Management of a disaster management : particular issue of the BioArchive® cryogenic tank

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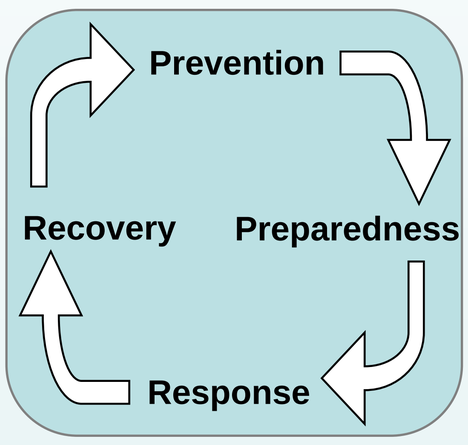
1 : Disaster management

No country, association, activity…is immunized from any kind of disasters such as **natural disasters** (floods, hurricanes, earthquakes, volcanic eruption…), **environmental urgent situations** (industrial or hazardous accidents…), **complex crisis** (power failure, attack of strategic installation...) and **pandemic emergencies**.

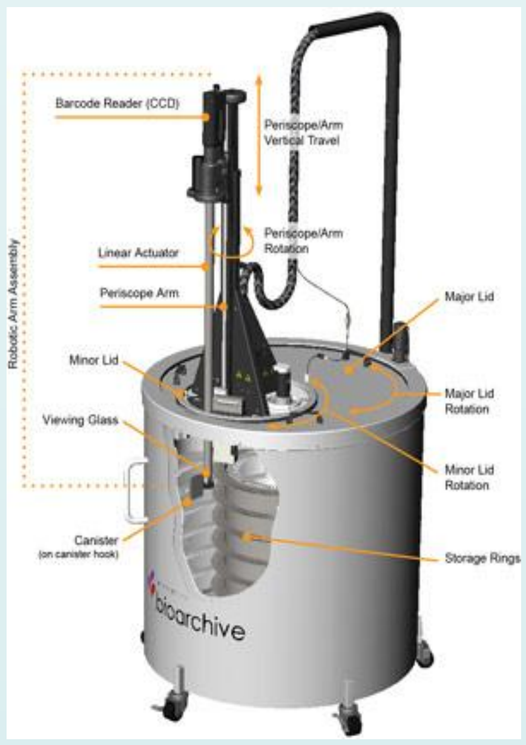
Impacts of these situations have be evaluated in large geographic areas as well as at a limited/local level when **disaster management (DM) plans** have to be put in place. DM is defined as the organization of resources and responsibilities for dealing with all aspects of emergencies. DM is stepped in a 4-phases cycle :



- Risk management & prevention to identify credible threats and implement preventive actions to limit and/or reduce effects of disasters.
- Preparedness to test DM plan, including personnel training, in order to determine feasibility and adequacy with emergency situation.
- Response to emergency with mobilisation of necessary resources.
- Recovery to restore and make the process available again.

2 : Cryogenic tanks and DM plan

Since 2000, Liege cord blood bank (CBB) has been using the BioArchive® (BA) system to cryopreserve and store cord blood (CB) units. This system, developed by the US Company ThermoGenesis (TG), is an automated & controlled rate freezer indented for cryopreservation and storage of volume reduced CB units conditioned in metal canisters. The BA tank is managed by a computer that pilots a robotic arm consisting of 3-dimensions moving periscope and canister hook for storage and retrieval. Cryopreserving, sample management and daily maintenance are fully automated. Volume of LN2 in BA provides over 2-weeks of safety for CB units (burn-off rate is slow due a closed system & BA is able to remain temperature < -150°C). However, access to cryopreserved products is limited without a fully operating system.



In cellular therapy field, DM plan on cryogenic tanks (especially with full automated ones) has to be considered closely in order to ensure integrity and easy access to cellular products.

FACT & JACIE standards as well as national regulations require to setup DM plans

3 : Risk management & prevention

- Depending on local situation, risk assessment must prioritize threats then minimize, monitor, and control the probability and/or impact of unfortunate event. Amongst those, 5 highly plausible causes have been highlighted to Liege CBB specific case :
  1. Temporary loss of environmental resources such as liquid nitrogen (LN2) or electrical power
  2. Crack in the Dewar with consequent loss of vacuum with high LN2 consumption and nitrogen evaporation in the atmosphere
  3. Fire and flooding inside the cryogenic room
  4. IT breakdown with loss of databases and/or no access to automated functionality of the BA system
  5. CBB personnel being understaffed due to epidemic situations
     (Other natural or climatic risks such as earthquake or bioterrorism have been as well established but not considered at high ricks.)
- Then, a DM binder (consisting of several completed checklists & annexed documentation) should be established to check that all preventive actions were put in place & all necessary resources would be available in a timely manner. This binder includes :
  - Description of internal & external chain of coordination, including list of contacts to empower an emergency plan, fire brigade, medical emergency, electricity company & liquid nitrogen supplier… (and back-up alternatives)
  - Completed checklists such as :

