CB Requirements in relation to managing the Novel Coronavirus (COVID-19) pandemic

The current pandemic of the Novel Coronavirus (COVID-19) may impact the CBs ability to complete the scheduled audits, thus potentially impacting the FSSC 22000 certification status of organizations.

Following discussions internally and with other Stakeholders, in particular following the Global Food Safety Initiative (GFSI) Coronavirus position paper dated 13 March 2020, the Foundation FSSC 22000 FSSC22000 has decided to grant an exception in the case of the Coronavirus where this is preventing CBs from travelling to organizations in affected areas/countries and no auditors are available/able to reach the site due to corporate company policies. In all cases, the CB shall have documented procedures and keep records of the activities mentioned below as required under FSSC 22000 Scheme version 5, section 5.10 of Part 3 Requirements for the Certification Process.

The Foundation FSSC 22000 requires its licensed CBs to undertake the following actions:

a) Follow IAF ID3:2011 *Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations*, available at www.iaf.nu.
The risk assessment shall as a minimum include the criteria as listed in section 3 of IAF ID3: 2011. The outcome of the risk assessment could lead to the suspension of the certificate and if so, the Portal shall be updated accordingly.

b) Surveillance (V5 upgrade) audits:
Risk assess the situation of the certified organization according to IAF ID3: 2011 and take appropriate action. Two options are available to CBs and certified organizations as listed below and both scenarios can be applied to the first surveillance audit following an initial certification.
- Option 1: Postpone the full surveillance audit by a maximum of 6 months within the calendar year
- Option 2: Conduct the surveillance audit as a staged (two part) process consisting of a remote audit followed by an onsite audit within 6 months. The remote audit combined with the onsite audit constitutes a complete surveillance audit.
  Where the 6 months between the remote and the onsite audit is exceeded, the full surveillance audit shall be conducted onsite within the calendar year or the certificate shall be suspended.

Option 2 – Part 1: V5 Remote audit requirements

i. The CB shall determine as part of the risk assessment and in conjunction with the certified organization, whether or not a remote audit is a viable option.
ii. If the remote audit is deemed to be a viable option, ICT means to be used shall be tested before the planned remote audit to confirm that the ICT is appropriate, suitable and effective.
iii. Follow the requirements of IAF MD4:2018 *The use of information and communication technology (ICT) for auditing/assessment purposes* (available at www.iaf.nu).
iv. The remote audit will normally be 1 day and the onsite verification audit the remainder of the total duration of the surveillance audit. The onsite audit cannot be less than 1 day and shall at least be 50% of the total audit duration. Durations shall be rounded upwards to half or full days taking into account that additional time might be required to conduct the remote audit.
v. The remote audit shall at least review the following key FSMS elements:
   - Key changes since the last audit e.g. HACCP plans, product recalls and significant complaint levels.
   - Status with regard to objectives and key process performance, management review and internal audits. It is required that certified organizations increase the frequency of internal audits in support of the FSMS and to ensure food safety.
   - Processing records including but not limited to the monitoring and corrective actions linked to OPRPs and CCPs;

- PRP records i.e. hygiene, pest control and maintenance records;
- A traceability test to ensure continued compliance with the Scheme rules;
- Emergency preparedness and response including the impact of the Corona virus on the supply chain of the organization and the potential impact on resources and food safety.
- Live video check of the manufacturing process, fabrication and hygiene of the site. Any video does not require recording but a record shall be kept of the duration of the live video and what was covered. This is to be recorded in the audit report.

vi. The remote audit shall be documented using the CB's own template, covering the requirements listed above, and clearly indicating the extent to which the ICT was used and the objectives achieved. The report has to be uploaded in the Portal as a special audit, with the justification of "Pandemic – Coronavirus" within 2 months of the audit.

vii. Any nonconformities identified during the remote audit shall be classified according to the scheme requirements and closed out within 28 days after the last day of the audit. In the case of a critical nonconformity, the certificate shall be suspended and a full new onsite surveillance audit will be required to lift the suspension within 6 months.

