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# RE: Call for submissions Inquiry into Occupational Respirable Dust Issues

## Reference of submission

This submission relates to part "d", with reference to, part "b" of the extended terms of reference. Namely;

(d) *the roles of government departments and agencies, industry, health professionals and unions in these arrangements*

Where arrangements refers to those in;

*(b) the legislative and other regulatory arrangements of government and industry which have existed in Queensland to prevent or reduce the harm caused by occupational respirable dust exposure to port, rail, power station, and other workers*

## Submission on behalf of:

This Submission is on behalf of **Cyclopharm Ltd** and is approved at the level of company Chief Executive Officer and Managing Director.

**Cyclopharm Ltd** is an Australian Limited company servicing the global medical community since 1986. **Cyclopharm Ltd** manufactures and assembles Technegas in Australia in a ISO13485 and cGMP facility.

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## Technegas

With specific reference to this submission Cyclopharm Ltd owns, manufactures and markets **TECHNEGAS;** a patented lung ventilation technology for the assessment and quantification of pulmonary disorders[1-3]. Technegas utilises a functional imaging modality known as **SPECT CT** (Single Photon Emission Computed Tomograpy *fused with* x-ray Computed Tomography) in a study know as a **V/Q** (Ventilation / Perfusion) **SPECT CT.**

Recent technological developments have allowed these **VQ SPECT CT** studies to produce a more "objective" conclusion[4-5] by providing both anatomical and functional information of the lungs[6]. **Quantification** of the V/Q SPECT CT provides the physician with quantitative functional lobular level data that when used in a baseline and follow-up regime can allow for objective assessment of changes in an individual's lungs[7-8-9].

## Cyclopharm's Submission

Cyclopharm respectfully submits that the current and recommended "Coal Workers Health Scheme" as detailed in the "Inquiry into the re-identification of Coal Workers' Pneumoconiosis in Queensland" should consider V/Q SPECT CT with Technegas as a diagnostic study to be included in the health assessment of coal workers. This is in specific reference to, the baseline and scheduled ongoing "health assessments" of coal workers.

This submission is in reference to Section 5 "Health arrangements for coal workers", Figure 7 "Flowchart of the process of the current Coal Mine Workers' Health Scheme" and Recommendations 43, 44, 45 and 46

Cyclopharm submits that this addition would provide the following benefits

1. More detailed analysis and understanding of a coal workers' baseline and ongoing lung assessment to assist in effectively monitoring the lung condition of these workers
2. A more objective study due to the ability to quantify results
3. Provide structural and functional information of the lung in this population
4. Higher sensitivity and specificity than Spirometry and Chest X-ray alone
5. Early detection of disease therefore assisting early intervention
6. Trending, leading to early detection of changes to an individual coal worker's lung ventilation
7. Detection of co-morbidities

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**Literature in support of opinion/submission**

- ***V/Q SPECT CT imaging in Lung Diseases***

Combining V/Q SPECT with low-dose CT would further enhance pulmonary embolism diagnostic accuracy and has application in various other pulmonary conditions. Indeed V/Q SPECT has been shown to have use as predicting postoperative lung function after lung volume resection, demonstrating regional changes of ventilation/perfusion in asthma, and estimating regional lung function in patients with interstitial pulmonary diseases.[10]

V/Q SPECT CT has further potential in COPD patients by enabling the evaluation of total lung function and the quantification of pathological extensions. It could also help categorizing the severity of functional changes and obstruction and identifying comorbidities[11].

- ***V/Q SPECT CT Early detection of lung disease***

Ventilation SPECT can generate quantitative data to measure lung function heterogeneity and detect mild ventilation heterogeneities even in lung-healthy subjects having normal lung function tests, which implies that it might be possible to differentiate ventilation heterogeneities earlier in a disease process than by lung function tests[4].

- ***V/Q SPECT CT quantification***

V/Q SPECT-CT images using both functional and anatomical images to define lobes (by Lung Quantification® from Hermes Medical Solutions) can improve lobar quantification and replace the segment counting method (ERS/ESTS guidelines) in the pre-operative assessment of patients undergoing partial lung resection. SPECT-CT may become the method of choice for assessing differential and lobar lung function in the pre-operative assessment for lung resection surgery[12].