BA checklist : to verify whether the system operates in accordance with manufacturers' specifications	☑ Checking of BA operating parameters ☑ Execution of daily, weekly, monthly & annual maintenance ☑ Checking of BA alarm system (low & high LN2 level…) ☑ Easy access to the cryogenic room ☑ Absence of cracks in Dewar ☑ Daily data base backup - software upgrading
LN2 checklist : to verify functionality of LN2 delivery as well as detection and solution for high LN2 consumption	☑ Check LN2 delivery system ☑ Check LN2 supply tanks and capacity - solution for back-up ☑ Existence of functional oxygen detector ☑ Presence of protective equipments against cryogenic burns and asphyxia
Fire detection checklist : to verify presence and functionality of fire safety system	☑ Automated fire detection on duty & alarm activation periodically checked ☑ Automatic/manual fire extinguishing system, or hydrants operational ☑ “Emergency exit” and “Non smoking” sign postings ☑ Absence of combustible/inflammable material in the room ☑ Secure firebreak doors
Electrical installation checklist : to verify functionality of electric power system	☑ Electrical board periodically checked ☑ No-break electrical system in use ☑ Temporary electrical installation as backup solution ☑ Detection of electrical potential variance / electromagnetic risks that may causes damages to electrical & computing equipments
Flooding detection checklist : to verify safety conditions against flood risk in cryogenic room	☑ Sewer point in the ground / water drainage hoses ☑ Automated flood detection system
Key personnel checklist	☑ List of CBB personnel as well as Thermogenesis / Concessus 24/24 ☑ SOP to manage understaffed CBB personnel

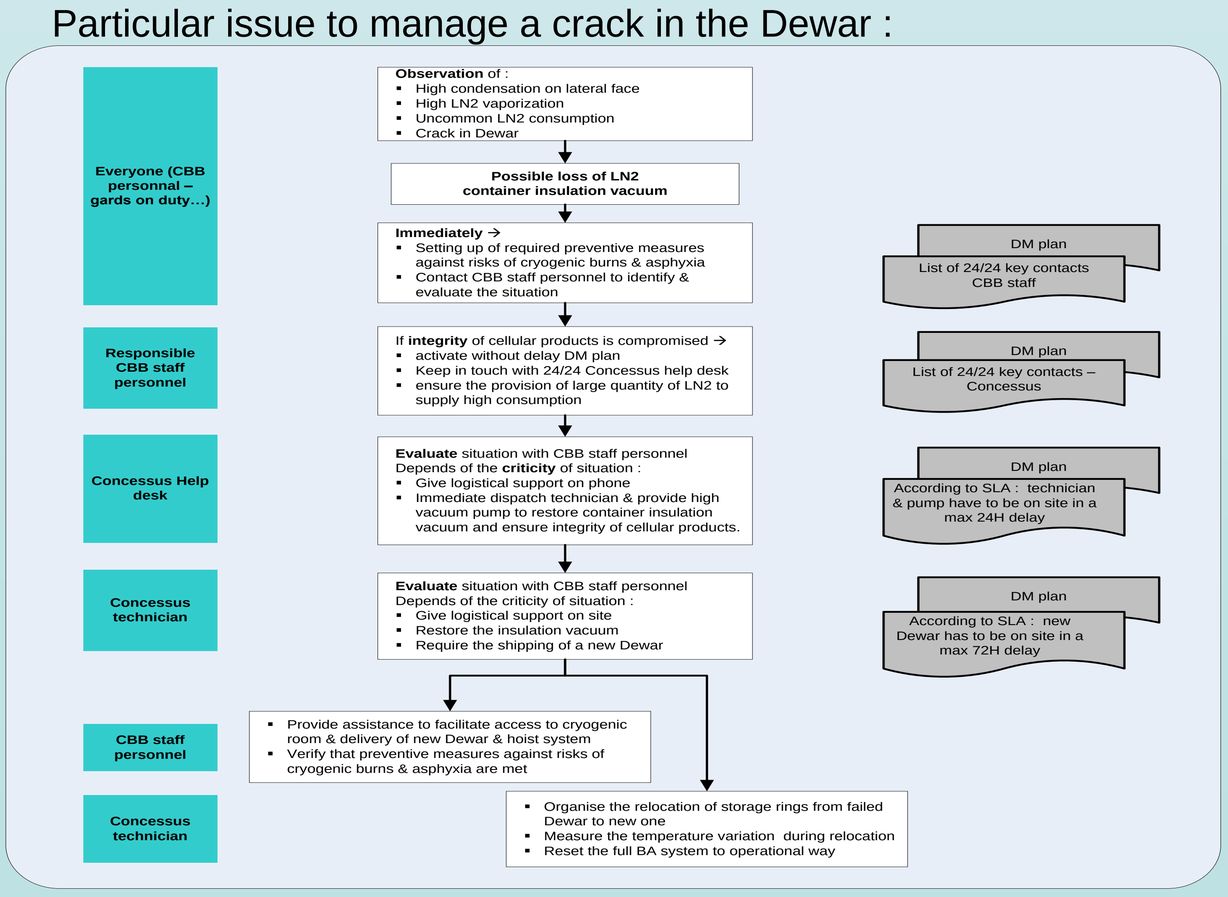
4 : Preparedness

Common preparedness measures include :

- DM plan communication to key persons (internal/external)
- If the DM plan can not be managed internally, adoption of a service level agreement (SLA) with external resources : Liege CBB, TG and Concessus (in charge with BA maintenance) have written & implemented a SLA to manage DM plan dedicated to BA. This written SLA includes :
  1. Establishment of chain of command, coordination & responsibilities
  2. Description of required resources to protect people & material goods
  3. Identification of required staff, equipments, premises, supplies…for use in response to or recovery from emergency (see§5)
  4. Identification of situations and stepwise scenarios including ways of mitigating each of them (see §5)
  5. Completed checklists & annexed documentation (see §3) .
- Training of staff members to set up and manage DM plans, including use of dedicated tools to retrieve a cryogenic bag manually (CBB staff) / Dewar replacement with manipulation of special hoist system to relocate storage rings from broken Dewar to new one (Concessus staff).
- Regularly testing of all preventive actions (see checklists on §3)

5 : Response

Particular issue to manage a crack in the Dewar :



6 : Recovery… & prevention again !

Recovery phase starts after immediate response to disaster in order to restore current operational processes as well as to implement more focused preventive measures to avoid another disaster occurrence…