



Countdown to the MDR

1. MDR Implementation
2. MDR Audits

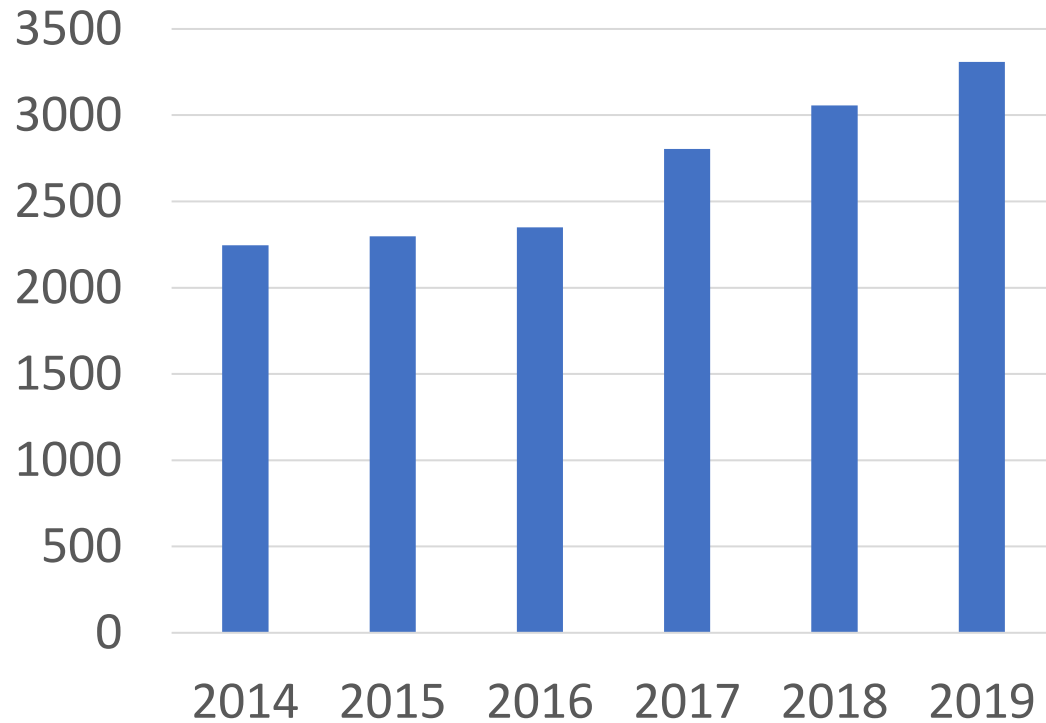
Wednesday 17 February 2021

MDR Implementation

