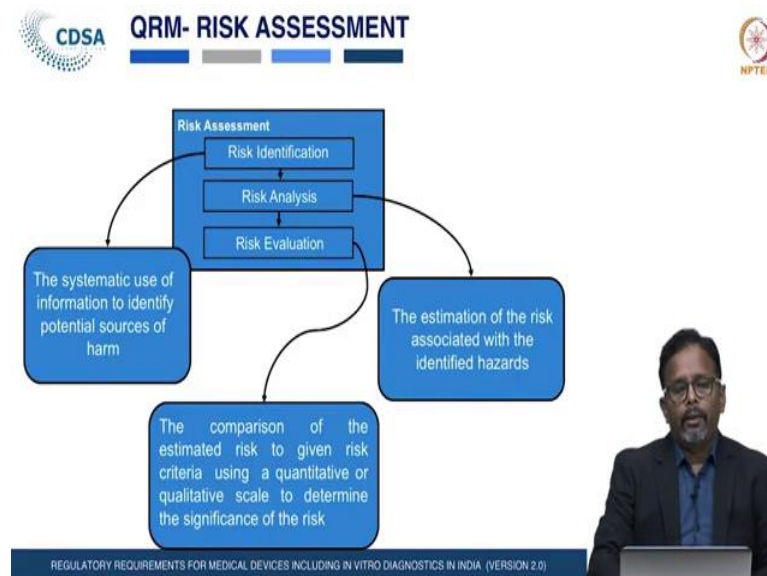
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The flow chart is there that is the typical where the first the manufacture they have to carry out the Risk Assessment. The risk assessment process first they have to identify the risk associated with their devices. Once it is identified, they have 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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The slide features a header with the CDSA logo on the left and the NPTEL logo on the right. Below the logos is a decorative bar with four colored squares (blue, grey, light blue, dark blue) and the word 'SUMMARY' in bold. A dark blue box contains the text 'In Lecture 9 (L9), we briefly learned about'. Two light blue boxes follow, containing the text: 'ISO 14971 provides manufacturers with a framework to manage the risks associated with the use of medical devices.' and 'ISO 14971 specifies a process for a manufacturer to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.' In the bottom right corner, a man with glasses and a dark jacket is shown from the chest up, sitting at a desk with a laptop. At the very bottom of the slide, a dark blue bar contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)'.

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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CDSA TEST YOUR KNOWLEDGE

1 What is the updated version of Quality Risk Management?
ISO 14971:2019

2 State true or false
ISO 14971:2012 is adopted by the whole world.
False

3 Fill in the blank
Potential source of harm is called as "____"
Hazard

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

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.