Attention ⚠ ISO 15223-1 4th Edition is ~~Almost~~ Here: How to Update Your Medical Device Labeling to Comply with the New Requirements

FREQUENTLY ASKED QUESTIONS

Below are the most frequently asked questions that are the outcome of the webinar hosted by Greenlight Guru, Attention ⚠ ISO 15223-1 4th Edition is Almost Here: How to Update your Medical Device Labeling to Comply with the New Requirements.

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Eisner Safety Consultants can assist your company by conducting gap assessments of your product(s) for your labeling (IFU's, technical documentation, markings, etc.) & packaging; determine applicable standards, regulations, laws, etc.; gap assessments against the Amended 60601 standards or conducting more detailed product and document reviews; MDR consulting support; Quality System Internal & Supplier Audits; among other compliance and regulatory support. We can provide public & tailored training on all these topics. Please feel free to contact us or schedule a call. Signup for our newsletter, and follow Leo on LinkedIn and Twitter.

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processes like CAPAs, risk, audits and more. Greenlight Guru's MDSP is used by thousands of organizations across the globe to push beyond baseline compliance and achieve True Quality for their medical devices. For more information, visit www.greenlight.guru.

Q1-1: When will manufacturers be expected to be compliant with the changes in ISO 15223-1:2021?

A1-1: It depends on when the applicable national regulator adopts the standard. The standard itself has no transition date noted as ISO doesn't allow publication of a transition date. No national regulators have adopted the ISO 15223-1 standard yet as it was just published by ISO on July 6, 2021. So, the transition period for each national regulator has not been identified yet and we will have to wait to see what is determined by each national regulator. Expect either the US or the EU will be the first countries to adopt the standard through their national standards bodies.

The EU MDR General Safety and Performance Requirements (GSPR) 23.1 (h) indicates: "the information supplied by the manufacturer **shall** take the form of internationally recognised symbols". Hence using such symbols in Europe is mandatory. This is independent of listing a standard in the Official Journal of the European Union (OJEU).

ISO 20417:2021 Medical devices – Information to be supplied by the manufacturer, establishes requirements for the general information that manufacturers have to supply with their medical devices and IVD devices.

ISO 20417:2021 is also on the list of standards to be harmonized under the EU Medical Device Regulation (MDR). It replaces EN 1041:2008+A1:2013, which has now been withdrawn by CEN.

Q1-2: When will the FDA Recognize the standard?

A1-2: Based on discussions with the FDA Standards & Conformity Assessment group I have confirmed that the FDA Recognized Consensus Standard timing is expected to occur by the end of this year (2021). Note, that the standard will be added to the

Recognized Consensus database (db) first to get into the manufacturers hands as soon as possible and then published in the Federal Register sometime later, as that is the normal process that the FDA has been doing for the last couple years.

Q1-3: When will the EU Harmonize the standard?

A1-3: The date of ratification (DOR) by CEN was July 4, 2021, for the EN ISO 15223-1 version of the standard and it is considered equivalent to the ISO 15223-1 other than the Annex Z's & the European Forward will be included in the EN version of the standard when the standard is Harmonized. The CEN db shows that the standard has been approved (Sept 9, 2021). EU Member States now have six months (til March 31, 2022) to implement (Date of Publication) the ratified text as their own national standard. You should be able to purchase a copy of the EN version of the standard from any CEN member body by this date. For example, thru BSI or Estonian Centre for Standardisation and Accreditation (One of the cheapest EU sources to purchase but need to purchase 2 copies of EVS-EN version to have a full access copy – still cheaper than most sources). Hopefully the standard will be Harmonized in the near future, but rumor on the street now is that the EU Official Journal may only occur a couple times a year for MDR & IVDR Harmonization. Do remember, that Europe no longer lists a transition period when standards are listed in the OJEU. The DOCOPOCOSS (Date of Cessation of Presumption of Conformity of Superseded Standard) has been deleted from OJEU listings. Further, since there were no standards listed on the final date of application of the MDR (May 26, 2021), all listings in the OJEU are immediately effective.

Q1-4: Does Health Canada Recognize the standard?

A1-4: Currently Health Canada doesn't show ISO 15223-1:2016 on their list of recognized standards for medical devices Effective 7 May 2021.

Q1-5: Do the changes in the standard impact all classes of devices at the same time?

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A1-5: The regulatory classification of the device should not impact the timing of when the standard is required to be implemented, in most, if not all regulatory schemes.