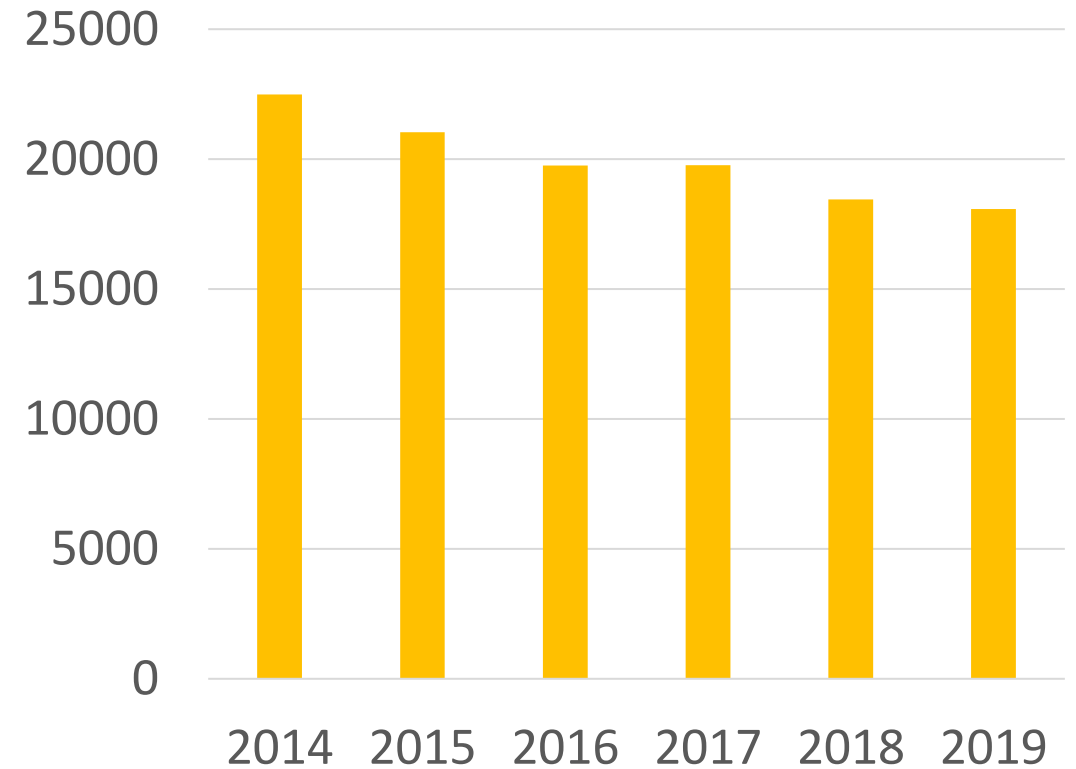


N=26
NBs

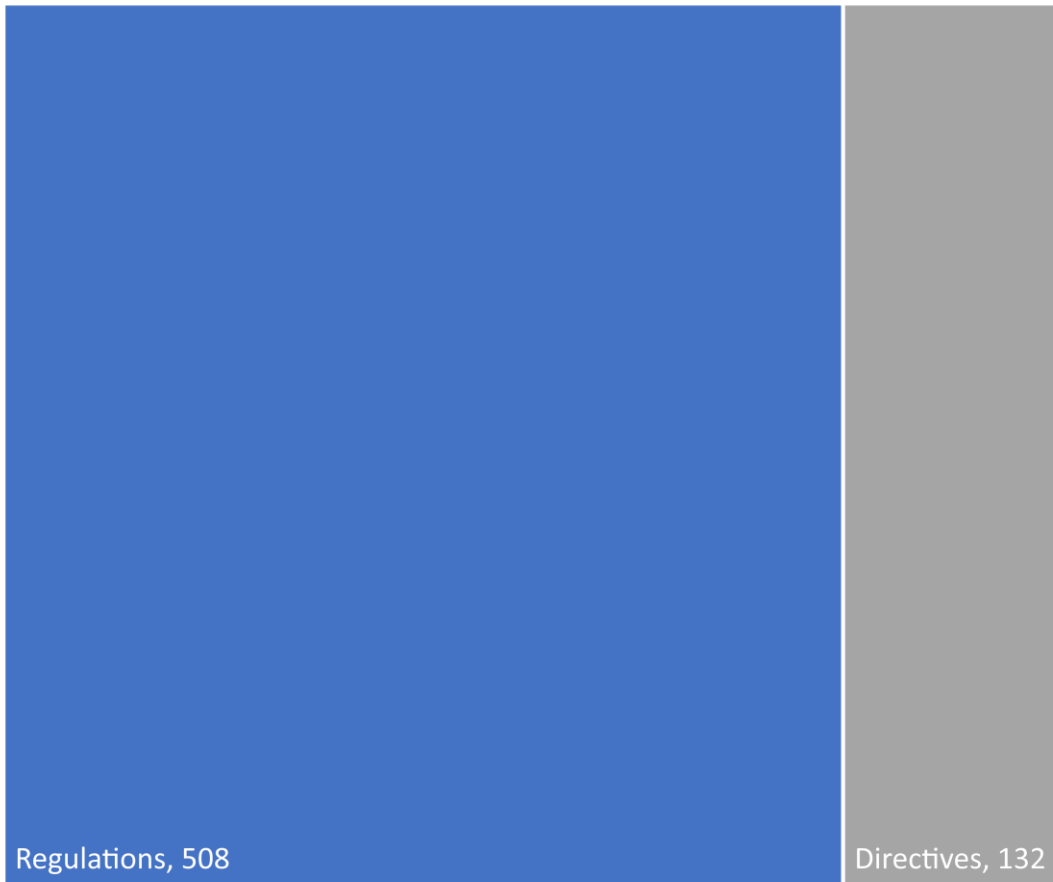
of Employees
(not including subcontractors)



