



The European Association
Medical Devices - Notified Bodies

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| Editors : Team-NB committee Francoise SCHLEMMER | Date : 18/11/2020 |
| Position paper Remote Audit Survey : Analysis | |

Thanks to EUSurvey, the European Commission's tool, all Medical Devices Notified Bodies (n=54) received on September 28th, 2020, an invitation to the survey '**Notified Body Experience with Remote Auditing**'. The survey was closed on October 29th. At that time, 37 Notified Bodies responded to the survey.

On November 2nd, a presentation with the responses from the 37 Notified Bodies in the form of graphs was uploaded in the Notified Bodies section of CIRCABC, the European Commission platform that provides a secured working area to share information among interest groups.

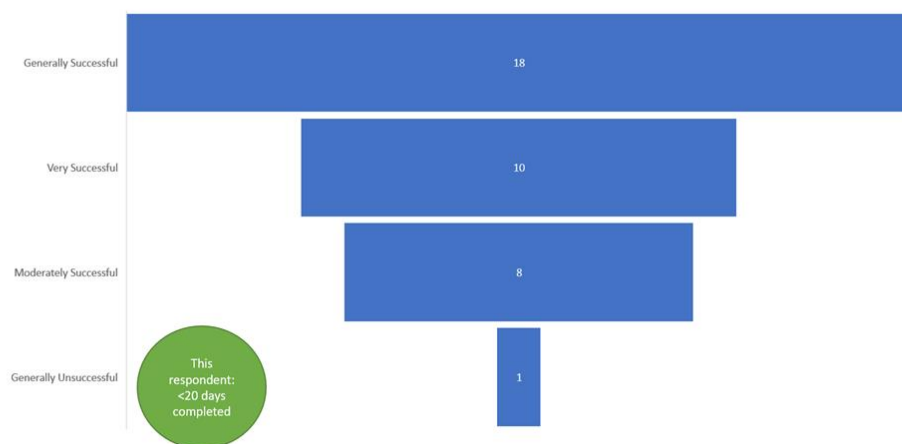
The results of this survey on remote auditing experience from Notified Bodies are showing some positive outputs.

First of all, the total number of audit days completed remotely / virtually was 12 860 against the directives and 389 days against the regulations for Covid-19 clinically necessary products or partial audits. These **significant numbers of auditing days** can allow us to consider these results as revealing.

Among those experiences **75% of these audits has been considered successful** or very successful.



What is your experience with remote audits?



The only negative experience was that of a notified body which carried out less than 20 days. It is true that auditors have experienced a significant learning curve for the preparation and delivery of remote audits, once this learning has been achieved the overall experience has been more successful.

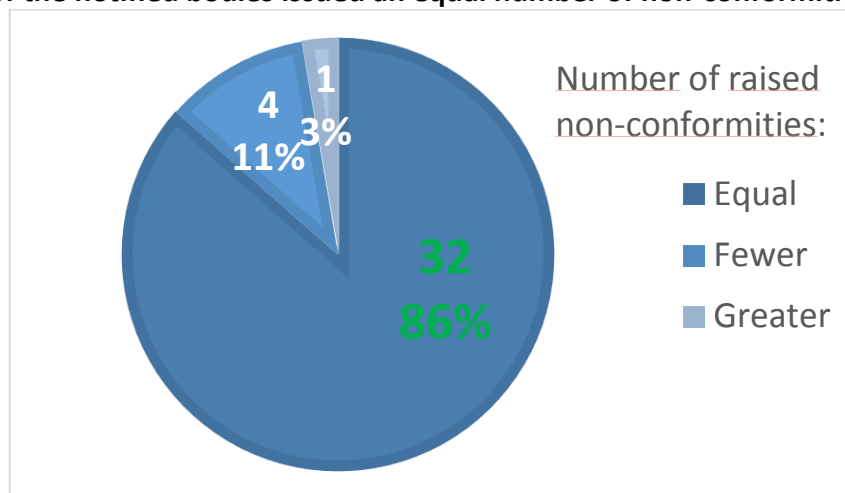
Ten different Notified Bodies have **been witnessed by authorities** knowing that the authorities have also, because of the circumstances, made their own audits in a remote way. Remote audits have allowed all global audits to be transparent to the authorities, and positive feedback was received in the majority of cases.

These remote audits **have allowed auditors to perform all necessary audit tasks:**

- ✓ interview operators of equipment
- ✓ interview document and record owners
- ✓ review documents
- ✓ video camera view of records, equipment, manufacturing areas
- ✓ ... not different from on-site tasks.

The remote auditing has not resulted in less robust audits, as there has been no significant impact on the number on non-conformities raised.

⇒ **86% of the notified bodies issued an equal number of non-conformities.**



In conclusion, this survey on remote auditing experience from Notified Bodies are showing that remote auditing is a convenient tool to allow audits to take place in a way that has no significant impact on the results. Remote audits and the associated rapid development of IT tools has also allowed the Notified Bodies to reduce their carbon footprint, meet UN Sustainable Development Goals, increase diversity and inclusivity, ensure competent and impartial auditors are used and increased transparency to the authorities.

The full survey is available on our web site as a graphical presentation in the news [Team-NB/News/Oct.29](#)

In case of any further clarification needed, please contact schlemmer@team-nb.org.