European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR Virtual Session

COUNTDOWN TO THE MEDICAL DEVICE REGULATION

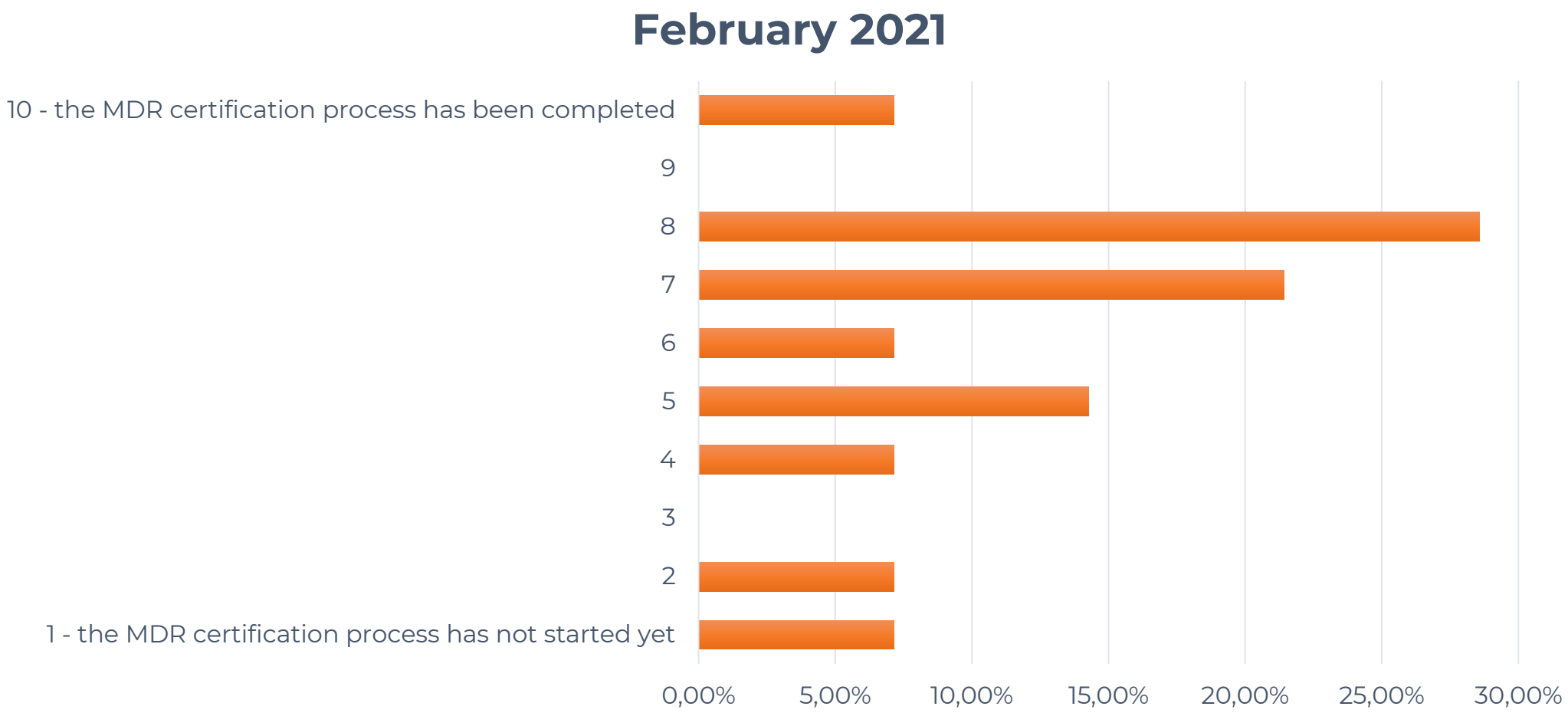
17 February 2021

Industry experiences in MDR audits

Philippe Soly

COCIR EU Regulatory Affairs Co-Chair

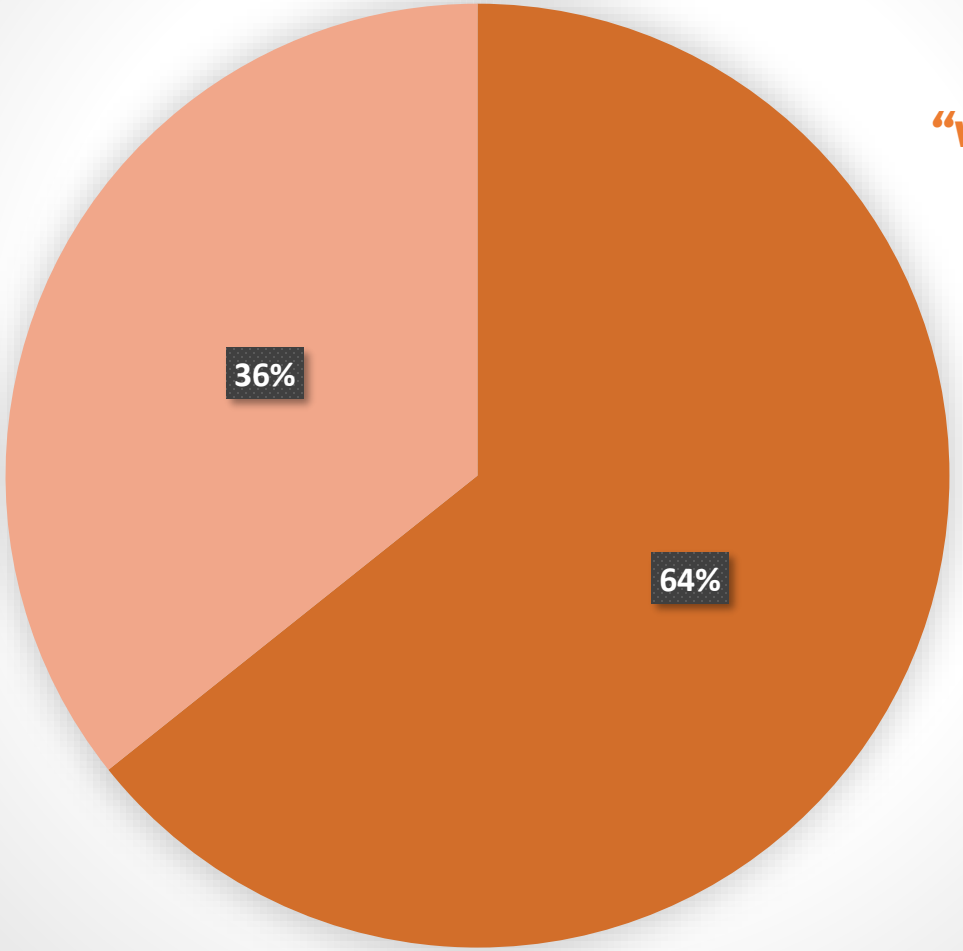
How advanced is the initial MDR certification process for your organisation?



Reported reasons for delays of MDR audits

- Late or (yet) no designation of Notified Bodies
- Resources of Notified Bodies
- Lengthy (sometimes more than six months) process for reviewing technical documentation (longer than under MDD)
- Lengthy discussions on clinical evaluation
- Delays in on-site audits due to COVID restrictions (and uncertainty about possibility to conduct remote audits)
- Delay in publication of Common Specifications for Annex XVI devices

Have restrictions due to COVID-19 impacted MDR audits for your organisation?



"very important impacts"

"serious business risk"

Impact of COVID-19 on MDR audits

COCIR Recommendation

Need for remote audits under the MDR in times of COVID-19

Background information

The Medical Device Regulation (MDR) enters into force on 26 May 2021. To place a new device or a device that has under-gone a significant change on the European market after that date, MDR certification must be in place – requiring an audit by a Notified Body. Annex IX 3.3 of the Regulation stipulates that "audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors".

Problem statement

The current COVID-19 pandemic causes travel and other restrictions leading to delays of initial MDR certification audits, as Notified Body auditors do not have access to the physical premises of the manufacturer. Many audits have been postponed until the end of 2020 or even 2021. Some companies are even still waiting for the exact audit date from their Notified Body. **There is thus a high likelihood that not all COCIR member companies will have achieved MDR certification by the end of May 2021, even though they are ready and have prepared everything for MDR compliance.**

Some Notified Bodies have already announced that changes to devices certified under the Medical Device Directives (MDD) are not possible anymore after November 2020. In addition, when production has been planned according to EU MDR, there are often limited possibilities to step back to MDD production (due to supplier capacity, parts availability, documentation to be reworked, etc.).