of Certificates

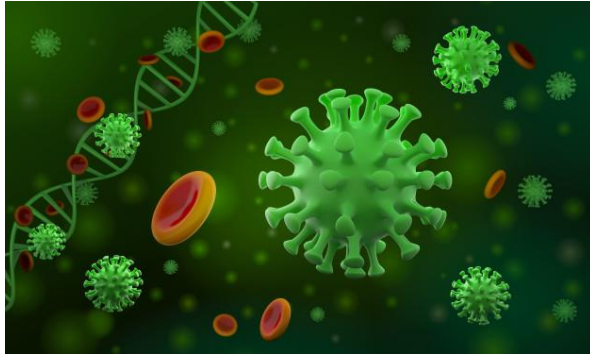


MDR Implementation



Remote Audits

IAF ID3 2011, ID4 2018, ID12 2015
UKAS TPS 62 2016



Audits postponed in North America
Mar 2020

Audits postponed in Europe
Feb 2020

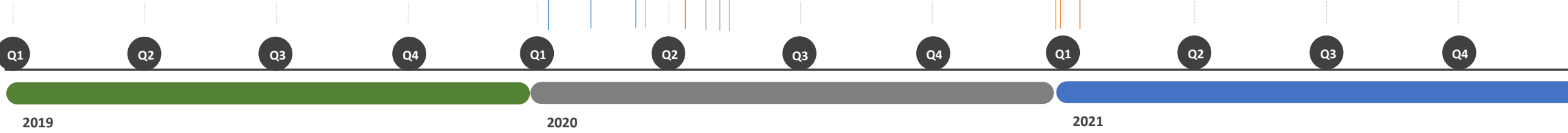
Audits postponed in China
Jan 2020

MDSAP Transmittal
2020 03, 04 & 05

MDCG 2020-4
UKAS TPS 73
SCC 2020 12
RvA T051

MDSAP Transmittal
2020 10

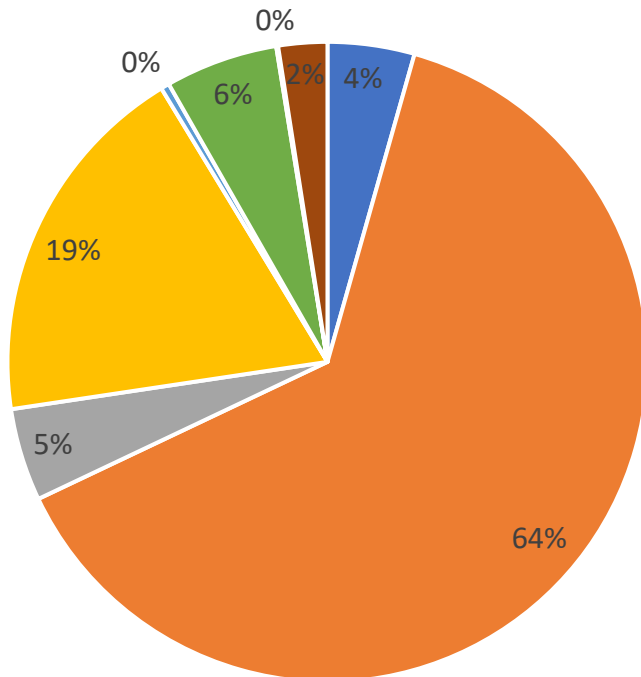
MDCG 2020-17
Commission Notice
2021/C 8/01



