Fourth Edition of IEC 60601-1

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Transcript

00:00:00 Speaker 1

This will quickly lead to one or the other manufacturer having to edit its architecture in order to be compliant again.

00:00:07 Speaker 2

Medical Device Insights.

00:00:09 Speaker 1

A podcast by the Johner Institute for medical device manufacturers, authorities and notified bodies.

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At the moment, we have no shortage of regulatory changes.

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If you just think about what the EU Commission is currently planning with the MDR IVDR 2.0,

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these are already massive changes.

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Most people probably notice that or have already noticed, what perhaps not everyone has noticed, is that for the medical-electrical products, as I think, a much bigger change is currently pending, namely the committee that 60601 is currently working on the 4.

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edition and one of the people who are involved in it, that is my dear colleague Mario Klasaschek, and I wanted to talk to him in this

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In today's podcast episode, let's take a first look at what they're working on and then maybe pick out one or 2 topics for us.

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Of course, we can't cover everything they're planning in one episode, but maybe we can do a few important aspects.

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Mario, first of all, welcome, nice to have you here.

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What is your job

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in this standards body?

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So do you then have a special subtask that you have been given, or are you just there, what do you mean easy, difficult enough?

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Someone from a big team and everyone is working on everything, how do you have to imagine it?

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What is your specific role, your specific task?

00:01:36 Speaker 1

Okay.

00:01:37 Speaker 1

Hello Christian, thank you very much.

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Yes, so there are currently over 300 people working on this new standard and of course we have divided into teams for this reason and have two main topics that we are working on.

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And I'm working on all the basic concepts.

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So that's actually the most important thing from a normative point of view.

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So what is basic security, essential performance characteristics, what are first errors, normal state.

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Without these foundations, the whole standard does not work.

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And I decided to work on this important part because I find that that's where most mistakes happen.

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Yes, that's the basis for everything else.

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As you say, these are the basic aspects.

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If that goes wrong somehow, the rest probably won't be much

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much better.

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Before you maybe focus too much on these topics you just mentioned, maybe just give you a quick overview.

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So, what changes are planned at all?

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So, what do manufacturers have to prepare for?

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So, will the 60601 still exist at all?

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Yes, or will they perhaps even be dissolved or split or merged somehow?

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So, what is seen from a high bird's eye view, what is it that you have to or can prepare for?

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Yes, so of course it remains.

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It is one of the most important documents we have for safe medical devices, but nevertheless there will be a fundamental change in the standard.

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For example, that the whole Part 1 standards, the particular norms, are merged into the main standard.

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The background is actually that maintainability and maintainability across the various parts of this standard was complicated and this has always led to misalignments.

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which is now mastered by writing everything into a main norm, so to speak.

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Of course, it will be extensive and new and very big.

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And what changes beyond that, albeit in a critique, is difficult to understand, what is a requirement and what is not.

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And the whole structure of the requirement will change, so that you can now clearly identify more requi-

rements.

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If the document is less text-heavy, it is much more worked in lists, which of course also

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thinking into the future, it becomes much easier for the language model to understand such a thing.

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So it's already moving in the direction of structured data.

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So you haven't quite arrived at the JSON or XML level yet, but that sounds relatively close.

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I think that's even the goal, that the standard can then be made available as XML.

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And for this we have already laid the foundation in the writing style, so to speak.

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That's great, you might get that from M.D.N.I.V.D.

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at one point or another.

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I find the approach interesting to make things more maintainable in software development by merging, you have exactly the opposite, maintainability by decomposition, yes, by forming modules that you always say have Strong Cohesion, Weak Coupling, but that seems to be different here.

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So maybe now is a bit of a theoretical question, but

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Would you like to say a sentence about it or is it already too spaced out at the beginning of the interview?

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No, so it will be much easier for the users, because the standard is now of course totally legible in context.

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So and before that, you had to, you had gaps, because you might not have been applicable to certain parts of the standard for your product, but the gaps were still important for understanding and in this respect it is now much more consistent and understandable and more comprehensible.

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Yes, so let's talk about usability, which we can do with it too.