Q2: Are the oval sterile barrier symbols required for devices that are not sold within the EU?

A2: The standard is voluntary, and it is based on the context that national regulations, if you the manufacturer decides to apply the symbols in the standard it will help to reduce the burden of translation in your labeling. This response applies to many of the questions in this list. Refer to Q&A10.

The symbols are voluntary in most regulatory schemes. Please verify with your regulatory affairs personnel or consultant if the standard is considered voluntary in the jurisdiction of concern. The beginning of the introduction of ISO 15223-1:2021 is noted below which talks about translation as it is related to symbols.:

> "...For simplicity and to avoid translation of text, this information can be provided as symbols that have a specific meaning. This document does not specify the information that needs to be provided, but does specify internationally recognized symbols for the provision of this specific information.
>
> The symbols included in this document have been published in ISO 7000, ISO 7001, IEC 60417 or have been subjected to a formal symbol validation process.
>
> This document is intended to be used by manufacturers of medical devices who market products in countries where there are specific language requirements..."

A good way to think about the voluntary use of symbols, unless required by a national regulator, is that a medical device manufacturer may choose in the following priority order (highest to lowest order):

1) use the symbols in this standard,

2) use other appropriate symbols (such as ISO & IEC symbols),
3) use accompanying text with the appropriate symbols (could be ISO & IEC symbols), or
4) develop your own symbols (not recommended at all).

The benefit of using symbols from ISO 15223-1 is that the symbols have been validated for understanding by the target group of medical device users (patients and clinicians, nurses, etc.) and the intent is to support national regulatory requirements such as the EU MDR / EU IVDR when the standard has been listed in the OJEU. FDA is active in ISO/TC210/WG3 which is the working group involved in this standard so they are also vested in this standard and have indicated they will Recognize the standard as noted in A1-2.

Q3: Will this new labeling requirement (ISO 15223-1:2021) completely replace the 2016 version of the standard?

A3: Yes, the previous 3rd edition (2016) is now withdrawn by ISO and has been replaced by the 2021 4th edition. However, it depends on the national regulator when and how they transition to the new edition of the standard and if they expect "State of the Art" (as is it commonly known under European Regulations).

Q4: Does the sterile barrier system symbols have to be added to sterile product for FDA product?

A4: Remember, using standards is voluntary as noted Q&A2. Currently, ISO 15223-1:2021 is not an FDA Recognized Consensus Standard but will be (refer to A1-2) and there will be a transition period adopted for it to be determined by FDA. I would highly recommend adopting these symbols for your medical devices as soon as possible as these symbols were designed by consensus of an international group of standards developers; they simplify the label of your product. The standards developers include manufacturers, regulators, consultants, and other interested parties. The FDA was involved in the development of a wide variety of standards including this specific one. They have been involved in the process, commented on the various stages of drafts, voted on the drafts, and are quite aware of these changes.

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Or at a minimum I would consider planning a strategy of when you will adopt the symbols in the standard for your US FDA submissions but please pass this approach by your regulatory affairs personnel or consultant to make sure it meets your product regulatory strategy.

Q5: Is the MD symbol 5.7.7 obligatory to use according to the MDR?

A5: It would be the easiest route to use the MD symbol, but a manufacturer could spell out 'medical device' if they prefer. Remember, 'medical device' would need to be translated into many languages in Europe. The MD symbol is the Medical Device Symbol (5.7.7) in ISO 15223-1:2021. The symbol was developed specifically to meet the GSPR 23.2 (q) "an indication that the device is a medical device", which was based on the already existing IVD symbol (5.5.1) created to support the EU IVD Directive 98/79/EC. See A1-3. The rationale was that using "MD" for the new MDR requirement would be consistent with the IVD symbol, making it recognizable. If you refer to Annex ZA.1 for the MDR for GSPR 23.2 (q) for symbol 5.7.7 the remarks/notes say it is "used to specify on the label that the device is a medical device." "Not covered for labelling of devices intended for clinical use only." Realize the MDR Annex ZA and ZB have been approved and the standard is pending citation in the OJEU so these comments could change.

After many discussions and the review of multiple comments by the ISO/TC 210 working group WG3, no better option came up during the development of the standard applicable to the broad range of medical devices that the symbol covers. Refer to Q&A12-2 for further discussion.

Q6: The Catalogue number Symbol (5.1.6) [REF in a rectangle] seems very similar to the Model number Symbol (5.1.10) [# in a rectangle] in ISO 15223-1:2021. What is the difference?