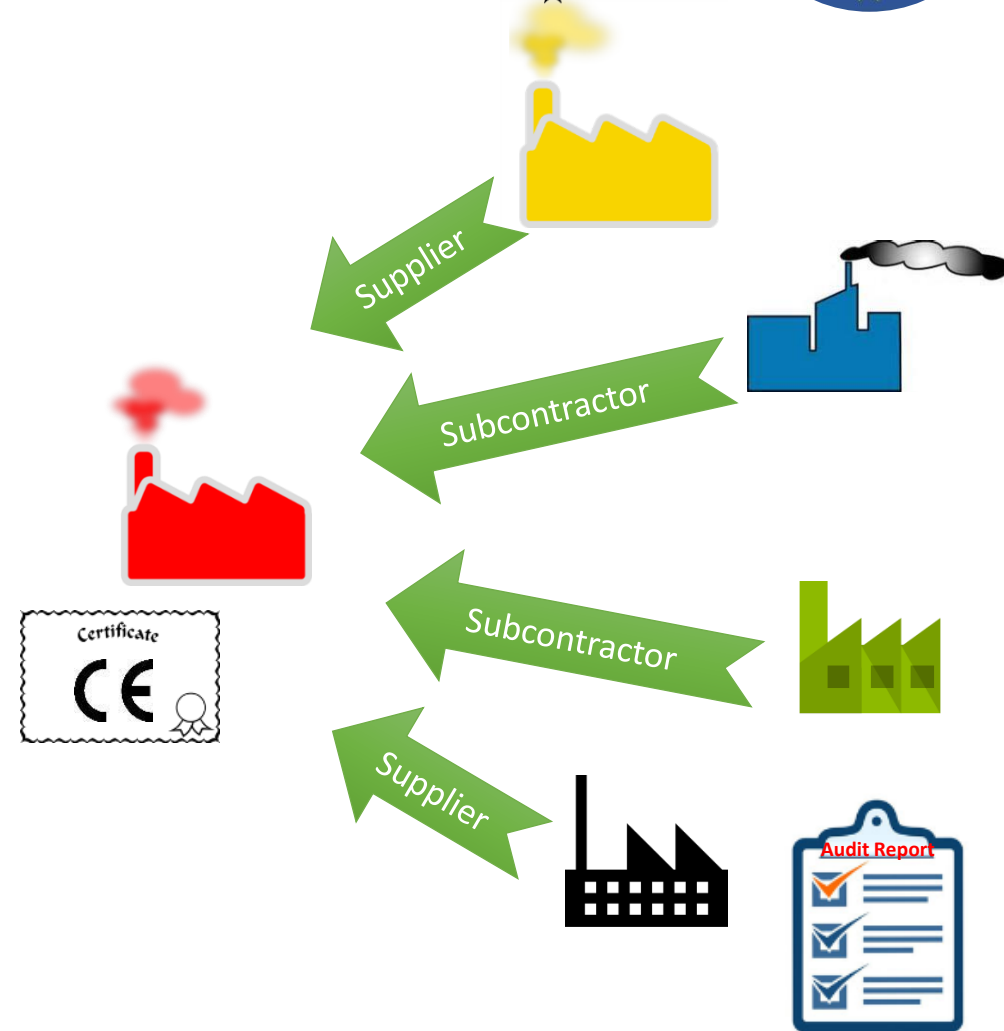
Remote Audits – n=37 – Nov 2020



How many audit days has your Notified Body completed remotely (AIMDD/MDD/IVDD)?



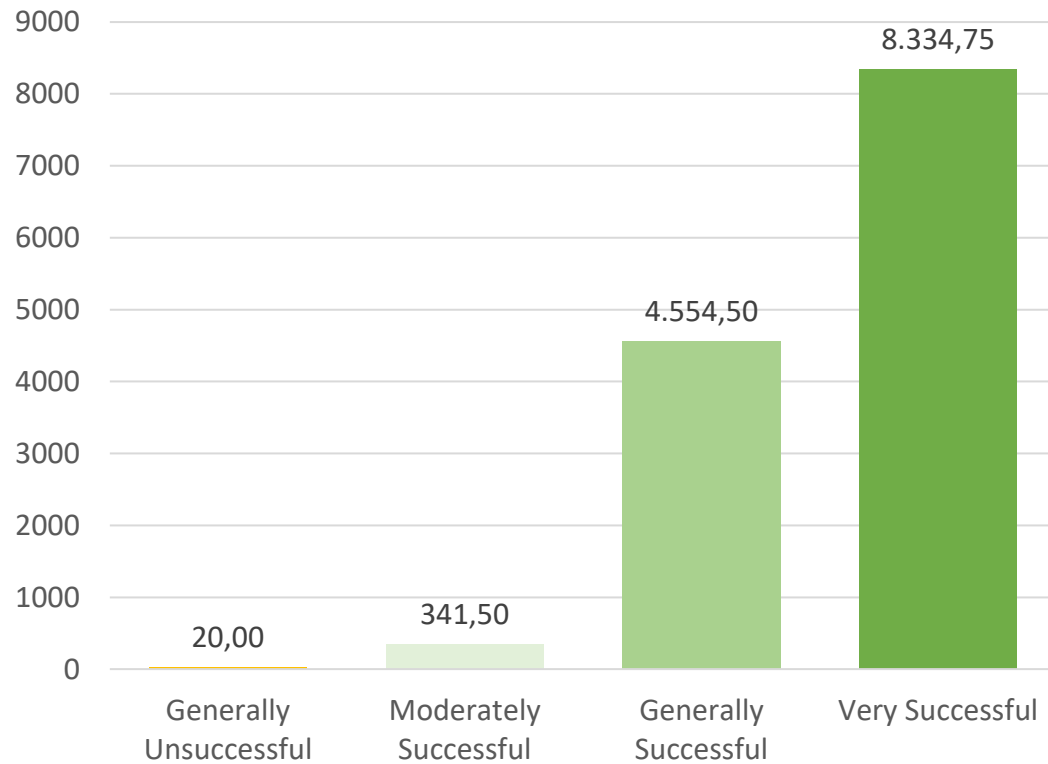
- Legal Manufacturers:Initial
- Legal Manufacturers:Surveillance
- Legal Manufacturers:Extension to Scope
- Legal Manufacturers:Re-assessment
- Suppliers / Subcontractors:Initial
- Suppliers / Subcontractors:Surveillance
- Suppliers / Subcontractors:Extension to Scope
- Suppliers / Subcontractors:Re-assessment