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Rejection, definitely and that for both, i.e. for all stakeholders, no, for the companies that develop it and also for the auditors who have to test afterwards or auditors who have to test afterwards.

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Mhm, you have already said in which area you are active, namely with all these basics, yes, that is, it is ultimately about the basis of the whole thing, also risk management, what is a mistake, how do I identify it, how do I evaluate it, you have also, I think, now said, topic,

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Initial failure safety and so on.

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Can you give us an overview of this basic area in which you are active?

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What changes are coming up?

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Exactly.

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The large framework of the norm is also drawn a little larger than it was in some cases in the past.

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That is also risk management, that will be a central point.

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This then involves exactly the questions, how do I have to behave a device in the event of an error or what is an error in the first place?

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When do I even qualify an error as a mistake?

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And that's where we quickly get into all these basic concepts: first-fault safety.

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There are many terms in it, which have often led to misunderstandings because the definition was not clear in the norm.

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The examples that Norm itself gave us were partly contradictory.

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It is very important to us that we straighten out the offenders so that they will hopefully be more understandable and comprehensible in the future.

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Let's pull out one of these terms, you just mentioned: first-fault safety.

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Can you pick us up again?

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So probably the concept will remain in principle for the time being, so that you help us to understand this term again, maybe with an example, maybe even demarcating normal state again.

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So you, there's a whole jumble of terms around this initial mistake.

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Could you bring us up to date again, i.e. what is today and then perhaps also what will change or be clarified.

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First of all, the philosophy remains that even if a first error occurs, the device must remain secure.

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Security is defined as freedom from unjustifiable risks.

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And this freedom, these limits as to when an unjustifiable risk is, is determined on the one hand by the manufacturer, but on the other hand also by the norm in many areas.

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And it has often been a misunderstanding whether every single error in the device is already a first error.

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I'll give an example.

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Let's say we have

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a control system on a heart-lung machine that regulates the blood velocity at the exit.

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And then the question was often, is an error within the control system already a first error or is the first error only there in the function that monitors this speed?

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In other words, what the actual risk control measure is.

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And of course, if I now say that I already consider the error in the control system to be the first mistake, then I only needed one more risk measure and was sure of the first mistake in the mathematics 1 plus 1 is 2.

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But it must be correct that the first mistake concerns the risk measure.

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And so is the definition.

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So a mistake is the failure of a single measure to reduce a risk.

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And so it would not be the failure of the control system or the error in the control system that would be the first error, but the first error would be an error or failure in the associated protective measure monitoring, speed of the engine.

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And that now has a completely different consequence in architecture.

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So if this is only the first error, then of course I have to recognize that this protective measure has failed, because I have to expect a failure in the control function at some point in a certain time.

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And I have to know this time in between so that I know how often I have to check this measure and, if necessary, take a second measure against it.

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And that is of course very relevant to architecture.

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And there is now clarification and the misunderstandings are cleared up.

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But so that I understand correctly, if he has to rework, it is not only because the fourth edition is stricter, but because he was already non-compliant according to the third edition.

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Did I understand you correctly?

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Yes, exactly.

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So it is not a change in the concept, but it is a clarification of where the standard had a gap.

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And this then led to interpretation errors on both sides, often on the part of the inspectors and the manufacturers.

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And we can see the consequence.

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So the FDE in particular criticizes the fact that there are still a lot of serious injuries to patients with medical-electrical devices, although this worm is there, although two instances are checking.

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But because it was misunderstood and wrongly followed or not followed at all.

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So I think I have learned that the concept of first-fault safety remains, even unchanged, but that there are new clarifications,

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as for this one, as far as the concept of first-fault safety is concerned.

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Are there any other things in this context cloud that you are working on besides describing or defining the term first-fault safety more clearly?

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Yes, so this, this concept of first-fault safety is exposed, so to speak,

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three components.

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We have just clarified one, Single Ford Condition, i.e. what is a first error, then also what is normal condition and what we also want to work out further, which is not at all clear in the norm today, is that there is also a whole temporal component in between, namely what is an example of a fault tolerance time.