A6: A model number can represent a product family or cover multiple catalogue numbers. At least one is required. Some manufacturers place both on the device labeling, depending on their product numbering structure, but due to space limitations and with so many countries requiring more and more labeling these days

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I would recommend sticking to one of these identifiers, if possible. Below are more specific details found in ISO 20417:2021.

Please refer to the definitions for Catalogue & Model number in ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*, also written by ISO/TC 210.

Catalogue number (3.3): value given by the manufacturer to identify a specific medical device or accessory as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for the end user)

Model number (3.17): letters, numbers or a combination of these assigned by a manufacturer to distinguish by function or type, a particular medical device, accessory or medical device family from another

Also, note that in ISO 20417:2021 in Annex A - Particular guidance & rationale for subclause 6.1.3 there is a nice example comparing model number and catalogue number.

Q7: Does this standard apply to disinfectants, software, combination devices (like a prefilled syringe) or just medical devices and IVDs?

A7: The ISO 15223-1 standard applies to all medical devices. The definition of medical devices in this standard is from ISO 13485 and states: "instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
— investigation, replacement, modification, or support of the anatomy or of a physiological process;
— supporting or sustaining life;
— disinfection of medical devices;

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— control of conception;
— disinfection of medical devices;
— providing information by means of in vitro examination of specimens derived from the human body;
and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means
Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:
— disinfection substances;
— aids for persons with disabilities;
— devices incorporating animal or human tissues, or both;
— devices for in vitro fertilization or assisted reproduction technologies.

Since the prefilled syringes may be considered part of the medical device combination product depending on the regulatory classification, I would recommend you ask your regulatory affairs personnel or consultant to make that determination, but I would assume that the answer is **yes** this standard would apply for the applicable symbols needed. As noted in some of my other responses in this document symbols like standards are voluntary and it is dependent on the national regulator to spell out what their requirements are.

Q8: Is the UDI symbol optional? Does it mean that we can add only the UDI carrier without the UDI symbol?

A8: The standard is written that the UDI is optional, but it is dependent on the national regulator if they will require the symbol. I would suggest that it would be wise to always use the symbol going forward, since products tend to have more than one barcode / QR codes on a product and not all of them are UDI carriers. So, it is to the manufacturer's advantage to include the UDI symbol (5.7.10) to make it clear to users and regulators of the device that a specific barcode(s) / QR code are UDI.

ISO 20417, 6.1.4 b) 1), requires the use of the symbol when more than one machine readable AIDC is on the label.

If you are short on space, don't forget that UDI barcodes can be a 'GS1 data matrix', instead of 'GS1 linear barcodes'. They are small and square (like a QR code) and they take up less space.

Q9: Why is the IFU considered the lowest level of risk mitigation as related to the "blue man" safety sign and so considered a primary risk control measure?

A9: The basics of risk management are based on a tiered priority system of risk control measures where the highest level is what you should strive for and the bottom level of this priority list should be your last resort risk control measure:

1) inherently safe design and manufacture,
2) protective measures in the medical device itself or in the manufacturing process; and lastly
3) information for safety and, where appropriate, training to users.

This is identified in clause 7.1 of ISO 14971:2019. The rationale for priority of order is noted in Annex A.2.7.1 of the standard which are derived from ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in international standards for medical devices*, and IEC TR 60513, *Fundamental aspects of safety standards for medical electrical equipment*.

The "blue man" safety sign per IEC 60601-1, ed. 3.2 should only be used when the IFU is the primary risk control measure. Also see ISO 20417, 6.1.5. Refer to A11-1 for more details on this issue. This is considered using the lowest level of risk management for a medical device which is not guaranteed to be followed by the appropriate party (user, operator, clinician, etc.).

Q10: Does the translation symbol need to be added to translated IFUs & does this standard (ISO 15223-1:2021) cover translations for different countries?

A10: Typically, the translation symbol will be located on the device label per the regulatory requirements per ISO 20417:2021, 7.4, but only when the translation is not controlled by the manufacturer. It should be added to your table of defined symbols in your device IFU, when for example you know your distributor will be using the

symbol the IFU that they have translated (or had translated). This symbol is not used for translated information that was controlled by the manufacturer.

The standard ISO 15223-1:2021 is voluntary but please note what is written in the introduction of the standard:

> "...For simplicity and to avoid translation of text, this information can be provided as symbols that have a specific meaning...
>
> ...This document is intended to be used by manufacturers of medical devices who market products in countries where there are specific language requirements..."

