ISO standard implementation impact in COVID-19 erra on UV-lighting devices

Valeria Nenova,
Faculty of Dental Medicine
Medical University of Sofia
Sofia, Bulgaria
lery.nenova@gmail.com

Maria V. Nenova, PhD
Faculty of Telecommunications
Technical University of Sofia
Sofia, Bulgaria
mvn@tu-sofia.bg

Desislava V. Georgieva, PhD
Department of Informatics
New bulgarian University
Sofia, Bulgaria
dvelcheva@nbu.bg

Vesselin E. Gueorguiev, PhD
Faculty of Computer System and Technologies
Technical University of Sofia
Sofia, Bulgaria
vegueorguiev@gmail.com

***Abstract* — The process of providing the safety of medical devices is very important in our days. Standards in the field are one of the most common and reliable criteria for assessment of the quality of such equipment. At the moment in the situation of COVID-19 the results during the process and after it are very important. Many manufacturers sell UV lamps in order to kill viruses and bacteria. The situation is almost the same with face masks.**

The proposed paper presents a survey and an approach for implementation of criteria in order to prove the safety of medical devices.

Keywords – medical devices, COVID-19, UV waves, ISO 13485:2016, ISO 15858:2016.

I. INTRODUCTION

The Coronavirus disease 2019 (COVID-19) was reported firs in December 2019 and then characterized as a pandemic by the World Health Organization on March 11, 2020. [1].

In the present situation of world pandemic because of COVID 19, it becomes really important the process of development and implementation of medical devices. One of the world wide known criteria to prove their quality are the requirements of International Standards Association (ISO). If they meet their Norma, then it gives assuredness in the quality of the equipment and devices used for prevention and treatment.

The presented work describes the specifics and problems in the development and implementation process of the ISO 13485:2016 and ISO 15858:2016 specifies minimum human safety requirements for the use of UV-C (UltraViolet light type C) lamp devices and solutions proposed to successfully pass the certification process. ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes has a last update from 2016. The main purpose of this standard is to provide and assure that the produced medical devices are under the control of the Organization manufacturer [2], [3].

At the begging of the process is a Quality Management System (QMS) as a necessary “evil” for medical device company, in most of the cases it is based on ISO 9001:2015. This is something Organizations must have in order to be compliant. If the companies already have QMS, thenext step for medical devices is the standard ISO 13485:2016.

This ISO specifies requirements for a quality management system that can be used by an organization to be implemented in one or more stages of the life cycle of a medical device, including design, development, production, storage, distribution, installation and service of medical issuance and final commissioning and transfer of medical production and design and development or provision of performed activities (eg. technical maintenance). [4]

The standard includes eight clauses, three of which provide guidance on the intended use of the standard. The remaining five clauses provide the framework for what is expected of organizations dedicated to the production of the medical device.

Actually for Organizations it is not obligatory to follow the requirements defined in ISO standards, especially in 13485:2016 and can become certified. But this step will help to manage better the business processes. This step will also provide prove for the safety of the use of medical devices on patients. [5]

II. UV LIGHT IMPACT

In this COVID-19 situation a big part of medical organizations and patients need a proof of the quality of the devices, especially in the case of face surgical masks and UV-ultraviolet light (UV) based equipment.

Because of the lack at of vaccine against the virus, at the moment, only preventive measures will work in the fight with COVID 19. The viruses cannot be classified as living organisms.

One of the most frequently used methods against the pathogens is UV lighting. The main problem is to prove that one type of UV waves can work against SARS-CoV-2 and COVID 19. One of the important things in the process is to choose the efficient length of the waves. The second but probably the most important is the *right dosage*. At the moment not all of the devices on the market are suitable and the most important is that not all of them are “safe” to use.

III. UV LIGHT TYPES

UV waves can be classified into three main types based on their wavelength: UV-A, UV-B and UV-C. The biggest part of UV radiation is UV-A. It reaches the Earth trough the

atmosphere. The other two types are absorbed by the ozone layer those are UV-B and UV-C light. The waves with the the shortest wavelength are UV-C, but in the same time they have the energy level which is highest.

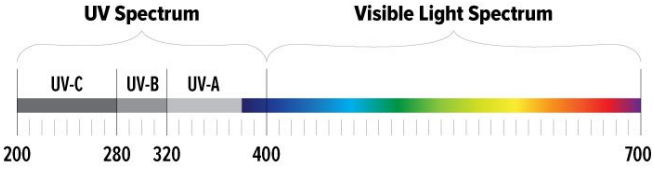

Figure 1. UV types of radiation

Wavelengths in the ultraviolet spectral band known as the "UV-C" is from 200 to 280 nanometers (nm). This type of UV radiation is the most effective for disinfection, which in our days is of vital importance. As it was mentioned above the longer the wave length is the less energy of UV can disinfect if applied in much greater doses.

UV-C photons are with the highest energy in the optical spectrum and therefore are the most photo chemically active.

