Risk Management Plan For the Hospital Environment

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***Abstract*—A risk management plan is placed in ISO 14971:2019 standard for mitigating different kinds of risk related to the use of medical electrical equipment including the electromagnetic interference (EMI) risk in the hospital environment. However, EMI accidents in the hospital are still happening indicating that further improvement in the risk management plan is required. Currently, the risk management plan in the standard does not factor in the hospital environment realistically, leading to incomplete risk analysis, evaluation, estimation, and control methods. Due to the dynamic environment of hospitals, the rule-based EMC approach is insufficient and the risk-based EMC approach should be utilized in improving risk management plans. In this paper, we utilized several risk-based EMC approach techniques and measurements such as the foot-printing technique, for properly examining the hospital environment, source-victim matrix tool, to categorize the severity of EMI issue, statistical tools like probability density function, cumulative density function, etc., to calculate probability and predict any future EMI risk. These techniques assist in the zoning of the hospital environment into low-risk, medium-risk, and high-risk for which risk control methods can be established. Overall, we hinted toward improving the risk management plan, in terms of flexibility, accuracy, and reliability, using risk-based EMC approach techniques**

Keywords— hospital environment, foot-printing, source-victim matrix, zoning, electromagnetic compatibility, electromagnetic interference, electromagnetic environment, risk-based EMC approach

I. INTRODUCTION

Medical electrical equipment (MEE) is ubiquitous in hospitals and prone to electromagnetic interference (EMI) issues, interference of electric fields generated by other electrical devices present in MEE vicinity and MEE itself. Such interference affects the normal working of MEE and even can lead to malfunction which can result in severe accidents [1]. A step towards minimizing it by managing risks (which are also non-deterministic by definition) is a risk management plan (RMP) for MEE which has been introduced in various standards, i.e. ISO 14971-2019 [2] and IEC 60601-1-2 [3]. A risk management plan (RMP) starts with the identification of hazards related to MEE followed by evaluation and estimation of such risks. After evaluation, various strategies are formed to control associated risks. Lastly, the effectiveness of such strategies are monitored throughout the life cycle of the MEE. All CE marked and FDA approved MEE are scrutinized following the rule-based electromagnetic compatibility (EMC) approach by the manufacturers before introduction and implementation in the hospital. It was expected that EMI issues will be greatly mitigated after following the aforementioned standards.

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However, according to [4], accidents due to EMI-based malfunction of MEE are still there, indicating that the rule-based EMC approach is potentially insufficient. This can be due to: 1) Standard update lag: RMP gets an update at least after 5 years [5] in the ISO 14971 standards. The rapid increase in wireless communication technology, like the introduction of 5G, 6G [6], etc., and the advent of new electrical devices, leads to an incomplete evaluation and estimation of risks before the implementation of MEE. The majority of work has been done on controlling the risk using several techniques such as shielding, filtering, grounding, using conductive paint, cable ties [7], etc. This can be resolved either by updating the risk management plan more frequently in the standard, which in our opinion is not feasible, or we require altogether a different and stringent approach to fight against the EMI issue. 2) Dynamic environment of hospitals: The majority of the MEE is tested in a controlled environment like an-echoic chamber labs as prescribed by the standards. Based on this test; evaluation, estimation, control, and monitoring steps are outlined in the risk management plan. However, a real-life hospital environment is a complex environment and can be divided into three types: free/open space environment, semi-reverberant environment, and reverberant environment. Depending on the number of reflections and quality factors, these environments can be distinguished as discussed later in this paper. At any given time, any place in a hospital environment can't be described by one environment. Generally, we observed hospital environment shows semi-reverberant environmental properties. Therefore, a hospital environment is considered complex from an electromagnetic (EM) point of view. Standard-based risk management plans in a rule-based EMC approach do not account for such changes in the environment. This leads to a wrong analysis of EMI risk which can lead to incomplete evaluation and estimation of risk resulting in inadequate risk control steps during EMI issues. Furthermore, it is impossible to apply any harmonized standards because no standard can be fitted into a complex environment. Hence, a risk-based EMC approach is preferred which can take the hospital environment into account while forming a risk management plan. Furthermore, the risk-based EMC approach will provide freedom of update in the event of the introduction of new technologies. 3) Prediction and future behavior: Rule-based EMC approach is a binary approach- it determines whether EMI will be there or not. Whereas, the risk-based EMC approach is descriptive in terms of probability and severity- it provides statistical analysis of potential future risk which can improve the risk analysis in RMP and allow us in minimizing the risk rather than overcoming EMI completely in real life.