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So this means that if a device is

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if it behaves incorrectly, this does not necessarily mean that the patient slips into an unacceptable, unjustifiable risk, but that there is a time against the patient.

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And as long as the error remains undetected, it tends to be difficult for the patient, depending on whether the device is critical or not, it will be

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I need to know that time.

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This means that my entire architecture must then be designed in such a way that I also know what the failure rates of components are and what times I have between two errors.

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It is sometimes said so, multiple error entry time.

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So this dynamic, which then .

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Today we look at architecture more statically, and in the future we will look at it very dynamically.

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This is missing from most security concepts and it will come.

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I understand that.

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Is my conclusion correct that this will also make the standard more extensive in order to be able to define all this once and then also to be able to define new additional requirements?

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Yes, I can say that.

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So today the standard, the basic standard, has a scope of approx.

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450 pages, depending on which language you read them.

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We are now working on a fragment that alone has 200 pages, with all the explanations at the end.

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The norm will be significantly larger.

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But that means that there are no more requirements, but many more clarifications.

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You just used the term fragment.

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I also know this from the usability sector.

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There is also a fragment.

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Earlier you said that it will be a thicker standard rather than many sub-standards.

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How does this fragment concept fit together with the statement that it is only one?

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Yes, so that's an internal term we're using right now.

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So we have divided ourselves into twelve fragments in these twelve teams, which will be put together at the end, but then there will be a basic standard, so to speak.

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And when writing, it is already noticeable that the fragments are sometimes larger, i.e. the individual sections become, so to speak, more extensive than the overall standard.

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Of course, that's clear, because we will of course then merge eleven sub-standards.

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But overall, the results of the work that have now been created are in some cases more extensive than the old sub-standards.

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Can you perhaps give us one or two more examples of the old ones, so that the listeners know what you mean by that?

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The classics are the alarm standards that everyone knows, dash-8.

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Then we have the stroke-1-6 for usability.

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It is clearly conceptually drilled up against what we have today.

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Today the standard consists of one and a half pages, now it is becoming very extensive.

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There are things like IT security that weren't even concrete in it before.

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We still have dash-11 for home use, dash-2 so dash-1-2 for EMC.

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These are those Part 1 norms that we know.

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There are 12 of them today.

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And they are then subsumed into it.

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Yes, that sounds like a very extensive work.

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I know that you currently have this focus in this one working group that deals with the topic of dealing with risks and that

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yes, also addressed concepts, first-father security also dealt with.

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If we zoom back for a moment, are there one or 2 changes in the other areas, in your neighborhood of the activities, about which you can already say something?

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Yes, so there will be

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In the area of EMC, changes will be introduced.

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Today, for example, we do not consider the biological effect of radiation on the patient at all.

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That comes at most because we may have radio systems in it.

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Then we have to do it, just through the Radio Equipment Directive or the FCC.

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And in the future, it will be normatively required that manufacturers must also evaluate the effect of radiation, i.e. the biological impact of the radiation of their devices on patients, especially in the case of body-worn devices and such things.

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That would be a point,

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What I have seen is that even all the temperature ranges in which devices function stably and function safely, there will be much stricter requirements in the future.

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There are also fundamental changes in the area of use specification, i.e. the specification, the patient in general.

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So far, we consider a patient to be a patient, regardless of whether it was a neonate or an adult or an elderly person.

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And in the future, we will open it up much further between children, neonates, adults, older people.

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There will be more areas and that means there will be more specific requirements for these categories.

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So if we categorize more, have more category-based requirements.

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So in summary, the new version of the 6601 has requirements that have not existed before.

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It has requirements that it creates strictly, i.e. where there were already some, but where the requirements are increasing.

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And there are areas where they are more differentiated

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now, as is the case right now, for example, with regard to age.

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And she has some that she simply formulates better.

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So these are, so to speak, on an abstract level what you are working on.

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Is there already a timeline for this?

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Yes, so the goal would be that by 2829 the fourth edition should be available achievable.

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I can‘t say now

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Once a year we have a synchronization meeting about everything, where the other teams are at the moment, whether the timeline is still tenable or not.

