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Review Article

Latest Risk Management guideline (ISO 14971:2019) & Environmental aspects of Medical Device

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Abstract

The use of medical device in patient is a critical step and requires an appropriate management system for its best practice and use throughout its complete lifecycle. Various countries around the globe have procedures and regulations in place for the safe production and use of their medical device. CDSCO, GOI (Government of India) under directorate general of health services in ministry of health and family welfare are the governing body in India which is responsible for the safe & effective use of medical device on patients under Medical Device Regulations, 2017. Recently, the third version of ISO 14971:2019 series has been notified and several aspects of this regulation include the best objectives to be achieved by the manufacturer by being compliant with the risk management plan set forth in the international standard on risk management system. ISO 14971 for medical device ensure companies produce a product which is safe and effective for use and for patients who unknowingly tend to accept the risk related to medical device which the experts design and manufacture. Risk management standard help a manufacturer build a risk management plan and carry out activities in compliance with the international guideline so as to minimize the risk possibility, occurrence and any hazard associated with it. This article focuses on the importance of ISO 14971 and structure the aim and standard. It also throws light towards the environmental aspects as an element of the management process relating to the threat posed to the surroundings by their use, as well as with various other steps taken by the companies to make the public aware of the product they use and unknowingly support the risk posed by the material that the product is composed of. Bio medical waste management is an initiative undertaken by India for the safe disposal and treatment of bio medical waste generated around us by various primary and secondary sources. This article gives a brief overview of guidance on risk assessment, management and control plans to be implicated by the company and steps taken to tackle and reduce harm to the environment posed by medical devices.

Keywords: Medical device, Risk Management System, Risk Management Plan, Biomedical Waste Management, Hazard, Safety & Efficacy, BRA, Sustainability, Environment

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1. Introduction

The health ministry of INDIA published medical device and IVD regulations (Medical Device rules) in 2017 which came into effect since January 1, 2018. (1) Under D&C act, medical devices are notified as a drug.

Sec. 3 (b) (iv) defines medical device as "devices intended for internal or external use in diagnosis, treatment, mitigation or prevention of disease in animals and human beings". (2)

One of the difficulties for medical device producers is to go through & pass the requirements rigorously which is a complex process and mandatory for safety compliance. The management of unavoidable risk associated with the product is the minimum requirement for its safety assurance for designing a product of innovative nature and in compliance with the regulatory requirement. (3) Risk can be defined as the combination of the probability in association with the severity and occurrence of harm that can change into a disaster. (4) Whereas the risk management is a technique of systematically applying the management approaches, procedures and practices including undertaking the assessment, evaluation and control of the associated risk. Though it is not possible to completely contain or avoid the risk, they can be made limited if companies know about the approaching risks and follow effective management techniques through risk management approaches. Under such condition, standards play a very important role in developing a

methodology which provides a common understanding among various producers, regulatory authorities and consumers. (3) ISO 14971 mentions about such standards. However there are certain influences of medical devices which affect the environment with toxic emissions of materials, chemical hazards and biological threats. Risk posed by medical device to the environment can be dealt with the help of a proper application of sustainable design guidelines. IEC 60601-1-9 standard require industries to follow sustainable and environmentally conscious design as well as document the inclusion of eco-friendly principles. (5) Many companies help customers take important claim for sustainability by being more transparent about the product & making them more conscious of the risk that medical device pose. (6) Around the globe, nearly 80% of hospitals are expected to incorporate these standards which emphasize healthcare organization's role towards encouraging humans about the eco-friendly products. (7)

Purpose and requirement

The purpose of this standard serves the compliance of medical device through the application of risk management guidelines and reduces uncertainties about the safety of a product. It delivers methods that are ideal for all stakeholders in eradicating the risks and help develop device that is proven effective. It outlines guidelines for regulatory authorities to assure that the manufacturers are implementing ideal procedures to achieve the objective of a safe & effective device for all. ISO TR/24971 is a guidance document for the application of ISO 14971. (8)

ISO 14971 includes special requirements as follows:

- Risk management system review by management
- Risk acceptability criteria and its policy
- Qualified personnel
- Adequate resources provisions (8)

2. Recent guideline and changes made to the new version of ISO14971:2019

ISO14971 got current version released in December 2019 replacing the prior two version of the standard, ISO 14971:2007 (1st international version) & ISO 14971:2012 (EN version of ISO for medical device selling). 2012 guideline is similar to the regular version of ISO 14971:2019 applicable in Europe which was published by European Committee for Standardisation with respect to the European directives 93/42/EEC, 98/79/EC & 90/385/EEC. (4)

ISO 14971:2019 is the 3rd version of this guideline consisting of the same concept with some additional definitions and clarifications although no major changes have been made in the management process. The three major changes are as follows (9):

1) New definitions
- Benefit - it can be described as a positive impact or an outcome that is desirable while using a medical device on the public health or in patient management.
- Harm- previously "physical injury" was mentioned in the definition but now this word has been deleted, whereas an injury or damage to the health of public, property and environment is mentioned.
- Reasonable foreseeable misuse- this term outlines the use of a product in a way that is not intended by a manufacturer. Misuse can either be unintentional or intentional and therefore can be called abnormal use.
- State of the art- risk policies are based on state of the art and ISO 14971:2019 now has a definition for it which includes developed stage of technical capabilities as services, process and regard products based on findings.

2) Criteria for overall risk acceptability
For the purpose of evaluation of residual risk, ISO 14971:2007 mentioned the "criteria defined in the plan for risk management", whereas the 2019 version makes a suggestion that in comparison to overall residual risks, different evaluation criteria for residual risk of individual risks can be used by the manufacturer.

3) More information in the guidance to the technical report 24971
The new version of ISO has 3 annexes consisting of much information and explanations along with examples transferred to ISO/ TR 24971 whereas the 2017 version have 10 annexes. (9)

Table 1 Comparison between ISO 14971:2007/ EN ISO 14971:2012 & ISO 14971:2019. Adapted and modified from (10)

ISO 14971:2007/ EN 14971:2012	ISO 14971:2019
1. Scope	1. Scope
2. Terms & definitions	2. Normative references
3. Risk management requirements **a.** Process of risk management **b.** Responsibilities **c.** Personnel qualification **d.** Plan for management of risk **e.** File for risk management	3. Definitions and terms
4. Analysis of risk **a.** process of risk analysis **b.** identification of safety characteristics and intended use of medical device **c.** hazards identification **d.** estimation of each hazardous situation for risk	4. Risk management requirements a. Process of risk management b. Responsibilities c. Personnel qualification d. Plan for management of risk e. File for risk management

5. Evaluation of risk	5. Analysis of risk a. Process of risk analysis b. Reasonable foreseeable misuse and intended use c. Identification of safety characteristic d. Identification of hazardous situations or hazards e. Estimation of risk
6. Control of risk a. Reduction of risk b. Analysis of risk control option c. Implementation of measures for risk control d. Evaluation of residual risk e. Analysis of benefit- risk f. Arising risks from measures for risk control g. Risk control completeness	6. Evaluation of risk
7. Overall residual risk acceptability evaluation	7. Control of risk a. Analysis of risk control option b. Implementation of measures for risk control c. Evaluation of residual risk d. Analysis of benefit- risk e. Arising risks from measures for risk control f. Risk control completeness
8. Report for risk management	8. Evaluation of the overall residual risk
9. Production- Post production activities	9. Risk management review
	10. Production- Post production activities a. Collection of information b. Review of information c. Actions

Figure 1. Various steps in the process of risk management of medical device

3. Plan for Risk Management

- Define & characterize the product included in the plan set out for risk management and the scope of the activities. It's conceivable to have many products described under a single plan of Risk Management.
- Recognize all risk management exercise arranged all through the product lifecycle
- Assign responsibilities & define roles. For the approval & review of risk documentation, identification of a team for risk management purpose is required.
- Define strategies to confirm risk control measures and steps to reduce risk to an acceptable level.
- Describe how post production data will be retained and accommodated into Risk management activities which is intended for a specific product. (4)

Risk Assessment

(Risk Evaluation+ Risk Analysis)

Risk Assessment has the activities relating to risk evaluation and analysis when put together forms the entire concept of risk assessment. Risk analysis and evaluation can be worked upon in a parallel fashion.