Remote Audits – n=37 – Nov 2020

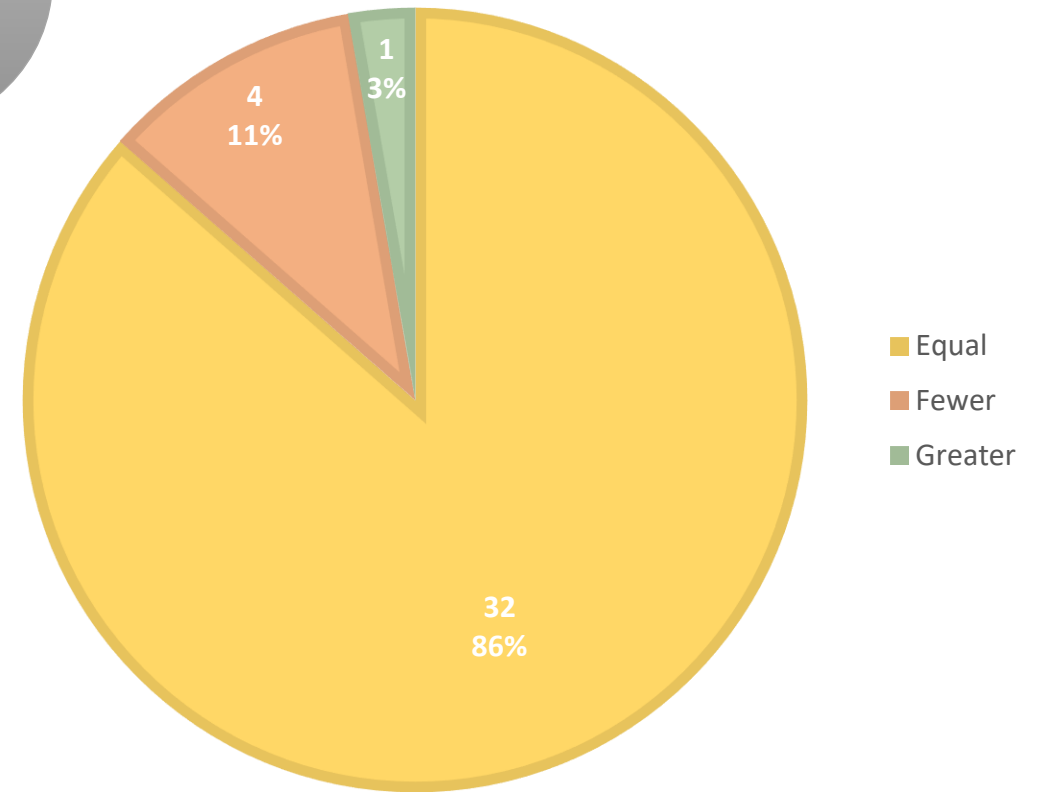


Total Number of Days of Remote Audits vs Experience of Remote Auditing



>13,000 days

OF NCS – ON SITE COMPARED TO REMOTE



