COVID-19:
Manufacturing and safety protocol in response to plant personnel being reported as COVID positive

The coverage of this document covers pharmaceutical manufacturing units (API and formulations) based in India.

The objective of this document is towards ensuring safety of the manufacturing and plant personnel at the plant premises and to minimise the risk and possibility of a COVID-19 outbreak in the plant premises. It aims to ensure that patients across therapy areas are ensured uninterrupted supplies through continued manufacturing operations without compromising personnel safety.

*This document **does not intend to replace the preventive measures** being taken towards employee safety – this is an addendum to define protocol in event of a plant personnel being reported as COVID-19 positive*

Version 1 – Dated 22nd April 2020
Document to be updated based on learnings from on ground implementation

Key measures to be taken in advance towards response readiness in case a COVID positive case is reported

Proactive isolation measures

a) **Shift isolation** – Attempts to be made to isolate the shifts where possible by a time gap of 10-15 minutes between 2 shifts to avoid physical contact between employees. Based on health profile of employees restrict the participation of people over 60 years of age/ people who have severe underlying chronic medical condition like heart or lung disease or uncontrolled diabetes. Shift isolation to be customized at a unit by unit level depending on the availability of manpower and type of manufacturing process (batch/ continuous).

b) **Vulnerable areas isolation** – Decentralization of common areas such as canteen as much as possible – i.e. each block/ unit to attempt to set up its own temporary canteen area with social distancing within this area to restrict cross-block employee movement. Use of change rooms by dedicated and staggered time slots. Regular cleaning of contact surfaces in change rooms even during a shift changeover to minimize possibility of transfer.

c) **Geo-marked isolation** within the plant – control the entry points at a sub-block building and floor level to mark change of physical position of employee. Allow entry only for critical reasons and educate personnel on restrictions of cross pollination of people across sub blocks/ floors

d) **Transport isolation** – transport schedule aligned to shift and geo-markers within plant to avoid contact exchange during transport, where possible.

Other preemptive measures

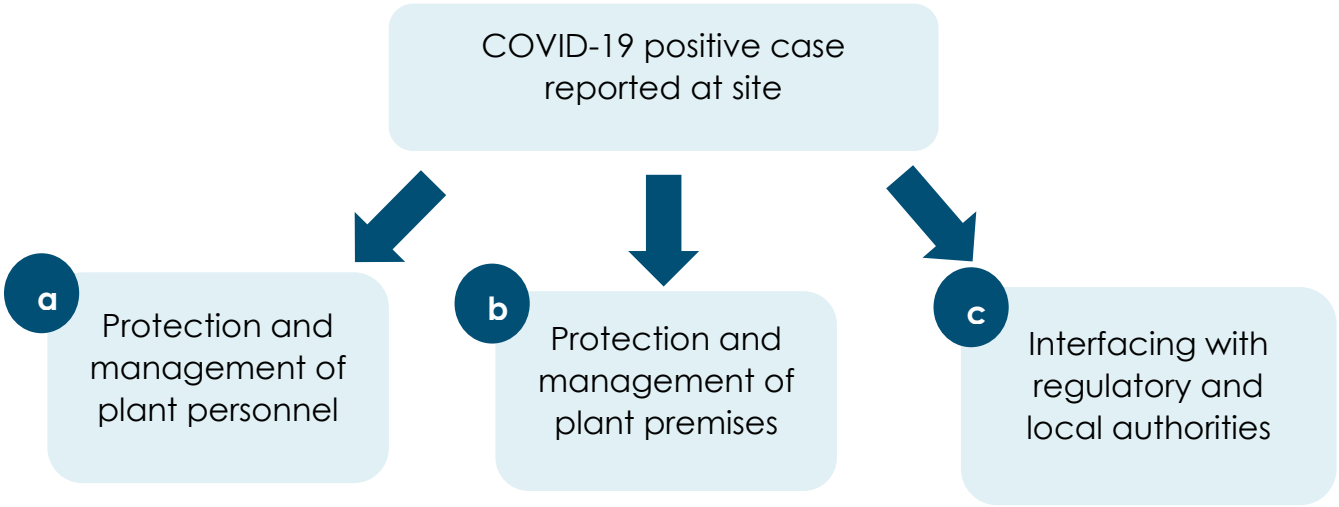
a) Pre-emptive daily monitoring of attendance of entire employee base to track continuous absence of more than 3 days – checks on these employees for any symptoms and support provided on diagnosis.