Option 2 – Part 2: V5 Onsite audit requirements

i. The onsite audit shall preferably be conducted by the same auditor who did the remote audit to ensure continuity.

ii. The effective close out of any nonconformities identified at the remote audit, shall be verified for effective implementation.

iii. The onsite audit serves as the verification audit with a focus on the remainder of the clauses not covered during the remote audit and the onsite production/GMP audit. It might be necessary to review parts of the remote audit again to ensure implementation of requirements. All the requirements of the Scheme shall be covered between the remote and the onsite audit and clearly reflected in the audit plans.

iv. Any nonconformities identified during the onsite audit shall follow the existing requirements of the scheme.

Option 2 – Parts 1 &2: Audit reporting

The surveillance audit report shall include all summarized information and findings of the remote and onsite audit (as required in Scheme Annex 2) that covers all the Scheme requirements and uploaded to the Portal. The report shall also reference the date and the duration of the remote audit.

The surveillance audit is only concluded once both the remote and the onsite audit have been successfully completed.

c) V5 Re-certification audits: in case the certificate will expire, a validity extension of up to 6 months is allowed following a documented risk assessment and a successful remote audit following IAF MD4:2018 *The use of information and communication technology (ICT) for auditing/assessment purposes,* available at www.iaf.nu.

The same two part process (remote and onsite audit) as described under the Surveillance audit Option 2 process shall be followed, including the specified audit criteria, audit principles and the audit process. The actions below shall be applied in addition:

i. Following the remote audit against V5 and closure of any nonconformities within 28 days, the current Version 4.1 certificate can be extended with a maximum of 6 months.

ii. Where the certified organization fails to close out the nonconformities or a critical nonconformity is raised, the certificate shall be suspended.

iii. The remote audit report, audit plan and the risk assessment shall be uploaded in the Portal as a 'special audit' and the subsequent certificate decision resulting in an extended certificate expiry date, shall be entered in the Portal at the latest 28 days after the decision has been taken. The justification in the Portal for extending the certificate shall be listed as "Pandemic – Coronavirus".

In all cases the CB is responsible for the decision to extend the certificate validity and is required to keep records to support the certification decision.

The onsite V5 audit needs to take place within the 6 months validity extension window, with sufficient time to ensure that the extended certificate does not expire, and continuous certification is maintained.

Upon successful completion of the onsite audit, including addressing any nonconformities as per the Scheme requirements, the recertification audit is complete.

Option 2 – V5 Audit reporting
The recertification audit report shall include all summarized information and findings of the remote and onsite audit (as required in Scheme Annex 2) that covers all the Scheme requirements and uploaded to the Portal. The report shall also reference the date and the duration of the remote audit.

The recertification audit is only concluded once both the remote and the onsite audit have been successfully completed.

Following a positive certification decision by the CB, a new V5 certificate can be issued. The new certificate dates have to be aligned with the existing certification cycle.

Example
The FSSC 22000 certificate is valid from 18/03/2017 – 18/03/2020. Following a positive outcome on the risk assessment and the V5 remote audit, the validity of the certificate can be extended by 6 months, therefore in this example the expiry date of the current certificate is extended to 18/09/2020. The onsite audit takes place in July 2020 with a certification decision date of 05/09/2020. The subsequent certificate is issued that aligns back to the previous cycle, therefore with an expiry date of 18/03/2023.

Should the CB not be able to conduct or complete the remote audit successfully, then the full onsite audit needs to take place prior to the expiry of the certificate or the certificate has to be suspended.

d) Continual re-evaluation by the CB of the certified site's ability to accept an on-site audit should be maintained and an audit shall be undertaken at the earliest opportunity. CB's shall establish procedures to determine via a risk assessment the order for audit rescheduling to take place.

e) Witnessing of CB auditors
   i. *Initial auditor qualification*: for initial auditor qualification (including the transfer of already qualified approved auditors from another CB), an onsite witness audit with a positive outcome is a pre-requisite for initial qualification. In cases where the witness audit has to be delayed, the auditor qualification process cannot be completed until such time as the witness audit has taken place with a favorable outcome.
   ii. *Maintenance of auditor qualification*: every 3 years a witness audit shall be conducted for already qualified FSSC 22000 auditors: where it is not possible to schedule the witness audit within the 3 year period, the witness audit can be extended with a maximum of 6 months from the due date. The witness audit report shall clearly state that the witnessing activity was delayed as a result of the Corona pandemic and uploaded to the auditor Portal in the normal way.