Risk Analysis – Risk analysis can be defined as "the use of information systematically in identifying hazard and helping in estimating the probability of risk". (3) A "hazardous situation" is one where the environment, people or property are introduced to more than one hazard(s), whereas a "hazard" is a harm of potential source.

Examples- hazards can be of thermal, biological, electrical, mechanical or chemical nature. It can also

include electromagnetic radiation or hazard through false information or advertisement.

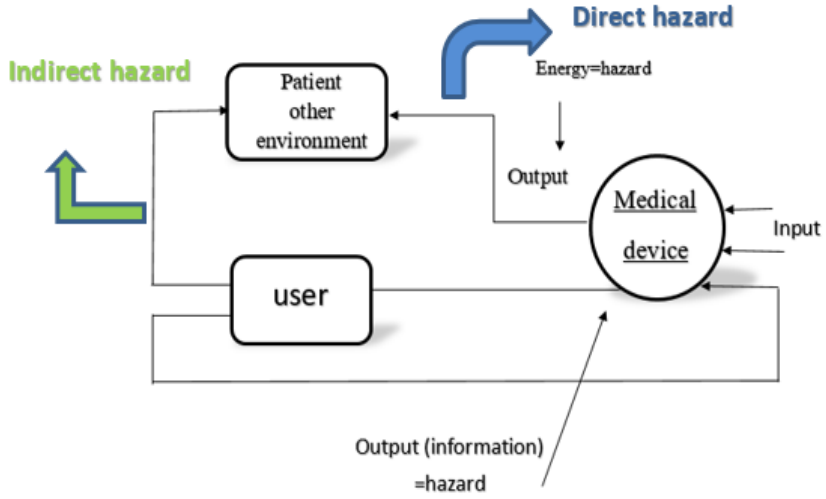

Figure 2. The flow of hazard through direct "blue arrow" & indirect "green arrow" output. (11)

Analysis of risk involves superficial steps mentioned as follows:

- Consideration of intended use of a specific product in order to understand the scope of a device which helps in documenting its intended use.
- Recognizing potential hazard that might be associated with the medical device and its potential source that may pose any harm while its usage.
- Defining sequence of situations and foreseeable events leading to a hazardous situation.
- Estimating the risk, severity of harm and the probability of its occurrence. (4)

A. Estimation of severity and probability of risk

As per ISO 14971, the combination of both severity and occurrence of harm is defined as risk. Estimation of risk can be inferred in terms of quantitative, semi-quantitative or qualitative scale. In case where varied techniques are used, the likelihood of determination of occurrence and severity of risk is common to determine. From figure 3, the intensity of risk, corresponding to the values of low, medium or high, can be inferred. (3)

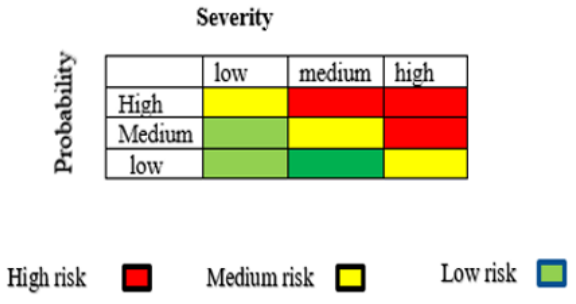

Figure 3. Graphical representation of risk (3)

B. Risk probability number

Risk priority number is used for prioritizing failure and evaluation of severity, detectability and occurrence of each failure through methodology of failure mode and effects analysis. Risk priority number for risk detectability can be calculated from occurrence and severity of risk. By assigning values as high (1), medium (2), low (3) to the qualitative values, risk priority number (RPN) can be useful in determining the overall risk (Fig. 4). (12)