Remote Audits

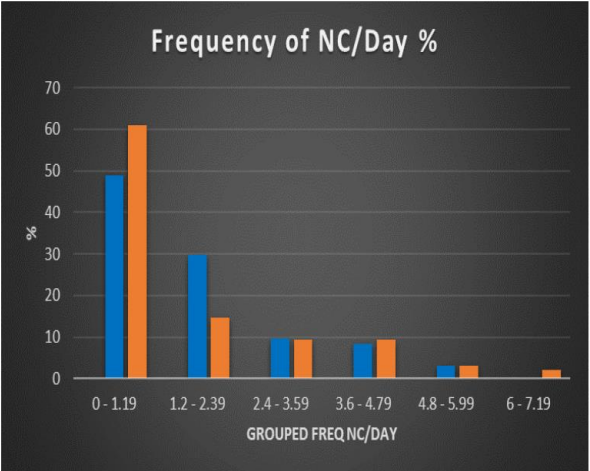
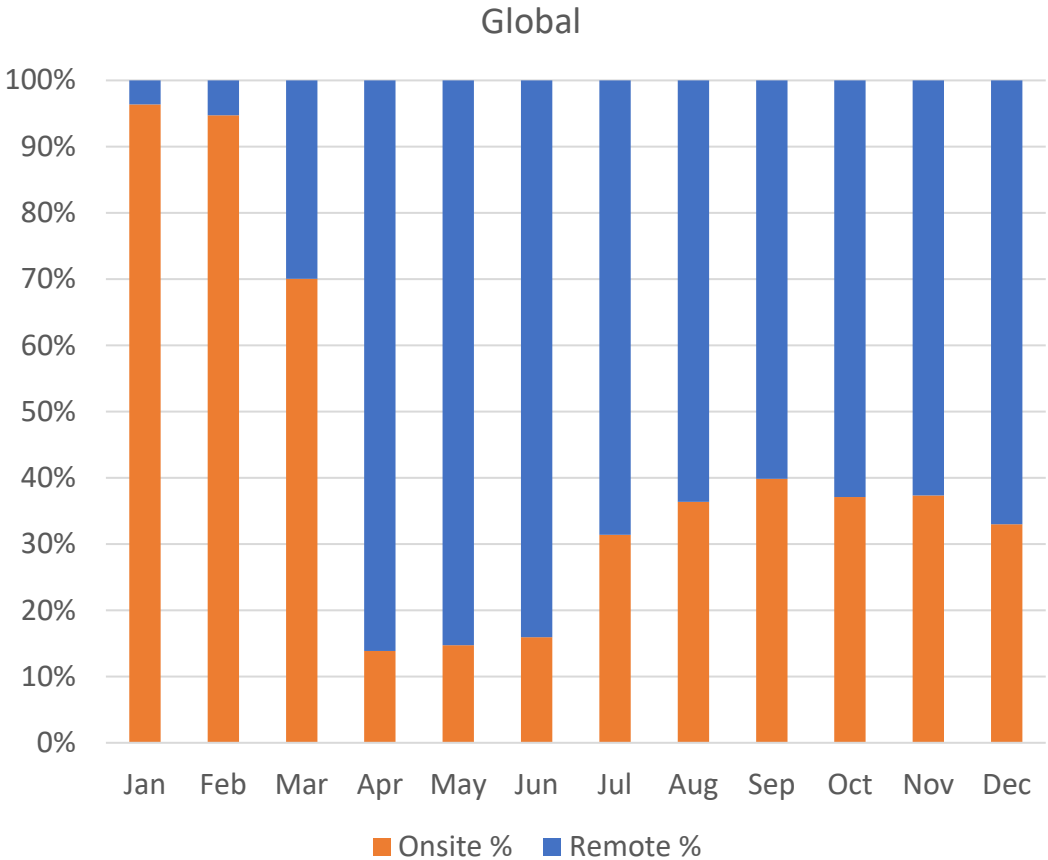


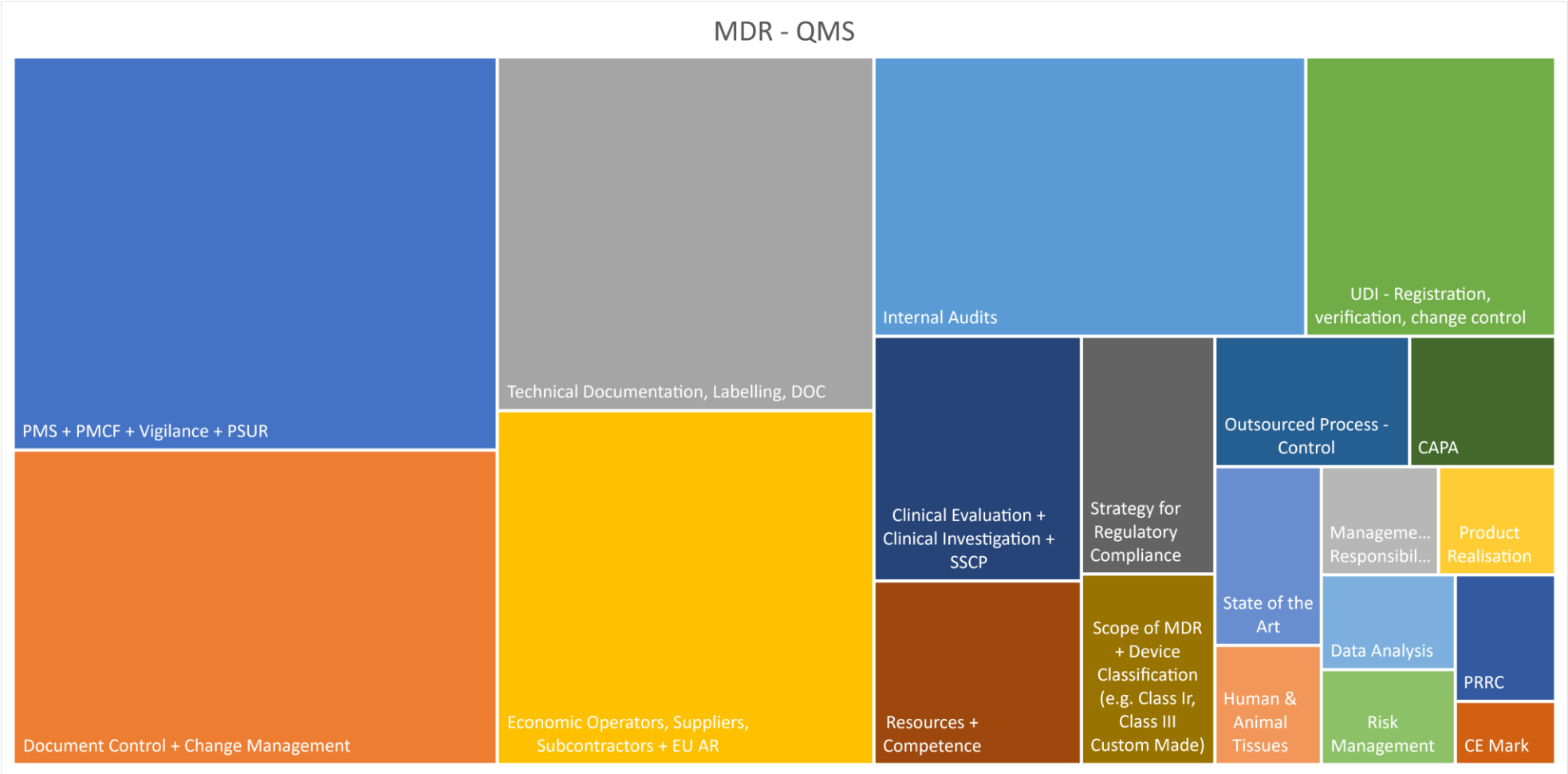
Figure 2 Grouped frequency data Remote (Blue) and Onsite (Orange)

