Health surveillance in silica exposed workers

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Many of the industries in GB in which exposure to Respirable Crystalline Silica (RCS) may arise have signed up to a Social Dialogue Agreement (SDA), a pan-European initiative to improve the control of silica dust exposure. In part, this agreement is a commitment to undertake health surveillance where this is necessary because of a potential continuing risk of silicosis, even when recommended engineering and other controls are in place. The appropriate target population for this surveillance would likely include all workers who are exposed to levels of crystalline silica that place them at risk of developing silicosis or other silica-related lung diseases.

Consequently, the GB regulator wishes to establish a standard for the health surveillance of silica-exposed workers, in order to assess whether dutyholders are complying with their duties under appropriate legislation.

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1 EXECUTIVE SUMMARY

There is uncertainty in Great Britain (GB) about what constitutes appropriate health surveillance for silica-exposed workers, despite evidence that new cases of silicosis are occurring. The latter is supported by data from UK-based, HSE funded, national surveillance systems for work-related illness. There is also evidence to suggest that the risk of silicosis is finite at current permissible exposure levels.

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Consequently, the GB regulator wishes to establish a standard for the health surveillance of silica-exposed workers, in order to assess whether dutyholders are complying with their duties under appropriate legislation.

1.1 OBJECTIVES

1) To identify existing recommendations for health surveillance for silica-exposed workers.

2) To assess the evidence base for these recommendations and other relevant evidence in the scientific literature.

3) To make recommendations for a standard approach to health surveillance for silica-exposed workers in the UK.

It is specifically not the aim of this report to review all the available wider evidence base related to silica-exposed workers, including annual estimates of decline in lung function, although mention of these issues will be made when they pertain to health surveillance for exposed workers.
1.2 MAIN FINDINGS

Whilst much data and research relating to the general adverse respiratory (and other) health effects of exposure to RCS exist, there are relatively few sources of evidence relating specifically to health surveillance for RCS-exposed workers.

General consensus exists, within the nine identified documents specifically dealing with health surveillance for RCS-exposed workers, that this process is important for identifying early adverse respiratory effects.

Health surveillance programmes should take into account regular and up-to-date measures or estimates of individual worker exposure to RCS.

General consensus also exists to support a baseline assessment of respiratory health for potentially RCS-exposed workers, with a subsequent annual assessment. Both of these should include use of a 'standardised' questionnaire and lung function measures, although an agreed standard questionnaire or data recording proforma is currently not available.

Whilst existing recommendations include regular (annual) lung function testing for potentially exposed workers, no agreed consensus exists to guide how best to interpret lung function changes over time, specifically in the context of identifying early silicosis, accelerated FEV₁ (Forced Expiratory Volume in one second) decline or COPD. Generic software supplied by NIOSH (Spirola) can assist with this requirement, but is not specific to harm caused by RCS.

No agreed consensus exists relating to the periodicity of chest radiographs required to identify changes of silicosis, although various approaches are suggested.

1.3 RECOMMENDATIONS

The development of health surveillance for RCS-exposed workers should be based upon the findings of appropriate workplace risk assessments.

Overall acceptance of RCS-based health surveillance programmes by workers is key to their success and, consequently, programmes should be developed in close consultation with workers, the latter potentially identifying a training need.

Health surveillance programmes for RCS exposure should make it explicitly clear to workers how they will be individually handled should they be noted to have at baseline, or develop, abnormal results during testing.

Records of information recorded by such programmes should be shared with the individual worker, and with consent passed on also to their primary care provider. This information should be kept separate from human resources within an organisation.
A standardised approach should be developed for health surveillance of GB RCS-exposed workers and should include a number of key elements, listed in section 8.2.1. Consideration should be given to developing a standardised questionnaire and a health surveillance data recording proforma.

Those responsible for developing and delivering such programmes require knowledge of the adverse health effects of RCS exposure, and of lung function and radiological abnormalities. This potentially identifies a training need.