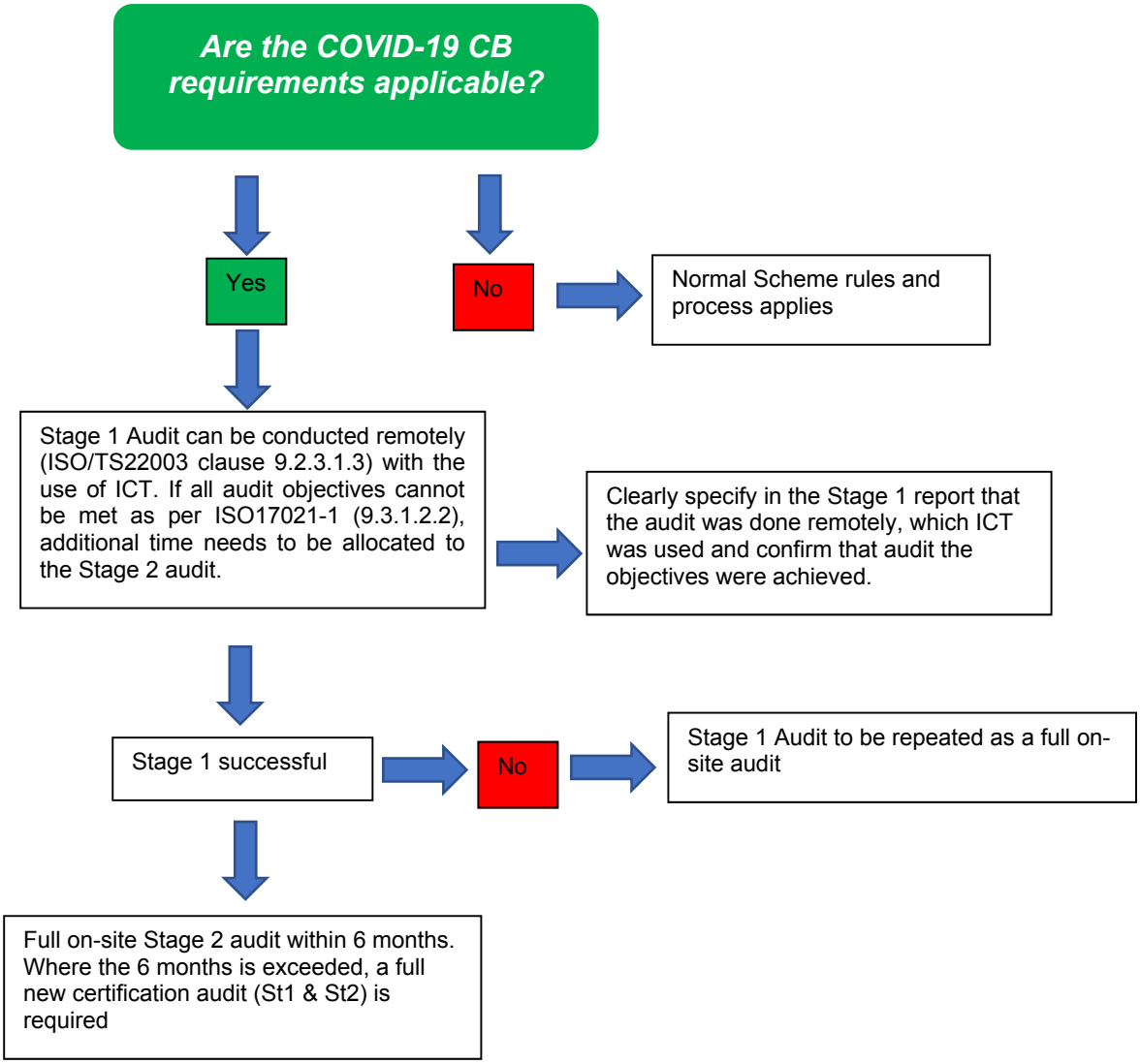
f) In principle, the CB shall follow AB guidance, where applicable, and in case this conflicts with these FSSC 22000 specific requirements, the CB shall seek approval from the Foundation to resolve the issue.

g) The exceptions as listed in this position paper can be applied under the following circumstances:
- The certified organization is situated in an area (town, city or province within a country) with known Corona cases or;
- The certified organization is in an area affected by government restrictions and/or official travel bans or;
- The certified organization's company policy is temporarily prohibiting visitors due to COVID-19 and not allowing auditors on their premises or;
- The CBs corporate policy is prohibiting auditors from travelling.