Risk-based EMC approach is in the research community for several years now and also been implemented by some marine industries (Llyod's register) in minimizing EMI issues [8]. Risk-based EMC approach provides several techniques,

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which are discussed later in this paper, that can help in determining the EM environment more realistically. However, implementing those techniques for the improvement of RMP is not discussed before. In this paper, we attempt to improve RMP using techniques introduced in the risk-based EMC approach. Initially, in this paper, we discussed factors such as infrastructure of hospital rooms, increment in electronic devices, and time variance behavior of sources that enhanced the EMI risk in the hospital environment. Following that, we discussed in depth various steps of the risk management plan mentioned in the current standard. While considering the real hospital environment, we suggested various areas of improvement in terms of flexibility, accuracy, reliability, etc. in the current risk management plan. We discussed various devices such as spectrum analyzer and methods such as quality factors to determine the real-hospital environment. We also discussed techniques like foot-printing [9], used to examine the electric field strength in the hospital environment, which is used in conjecture with various statistical tools and source-victim matrix [10], zoning of the hospital environment can be done. Zoning can be defined as low-risk, medium-risk, and high-risk environments. Once the zone is defined, risk control methods can be formed for each zone. Before implementation of any MEE, manufacturers should adhere to the corresponding risk management plan, depending on where it will be installed in the hospital. Creating a risk management plan based on the hospital environment or zones will also provide us an extra degree of freedom in case of the environment changes, like from low-risk to medium-risk. Lastly, we hinted toward the improvement of the risk management plan by presuming the effect of each technique introduced in the risk-based EMC approach. We believe that such a risk management plan can further mitigate the accidents in the hospital environment due to EMI

II. Factors led to the Risk of EMI Increment in Hospital

Various factors are involved in the hospital that can lead to EMI risk or its increment:

1) Infrastructure of the hospital rooms- Metal coating on hospital's doors, windows, floor, walls (concrete, doped glass), ceiling, pipes, cables, etc. makes them reflective for electromagnetic waves [11]. This leads to multipath behavior of EM waves increasing chances of constructive interference resulting in enhanced electric field strength which doesn't always decrease with increasing distance between source and victim making the hospital environment a complex environment.

2) Enhancement in the usage of wireless and other electronic devices in the hospital- Electronic devices, electric cars, elevators, antennas that are installed in various locations inside and outside the building, and routers installed inside the room are some of the EMI sources. With the increment usage probability of EMI increases. Furthermore, devices from the same manufacturer working at the same frequencies can cumulatively enhance the electric field strength [12]. Bluetooth and Wi-Fi-enabled devices sharing the same frequency spectrum (2.4 GHz) can also interfere with each other [13]. Furthermore, some of these sources change their location unpredictably over time. Overall, it enhanced the complexity of electromagnetic fields inside the hospital.

3) Time-variance behavior of sources- Faster switching electronic devices are also present in a hospital environment. Due to such devices and digital modulation schemes, radiated fields by such emitters are time-variant as discussed in our previous work [14]. These emitters can have different types of time-variance behavior and can be categorized into short-term, mid-term, and long-term time-variance. Devices with short-term time variance behavior such as GSM don't show a continuous signal but send a high-intensity short-duration pulse. If the testing is not done on similar modulation schemes, these devices can be an EMI risk and should be identified. Mid-term time-variance behavior is related to randomness created due to the movement of sources. Various sources such as mobile phones, laptops, LEDs, Bluetooth and radio transmitters, etc. are not fixed at a certain location and randomly move in and around the hospital. It was shown that some of these devices when in standby mode lead to a higher risk of EMI. Apart from its movement, the quantity of these devices in hospitals is also not fixed leading to difficulty in understanding the EM environment. Long-term time variance behavior is generally related to the aging of MEE. Old parts of MEE can create interference with other new MEE [15]. Overall, the time variance behavior of sources further makes the hospital environment more complex.