In parallel to the development of a standardised approach, further GB-based work with workers and employers should be carried out to gain, from a retrospective assessment of health surveillance data, a better understanding of the local context. Specifically, a better understanding could be developed of the ideal periodicity of the various components of health surveillance and of predictive factors that are associated with the development of silicosis, accelerated lung function decline and COPD.
2 INTRODUCTION

2.1 Health Surveillance for Silica-Exposed Workers

The purpose of medical surveillance is to detect early any potential adverse health effects from workplace exposures. If adverse health effects are detected early enough, then interventions can be introduced to potentially lead to disease prevention, or to slow the progression of an established disease process.

There is uncertainty in Great Britain about what constitutes appropriate health surveillance for silica-exposed workers, whilst there is some evidence\(^1\) that many more cases of silicosis will occur than are currently identified by HSE supported national surveillance systems for work-related illness.

Many of the industries in GB in which exposure to RCS may arise\(^{ii}\) have signed up to a Social Dialogue Agreement (SDA), a pan-European initiative to improve the control of exposure. Part of the agreement is a commitment to undertake health surveillance where this is necessary because of a potential continuing risk of silicosis, even when recommended engineering and other controls are in place. The appropriate target population for this surveillance would likely include all workers who are exposed to levels of RCS that place them at risk of developing silicosis or other silica-related lung diseases.

Consequently, there is a need for the GB regulator to establish a standard for the health surveillance of silica-exposed workers, in order to assess whether dutyholders are complying with their duties under appropriate legislation. This requirement must also be seen in current context, as historic models of health surveillance are changing to more active approaches, dealing not only with a more passive process, but also acting on prospectively recorded data in an attempt to impact on disease progression.\(^1\)

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\(^{i}\) The Regulatory Impact Assessment for the current WEL for silica, and the first report of the cancer burdens project

\(^{ii}\) All bar construction and stone-masonry
3 BACKGROUND

3.1 Respirable Crystalline Silica

Crystalline silica is one of the major components of soil, rock, sand, granite and many other minerals found in the earth’s crust. It consists of silicon and oxygen atoms (silicon dioxide [SiO₂]) arranged in a regular crystalline structure. Silica may be free, that is not combined with any other elements, or combined with other cations to form silicates.

There are three major types of free crystalline silica used in industry: (i) quartz (the most common), (ii) cristobalite and (iii) tridymite, although other less common types also occur. Quartz, cristobalite and tridymite when cut, drilled or ground all produce a respirable particle size, and exposure to these particles can occur during many work tasks including sandblasting, mining, rock drilling, quarrying, brick cutting, glass manufacturing, tunnelling, foundry work, stone working, ceramic manufacturing and construction activities. Although the majority of these tasks and occupations will be associated with mixed dust exposures, the effects of free crystalline silica are likely to predominate.

Diatomite, another siliceous rock, consists mainly of fossilised skeletons of a unicellular aquatic plant, which is biologically dependent on silicon. Small quantities of this are mined in the UK, but it is mainly imported from other countries. It is processed and then used in several industries in the UK. It can be used as a filtration aid when manufacturing beer or wine or liquids in the pharmaceutical industry. It can also be used for heat or sound insulation or used as a mild abrasive by silversmiths, as well as numerous other uses.

In GB, RCS exposure has been assigned a workplace exposure limit (WEL) of 0.1mg/m³ expressed as an 8-hour time weighted average (TWA), implying that any exposure should be reduced to below this WEL, and in fact as low as is reasonably practicable. Exposure to RCS is also subject to the Control of Substances Hazardous to Health Regulations 2002 (COSHH).

3.2 Health Effects of Respirable Crystalline Silica (RCS)

The main adverse health effects associated with RCS are described briefly below.

Exposure to RCS has many adverse health effects including silicosis, chronic obstructive pulmonary disease (COPD), lung cancer, pulmonary tuberculosis and some connective tissue disorders.

3.3 Silicosis

Silicosis, asbestosis and coal-workers' pneumoconiosis (CWP) all belong to a group of diseases called pneumoconioses, a generic term used to categorise
dust-related lung diseases. These pulmonary diseases are characterised by non-neoplastic, (non-malignant) predominantly fibrotic changes in the lungs caused by inorganic dust exposure, such as coal dust, asbestos, or RCS\textsuperscript{2}.