So, yes the standard is written for translations for different countries as symbols can be used for any country based on the validation of the symbols in the standard. Refer to A12-1.

The translation symbol (5.7.8) is for entities responsible for the translation activities (such as the Importer, Distributor, dealer) not the manufacturer. This is to identify that the translated information was not provided by the manufacturer, and not a modification of the device. The symbol was introduced to meet the MDR requirement below.

See EU MDR 2017/745, article 16, "Cases in which obligations of manufacturers apply to importers, distributors or other persons"
...

> “(2) For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:
>
> > (a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

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> (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.
>
> (3) A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established."
> ...

Based on paragraph (3) of Article 16 of the EU MDR a distributor or importer that translates as mentioned in point (a) of paragraph 2 shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device (this could be the IFU), the activity carried out together with its name, registered trade name or registered trademark, registered place of business and the address at which it can be contacted, so that its location can be established.

Each regulatory authority may impose different requirements on who they want to disclose to identify translated information. Please confirm with each regulatory authority what those requirements may be as they may vary significantly per country.

Q11-1: Can we use the "blue man" safety sign as a "worst case" even though the IFU is not actually a primary risk control measure)?

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A11-1: **NO,** that would be a misuse of the mandatory action safety sign. Just as you would not use a high voltage safety sign on a low voltage terminal. Please also refer to Q&A9.

If your risk analysis doesn't rely on your IFU as a primary risk control measure, it is not recommended to use the "blue man" safety sign on the medical electrical device. This is because you are not meeting the intent of the requirement in clause 7.2.3 (first paragraph) of IEC 60601-1, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, Edition 3.2 (2005 + A1:2012 + A2:2020) (Refer to Q&A9).

If you are not relying on your IFU as a primary risk control measure then the Consult Instructions for Use symbol (5.4.3 of ISO 15223-1, ISO 700-1641) should be placed on the medical electrical medical device per IEC 60601-1, ed. 3.2, clause 7.2.3, second paragraph (Refer to Q&A9). Please also refer to Annex A, Subclause 7.2.3 for more details.

IEC 60601-1, ed. 3.2 was revised to fix the issue that was misunderstood by the test labs which were almost always expecting a "blue man" safety sign be applied on the medical electrical device based on the previously written requirements in IEC 60601-1 as noted in response of A11-1. In the past many manufacturers used both the "blue man" safety sign the consult the IFU symbol (5.4.3) causing potential confusion to the user of the device.

The "blue man" safety sign is for use with any devices (medical and non-medical). Refer to ISO 20417:2021, 6.1.5 which refers to medical devices which broadened from just active medical devices (from IEC 60601-1:2005 and later) to include non-active medical devices.

Q11-2: Can any culmination of the Caution and Consult Instructions for Use ("i" in a Booklet) symbols be used to replace the "blue man" safety sign? Isn't the "blue man" safety sign supposed to be a color only safety sign per ISO 7010 and not in black & white, which is what works best for Tyvek labeling situations?

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A11-2: No, the Caution symbol (5.4.4) is not the same as the Consult the IFU symbol (5.4.3) as noted in the Restrictions for Use of 5.4.4 saying the Caution symbol shall not be used to mean Consult the IFU symbol and neither of them are equivalent to the "blue man" safety sign as they don't specifically deal with primary risk control measure which is required for the IEC 60601-1, ed. 3.2 requirement as noted in A11-1.

The "blue man" safety sign (ISO 7010-M002, or in IEC 60601-1, Annex D, Table D.2, No. 10) is required to be blue and white per ISO 7010. Per ISO 7010 safety signs are required to be the colors noted in the safety sign so ISO 7010-M002 is required to be blue & white so a Tyvek black and white safety sign would not meet this requirement. See A11-2. You may be able to try to use risk management and work with your regulator / notified body but please be careful as this may not work for all jurisdictions.

Another way to look at the above response: The color is an integral part of the message and is therefore required. Would you accept a black and white stop sign instead of red and white sign?

Q11-3: When to use the Caution symbol?

A11-3: Use the Caution symbol (5.4.) to raise awareness to avoid an undesirable consequence (a hazard, hazardous situation, etc.) to indicate use caution when operating the device or operator action to avoid an undesirable consequence. The symbol "Consult instructions for use or consult electronic instructions for use" (5.4.3) is solely to indicate the need for the user to consult the IFU.

Q12-1: Are all symbols that are included in ISO 15223-1:2021 validated and how does that process work?