There are several other factors that make the hospital environment a complex environment such as no fixed distance between source and victim, the introduction of 6G, outdated standards through which MEE are verified and tested, etc.

Overall, the aforementioned factors impact the operation or lead to malfunction of MEE resulting in various minor and some life-threatening accidents as represented in Maude's report [4]. Figure 1 shows accidents related to EMI issues have increased considerably in the last decade. Furthermore, some of the issues either go unreported and most of them even cannot be possibly identified as EMI-based issues. We believe EMI-based accidents will be larger than represented by Maude's report. Hence, EMI issues should be either controlled or eradicated by some method. ISO 14971:2019 provides an in-depth risk management plan which has the ability to overcome EMI issues. This risk management plan is discussed in the next section.

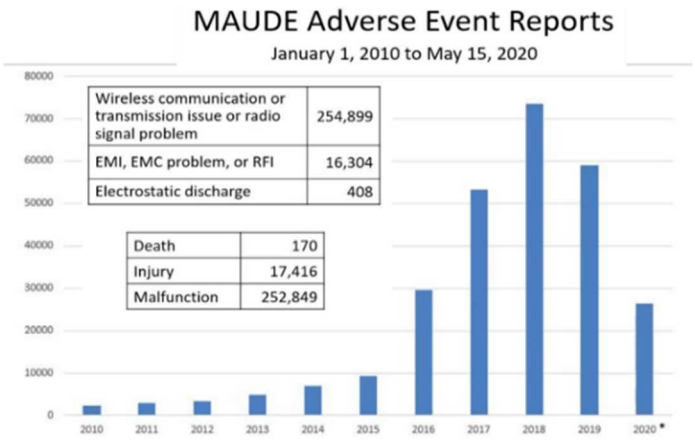

Fig.1 Maude's database shows accidents related to EMI in hospitals in the last 10 years across the globe

III. . Risk Management Plan in ISO 14971:2019 Standard

In order to overcome the potential risk of EMI increment in hospitals, a proper set of risk management activities should be planned. All the manufacturers, before implementing any MEE in hospital, should create and record a risk management

plan which should include at least the following information [2]:

-the extent of the intended risk management activities;
- defining and characterizing the MEE and life cycle stages to which each plan element applies;
- proper assignment of duties and authorities;
- requirements while reviewing risk-management activities;
- risk acceptability criteria including those criteria wherein the likelihood of harm occurrence can't be estimated;
- a technique for evaluating the total residual risk;
- set criteria for the acceptance of the overall residual risk based on the manufacturer's acceptable risk policy;
- activities relating to the verification of the execution and effectiveness of risk control measures;
-activities relating to the gathering and assessment of relevant production and post-production information;

Such a risk management plan must be included in the risk management file. In order to properly encompass the aforementioned information, ISO 14971:2019 (E) standard presented a model of the risk management plan for the manufacturers to follow. A risk management plan is a sort of flow diagram, as shown in figure 2, and includes the following major steps:

1. The risk analysis
2. The risk evaluation
3. The implementation and verification of the risk control measures
4. The evaluation of the residual risks
5. Review process
6. Activities during and after production.

In the risk analysis step, intentional usage such as operating principle, use environment, patient population, etc