- ***V/Q SPECT In globai coal mlning and poilution studies***

As assessed by quantitative Technegas ventilation SPECT, patients with silicosis reveal impaired ventilation that correlates well with the functional state of the silicotic lung, the severity of the disease and the extend of the parenchymal morphologic changes observed by HRCT (such as nodules, septal thickening and bulla)[13].

More than one in four of these miners had evidence of CWP, abnormal lung function or both. The current approach to dust control and provision of safe work conditions for central Appalachian underground coal miners is not adequate to protect them from adverse respiratory health effects.[14]

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We found that patients with coal worker's pneumoconiosis exhibited significantly impaired pulmonary functions vs. controls. Some of these functions include poor ventilation and diffusion function as well as high airway resistance. These results also sug-gested that imbalanced ventilation/perfusion ratio and re-duced ventilation capacity and pulmonary ventilation area caused alveolar hypoxia. Increased pulmonary vasodi-lation, high vascular smooth muscle tension, and small airway obstruction were observed simultaneously when pulmonary hypertension occurred. Diffusion dysfunction is also observed, as small pulmonary vascular occlusion causes poor alveolar perfusion.[15-17]

- ***V/Q SPECT CT – treatable traits***

Treatable traits is a new and emerging approach to lung disease conditions which is to focus on the identification and treatment of disease components for chronic obstructive airway diseases such as asthma and COPD.[18]

- ***Technegas in ILD***

Quantitative V/Q SPECT CT using Technegas is considering to be an effective means to evaluate the status, the progression and pathology of interstitial pulmonary disease (ILD) and to detect early impairment of lung function[19].

- ***Why Spirometry is not sufficient***

In some patients with coexisting emphysema and interstitial fibrosis, normal spirometry and lung volumes with severe compromise of gas exchange happens. The relatively preserved lung volumes may underestimate the severity of idiopathic pulmonary fibrosis and attenuate its effects on lung function parameters[20].

Therefore, spirometry is not sufficient to diagnose lung disease and monitore its progression. As Technegas penetration depends on the small airway func-tion, and bronchial deposition increases in small airway disease allowing detection of airway obstruction earlier by Technegas ventilation image than by spirometry.[3]

- ***Why plain film Chest X-ray is not sufficient***

chest X-rays can entail diagnostic uncertainties. the Low dose CT (LD CT) carried out pursuant to this examination protocol is far superior to the chest X-ray and should be used as a diagnostic tool.[21]

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## Other Benefits

It is noted (Monash Recommendation 13) that the Coal Workers Health Scheme should transition to an electronic system. Further, within the report, there appears to be a lack of ability to electronically trend an individual coal worker's health assessments that would allow for early detection and follow-up. It is Cyclopharm's opinion that V/Q SPECT CT could assist in achieving an outcome of electronic follow-up and trend analysis. V/Q SPECT CT provides a digital result as opposed to the analog results obtained through Spirometry Chest X-ray.

The images obtained from V/Q SPECT CT can subsequently be subtracted from follow studies in order to provide images which allow a physician to assess changes only from study to study.

## Conclusion

Quoting Dr Cohen as referenced in "Black Lung White Lies, May 2017"

*Dr Cohen stressed the importance of spirometry and lung function testing:*

*"I think that spirometry and lung function testing is, if not the same, maybe even more important than chest imaging because spirometry and lung function is really what correlates with someone's impairment, whether or not they are short of breath."* (pg 172 Inquiry into the re-identiiaction of Coal Workers' Pneumoconiosis in Queensland")

V/Q SPECT CT with Technegas is an advanced form of lung function testing. It is a combination of functional and structural assessment and imaging at the alveolar level providing both visual and quantifiable data for assessment and monitoring by physicians. While spirometry gives a macro result of how well a person inhales and exhales air, VQ SPECT CT with Technegas provides the micro detail of how the lung is functioning. Spirometry is highly dependent on the administrator of the test for its accuracy while V/Q SPECT CT does not present the same limitations.

It is Cyclopharm's opinion that V/Q SPET CT with Technegas could provide early detection of changes in the lung and has a higher sensitivity and specificity than spirometry and chest x-ray. Cyclopharm believes that including V/Q SPECT CT with Technegas in the Coal Workers' Assessment adds essential and critical data to the assessment, monitoring and management of coal workers.

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