n=100 remote & on site – Stage 2, CAV, re-assessment



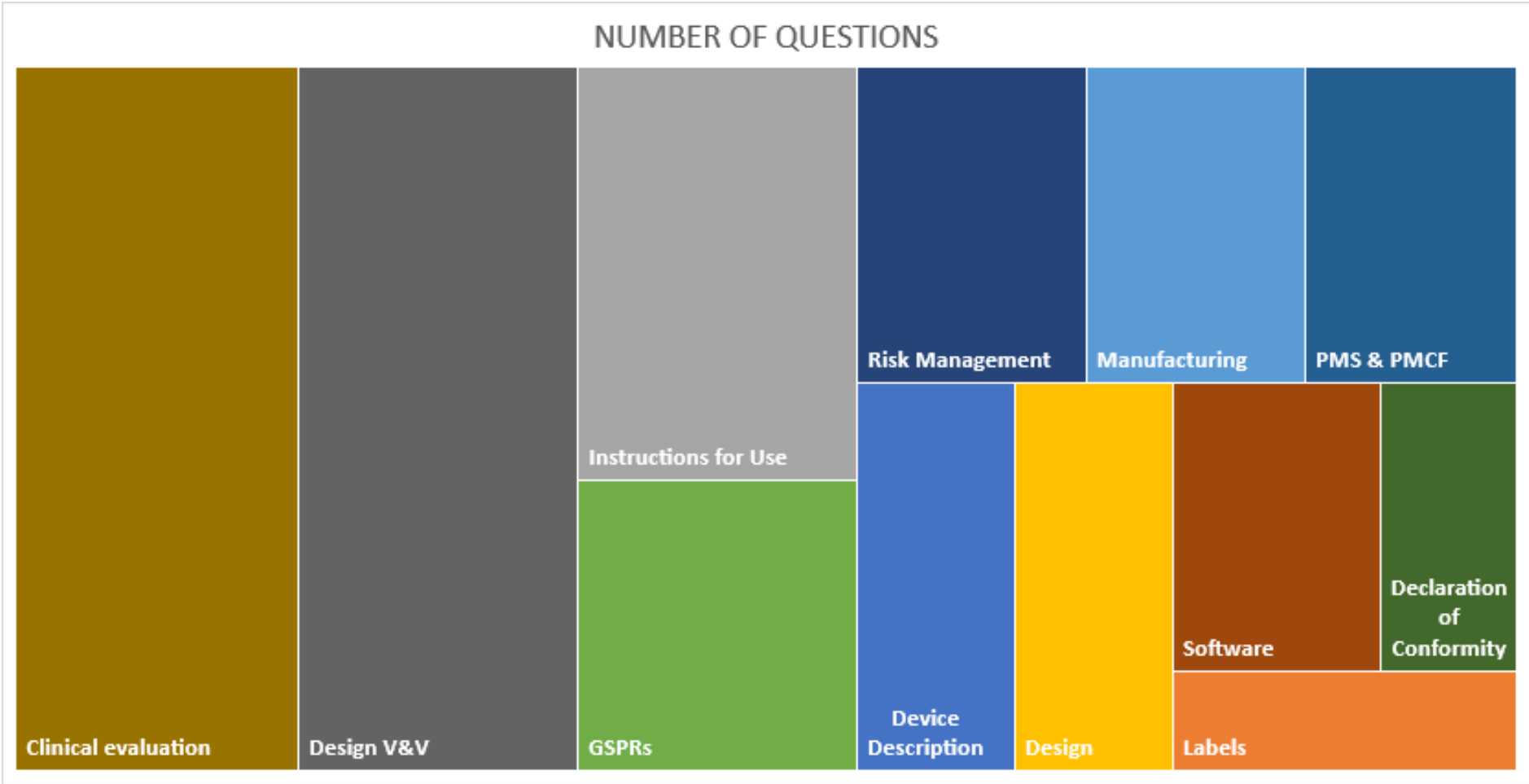
Figure 6 Average NC/Day per clause for remote cohort (Blue) and onsite (Orange)