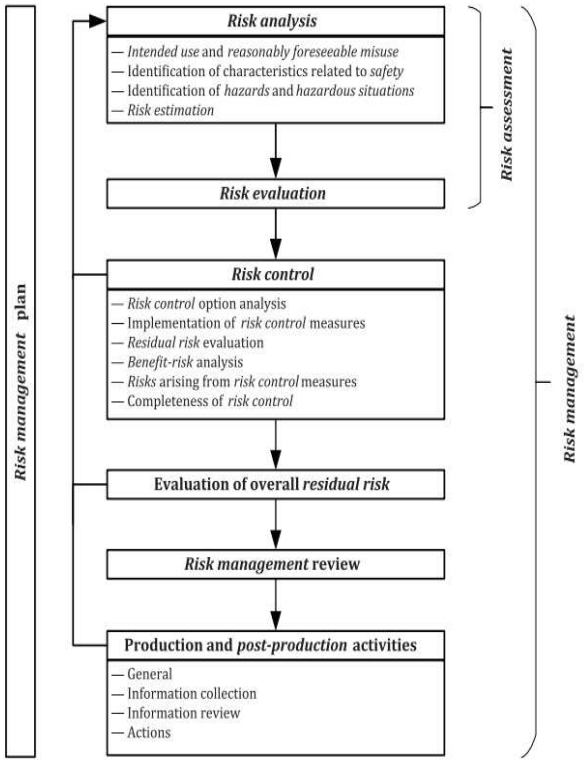

Fig.2. Risk management plan as mentioned in ISO 14971:2019

TABLE I. SEVERITY AND PROBABILITY MATRIX

		Qualitative severity levels		
		Negligible	***Moderate***	***Significant***
Qualitative probability levels	***High***	R4		
	Medium	R3		R1
	Low		R2	

and expected misusage of MEE should be identified. Risk analysis should also consider the type of electromagnetic phenomena present and which can be categorized into conducted, radiated, electrostatic discharge, or intentional EMI. Qualitative and quantitative analysis of the safety of MEE should also be documented in this step. The immunity test level of MEE is an important parameter to analyze the safety of MEE and is mentioned in IEC 60601-1-2 standard. Keeping in mind that the immunity test level is changing with every update in standard, the safety of MEE should be tested properly. Known and foreseeable hazards and related hazardous situations should be identified and mentioned. The risk associated with such a hazardous situation must be estimated and quantitatively categorized based on the possibility and severity of harm.

In the risk evaluation step, the manufacturer must analyze the anticipated risks for each recognized hazardous condition and determine whether the risk is acceptable or not, using the risk acceptability criteria. Risk acceptability criteria are established before risk analysis begins by the top management personnel and is documented as a part of the manufacturer's policy. Risk evaluation can be done using qualitative probability levels and qualitative severity levels matrix as shown in table I. Negligible severity level indicates temporary discomfort, moderate indicates long-term damage and significant indicates permanent damage. High, medium, and low probability levels can be distinguished on the basis of frequency of EMI occurrence such as daily, once in a month, or once in a year.

In the above example (Table I), risk in the grey boxes (R1 and R4) indicates the unacceptable risk and those in white boxes (R2 and R3) are an acceptable risk. Appropriate risk control measures must be performed in hazardous situations that provide an unacceptable risk.

In the risk control step, the manufacturer must select appropriate risk control strategies for lowering hazards to an acceptable level. The risk control strategies can either lessen the intensity of the injury or the likelihood of the harm occurring, or both. In order to achieve that, manufacturers can either update the MEE design and manufacture for enhancing safety or/and introduce protective measures in MEE itself or/and provide proper training to users. Some examples of EMI mitigation design techniques are shielding, filtering, grounding, galvanic isolation, etc. Proper instruction on operation, maintenance, and repair can also be included in the risk control step. All the strategies should be documented in the risk management plan. Each risk control measure should be verified after implementation. The efficiency of risk-control methods must be evaluated and authenticated following risk acceptability criteria. Evaluation results must be documented as well. Manufactures should exhaust all risk control options to deem risk acceptable. If the risk is still unacceptable after implementing risk control strategies, manufacturers should compare the benefits of intended usage with the risk. If the risk outweighs the benefits, the

manufacturer should modify either MEE or its usage. If benefits outweigh the risk, manufacturers should evaluate whether newly introduced risk control options don't create potential risk. All these findings must be documented in the risk management file.

In the remaining steps, evaluation of the overall residual risk posed by MEE should be done and documented wherein residual risk contribution, and benefits of intended use are taken into account. Following that, a thorough review of all aforementioned steps is done before introducing MEE to the market, and review results are documented. Lastly, all the information related to MEEs during production and post-production is collected and documented to complete the risk management plan.