b) Continuous sanitization at defined frequency of entry-exit points and key common areas – sanitization protocol to be signed off with local authorities where possible

c) Dedicated housing for key personnel at manufacturing campus or separate/near-by housing facility, where possible – For critical portfolio segments, employees to be provided housing, essentials and stay for up to 60 days to isolate them from external sources

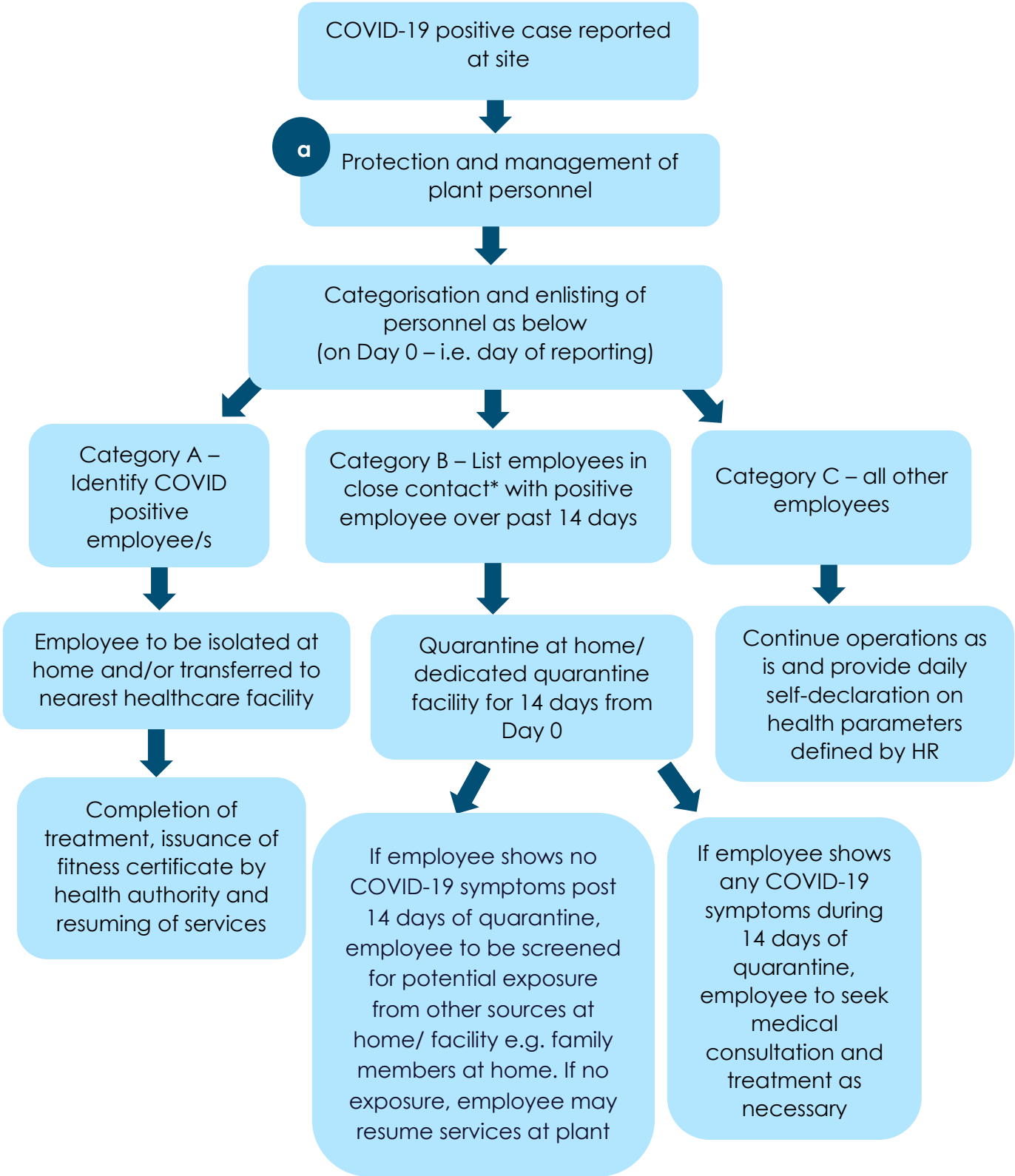
d) Daily self-reporting/ declaration of health parameters by all personnel, preferably through an online tool aligned to a risk matrix. Employees/ contractors to be screened through thermal scanners at all entry points.
e) COVID evacuation mock drills to enable safe evacuation and shutdown
f) Training and capability building of backup/replacement employees in case critical employee gets infected
g) Proactive alignment with local and state Government on a jointly acceptable sanitization protocol where possible (outlined in Appendix)
h) Quick testing for suspect employees enabled by Government or private partnerships where possible
i) Use of personal protective equipment (PPE) including masks by all employees and support service providers/ contractors
j) Social Distancing protocols to be established inside all plant and related areas including canteen, common change blocks and transport
k) Guidelines for on-site doctors to be provided on isolation and protocol of COVID positive case at site