In [6] Carmelo De Maria, Licia Di Pietro, Andrés Díaz Lantada, June Madete, Philippa Ngaju, Makobore, Mannan Mridha, Alice Ravizza, Janno Torop, Arti Ahluwalia, Safe innovation: On medical device legislation in Europe and Africa,] is reported that is used a new approach according to which is implemented single-wavelength UV-C light at 222 nm generated by flattered excimer lamps, which inactivates airborne viruses without inducing biological damage in exposed human cells and tissue. [6] .

UV type	NANOMETERS (nm)	SAFE for skin and eyes	Applied to/practical uses
VUV Far-UV	100-200	Yes	Medical equipment
Far-UV	207-222	Yes	Germicidal, most effective for disinfecting, sensing
UV-C	200-280	No	Germicidal, most effective for disinfecting, sensing
UV-B	280-315	No	Curing, tanning, medical applications
UV-A	315-400	No	Curing, tanning, lithography, sensing, medical applications

Table 1. Ultraviolet light impact

Specific feature of UV-C light is its possibility to kill the living bacteria. One other parameter which is also important is the size of COVID-19 and viruses in general. Typically, they are less than one micrometer, which is a huge problem for the face mask manufactures to meet such type of criteria. The mechanism for making the virus non-infectious is to use UV-C light which interact with the RNA (ribonucleic acid) and DNA (deoxyribonucleic acid) molecules of the viruses. The size of the virus in the scientific works reported is between 60 nanometers (nm) to a maximum diameter of 140 nanometers (nm).

IV. Stages of implementation of a ISO standard

In order to use an equipment for disinfection and to be sure that this equipment is build according to requirements for safety, it should be checked whether it has ISO certification or CE mark. [7], [8].

On the First stage should be defined:

- the Scope of the system, management commitment and Responsibilities – it includes the definition of Policy, objectives and Quality Manual;
- development and implementation of procedures – procedures of document and record control, action of information, internal audit, corrective and preventive actions and etc.;
- develop risk management process for production – record of risk management activities;
- implement process procedures – procedures for production, purchasing, development and etc.;
- perform training and awareness programs – the prove are training records;
- operation of MDMS (Medical device management system) – records identified by MDMS;
- conduct Internal audit – internal audit program, internal audit plan, internal audit report. After the internal audit report comes the stage for corrective actions if such were stated during the internal audit process;
- management review – the records is a Protocol or MR minutes;
- next important stage is the choose of Certification body;
- Stage 1 certification audit – review of the documents of the system by CB;
- Stage 2 audit report – review of the really working system;
- Corrective actions after the Certification audit;
- Receive of Certificate for Compliance with the requirements of the standard.

After that process follows the process of implementation of a system covering also the requirements of the ISO 15858:2016, which specifies minimum human safety requirements for the use of UV-C lamp devices or certification only against 13485 could be done.

V. Medical device as a term

The term - medical device is defined in the standard as any instrument, apparatus, device, machine, appliance, implant, in vitro reagent, computer program, material or similar or related object which is intended by the manufacturer to be used alone or in combination on humans for one or more medical purposes for:

- diagnosis, prevention, surveillance, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation of disability,
- examination, replacement, modification or support of an anatomical part or physiological process,

- supporting or maintaining vital functions,
- pregnancy control,
- disinfection of medical devices,
- provision of information by means of in vitro examination of samples obtained from the human body,

and which does not achieve its principal action as intended in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its action by such agents. [3]

NOTE 1 to the term: Products that can be considered as medical devices in some jurisdictions but for which there is still no harmonized approach are:

- disinfectants;
- aids for people with disabilities;
- articles containing animal and human tissues;
- in vitro fertilization products or assisted reproductive technologies.

If a medical device is sold on the European market, specific European Directives need to be met. The regulatory processes of medical devices are based on the Medical Device Directive (MDD), which consists of three core directives for safety regulations and marketing of medical devices: the Active Implantable Medical Device Directive (AIMDD 90/385/EEC), the Medical Device Directive (MDD 93/42/EEC) and the In Vitro Diagnostic Medical Device Directive (IVDMDD 98/79/EC) [9].

VI. Medical device algorithm

There exist several types of algorithms for medical devices and for each one of them is specified a conformity assessment procedure. In some cases, the manufacturer has a choice of conformity route. [10-12] A possibility is to go for Annex II or Annex III and examination of Notification Body. The next step is to go for Declaration of conformity or after Annex III to go for Annex V - Production quality assurance audit by NB to ISO 13485:2016. Next is Application for CE mark which also can be made by NB or without NB. The difference is that NB proves the quality documentation and the whole process, but the Organizations can decide just to put the CE without the number of the Notification Body.

VII. UV devices

UV-C lamps are electronic products. The FDA (Food and drug administration) regulates electronic products that emit radiation (both non-medical and medical products). ISO 15858:2016 specifies minimum human safety requirements for the use of UV-C lamp devices. It is applicable to in-duct UV-C systems, upper-air in room UV-C systems, portable in-room disinfection UV-C devices, and any other UV-C devices which may cause UV-C exposure to humans.