IV. Area of Improvement in Risk Management Plan

While the risk management plan mentioned in the standard provides exhaustive steps for manufacturers to follow in order to mitigate EMI issues in the hospital environment, some improvements in terms of flexibility, accuracy, adaptability, reliability, and complexity can still be done. Risk analysis and risk evaluation steps in the risk management plan can be benefited from some improvement. While analyzing the risk, manufacturers test the MEE in a controlled environment as prescribed in a standard. However, in reality, the hospital environment is a complex environment. A hospital environment at any given time and space can exhibit properties of a semi-reverberant environment [16] on the basis of the degree of reflections possible. Wherein a free space environment there is a single wave propagation path between two points, in other words, no reflections, reverberant environment offers multiple propagation paths because of a high amount of reflections. Due to this, unlike in a free space environment, analytic determination of electric field in a reverberant environment is tedious or impossible, and electric field strength can be considerably higher than the free/open space environment at a set source-victim distance. The semi-reverberant environment is anything between free/open space and a reverberant environment. In reality any enclosed real environment, like the hospital, properties cannot be representative of one single environment but rather oscillates between environments depending on the number of reflections present at any given time. In the hospital, the number of reflections in all the spaces is not the same and therefore a risk management plan should be flexible enough in order to accommodate the change in the environment but it is difficult for any harmonized standard to be fitted for a complex environment. Hence, a risk-based EMC approach is developed to find techniques and measurements (T&M's) which can help us in understanding the actual hospital environment and related EMI issues. To analyze the hospital environment accurately and categorize it into free/open space, semi-reverberant, or reverberant, a volume sampling technique can be utilized wherein a transmitting discone antenna can be placed at a fixed position and a planar inverted cone antenna can be used to sample the volume in the radius of 3m and 50 spatial locations around the transmitter. Both antennas can be connected to a vector network analyzer performing an experiment in frequency sweeps with a fixed range. In order to minimize direct coupling between antennas, perpendicular polarization can be used. This way we can measure the whole environment. Following that, several methods such as quality (Q)-factor, insertion loss, the goodness of fit test, Rician k-factor, etc. can be utilized as a matric to analyze each type of environment quantitatively [17]. For example, with the power received and power transmitted value, Q-factor can be calculated for all the concerned environments and if the value is an order of less than 2 it can be declared as a free/open space, and if it is above 30 then it can be declared as the reverberant environment. Anything in between 2 and 30 will be a semi-reverberant environment. Once the environment is accurately determined, electromagnetic field strength should be measured and one good technique is foot-printing. In such a technique, one antenna is placed in a standing position for a certain amount of time to receive the electromagnetic field strength inside the room. A spectrum analyzer can measure the magnitude of the signal received within a set frequency range for a set period of time as shown in figure 3. More detailed information is discussed in our previous work [14].

The foot-printing technique identifies permanent electromagnetic radiation sources in and around the hospital, as well as portable and mobile sources. It should be noted that the electromagnetic environment is quite dynamic and foot-printing in the same region at various times may provide different results**.** Using statistical tools like the power density function (PDF) it is possible to calculate the probability of surpassing a critical level above which there is a risk of EMI. Gaussian PDF can be fitted on any histogram of power received at any particular frequency. Gaussian distribution can be considered as the best first assumption. Later for the same fitted distribution, a cumulative distribution function (CDF) can be done to get the cumulative probability of surpassing a critical level. With the use of these statistical analyses, we can assess the probability of receiving high power, which might result in EMI in a hospital environment. The risk-based EMC approach necessitates estimating the probability of EMI occurrence and the severity of such EMI. Currently, manufacturers, while examining the EMC or EMI risk, test the MEE at a set electric. field strength, as mentioned in standards, for all kinds of use environments. This lead to an incorrect analysis of risk as the electric field strength is not only different in a different environment but also not constant in any particular space in a hospital.