A12-1: All the new symbols in ISO 15223-1:2021 are validated and "approved" for use. Some of the symbols in ISO 15223-1:2021 don't meet the requirements of ISO/TC 145 for ISO 7000 which has some specific graphical requirements, examples of these items being symbols not containing text such as the new symbol Sterilized using vaporized hydrogen peroxide 5.2.10, or MD 5.7.7, or UDI 5.7.10. So, the new symbols in ISO 15223-1:2021 are validated using ISO 15223-2 process which goes through the

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usability process. Some symbols in ISO 15223-1 that don't appear in the ISO Online Browsing Platform (OBP) would be because it doesn't meet the requirements of ISO/TC 145 for ISO 7000 as stated above. Some examples would include the MD, IVD, and the Sterilized using vaporized hydrogen peroxide symbols all don't appear in the OBP but are approved for use and are included in ISO 15223-1:2021.

Q12-2: How do we propose a new symbol for ISO 15223-1? Some of the new symbols that were asked about from the list of questions from the webinar include: a) double sterile barrier with a protective packaging, b) creating a symbol similar to 5.4.8 (contains biological material of animal origin), but specifically specifying bovine origin, and c) to express quantity?

A12-2: These are not symbols that has been generated as of yet. Some of these symbols have been informally communicated for the 5th edition of the standard. There is an existing ISO symbol package quantity, ISO 7000-2794, that can be used.

Q12-3: What is the process to propose a new symbol to the ISO 15223-1 standard?

A12-3: If you would like to propose a symbol for ISO 15223-1 the formal process is to go through your National Member Body (i.e. ANSI via AAMI, BSI, DIN) to submit your proposal. You would provide a proposal on an ISO comment form. The NMB will discuss and forward the comments from their NC that they agree on to the ISO committee ISO/TC 210/WG3 for discussion and balloting during the development of ISO 15223-1. Another option is to informally propose a symbol to add to ISO 15223-1 by sending a note to the convenor of ISO/TC 210/WG3, *Symbols and nomenclature for medical devices*, Mrs Lena Cordie-Bancroft at lena.cordie@qualitasproserv.com or through the RAPS Regulatory Forum Exchange - RegEx forum if you're a RAPS member or through the ISO platform for the ISO/TC210 WG3. OR

As presented recently at an MD&M West presentation propose a symbol for the next edition of the standard. If you would like to propose a new symbol idea for the standard follow the process documented in ISO 15223-2 that is summarized as:

1) Create multiple possibilities using the instructions and rules found in IEC 80416-1 and IEC 80416-2

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2) Test the possibilities using the process found in ISO 15223-2 (part of the process is usability testing)
3) Include multiple geographies and backgrounds
4) When you have a winner, work with your national committee to submit the symbol to ISO/TC210/WG3
5) ISO 15223-1, after balloting & approval by ISO/TC 210/WG3, must submit the prospective symbol to ISO/TC145, or IEC/SC3 as part of their process.
6) The symbol needs to be accepted by ISO/TC145, or IEC/SC3 for inclusion in the appropriate symbol or safety sign standard.

Q13: Can you summarize new required symbols that will need to be adopted? How do you know which standards for symbols apply to your device (or for each level of packaging)? Does ISO 15223-1 capture all those standards you referenced?

A13: The presentation covered the major changes to ISO 15223-1:2021 from 2016. Each company will need to do their own gap analysis to determine which requirements will apply to their products / product lines / level of packaging. ISO 15223-1:2021 doesn't cover all applicable symbols for a medical device that will apply to their devices and packaging / labeling. ISO 20417:2021 is a good starting point and it also points to some other symbol standards. As mentioned during the webinar some of the other important symbol standards to consider include:

— ISO 7000, *Graphical Symbols for use on equipment*,
— ISO 7010, *Graphical Symbols – Safety Colors & Safety Signs*,
— IEC/TR 60878, *Graphical symbols for electrical equipment in medical pr*actice, and
— IEC 60417, *Graphical symbols for use on equipment*.
Additionally, you will find that there are device specific standards (i.e. IEC 60601 series, ISO 14708 series, etc.) that may have additional symbols in them.

Some are probably covered by these symbols standards mentioned above already but there may be other device specific standards that may have additional symbols and maybe even guidance documents and national standards that apply. You will have to do specific gap assessment for your device to determine these symbols.

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Remember, using symbols makes your labels simpler. They help you.

Q14: For EU MDR/IVDR remediation process. Shall we wait for harmonized standards to release?

