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Factory

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Arima, Trinidad

November 4, 2020

Honourable Minister Mr. Danguillaume Oduber
Minister of Tourism, Public Health and Sports
L. G. Smith Boulevard 76
Oranjestad
Aruba

Dear Sir,

Re: Ultra Low Temperature Storage of Potential Covid-19 Vaccine and Related Cold Chain

Mecalfab Limited is the regions' leading refrigeration engineering and design-build contractor with over 6,000 installations over the last fifty (50) years. Our customer base spans from food distribution, through retail, hospitality and health care. Over the years we have built all of the medical chillers for NIPDEC in Chaguaramas (C40 warehouse).

Design Brief

- Safe, reliable and efficient storage of 5.1.1c of emerging mRNA, viral vector, non-replicating viral vector Covid-19 vaccines requiring -60C to -80C storage.
- Provision of fail-safe operating conditions (multiple units, each with dual refrigeration systems, back-up generator, liquid nitrogen, Solar PV)
- Commission, testing and monitoring of performance 24/7/365

Assumptions

-80C storage temperature. Packaged in boxes measuring 3" x 2" x 6" containing 10 doses.

Commentary

-80C is equivalent to -112F and requires very specialised 2 stage "cascade" type refrigeration equipment. There are numerous manufacturers in North America and the Far East that make these ultra low temperature (ULT) medical freezers as a simple Google search would reveal.

According to the World Health Organization, nearly 20 percent of temperature-sensitive health care products are damaged during transport, and 25 percent of vaccines reach their destination in a degraded state due to breaks in the cold chain.

There are specific operating conditions for these freezers and the elimination of humidity (moisture) in the room is of primary concern to reduce the impact of frost build-up inside the freezer.

This can be achieved by locating the freezers in sealed air-conditioned rooms with smaller vestibule rooms protecting entrance/exit doorways. The doors would be operated by motion sensors so that they are non-touch removing the need for the operator to manually open the door.

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A review of online electronic media articles suggests that the projected cost of the Covid-19 vaccine is in the range ^{5.1.2b} per dose plus transportation. ^{5.1.1c} could therefore cost between ^{5.1.2b}. This makes it imperative that the ULT freezer chosen offers the very best in reliability, independent stand-by refrigeration and emergency back-up systems.

Emergency back-up in the case of refrigeration failure is achieved by having two (2) independent refrigeration systems within the freezer cabinet. A liquid nitrogen back-up system is also used by this adds another level of cost and complication. A CO2 back up system cannot maintain the required -80C storage temperature so is not an option.

In the case of electrical supply failure, a suitable sized central diesel stand-by generator with automatic transfer switch would be an option. Due to the very high value of the freezer contents two (2) independent stand-by generator systems could be deployed. A Solar photovoltaic system with battery storage could also be deployed to supply the kilowatt (kW) capacity required to power these freezers.

Equipment Commissioning and Validation

These critical ULT freezers must be installed and commissioned according to strict manufacturers recommendations. Prior to use all ULT freezers must be validated via IQ/OQ and PQ protocols. Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) or instrument performance verification (IPV) services verify and document your unit's ability to meet manufacturer design specifications for performance.

IQ—provides documented evidence and verification that the instrument has been delivered and installed according to manufacturer's specifications

OQ—provides documented verification that the instrument subsystems are operating as designed. Verifies that the functionality of an instrument meets the manufacturer's operational specifications.

PQ or IPV—provides documented verification that the instrument system can perform effectively and reproducibly within performance specifications. Helps ensure confidence in results by verifying that the accuracy and precision of an instrument is maintained.

Our Recommendations

- Ultra low temperature upright freezer/s in the capacity range 700-800 litres (24 Cubic Feet - 28 Cubic Feet) with storage capacity for 120,000 doses at any one time.
- Twin independent refrigeration systems per unit to provide back-up in the event of refrigeration failure.
- Conditioned room to house ULT freezer/s with motion sensor doors and vestibule
- One (1) or two (2) diesel stand-by generators with automatic transfer switch
- Solar photovoltaic system with fail-safe battery storage
- Comprehensive IQ/OQ/PQ protocol
- Spare parts and consumables

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Proposed dual refrigeration ULT vaccine freezer

We represent the PHCBI range of ultra low temperature freezers.

Budget Costing - Dual Refrigeration Unit

One (1) ULT freezer with **dual refrigeration** systems, CIF

Liquid nitrogen back-up system

Note above costs include 20% import duty.

Provision of liquid nitrogen central storage tank and associated plumbing

IQ/OQ/PQ protocol, installation and commissioning

12kW solar photovoltaic system with fail-safe battery back-up

TOTAL

5.1.2b

Please note that time is of the essence with this project as all the ULT freezer manufacturers are experiencing very high demand for obvious reasons and the closer we get to an actual vaccine the worse this situation will become.

I trust the above is of interest and look forward to any further information we can provide.

Yours faithfully,
MECALFAB LTD.

5.1.2c