Risk priority number = severity x probability of occurrence x probability of detection (S x O x P)… (1)

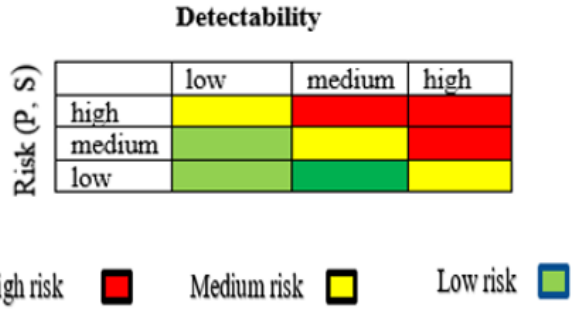

Figure 4. Graphical representation of determination of risk detectability (3)

Risk Evaluation

Risk evaluation can be defined as the acceptability of certain risk on the basis of comparison between the estimated risk and standard risk criteria and define the level of risk acceptability. When a risk has been assessed, risk evaluation decides whether the reduction of risk is required or not on the basis of pre evaluated risk outcomes. A typical practice to evaluate the risk is to distinguish which time zone (high, medium, low) need reduction of risk and which are acceptable to a limit. Most likely, the product coming under high and medium risk level need risk reduction. (4)

Risk Control Parameters

The control over risk can be accomplished by appropriate decision making and ability of taking required action so as to keep the risk within the levels of acceptability by using proper risk control techniques which are further documented for future reference.

Verification of applied control mechanism is required by each manufacturer.

Mitigation of risk- It can be defined as a stepwise follow-up of specific measures to eliminate as much risk as possible associated with the company's operations. Though it might be adding an extra cost to the organizations budget, the best cost effective method that can be used is by comparing the risk criteria (predetermined) with the risk probability number.

Determination of risk threshold- Determination of risk threshold value is the first step in the risk control approach. It calculates the amount of risk that can be tolerated by a company. The acquired numbers after the method implication shall be communicated to the respective companies and all associated parties for their decision making.

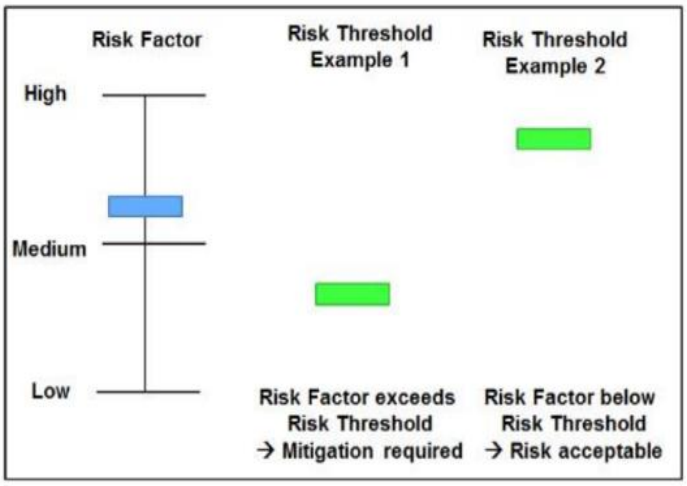

Figure 5. Risk Priority Number (RPN) vs Risk Threshold (3)

As per the above figure, risk is acceptable when the risk factor is below risk threshold. Whenever the risk factor exceeds the risk threshold, risk mitigation is required to keep the overall residual risk factor below the value of risk threshold.

Priority of risk control option- there is a list of priority as per which risk control measures should be taken, which includes focus on the following factors:

a. Design safety
b. Protective measures for medical device process and/or manufacturing
c. Use of instructions or safety information such as labelling

BRA (benefit- risk analysis) - this concept helps in determining the medical benefits in view of whether the medical device benefit outweigh the potential risk. If there is evidence of residual risks, then BRA analysis should be very well documented providing objective and rationale for why the unacceptable risks are outweighed by the benefits of the medical device. If the company succeeds to do so, then the company may move forward with the special provision of BRA with unacceptable risks.