MDR Audits – QMS



2019
&
2020

MDR Audits – Technical Documentation

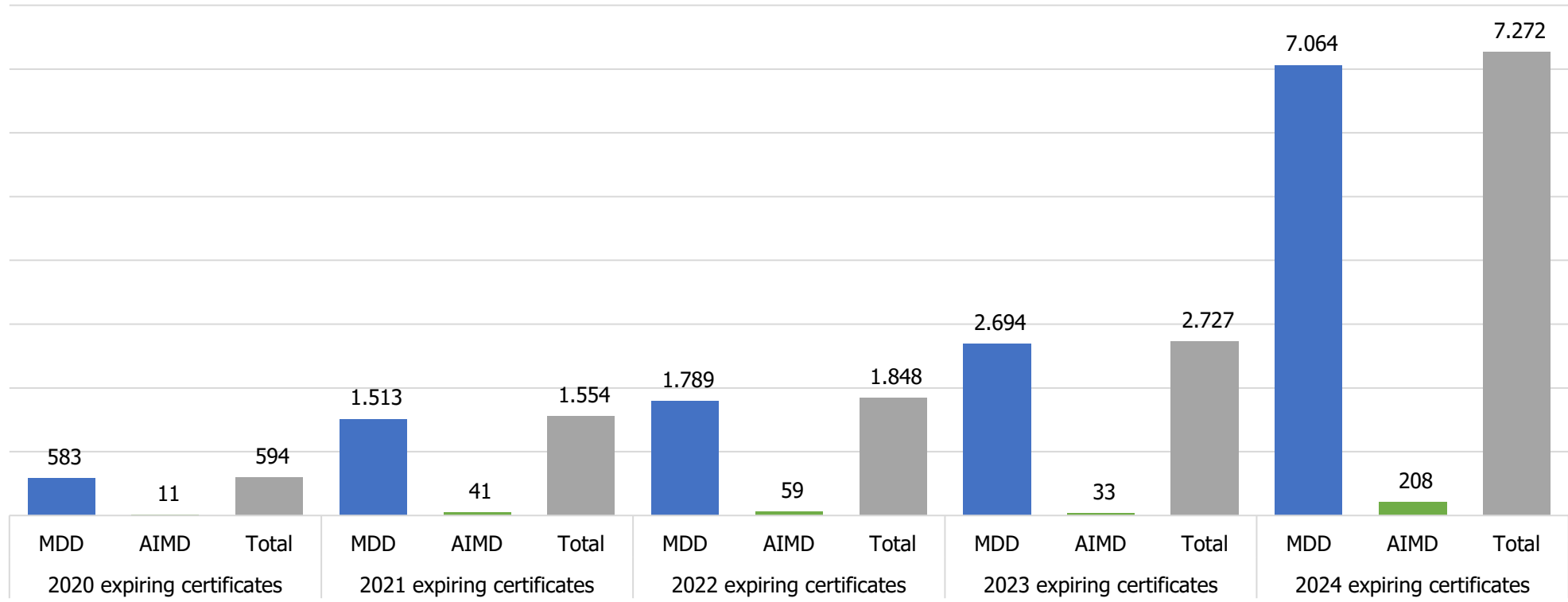


2019 & 2020

Expiring Certificates – n=34 – Sept 2020



How many certificates will expire in the future?



MDR Audits – Don't wait ...

Countdown to the MDR

Questions & Answers