The foot-printing technique in conjecture with statistical tools can provide a proper benchmark of electric field for manufacturers to test MEE which of course will be different depending on the space MEE will be implemented. This can improve the risk analysis. It will be better to use this technique before implementing any MEE in that environment as this technique will indicate if the environment is safe for the MEE or not. Another technique we can utilize is a source-victim matrix tool. In the hospital environment, there are several EMI sources and victims and this tool can show the interaction between all the source-victim pairs depending on the level of severity and probability parameters of those pairs. Potential sources inside a room, such as wireless devices, and potential victims, which are mostly all MEE in the room, can be used to create a source-victim matrix. Each source-victim pairing has its own set of risks that can be accessed separately. To determine the expected risk, the probability and severity must be examined. It is a well-known technique for determining the level of risk in the marine environment. It is feasible to determine the total risk of EMI in the case of the selected

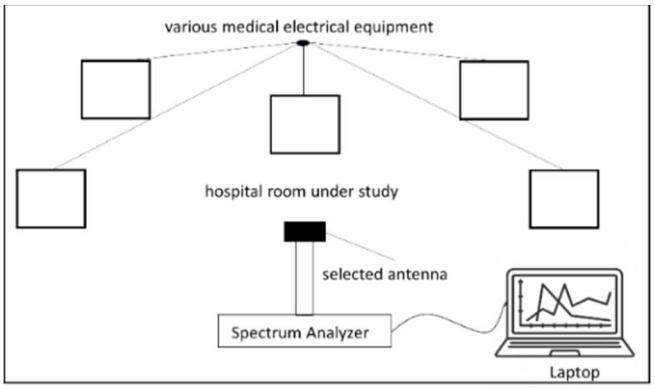

Fig.3. Foot-printing setup

pairings based on the combination of these severity and probability parameters. Table II shows an example of the source-victim matrix, where the dark grey color box indicates the high risk, the light grey box indicates medium risk and the white box indicates the low risk. Here, S(1,2,3,14)V(1,2,5)means sources 1,2,3,14 with high probability interferes with victims 1,2,5. Having such a matrix wherever MEE will be implemented will help in the correct evaluation of risk.

The source-victim matrix will show the victim who has the highest risk of EMI, and the foot-printing will indicate the type of EM environment inside the room, providing the perfect estimation of the risk of EMI. It will also help to divide the hospital environment into different EMI zones: low-risk, medium-risk, and high-risk zone. A low-risk zone is defined as a location where the electromagnetic field radiation inside the room is very low and does not exceed the critical level, and the source-victim matrix indicates that there is no chance of interference because the pair falls into the minor probability and negligible severity category. A medium-risk zone is defined as a location where the electromagnetic field radiation inside the room may exceed the critical level, and the source-victim matrix indicates that there is a chance of interference because the pair falls into the combination of moderate or minor probability with serious or negligible severity category. A high-risk zone is defined as a location where the electromagnetic field radiation inside the room will exceed the critical level, and the source-victim matrix indicates that there is a chance of interference because the pair falls into the combination of probable, moderate, or minor probability with critical or serious severity category.

Zoning of the hospital environment is important because it is not accurate to believe that all the free/open space environments will be low risk or that all reverberant environments will be high risk. Free/open space can also be high risk or a reverberant environment can also be a low risk depending on the source-victim matrix. There is no zoning in the hospital environment yet. But zoning is already being used in the marine environment. The main intention of zoning is to establish distinct environments in which various MEE intended to do the different tasks may operate safely. Like this, electromagnetic disturbances are confined to their respective zones where they are generated. This separation will keep different types of MEE from interfering with each other and also with other wireless devices present inside the room. Because of zoning, each zone can have its own EMC measures. A failure of a single piece of MEE will not result in widespread disturbance. As a result, zoning will boost robustness while reducing complexity [18].

TABLE II. SOURCE-VICTIM MATRIX

		Victims(V)		
		Critical	***Serious***	***Negligible***
Sources(S)	***Probable***	S(1,2,3,14) V(1,2,5)	S(1,2,3,14) V(3,4,6-10)	
	Moderate	S(4-9) V(1,2,5)	S(4-9) V(3,4,6-10)	
	Minor	S(10-16) V(1,2,5)	S(10-16) V(3,4,6-10)	

V. MODIFIED RISK MANAGEMENT PLAN

Risk-based EMC approach has been utilized in the last several years and proved to be better than the rule-based EMC approach in various aspects. As discussed, it also provides several techniques which bring us closer to understanding potential EMI issues and correctly predicting possible EMI-based risks in the real hospital environment. As these techniques have been around in the research community for the last several years, nobody has attempted to integrate them into the risk-management plan and therefore manufacturers are still relying on standard offered risk management plans. Herein, we attempt to modify the risk management plan by utilizing the aforementioned techniques. The modified risk management plan is shown in figure 4.

