



Controlled Environments Discussion Group

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Controlled Environments Discussion Group

The Long Road to Mitigation



01



- Research protection – a risk management process first, insurance as the backstop
- Biobanks – the gold standard for contents protection
- Alarms and how to ensure that they meet the “mitigation standard”
- Can I use a UPS or a portable generator instead of an automatic generator?
- What strategies can I use to justify the capital cost of a generator?
- What maintenance needs to be done to become mitigated and how do I document that?
- What should I do if I haven’t valued my CE contents?



Several very bad years of TCE/CE losses

- 17/18 - \$9m
- 19/20 - \$7m

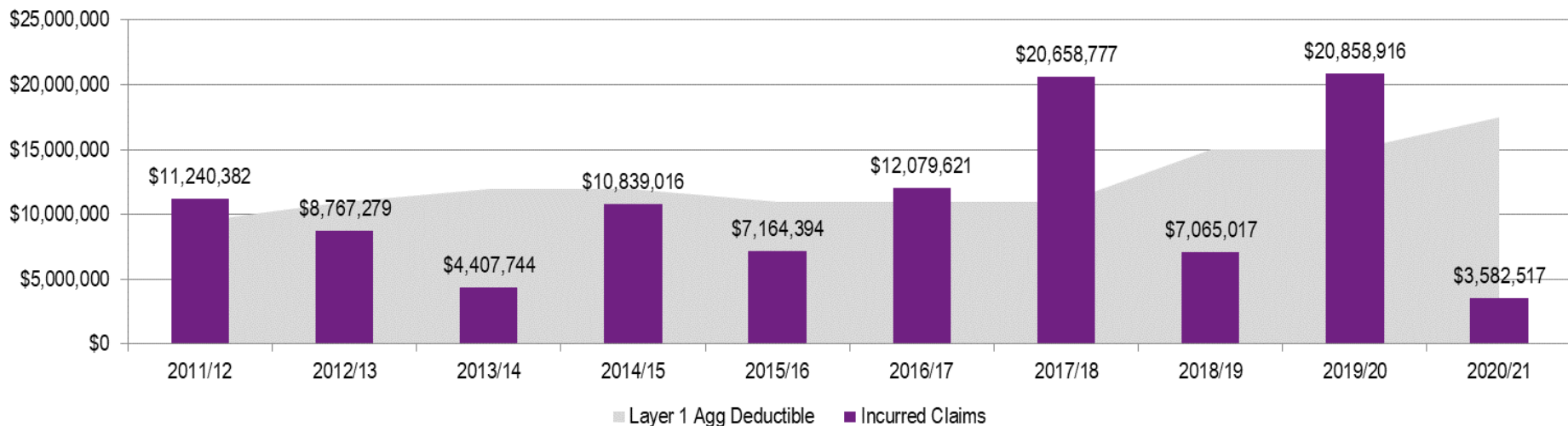
Cross class aggregate reinsurers went for a bath in both years with research losses well above normal.

Needed assurance that the Mutual was taking steps to the address a deteriorating trend

The change from TCE to CE and the introduction of mitigated and non-mitigated is designed to drive a risk management approach to research protection



Unimutual XCA, Incurred Claims v Agg Deductible (@ June 30 2021 Claims update)





Front and Back End

At the front end

We work with Members to:

- develop inventories and value contents,
- improve research protection,
- perform CE mitigation gap analysis.

At the back end

We work with reinsurers to:

- understand the risks they are underwriting
- the steps Members and the Mutual are taking to mitigate them.

Biobanks – The Gold Standard



02

The Gold Standard Guidance

US National Cancer Institute Best Practices for Biospecimen Resources 2016

B.2.6.5.

Automated security alarm systems should be in place to continuously monitor the function of storage equipment and should have the capability to warn when equipment failure has occurred.

Backup equipment, such as an alternative power source, should be set to activate automatically when necessary and should be tested regularly.

Written SOPs that are tested on a routine basis should be in place to respond to freezer failures, weather emergencies, and other disaster recovery/emergency situations

Covers inventory and sample tracking plus many other risk related matters

<https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf>



Alarms



03



Mitigation - Alarms

Must be:

- capable of detecting the change in environment
- capable of notifying the change
- monitored by a back to base location 24 hours – 7 days per week
- serviced in accordance with manufacturers specifications

A battery back up is advisable in the event of a circuit failure.

Automatic Emergency Power



04



Mitigation – Emergency Power

Must be:

- capable of automatically supplying emergency power in the event of a mains outage
- serviced in accordance with manufacturers specifications

Generators will not start up as a result of loss of power to an individual circuit.

Trailer mounted units require human intervention

A UPS will only provide power for a limited time.

Cost Justification



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Cost benefit analysis

You have a 20 Controlled Environments containing \$20m of research without back up power

The risk is valued as $\$20,000,000 \times 0.03 = \$600,000$

The treatment is to install an back up generator

Treatment cost = \$1,250,000

Treatment life = 20 years

Annualised treatment cost = \$62,500 including \$3000 a year for monitoring and maintenance

Reduced risk = $\$20,000,000 \times 0.01 = \$200,000$

Risk Reduction = \$400,000

Cost : Benefit ratio = 1:6.4



Maintenance



06



Maintenance

The controlling mechanism, for example a minus 80-degree freezer, must be serviced to manufacturer specifications.

For research grade freezers and walk-ins and other specialised equipment – use a service provider where possible.

Ideally maintain all equipment but especially that you want deemed as mitigated

A maintenance matrix has been drafted – it is guidance rather than prescriptive

Documentation needs to be kept as evidence

Which device, what was done, by whom and when.

Class of CE	Type of CE	Component	Task	Authorised Person	Frequency	Failure Mode	Notes
Ultra-low Temperature Freezers	Minus 80 ULT Freezer	Door gasket	Remove ice from door gasket and check for splits or perishing	staff	fortnightly	Perishing and splitting due to excessive ice build up	Use a cloth and gently remove ice
		Internal doors	Remove ice build up	staff	fortnightly	Damage to hinges and latches	Use an ice scraper to remove excess ice
		Vacuum relief port	Remove ice build up	staff	fortnightly	Damage to door gasket	Use a cloth and gently remove ice
		Air Filters	Clean air filters of dust and built-up grit	staff	Every 1 or 2 months	Overheating and additional pressure on compressors	Gentle use of a vacuum cleaner
		Condensers	Clean condensers	contractor/staff	Every 6 months	Overheating and additional pressure on compressors	Vacuum the condenser
			Clean condenser filters	contractor/staff	Every 3 months	Overheating and additional pressure on compressors	Shake off dust and wash
			Check condenser fan operation	contractor/staff	Every 6 months	Overheating and additional pressure on compressors	If not working replace immediately
		Compressor	Clean and check compressors	contractor	6 -12 months	Secondary compressors tend to fail more often	Compressors can be replaced
		Batteries	Check battey charge and life	contractor	6 -12 months	Flat battery	Test with a voltmeter - if less than 10 amps- replace

Inventories and Valuation



07



CE Data Base

Know what you have, where it is, what is in it and what the contents are worth

ReSure compatible template is available to download from the Unimutual website (see resources on next page)

Records details on alarms, back-up power maintenance and content values

Will help you understand what is mitigated and what is not

If you can't measure something – how can you manage it?

- <https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf>

The following resources can be found at the Unimutual website here: [Protecting your research in Controlled Environments \(CEs\) - Unimutual](#)

- Valuation guidelines
- Resure CE database template
- CE Research Projects Costs calculator

Please email service@unimutual.com.au for details of your login access to the “Member Only” content of the website.