Whilst accepting that any one estimate of incidence will not reflect the true underlying picture, the incidence of new cases of silicosis in the UK is now low and appears to be gradually falling. There were 95 cases of silicosis in 2007 and 85 in 2008 reported from the Industrial Injury Disablement Benefit (IIDB) scheme. There were 14 deaths from silicosis reported in 2006 and 7 in 2007 \textsuperscript{3}.

\textbf{3.4 Pathophysiology}

Silicosis is defined as pulmonary fibrosis resulting from a chronic inflammation, involving phagocytosis of the inhaled RCS by alveolar macrophages and its deposition in the lung interstitium. Deposited silica damages macrophages and epithelial cells, which release various enzymes and inflammatory cytokines, including tumour necrosis factor alpha and interleukin-1.

These inflammatory mediators begin destroying the lung parenchyma by attracting other inflammatory cells (macrophages, neutrophils, and lymphocytes).\textsuperscript{4} It has been suggested that initial exposure to low doses of silica may cause hilar lymph node fibrosis, which may reduce the worker’s ability to clear the lungs of subsequently inhaled dust\textsuperscript{5,6}.

Silicosis is characterised by the formation of hyaline and collagen nodules in the lung parenchyma and can be described as ‘simple silicosis’ or ‘complicated silicosis’. The term ‘simple’ or ‘complicated’ is defined radiographically, depending on whether the worker has presence (complicated) or absence (simple) of large opacities on their chest x-ray suggesting coalescent fibrosis, also often termed progressive massive fibrosis, or PMF.

The presence of complicated silicosis is normally associated with the development of more significant clinical features, including breathlessness and respiratory disability, whilst simple silicosis is normally not associated with significant clinical problems. Whilst complicated silicosis is not dependent on the worker having further clinical complications such as tuberculosis, co-infection with tuberculosis or the development of lung cancer can be seen as added complications. It is not the intent of this review to comment further in relation specifically to the lung cancer risk posed by exposure to RCS.

Simple silicosis normally results from long-term exposure (more than 20 years) to low amounts of silica dust, with nodule formation both in the lung and in the thoracic lymph nodes.

Accelerated silicosis occurs after exposure to larger amounts of silica over a shorter period of time, normally between 5 to 15 years, again with nodule formation in the lung and lymph nodes. Time to the onset of clinical features, including symptoms, is shorter in comparison to simple silicosis.
Acute silicosis is a rare complication of normally short-term exposure to very large amounts of silica, leading to an acute pneumonitis and alveolar exudate. This condition is life-threatening, and associated with very significant clinical consequences.

3.5 Tuberculosis

Individuals with silicosis are at higher risk of developing pulmonary tuberculosis (pTB) in addition to complications due to co-infection with fungal or bacterial agents.

3.6 Chronic Obstructive Pulmonary Disease (COPD)

COPD is typified by slowly developing, largely irreversible, airflow obstruction. The commonest cause of COPD is cigarette smoking, although certain genetic disorders as well as air pollution and occupational exposures can contribute. Many studies now identify general occupational exposures to generic vapours, gases, dusts and fumes as an important causative consideration for COPD, summarised both by the recent American Thoracic Society (ATS) consensus and a summary of published evidence following the consensus publication.

With particular relevance to RCS exposure and the development of COPD, various reviews have added to the evidence base.

A systematic review of the published evidence regarding COPD and exposure to dust was carried out in 1993. Four cohorts (13 studies) met the methodological criteria set by the reviewers; of these three were coal miner cohorts and one a cohort of gold miners. The review concluded that gold miners were at greater risk of developing COPD than coalminers, particularly if they also smoked tobacco.

Epidemiological and pathological evidence relevant to the development of COPD in silica-exposed workers was recently reviewed by NIOSH. This review suggested that chronic exposure to RCS, that does not cause disabling silicosis may cause emphysema, chronic bronchitis or small airways disease that could lead to airflow obstruction. Whilst this review recognised that severe silicosis can cause significant lung function impairment, evidence from epidemiological studies of workers exposed to RCS showed a significant exposure response relationship for cumulative dust exposure and airflow obstruction which was independent of the presence of silicosis. This review reported emphysema as being the predominant pathology associated with airflow obstruction in RCS-exposed workers, and summarised that chronic lower levels of RCS exposure may lead to the development of emphysema, chronic bronchitis or mineral dust airways disease (MDAD) that can lead to airflow obstruction.