It is not applicable to UV-C products used for water disinfection. The bigger part of those devices at the moment are not certified, but because of the big demand they are sold anyway.

The maximum daily dose per person is set to be 6 mJ/cm2. However, in case of direct exposure to UV-C and according to this standard, any operator could be safely exposed every day to 1 min at a distance of 4 m from the device. Despite of the evident low risk of exposure, it is recommended to use protective clothing and goggles, typically used for occupational safety and for health purposes. A survey on the implementation [13, 14].

The sensitivity to UV-C of microbes suspended in the air is much greater than on surfaces. As several studies confirm, pathogens are more vulnerable to UV inactivation in the air. That is why the type of surface is not so sufficient to deactivate a virus or bacteria. It is important to calculate the time exposure to the light and on what kind of parameters it will depend.

The time for exposure in order to disinfect a room is a function of many parameters:

- Pathogen UV-C susceptibility;
- The initial radiation power of the UV-C;
- According to this power of the device the size of the premise which should be disinfected;
- Time of exposure;
- And etc.

The distance from the UV-C device depends on the exposed microbial surface and other parameters.

It depends also on the dosage, on the surfaces and one of the requirements is 90% of coronaviruses to be disinfected. The dose is estimated in mili-Joule per square cm. This level can be reached with around 25 mJ/cm2.

If the CORONA 19 is in aerosols the situation is a little bit different.

All those specifics are important for disinfection process especially in schools and universities. As part of the daily cleaning process, schools might request to improve cleaning procedures by implementing disinfection in classrooms, bathrooms and corridors. Within minutes the used UV devices will take the responsibility of deactivating viruses (and any pathogen) on surfaces and in the air. Walls, boards, doors, tables would be omnidirectionally exposed to a powerful UV-C radiation minimizing the presence of viruses. It is important that those devices can be operated by the usual cleaning staff immediately after completing a full training session.

IV. Model of UV-C medical device compliance process

Actually for the UV-C devices is not obligatory to be classified as a Class of medical equipment. Only in a case of need to prove that production is safe it can be certified according to the ISO standards or to go for CE mark procedure.

V. Conclusion

The presented survey shows a system approach to develop management systems compliant with requirements of ISO standards. The work describes the specifics and problems in the development and implementation of the ISO 13485:2016 and ISO 15858:2016 specifies minimum human safety requirements for the use of UVC lamp devices. Main steps of the process are described. An algorithm for assessment of medical device is presented with extension for human safety assuredness. A special attention was paid to UV devices for disinfection.

Actually after the start of usage of UV type C devices for disinfection the level of doctors infected with COVID-19 is dramatically reduces.

REFERENCES

[1] Wold Health Organization - https://www.who.int/emergencies/diseases/novel-coronavirus-2019

[2] ISO 15848:2016 UV-C Devices — Safety information — Permissible human exposure, 2016.

[3] ISO 13485:0216 Medical devices - Quality management systems - Requirements for regulatory purposes, 2016.

[4] Medical Device Directives. http://ec.europa.eu/growth/ sectors/ medical-devices/regulatory-framework/revision _i t, 2017.

[5] The British standard institution. medical device directive. https://www.bsigroup.com/en- IL/Medical- Devices/Our- services/ European- Medical- Device- Directives/, 2017.

[6] Carmelo De Maria, Licia Di Pietro, Andrés Díaz Lantada, June Madete, Philippa Ngaju, Makobore, Mannan Mridha, Alice Ravizza, Janno Torop, Arti Ahluwalia, Safe innovation: On medical device legislation in Europe and Africa,

[7] Wellkangtech consulting, guidelines for classification of medical devices. http: //www.ce-marking.org / May 2017.

[8] Notified body. http://ec.europa.eu/growth/tools-atabases/nando/index.cfm, Fuseaction=notifiedbody.main. 2017.

[9] E. French-Mowat, J. Burnett, How are medical devices regulated in the european union?, April 1, J R Soc Med, 105, pp. 22-28, 2012.

[10] Kaplan AV , Baim DS , Smith JJ , Feigal DA , Simons M , Jefferys D , Fogarty TJ , Kuntz RE , Leon MB . Medical device development: from prototype to regulatory approval. Circulation 2004;109(25):3068–72 .

[11] Medical Devices Harmonised Standards. http://ec.europa.eu/growth/single- market/european- standards/harmonised- standards/medical-devices/ , 2017.

[12] Class I Medical Device. Conformity Assessment Routes http://www.ce- marking.com/medical- devices- class- i.html〉[verified on May]; 2017.

[13] Pachamanov A., S. Petrov, K. Nikolova, Hybrid lighting system for tunnel daily adaptive lighting, Lighting2016, Proceedings, ISBN: 978-619-160-705-1, pp. 40-45.

[14] Petrinska I., Kamelia Nikolova, Dilyan Ivanov, Kamen Georgiev, Estimation of the uncertainty in measurement of light distribution of luminaires by means of telecentric photometer, 2019 Second Balkan Junior Conference on Lighting (Balkan Light Junior), DOI: 10.1109/BLJ.2019.8883663.