Protocol at plant/ R&D centers if any employee reports COVID-19 positive



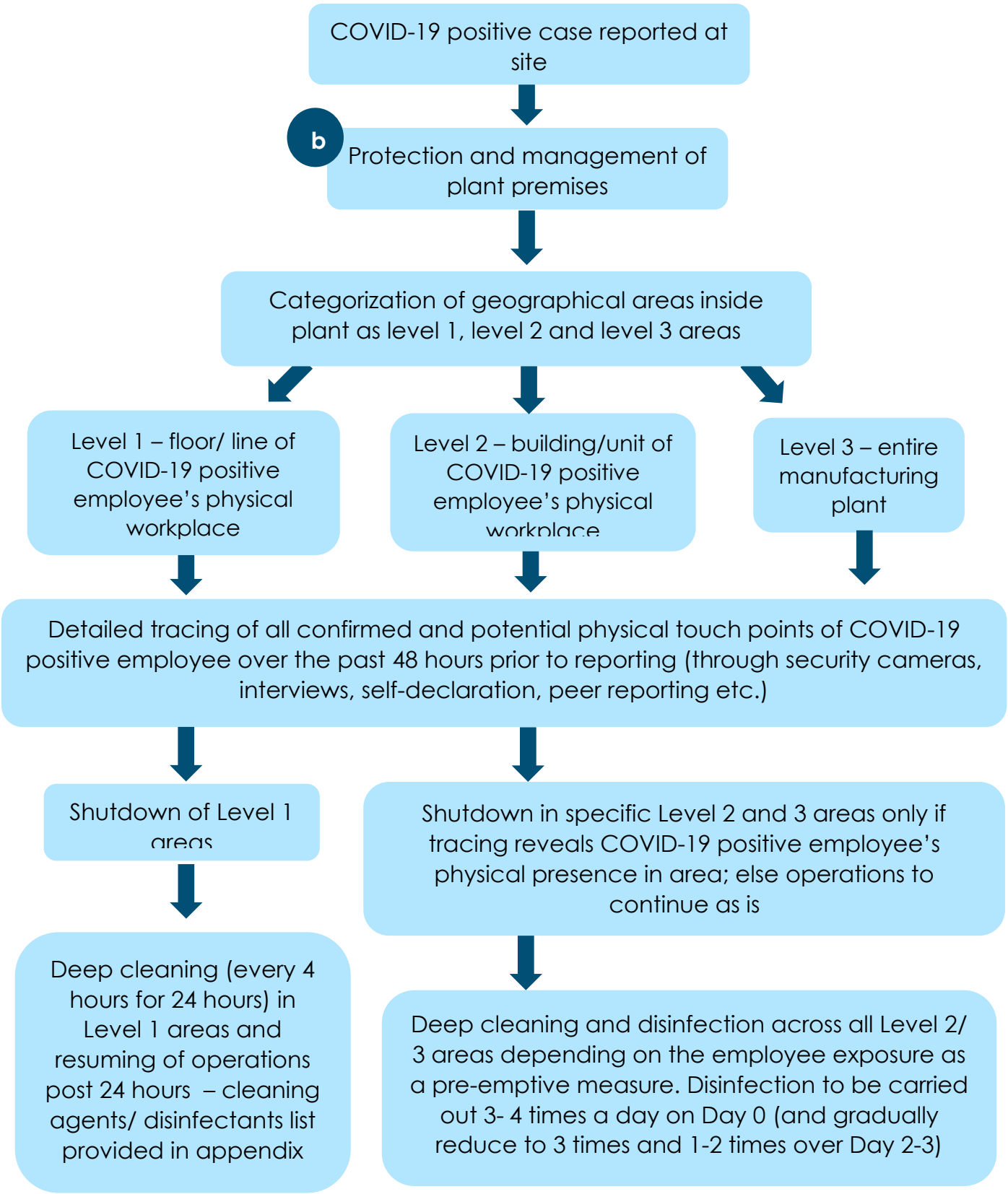
The overall protocol is divided in to 3 parts as below –
a) Protection and management of plant personnel
b) Protection and management of plant premises
c) Interfacing with regulatory and local authorities