Overall Acceptability of Residual Risk

The acceptability level of risk shall be determined to know whether the benefits outweigh the level of associated risk of medical device. In this step, the company is going to conduct similar criteria of occurrence, severity, risk & risk level acceptability throughout the entire process. If it is concluded that the entire product's overall residual risk is far from acceptable, then this is known to be an another case where a company can apply for a benefit-risk analysis (BRA). The BRA must be included with a Report of Risk Management.

In case where the overall residual risk related to entire product is found to be at an acceptable level, this should be documented with a decision in support of the company's rationale. It may also be included in Risk Management Report. (4)

Management Review and Report

Review of risk management is essential in order to prepare a management report of risk associated with the medical device before sending it to the commercial production. This step includes review of risk management plan in order to ensure that the plan was successfully executed and documented to make out whether the overall residual risk is acceptable or not. Further, this review information is documented in a report which is termed as a Risk Management Report which provides evidence of proper execution of risk management plan, to make sure the objectives set in the risk management plan were met, and to confirm if production and post- production information are well established. (11)

Production Information

The information related to the production and post-production activities, in the latest 2019 series, has undergone new changes relating to more detailed & precise description of activities and requirement. The steps that a manufacturer needs to take are divided into 4 sections as per the clause as follows:

- The first step requires a system for collection and review of data followed by appropriate feedback & monitoring process as mentioned in the QMS

system. The activities related to the set up for information collection and review should be mentioned in the Risk Management Plan.

- The second step is about the collection of relevant information from the supply chain, from the users and information about a medical device made public in the market.
- The third step necessitates the review of information by the manufacturer to draw out a conclusion about the product safety. The manufacturer needs to see whether the benefit of the product still outweigh the risk, a previously estimated risk is any longer acceptable, or a previously identified hazard still exists or not.
- In the fourth step, the manufacturer needs to take action after the review of the information in the Risk Management Plan. The manufacturer should assess whether new risk control measures are required to implement, or a previously identified risk needs to be assessed again. Additionally, action on marketed medical devices is also suggested. (11)

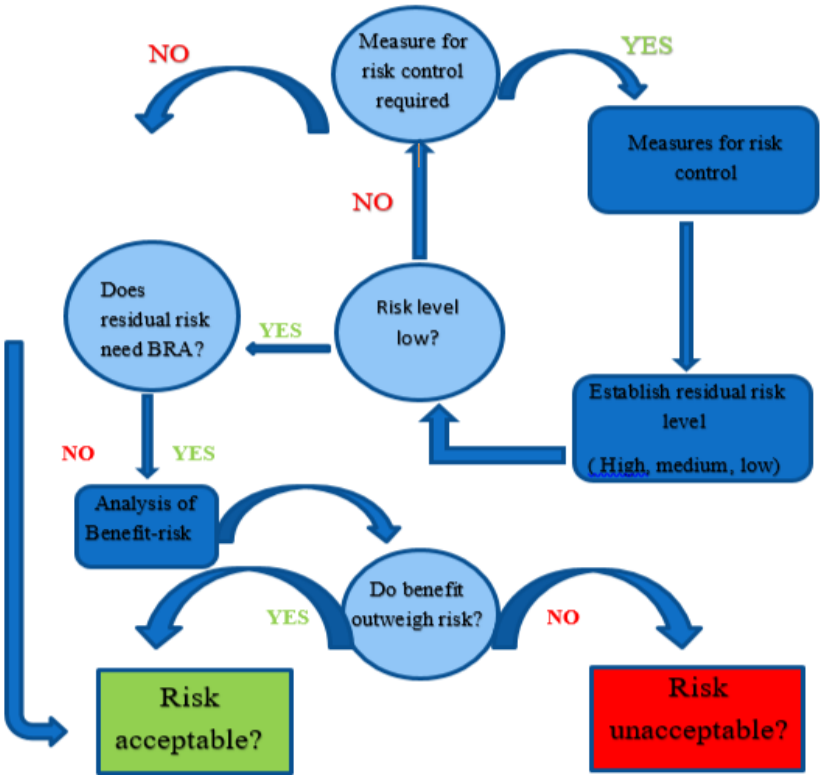

Figure 6. Risk control steps drawn out to determine the level of acceptability of risk (4)

The Production & post production information follows CAPA, audits, feedback by customer & out of conformity materials, as a part of risk management plan which is a process of total product lifecycle.