In cases where the Certified Organization's policy is prohibiting auditors from entering the site, it is expected that CBs work with these organizations to facilitate and plan the audit using the options provided. Likewise, where the CB's corporate policy is preventing auditors from travelling, all options as provided needs to be explored to facilitate audit planning and continued certification.

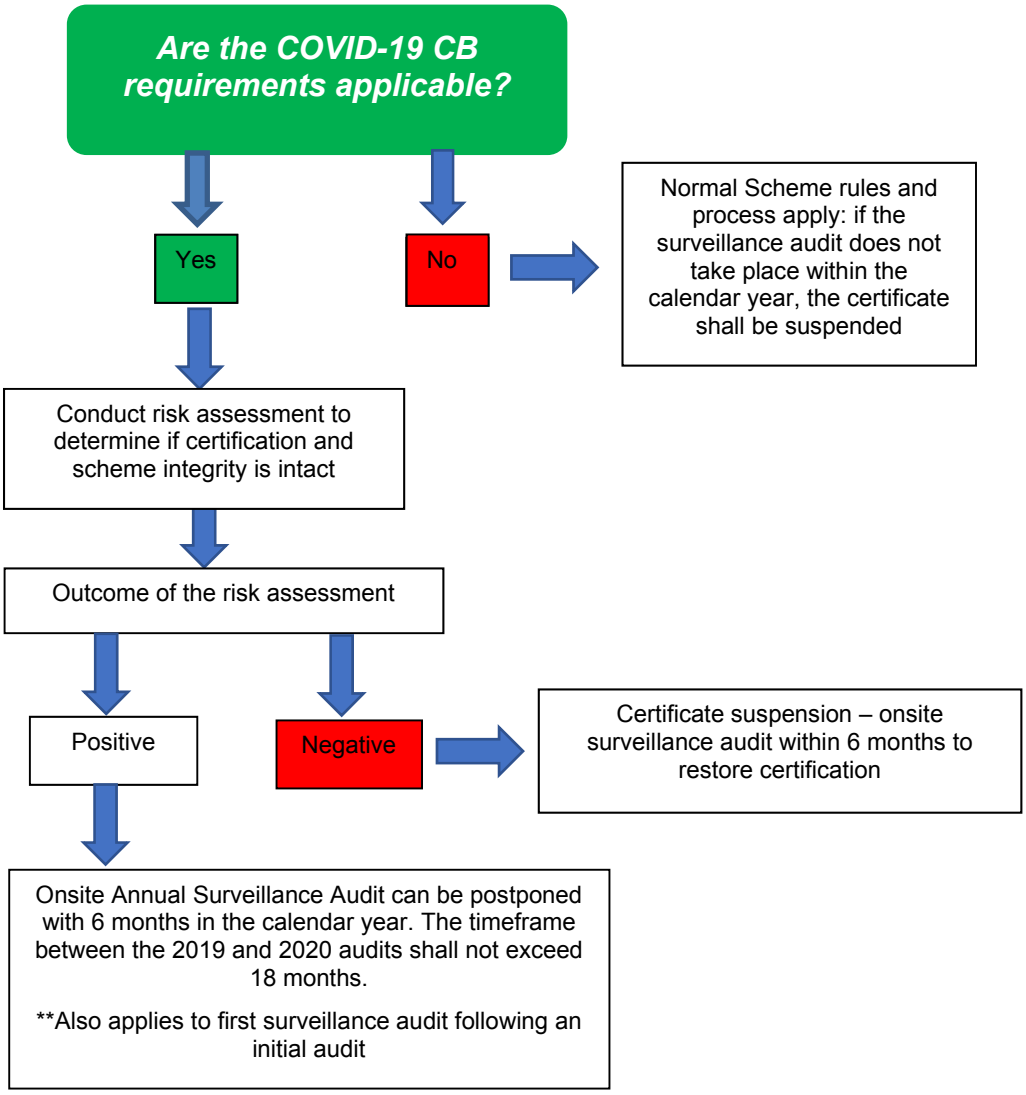
The cost to deliver the audit cannot be a determining factor and the exception cannot be applied to Stage 2 audits (initial certification), scope extension and follow-up audits