a) Protection and management of plant personnel

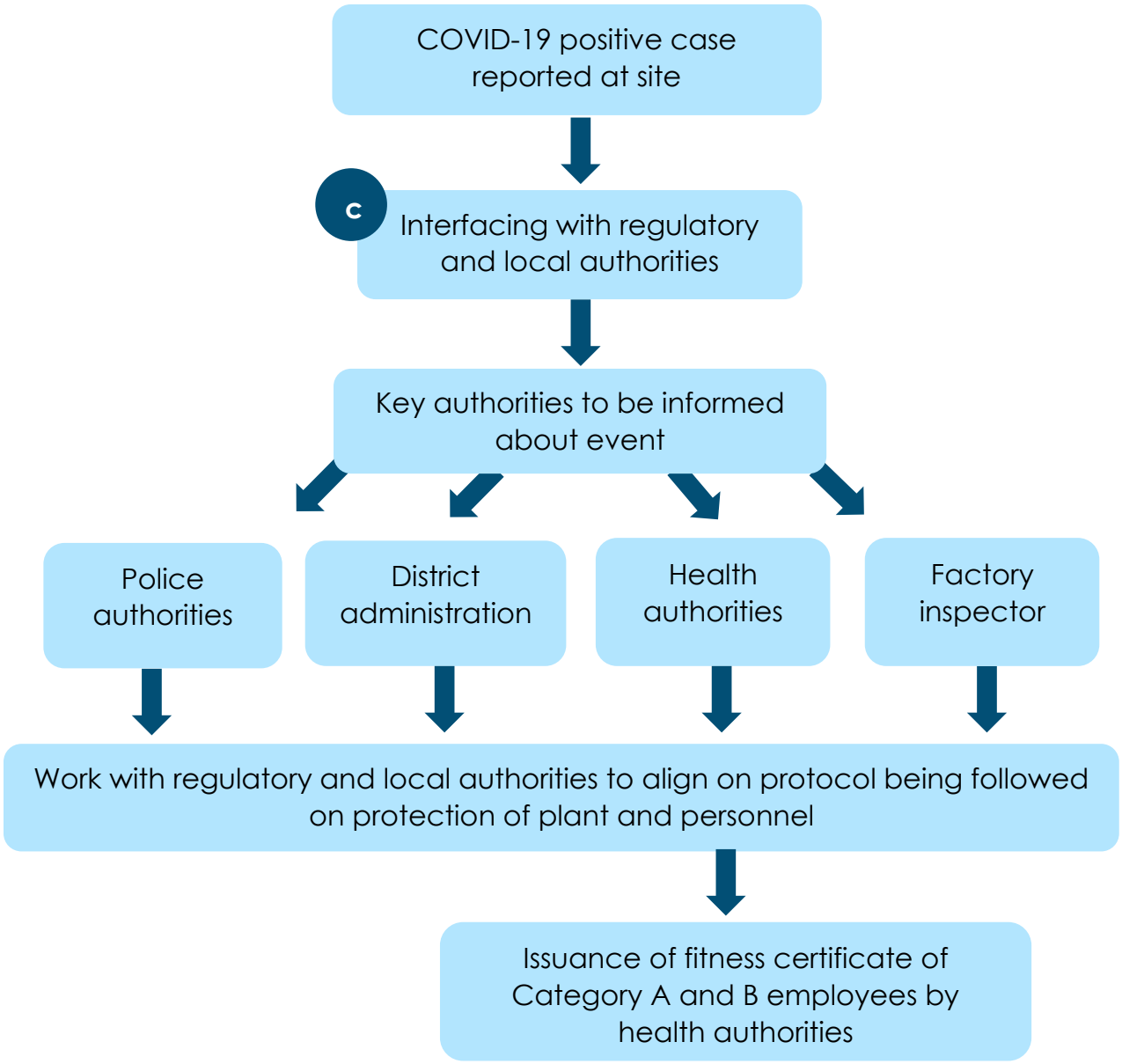


**Refer appendix for detailed definition of close contact*

b) Protection and management of plant premises



c) Interfacing with regulatory and local authorities



Above procedure is to be followed for consecutive cases beyond the first case as well.

- *For instance, if on 15th of the month the first case (Case 1) is identified, it would be considered as Day 0 and 16th would be considered as Day 1.*
- *If a new case is identified from Category C (Case 2c) on 16th, then 16th would be considered as Day 0 for Case 2c and entire procedure would be repeated.*
- *If a new case is identified from Category B (Case 2b) on 16th, then 16th would be Day 1 as Category B employee is already in quarantine.*

Appendix – List of recommended cleaning agents/ disinfectants

Following common disinfectants/ sanitizing solutions have been found effective against COVID-19 at manufacturing units

Cleaning agent	Type of surface	Concentration	Cleaning Frequency
Sodium Hypochlorite	Hard surfaces like staircases, floors, security booths etc.	Recommended 1% freshly prepared	At least once per shift
Phenolic compounds	Floor cleaning	Manufacturer Recommendation	At least once per shift
Quaternary ammonium compounds	Surface disinfection like equipment surfaces	Manufacturer Recommendation	After cleaning
70% alcohol	Surface sanitizer	70%	Hand sanitization, general sanitization where Sodium hypochlorite cannot be used
Hydrogen Peroxide	Surface sanitization	Manufacturer Recommendation	Area sanitization using fogging

**Footnote – reference page 4 – Definition of close contact*
"Factors to consider when defining close contact include proximity, the duration of exposure (e.g., longer exposure time likely increases exposure risk), whether the individual has symptoms (e.g., coughing likely increases exposure risk) and whether the individual was wearing a facemask (which can efficiently block respiratory secretions from contaminating others and the environment. A potential exposure means being a household contact or having close contact within 6 feet of an individual with confirmed or suspected COVID-19 for a prolonged period (>15 minutes without a face mask). The timeframe for having contact with an individual includes the period of 48 hours before the individual became symptomatic."