4. Environmental aspects of Medical Device

Sustainable Design

Design of medical device has a huge impact in the protection against the risk and harm that cannot only be posed to patients but also the environment. Sustainability design in electrical devices meets the requirement by the regulatory authorities. Environmental conscious medical device spread its roots across various industries. The standard set forth by IEC 60601-1-9 Electro-technical Commission outlines guidance for a design that helps in developing a sustainable Eco friendly medical device. (5)

5. Overview of the standard IEC 0601-1-9 for an Environmental Conscious Design (5)

It was published in 2007 and amended in the year of 2003. It is an internationally accepted standard for the compliance with various aspects of medical device including safety performance. The standard should be applied throughout the lifecycle of medical device from 1st stage of development to end-of-life phase. Manufacturer are required to demonstrate the use Eco. Friendly principle for the design

Requirement- IEC 0601-1-9 is linked with many other standard which includes ISO 14971; ISO 14001; ISO 14062. In this article ISO 14971 requirements applicable to IEC standard for sustainability is discussed.

Environmental protection is considered as one element of a risk management plan in compliance with ISO 14971. It deals with the impact of medical device to the environment. Several threats to the environment are considered which include-

- Toxic emission of material
- Biological threat
- Release of chemical toxin or hazards into the environment.

Initial assessments of above factors contribute to the development of medical device with valuable input for whole sustainability program and risk management process of medical device.

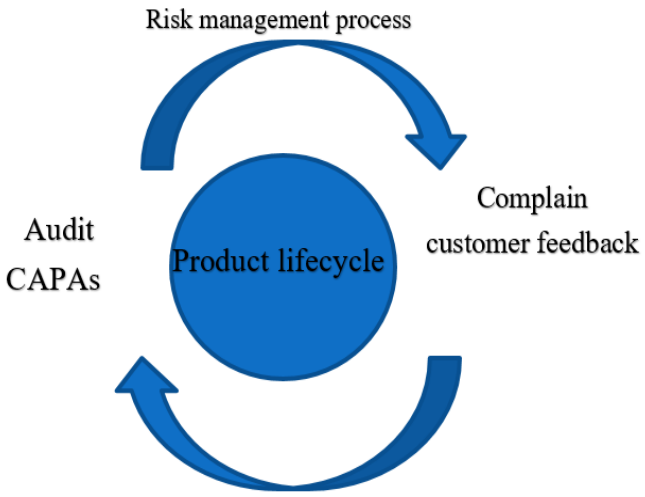

Figure 7. Product lifecycle which is followed for compliance and quality of a device throughout its lifespan from earliest stage of design to distribution and commercialization (4)

Conformity

While demonstrating compliance with the standard, manufacturer needs to handover various kinds of document including-

- Document specifying design, description of process which identify environmental aspect of medical device including adverse environmental impact
- Set of information on label or packaging, or documenting a section relevant for reducing the risk of environmental hazard during normal use
- End-of-life information management (5)

Consumer's consciousness towards threat to environment (6)

When it comes to environmentalism, companies don't have best to keep record of it but some parameters can be adopted for changing that. Sustainability requires a collaborative approach and a system of accountability. Each person has a responsibility to combat changing climate for a better future. Here are few factors of medical device provided by companies that help people go green.

Transparency Medical device manufacturers by being transparent about the materials and processes they use, makes eco conscious consumers and inform them about what they are using. Most companies don't indulge in such things to hide their unsustainable practice from getting public.

MedTech Europe has taken a step forward towards a *policy of full material declaration*, which means it is clear about its products and material used in making such products.