In our opinion, the risk-management plan should start with the identification of the risk environment. In this step, manufacturers and technicians working at the hospital should first identify in which environment MEE will be implemented. They should also document which environment amongst free/open space, semi-reverberant, or reverberant environment is considered during the risk management plan. For each type of environment, critical electrical field strength should be calculated. This step enhances the flexibility and adaptability of the risk management plan in the hospital environment. Once this process is done, manufacturers should test MEE according to the critical electrical field strength before analyzing any risk. The result of such a test should be documented in the risk management file. This impacts the accuracy of the risk management plan. Following that risk analysis can be done according to the standard discussed before in the risk management plan. Apart from what was discussed before, in the risk evaluation step manufacturer should evaluate each of the hazardous situations in a given space and zone them into low risk, medium risk, and high risk using the source-victim matrix. It can help the manufacturer to decide which is acceptable and which risk requires risk control measurement. The manufacturer should also predict whether a low-risk zone can be changed to medium or high risk in foreseeable future. This enhances the reliability of the risk management plan. These findings should be documented in the risk management file. The manufacturer should create risk control methods as discussed before for each zone. The remaining steps; residual risk evaluation, risk management review, and post-production activities; can be documented according to the standard while keeping in the mind the type of environment for which the risk management plan is made for.

Overall such a modified risk management plan can be more suitable for a complex environment such as the hospital. However, we believe with the introduction of a new technique in the risk-based EMC approach area, this management plan can be further improved.

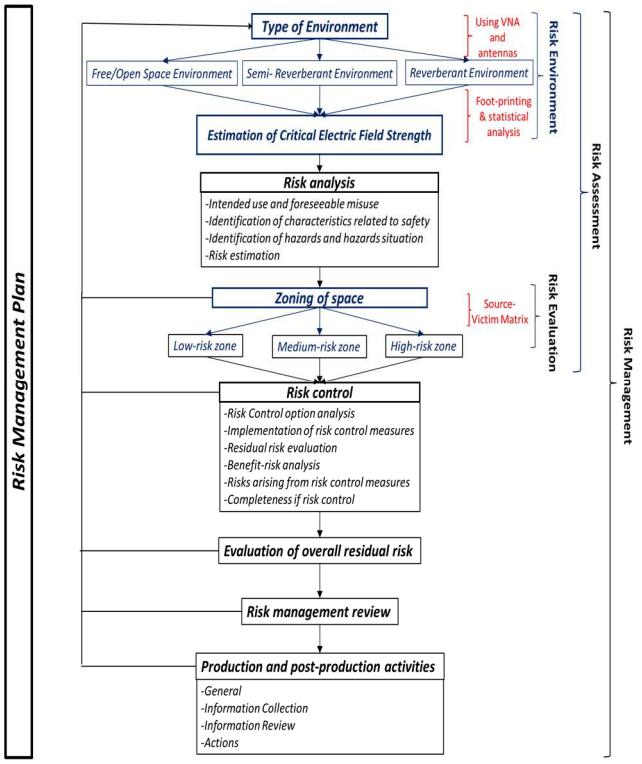

Fig.4. Modified risk management plan

VI. Conclusion

Medical electrical equipment (MEE) is prone to EMI risks in the hospital environment which can result in its malfunction leading to severe accidents. In order to overcome this issue, ISO 14971:2019 standard is in place and followed by manufacturers before the implementation of MEE in hospitals. In this standard, a risk management plan is mentioned which includes risk analysis, risk evaluation and estimation, risk control, evaluation of overall residual risk, risk management review, and post-production activities. These steps should be documented and a risk management plan should be created by every manufacturer before the implementation stage. This standard-based risk management plan does not examine the full impact of the characteristics of the environment. It is important because the hospital is a complex environment and changes with time and space. Hence in this work, we suggested improving the risk management plan through the assistance of various techniques introduced by the risk-based EMC approach. We discussed how foot-printing and statistical analysis helps to divide the hospital environment and the source-victim matrix helps to do zoning of space based on low-risk, medium risk, and high-risk EMI.

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