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8th April, 2020

Our ref: Covid-19 Update

To whom it may concern,

Please find below a paper outlining the effect of Covid-19 on BSI and other certification bodies, identifying serious risks to global healthcare oversight unless suitable, immediate and unified action is taken.

Problem statement

BSI has been operating under contingency measures following the principles laid out in IAF ID3:2011 since the 4th February, limited initially to China and then rapidly escalating globally.

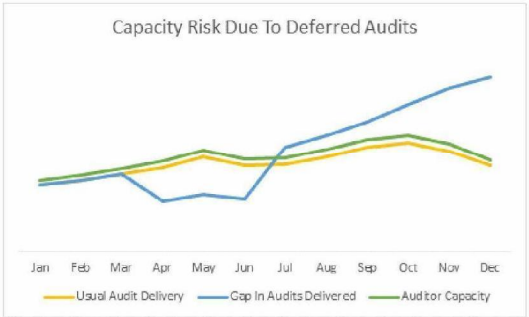
As government stay at home orders roll out, social distancing requirements and other travel restrictions take effect, we have observed and are continuing to witness a tremendous impact on BSI's and our client's compliance to visit cycles.

Two significant issues are combining to create an untenable position:

- clients with existing ISO 13485/MDSAP/Directive certification increasingly refusing to accept remote surveillance audits due to running skeleton staffing, shutting down sites temporarily or stating an inability to use remote auditing technology.
- a number of audit types that cannot be delivered remotely due to regulatory viewpoints regarding their non-applicability. For example, MDSAP initial, MDR audits, subcontractor verification audits, Unannounced audits, extensions to scope, microbiology and some types of non-conformity close-out audits. In fact, there are MORE types of audits that cannot be conducted, than are allowed to be delivered remotely.

The following numbers as of 06 April 2020, convey the scale of the problem:

Deferrals	**Partially Remote Audits**
Manufacturers deferring audits - 119 Audits deferred - 130 Audit days deferred – 400+ Unannounced audits deferred - 58	Manufacturers with Partial Remote Audits - 101 Partially Remote Audits - 121 Audit days deferred for onsite delivery later - ~150



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BSI had a full audit diary in H2 2020 before this and well into 2021. So, catching up on these audits will take an estimated **12 -18 months**. As we progress into May and beyond, without respite, these figures are expected to grow exponentially.

As elective procedures in hospitals across the world continue to be cancelled, medical device manufacturers are seeing their shipments drop by at least 20% and this will continue to worsen. This will potentially lead to staff layoffs and site closures, further compounding the problem.

This situation has now meant that BSI, along with many other Notified Bodies, AOs and CABs, will have too many audits deferred to Q3 and Q4 (even assuming that we can get back on site in Q3) to be able to maintain compliance to regulatory and accreditation requirements potentially leading to certificate suspensions and/or cancellations. This may also lead to more requests for Regulatory Authorities to assume responsibility for devices with a lower level of oversight from CABs.

All the above factors present a serious risk to the functioning of the entire health-care system and most importantly, patient safety as outlined below -

- If manufacturers cannot support/host remote surveillance audits, and certification bodies cannot complete the deferred work within the stipulated 6-month time, suspension of certificates is inevitable leading to loss of access to medical devices on the market that are critical to patient safety
- Inability to remotely audit existing and new critical sub-contractors of manufacturers will hamper ramping up of production of critical medical devices required to fight the Covid-19 virus in the short-term.
- Due to a lack of auditing work arising from Covid-19 situation and the regulatory requirements related to remote audits, the massive resourcing effort introduced by Notified Bodies/CABs over the last two years will go to waste. Staff may have to be temporarily furloughed or permanently laid off, as the business cannot support that level of resource with such a limited demand. Re-mobilisation of staff temporarily furloughed will slow down and adversely affect the NBs/CABs future operational and delivery capabilities adversely affecting the supply of medical devices.
- The mandatory requirement of delivering audits every 12 months, will not just fail in 2020, but in 2021 and possibly 2022 due to the domino effect. It is simply not possible to deliver a years' worth of work in 6 months and catch up overnight. A CAB/AO/NB cannot temporarily increase resource for a such a situation (and then lay off staff 6 months later) and external resources can no longer be used under MDR/MDSAP due to the stringent impartiality restrictions. This would have to be a grindingly slow catch up process, potentially causing overwork and employee attrition which in turn will adversely affect patient access to safe medical devices.