Provisions of Recycling Options

Use of disposable packaging for medical device is a traditional way of packaging system around the globe which comes with a downfall of posing threat to endangered species on planet, cause pollution and recycling all of them is not a simple but complex process although they can be convenient and cheap for use but not so eco-friendly.

Few companies, for example Roche Diabetes Care, have system for services which offer to help recycle packaging of their product. The insulin pump tubing of Swiss company's comes in Tyvek plastic and needs specialists for recycling purpose. When customers *send their packaging to a recycling centre*, they don't let the material to be present in a landfill.

Manufacturing of sustainable nature

The process of manufacturing across the industries around the globe is notorious in terms of generation and emissions of waste, so purchase of any kind of product may be posing harm to the environment. Cleaner methods of production are helping solve that problem.

Researchers have found use of *3D-printed artificial organs*, which is known to increase the sustainability by adding material instead of cutting it away, hence a more eco-friendly method of manufacturing.

Extended Lifecycles

Management of waste is one of the toughest challenge as people tend to carelessly throw away things instead of reusing the, which lead to overcrowded landfills. This problem won't last long if manufacturers focus on pursuing steps to make products for use over longer period by creating devices that reduce the frequency ay which it gets thrown away.

This longevity or extended period of use leads to less pollution rate and a more manageable load of work on recycling plants

Promotion of Eco-Friendly Behaviour

Manufacturers are involved in promoting eco-friendly consumers by increase in promotion of practices which are sustainable. Conferences such as *CleanMed* shows the ways in which *companies are going green* which inspires other businesses/ individuals to promote similar steps

The use of green practices showcase the corporations and individuals alike can live lives a sustainable way. Medical device producers can influence consumers for

eco-friendly future, by arming people with appropriate knowledge and means to go green in their lives.

Management of Biomedical Waste in India

The government of India notified Biomedical Waste rule in 1998, by the ministry of environment and forest. (14) The generation of bio medical waste coming from health care facilities like diagnostic laboratories, microbiological labs etc. known as health care waste (HCW) leads to the release of microbiological hazards which causes serious impact on public health risk. (15) As per the recent revised guidelines for BMW rules, 2016, "BMW treatment and disposal facility" is defined as a facility where the disposal or treatment of waste is carried out in common bio- medical waste treatment facility (CBWTF) for disposal. (16) Clinical international epidemiology network found existing use of practices related to BMW across various health care facilities during 2002-2004. The new guidelines focus towards the new means of improvement in transportation, segregation, method of disposal in order to change the dynamics of bio medical waste treatment and disposal by reducing pollution level in India. The BMW rules 2016 have expanded the scope of waste management to various health camps such as surgical camps, blood donations & vaccination camps. The occupier having administrative control over health care facilities has been revised. The concept of BMW management follows 3 R's- recycle, reuse, reduce. (17)

Hospitals in countries such as Latin America, USA, Netherlands, Spain, Norway, France, UK have waste production of nearly 3.8 Kgs 4.5 Kgs 4.2 Kgs, 4.4 Kgs, 3.9 Kgs 2.5 Kgs 3.3 Kgs per bed every day individually which is on exceptionally higher side as contrast with nation like India which is a developing country. Many health care centers like hospitals produce 1-2 Kgs for each bed every day in India, with the exception of the tertiary consideration medical hospitals like SKIMS and AIIMS which produce higher wastes. As indicated by World Health Organization (WHO), around bio chemical waste of 85% is really unsafe and around 10% is known to be infectious while 5% is non-infectious and require methods in place for dealing with such hazardous materials. This can bring about elevated level of natural contamination, apart from presenting a danger to welfare of the living beings. The major goal is waste isolation, best at the beginning to be marked as non-reusable or re-suable, non- hazardous and hazardous materials.