A GB-based review of the evidence for an increased risk of COPD in occupations and industries where RCS is the primary exposure was published
in 2007. Certain occupations, including construction, tunnelling, cement industry, brick industry, pottery and ceramic work, silica, sand, granite and diatomaceous earth industries, gold mining and iron and steel founding, were all found to have consistently elevated risks of developing COPD associated with silica dust exposure, after taking into account the effect of confounders. This review also suggested that the cumulative effect of RCS exposure on airflow obstruction is independent of a diagnosis of silicosis.

Following review of longitudinal lung function data, a level of exposure to silica dust where significant loss of lung function occurs was suggested to be between 0.1-0.2mg.m\(^{-2}\). In the absence of silicosis, a disabling loss of lung function was estimated not to occur until approximately 30-40 years of exposure, assuming average lung function losses, although no estimates were made for more susceptible workers with greater than average year on year lung function loss.

3.7 Rheumatoid silicotic nodules

Larger than average size nodules (3-5mm diameter) can be found in the lungs of some workers with silicosis who also have rheumatoid arthritis (or with circulating rheumatoid factor without arthritis).

3.8 Lung Cancer

The International Agency for Research on Cancer (IARC) has identified RCS as a potential human lung carcinogen. It has been debated whether silicosis rather than silica exposure is the most important risk factor for lung cancer.

3.9 Autoimmune Disease and Renal Disease

The most frequently reported autoimmune diseases associated with RCS exposure are rheumatoid arthritis, systemic lupus erythematosus (SLE), scleroderma and sarcoidosis.

3.10 Occupational Asthma

There is currently no published data linking silica with the onset of occupational asthma.
AIMS & OBJECTIVES

Aims:
The aims of this report are to:
1) Identify existing recommendations for health surveillance for silica-exposed workers;
2) Assess the evidence base for these recommendations and other relevant evidence in the scientific literature;
3) Make recommendations for a standard approach to health surveillance for silica-exposed workers in the UK.

Objectives:
The objectives were:
1) To carry out a literature search and a search of the internet and relevant ‘grey’ literature (e.g. statements by other regulatory authorities) to review what recommendations by authoritative bodies already exist for health surveillance for silica-exposed workers.
2) To assess the extent to which those recommendations are based upon current clinical evidence and the quality of the evidence base underpinning them.
3) To identify and assess other scientific literature which could be considered in developing an HSE-approved standard approach to health surveillance for silica-exposed workers e.g. international organisations of standing such as the International Labour Organisation.
4) To use the information from the above search to make recommendations for a standard approach to health surveillance for silica-exposed workers in the UK.
5) To produce a summary report paper for HSE and its stakeholders.
5 METHODS

A search of the current available literature on health surveillance in silica-exposed workers was carried out. Search areas included:

- Journals of peer reviewed evidence
- Conference papers
- Internet
- Printed abstracts
- Regulatory Authorities

A search strategy framework was developed within the study team, noted in Table 1, with assistance from the HSL Infocentre. Two team members (LB, JB) initially appraised the resulting output from the search, the numbers of documents within which are shown in Table 2.

The evidence was initially scanned and abstracts/papers were reviewed if thought relevant to health surveillance programmes or advice for silica-exposed workers given the two key questions prompting review of the literature, namely (i) what are the existing recommendations for health surveillance in silica-exposed workers and (ii) what is the evidence base for any existing recommendations for health surveillance in silica-exposed workers?

Following the initial literature search, relevant findings were entered into an evidence table to facilitate summary of relevant papers, and to allow easier stratification into themes. The evidence tables were then reviewed by the whole study team to assist with the development of this report.