In conclusion, if the current situation continues, we expect delays in product launches (or even shortages) for certain imaging, electromedical, radiotherapy and software devices next year. This is especially concerning as the pandemic situation is worsening and it is not clear if all re-scheduled audits will actually take place as planned. **If no solution is found, we see a direct threat to the availability of innovative medical devices to European healthcare systems and to the competitiveness of the medical device industry in Europe.**

Recommendation

In these extraordinary circumstances, urgent action is needed to allow **conducting initial MDR certification audits remotely** by using the latest Information and Communication Technologies[1]. **COCIR calls on the Medical Device Coordination Group (MDCG) to expand the current guidance[2] on remote audits to all (not only essential for COVID-19) devices under MDR**. A condition may be introduced that the on-site audit must take place at the next surveillance audit.

[1] See also March 2020 guidance issued by the International Accreditation Forum (IAF) that proposes alternative auditing methods in extraordinary circumstances. The IAF also published a statement with specific guidance for COVID-19.
[2] April 2020 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_4_nb_audits_covid-19_en.pdf

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- Travel restrictions, quarantine requirements, home office
- Postponement of on-site audits (by six – 12 months)
- Remote audit conducted that then was not accepted by regulator
- Delay on planning and certification process
- Delays in MDR certification of new devices
- Reversion to MDD and stop of product conversion to MDR due to delay in MDR certification
- Additional costs and time spent by manufacturers

Areas for further clarification

- Learning curve for both Notified Bodies and manufacturers
  - E.g. new guidance documents on software (qualification & classification, clinical evaluation & cybersecurity)
- New guidance documents are published during MDR implementation and audit process
  - No transition periods for MDCG guidance documents
  - Uneven interpretation between NBs due to need for internal trainings etc.
- Sampling for the assessment of the technical documentation (MDR article 52.4) based on guideline MDCG2019-13
- Information on EC Certificate
- Requirement for micro-biology audit
- Annex IX assessment of significant changes
- Article 83.4

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