DECISION TREE FOR INITIAL (V5) AUDITS



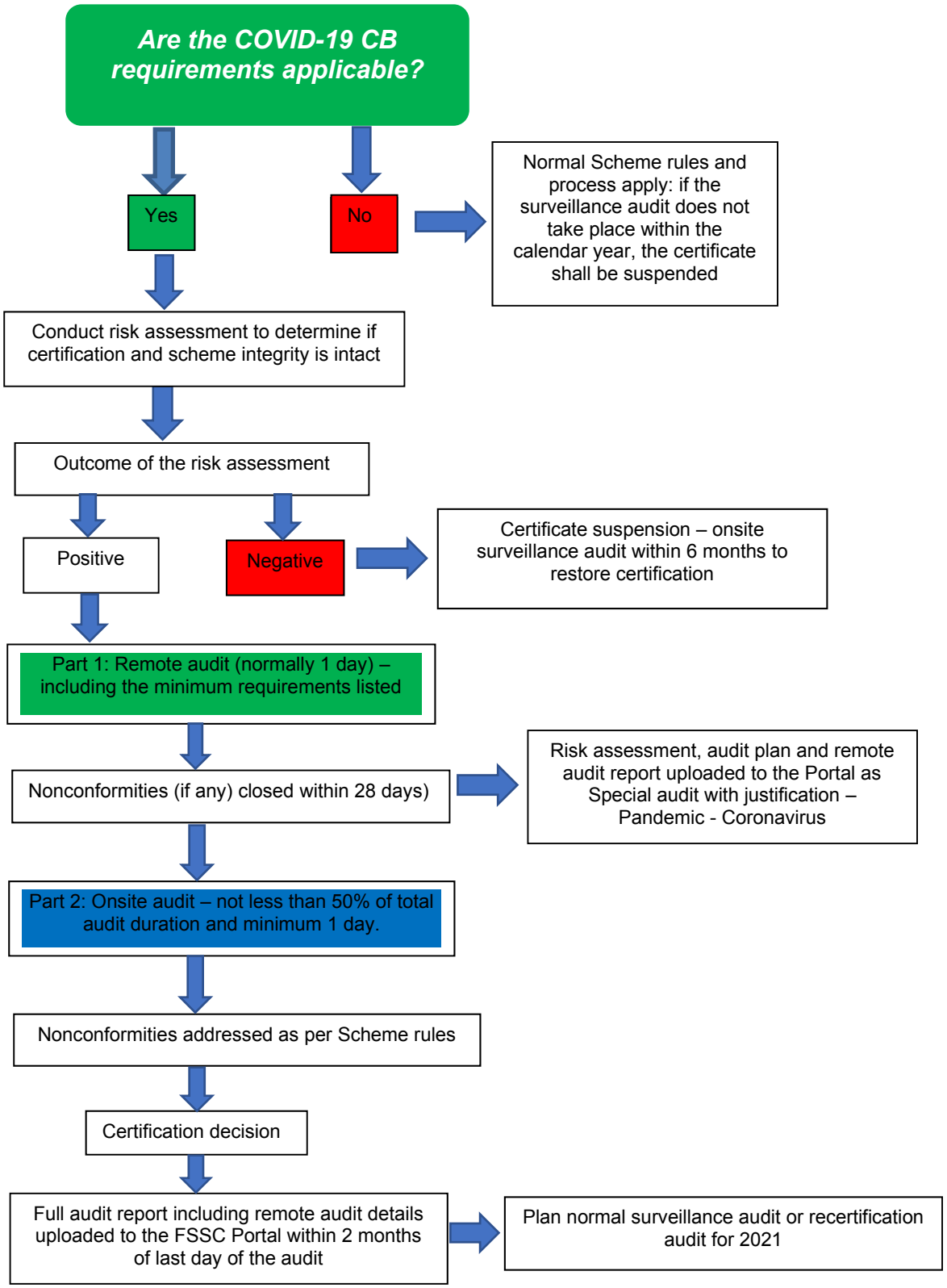
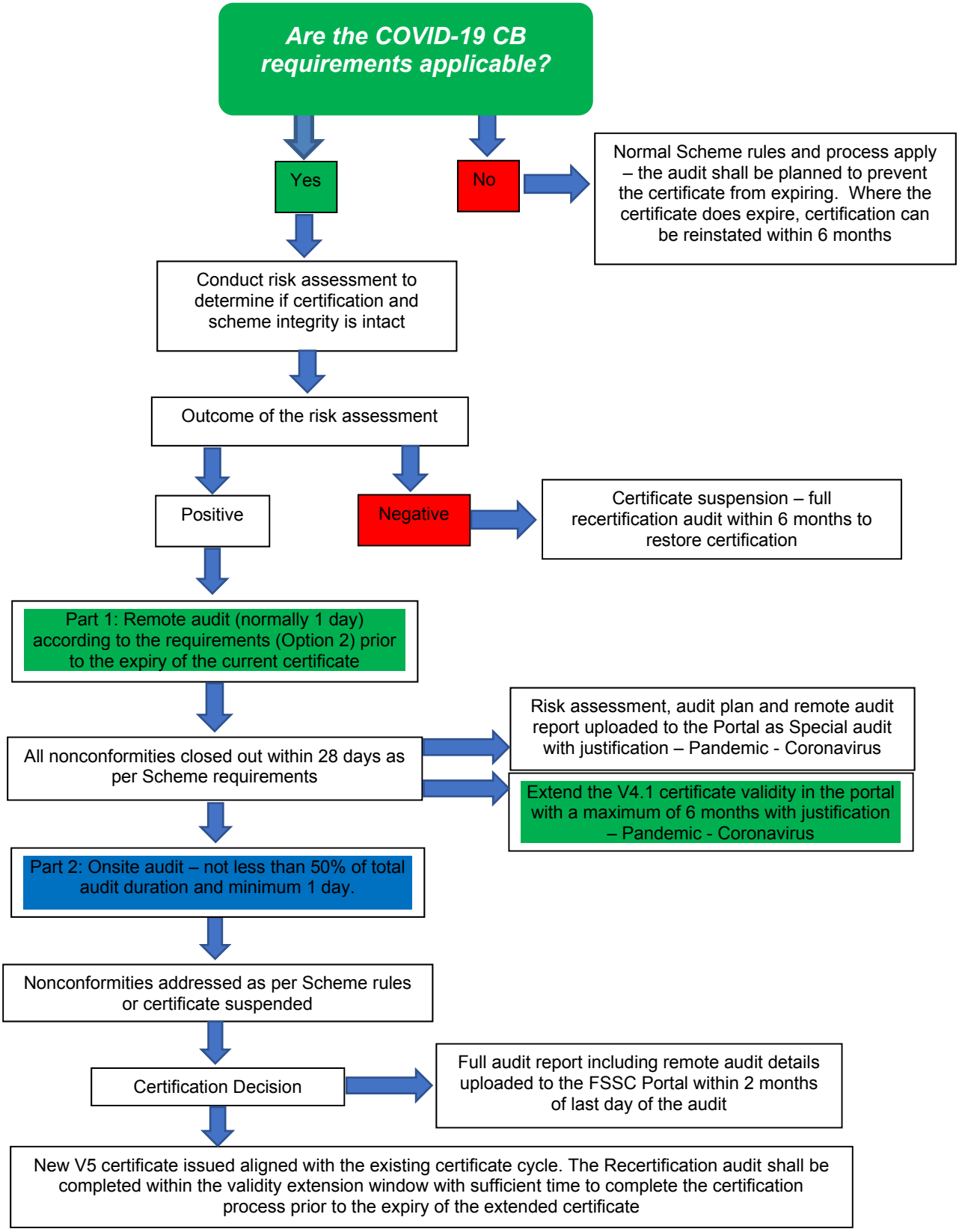
DECISION TREE FOR SURVEILLANCE (V5 UPGRADE) AUDITS

OPTION 1: SURVEILLANCE AUDIT POSTPONED



DECISION TREE FOR SURVEILLANCE (V5 UPGRADE) AUDITS

OPTION 2: SURVEILLANCE AUDIT (TWO STAGES)



DECISION TREE FOR RECERTIFICATION (V5) AUDITS