A14: No, don't wait any longer. See also A1-1. Start your remediation process immediately otherwise you won't be ready in time. There is a lot to do to be ready for lower classification devices and even more for higher classification devices. There are long lines for Notified Body access, if applicable, and you need to be working on your regulatory strategy with your regulatory affairs personnel / consultants and other personnel impacted. This impacts the whole company not just regulatory – for example it impacts your QMS, operations, production and others. You should have started planning for this more than a year ago.

Please note that a very short list of EU MDR & IVDR Harmonized Standards has been published on 16 July 2021. Go to https://bit.ly/MDRandIVDRHarmStds. As A1-3 indicates rumor on the street now is that the EU Official Journal may only occur a couple times a year for MDR & IVDR Harmonization, so don't expect them to be published more than 2 or 3 times a year. As the manufacturer, you get to choose your evidence and there is no need to wait for the OJEU listing before using a standard.

Q15: How is the temperature limit symbol & other environmental symbols used?

A15: The temperature limit symbols 5.3.5 (lower limit), 5.3.6 (upper limit) & 5.3.7 (upper & lower limits) of ISO 15223-1 are to indicate the temperature limit(s) the medical device can safely be exposed and this will be noted on the packaging of the device for the storage temperature, or transport temperature and / or on the medical device for temperature for use. This information should also be noted in the IFU and the symbols should be noted in the table of defined symbols in the IFU.

There are also two other environmental limit symbols of interest in ISO 15223-1 for atmospheric pressure limitation (5.3.9) (upper & lower limits) and humidity limitation (upper & lower limits) (5.3.8).

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Annex A of ISO 15223-1 used to have examples that showed examples of how the ranges were used for the temperature limits but those were dropped from the ISO 15223-1:2021 version of the standard. They did keep in the examples for the showing the limits for Humidity limitation (A.14) and Atmospheric pressure limitation (A.15).

Q16: Is the IFU symbol (5.4.3) applicable for hardcopy IFU and eIFU?

A16: The symbol "Consult instructions for use or consult electronic instructions for use" (5.4.3) are similar but different. One is for a hardcopy of the IFU and the other is for an electronic version of the IFU. Please note to refer to examples of the electronic IFU symbols in Annex A, A.16. See also ISO 20417:2021, 6.1.3 d) 1) i) and 6.1.5 b)

Q17: Anything specific for Software as a Medical Device (SaMD)?

A17: This standard ISO 15223-1:2021 applies to all medical devices (refer to the definition for a medical device in A7 which includes software) so anything that is applicable to SaMD would apply. So, IFUs, translations, cautions, no sterilizations (let's hope), and many other things would apply.

Q18: What are the rules for using the symbols on products - do the symbols have to be licensed?

A18: In ISO 15223-1:2021 there are no requirement that you use ISO licensed symbols. The ISO standard is copyrighted so you aren't allowed to reproduce any part of the standard, which means the symbols aren't allowed to be reproduced without ISO's permission. Since the ISO standard and the contents of the standards are copyrighted the only option is to purchase the symbols online at the ISO online browsing platform for 30 Swiss Francs currently per symbol at https://www.iso.org/obp/ui/#home and click on the graphical symbols selection circle, enter a search term or the ISO identifier number, if known (for example the “Consult IFU” symbol ISO identifier 1641 would result in the search finding it. It is ISO 7000-1641) or purchase a symbol collection on a yearly subscription for ISO 7000 or ISO 7000 / IEC 60417.

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Q19: During the presentation it was mentioned that Annex C, Terminology Alphabetized index of defined terms would be included in ISO 15223-1:2021, fourth edition. When I received my version of the standard it didn't include Annex C.

A19: The presentation was based on the FDIS (Final Draft International Standard) which is pre-publication document. The ISO decided to drop the Annex C when they published the final version of the standard. Please contact me if you have a question around this issue directly. For the English language standard, the terms are all defined in the Clause 3 in alphabetical order.

Q20: Do we need to submit a change notification to our EU notified body if we implement the changes described in ISO 15223-1:2021 (fourth edition)?

A20: Yes, labeling changes may be considered substantial/significant changes and you would need to notify your EU notified body of such a substantial/significant change. You really don't want to do any changes that may impact any devices that are marketed under an the MDD or AIMDD related to Article 120(3) of the MDR or IVDD related to Article 110(3 & 4) IVDR as that would likely mean your device would need to switch immediately to the MDR or IVDR as applicable.

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