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But it will be sporty, it will be very sporty.

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That is already clear.

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But with this scope, it has to be said, it is also justified to a certain extent.

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I would like to remind you that the 62304 has been unchanged since 2015, so for ten years or eleven years.

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And that in the area like software, that I dramatically

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and the 2015 version was still half an update to what was written in 2005.

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Well, we have colleagues at the institute who weren't even born.

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Yes, you have to understand, I mean as an example, it was now in my group, we have been discussing now since our last meeting in Milan in November, we are now discussing the concept of single-flow conditions again, always have four meetings for the first two weeks of the month.

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at unchristian times, so that it becomes neutral for everyone.

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And sometimes they discuss three hours in one formulation.

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So it's so important to us that we do it right.

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We are all technicians and not lawyers.

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And it is difficult to formulate a sentence that is unambiguous, so to speak.

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Although the technician has a high opinion of it and sometimes does it better than the lawyers perhaps explicitly don't want to.

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So this sharpness and this precision in thinking, that's exactly what we lack in our regulatory system.

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You just told us the time frame, so it's not something we have to calculate in the next 2 years, I would say, because you said 2829 and that's rather a bit sporty.

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So that means it will probably not be there at 28, at least not at the beginning.

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That means we're talking about at least 2 plus years here.

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Are there still things that manufacturers should consider now,

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perhaps also in view of the fact that medical devices do not want to be completely redeveloped every two years.

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Is there anything where you can prepare yourself so that you don't get hit particularly hard by this new edition of the norm afterwards?

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Yes, absolutely.

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So the norm, it will certainly not decide as a whole only then.

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There will be versions that can be purchased beforehand and I would then advise the manufacturers to also use our

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Raider then maybe even track what already exists, what is released, in order to prepare for it at an early stage.

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We all know that device development takes three years, three to four years.

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And even if you take into account a transitional period, the time is quickly over.

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In other words, companies that are currently in the process of developing new devices or in the lifecycle

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are in the process of planning the next revision steps, should already start thinking about their security concept, first of all, do I have a security concept?

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So to check and see, could we slip into a trap if we want to sell the devices for another eight years?

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You said something earlier, which I would like to emphasize and repeat at this point.

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You said that many believe that they are compliant with standards, but often in

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have errors in thinking, so to speak, in the basics.

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As an example, you had mentioned manufacturers who see an initial error as the failure of a control unit and not the risk-minimizing measure and then you are through this whole chain one step too early and the measures do not take effect and that is not only strictly speaking, it is even now a non-conformity and I think these are the things that you have to check very carefully,

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because no matter which variant 60601 will take effect, it is not compliant and also independent of the grip of any legal requirements, that simply makes the products unsafe.

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Exactly, and these are exactly the things where you can help.

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So I would say, I'll also put your contact details in the video description or in the podcast show notes afterwards, so that you can check it again, because these are things that are just hard to change afterwards.

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Absolutely, especially

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Devices are becoming more and more complex, they are not getting simpler.

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And in this context, parts that the standard formulates very simply, sometimes have to be considered very differentiated for a product and sometimes the boundary is fluid and you have to look closely and create an explanation why you are doing it this way now.

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And this justification is often missing in the documentation.

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They are all assumptions that are implicitly somewhere in the developer, but are written down somewhere and therefore even a reviewer cannot understand it.

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Mario, I would say that you have given us a great insight and first overview.

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You had reported, so once very important, that there will be a new edition of the 60601 and thus what a major upgrade is, so not just a correction.

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You have reported that this standard will be much, much more extensive because it will summarize all

the dash 1 parts.

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We have seen that it makes new demands, but also in some cases more finely differentiated and

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clarifies things.

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And as an example, we talked about the topic of first-fault safety.

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And that was the point again at the very end: This precise understanding of an initial error is the prerequisite for being able to manufacture compliant and safe products at all.

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And that's exactly where you help.

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Yes, Mario, all that remains for me to say is a very big thank you.

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With pleasure, at any time.

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Bye.