Table 2 Various methods of disposal of waste in different countries (18)

Country names	Methods for disposal of bio medical waste
India	Incineration, Landfill Autoclaving, Recycling, reuse, reduce
Mongolia	Autoclaving, open burning or open dumping, Incineration,
Iran	Sewers, Incineration, Incineration
Bangladesh	Landfill dumping
Malaysia	Recycling, Incineration, Landfill,
Libya	Incineration, Dumping
Greece	Landfill, Pyrolytic combustion, Recycling- Reuse

Biomedical waste generation sources & its treatment methods

Despite of the fact that the waste management of solid has become one of the most significant subject, yet at the same time local bodies can't give the best possible consideration towards some exceptional waste production sources out of which biomedical waste is the one. The biomedical waste source, as per the quantities, can be of primary source and secondary source.

Table 3 Generation of bio medical waste through primary and secondary sources (18)

Primary sources		Secondary sources
Labs	Industries	Educational centers
Hospital	Medical college	Physician's clinic
Centre for dialysis	Blood bank	Funeral activity service
Dispensaries	Nursing homes	Home treatment
Nursing home	Centers for immunization	Ambulance

Colossal measures taken in India for medical facilities are generating constant biomedical wastes such as tissues, body organs, parts, blood & fluid alongside material such as solid linen, plaster, bandage & cotton. Wastes of such categories are extremely hazardous and contaminated. It is exceedingly fundamental to properly collect, segregate, store, move, treat and set out waste in the safest manner. The most common method of treating waste in India is incineration in light of its minimal effort; however it causes terrible natural impacts. Other than this method, strategies like autoclave & dielectric method of heating, microwave treatment, pyrolysis-oxidation, depolymerisation are utilized in certain spots in India.

6. Conclusion

Utilization of medical device by people should be in support of safety aspect for usage. However, risk and danger can't be brought down entirely but they can be significantly made limited if organization knows about those approaching risks and take in effect a proper risk management process. ISO 14971 is the international standard for management of risk to a certain level of acceptability in terms of medical device by giving methodical structure of dealing with hazard, providing

manufacturing policies, approaches, practices and methods. The plan state that the manufacturer should follow a proper established internationally accepted risk management process for medicinal product through risk assessment plan, risk assessment, risk analysis, risk evaluation and control, residual risk acceptance and post production information. It also focus on information regarding qualification of working staff, experts who perform the risk management and well documentation practice of procedure.

Table 4 Biomedical waste categories and their method of disposal/ treatment (19)

Category	Waste source	Disposal/ treatment method
1	Chemical source (such as use of chemicals in the production of disinfectants, insecticides and biologicals)	Liquid Discharge into drains and solid into landfills or chemical treatment
2	Solid waste source (disposable items such as IV sets, catheters etc. other than sharp material)	Shredding/ mutilation, autoclaving/ microwaving
3	Liquid waste source (such as cleaning , disinfecting, washing activities in labs)	Discharge into drains, chemical treatment
4	Soiled materials (items soiled with human fluids such as cotton, plaster, dressings, bedding etc.)	Microwaving/ autoclaving incineration
5	Sharp waste (scalpel, needle, blades, syringe etc.)	Mutilation, shredding, autoclaving, disinfection.
6	Discarded cytotoxic drugs & medicines (outdated or discarded medicines)	Secured landfills disposal, destruction
7	Waste of microbiological and biotechnological nature (waste generated from laboratory cultures, specimens, vaccines, devices used for culture transfer etc.)	Autoclaving/ incineration by microwaving
8	Waste source from animals (animal tissues, organs, parts, fluids. Wastes generated by colleges using animals for experimental purpose, veterinary hospitals, etc.)	Burial/incineration
9	Waste of human anatomical nature (human organs, body parts, tissues)	Burial/incineration

In mitigating the risk, consider its impact on environment and design a sustainable medical device, is an aspect of dealing with hazard that these devices pose. For the prevention of patients from hazard associated with a medical device, ISO 14971 is essential for implementing in companies the plan with keeping in mind the hazardous impact that it has on environment which become one element of risk management plan of ISO 14971. Along with the companies initiative to deal with the patients hazards, awareness among users about the kind of medical device and their material they support while buying a product help develop complete system for taking steps towards green and sustainable environment around us.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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