Due to the risks detailed above, it is foreseen that patients will not receive their lifesaving and life enhancing treatments as a result of the potential for hundreds of companies and many more products to be out of compliance over the short and medium term. The benefits of the legislations such as MDSAP and MDR will not reach patients as CABs/AOs/NBs cannot progress with certification without establishing QMS compliance. In this context, we propose the following solutions.

Solutions

There needs to be a multi-pronged solution to this issue, to address the two root causes listed in the problem statement.

1. **Increase the uptake of remote audits.**

   Clients are perceiving the level of pressure from CABs/AOs/Notified Bodies to accept remote audits as unacceptable and a 'money grabbing' exercise whilst businesses are on their knees. Regulators need to actively participate in openly supporting the remote audit process and highlighting the risks of suspension and deferral, especially when manufacturers are continuing their production activities and placing devices on the market.

2. **Allow more time to resume on-site audits.**

   Allow the continuation of remote audits till the end of 2020 and beyond if required, after social distancing and travel restrictions are lifted. The efficiencies of not travelling will allow CABs/AOs/NBs to catch up more quickly with the backlog of work.

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3. Expand the use of remote auditing.

Regulators need to accept that Covid-19 is an unprecedented situation, and that the current approach will turn 2021 and 2022 into a prolonged crisis.

By accepting a risk-based approach to a wider use of remote auditing in 2020 and beyond, patients and regulators gain the benefits of:

- Increased number of devices transitioning to MDR with its increased regulatory control
- CAB/AO/NB control and stability reasonably quickly re-established
- Manufacturers able to get new and innovative devices onto the market thus benefitting patients
- Maintain supply of existing devices under CAB/AO/NB oversight rather than regulator – who can then focus their resources on addressing Covid-19 issues and market surveillance.
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Proposal:

There are some audits that can never be entertained as remote – for e.g. Unannounced audits due to their very nature. However, it is possible to conduct most other audit types remotely and robustly if a risk-based approach can be applied.

1. Allow remote auditing for transition to MDR of devices that are already certified under the Directives

2. Initial assessments for all schemes

Due to the current challenging circumstances, and due to the regulatory policies of not allowing remote initial assessments, there will be a huge lag in getting products to market for novel devices and new manufacturers. Remember this is in the light of many CABs/AOs/NBs not accepting many new clients due to a combination of early renewal requests under the Directives, ISO 13485:2016 transition and CMDCAS to MDSAP transition. So, we have a 2-year pipeline lag for innovation so far.

Initial assessments are riskier to do remotely as there is little history regarding the manufacturer's experience and compliance capability.

Option A: Allow remote Stage 2 assessments for virtual manufacturers with most of the manufacturing outsourced and also for manufacturers of software only devices.

Option B: For higher risk manufacturers, conduct 50% of the stage 2 remotely, but do not issue a certificate until a subsequent on-site assessment has been completed. This means that only a smaller percentage of days carries forward. If the whole duration carries forward, it will not fit in to Q3/4 and the pipeline lags at least another 6 months.

3. Extension to scopes

Since the Manufacturer would have already been certified it is less risky than initial assessments detailed above. However, some the audits may have to cover some manufacturing aspects if they haven't been previously audited. Consider allowing remote audits if simple low risk processes, virtual processes, software. Or if client can support video streaming, use to audit manufacturing and verify results at next surveillance audit.

4. Transfers

Limited client history so can be some risk. Allow transfers based on remote audits.

Overall, it is imperative to recognise the knock-on effects of the truly extraordinary challenges the world is currently facing and the impact on future access to safe and innovative medical devices that are critical for patient safety. These exceptional circumstances call for unified and risk-based approaches by Regulators and Notified Bodies to ensure continued access to medical devices and to uphold a high level of patient safety.

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Yours faithfully