As this project was not intended to be a systematic review of the literature, it was not considered appropriate to use a grading system such as SIGN for evidence grading. Furthermore, certain of the evidence sources were from ‘grey’ literature, not lending themselves to a formal grading system.
Table 1 Search Strategy

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Table 2 Flow Chart for Document Selection

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<td>Documents of relevance to the key questions</td>
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<td>Documents for inclusion as evidence</td>
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<tr>
<td>Documents used as a basis for recommendations</td>
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6 EXISTING RECOMMENDATIONS

Although there was a great deal of literature regarding the health effects of RCS, there was much less available data relating specifically to silica-exposed workers and associated health surveillance.

The nine key sources of key information have been listed in Table 3, and are dealt with in detail below.

6.1 NEPSI – SOCIAL DIALOGUE AGREEMENT

In October 2006, an autonomous social dialogue agreement (SDA) was signed by members of the multi-sectorial Negotiation Platform on Silica (NePSi). The aim of this agreement was to improve the health and working life of workers exposed to RCS employed in the EU. The agreement included a comprehensive guidance document giving advice on the practical application of the safe handling of the RCS and included guidance on dust monitoring, training, further research and health surveillance.

This agreement is due for renewal in October 2010, but currently gives some health surveillance guidance.

It advises that an initial risk assessment should be carried out for each workplace to identify whether workers are at specific risk from RCS. If workers are thought to have specific health risks, a health surveillance programme should be implemented, and should include the following:

1. The production of a confidential medical file for each employee when joining the workplace, kept in a secure place. It should be stored for 40 years following end of exposure. The medical file should include:
   - Identification data;
   - Demographic data;
   - Job profile;
   - Full occupational history and extra-occupational activity history including any exposure to harmful dust, fumes, gases, vapours or other agents;
   - Medical history focusing on respiratory symptoms;
   - Smoking history.
2. Medical examination, concentrating on the respiratory system.
3. Spirometry using ATS/ERS standardized testing.
4. Full size postero-anterior (PA) chest x-ray. These films should be assessed by a qualified and trained radiologist or pulmonologist and classified according to the International Classification of Radiographs of Pneumoconioses (ILO).

It also states that workers who have left work or stopped being exposed to RCS should also be able to benefit from medical follow up at their request.
This health surveillance guideline does not, however, state how frequently health surveillance should be carried out, leaving this to the discretion of the health professional undertaking the surveillance.

The document does not cite specific references, except for the ATS/ERS lung function measurement details, although it does generically cite papers as evidence supporting the health surveillance guideline.

6.2 WORLD HEALTH ORGANIZATION (WHO)

The WHO published a comprehensive document in 1996 summarising screening and surveillance issues for workers exposed to mineral dust. Although not specifically a health surveillance document for silica-exposed workers, a section is included on screening and surveillance relating to RCS exposure.

The WHO states that the potential level of workplace exposure to silica (or any other hazardous dust) will determine the individual surveillance programme, although major components of a health surveillance programme would include:

1. Periodic identification and collection of health information
2. Evaluation and interpretation of the information
3. Reporting and intervention for the purpose of prevention

Similarly, the WHO believes that surveillance programmes are established to achieve one or more of the following goals:

- Tracking trends in disease incidence across industries, over time and between geographical areas
- Defining the magnitude or relative magnitude of a problem
- Identifying new hazards, risk factors or populations subject to risk
- Targeting interventions
- Evaluating efforts of prevention and intervention

The WHO sets out certain core elements for surveillance programmes. Firstly, that the surveillance programme is managed by a healthcare professional with specific training and experience in occupational health, being trained for the role and having the appropriate skills to carry this out. Again, the provider of this service must be knowledgeable about the local or national rules, regulations and laws surrounding the industry or sector in question.

The WHO also stresses the importance of record keeping. Confidentiality and security of medical surveillance data should always be maintained, advocating that surveillance data should be separate from general human resources records and should be kept securely for an extended period (it suggests 30 years) after the last date of employment of the worker they belong to. The latter point is made because of the potential long latency (period between first exposure and the development of disease) of silica-related disease. It is also
suggested that information in the record should be available to the workers and the workers’ health care providers. Along with personal surveillance records, documentation should also be kept of any quality assurance evidence (e.g. spirometer calibration records) to ensure tests are valid, accurate and directly comparable over time.

The WHO suggests that a questionnaire should be administered that will systematically enquire about work practice and exposures; it should include work history and document any relevant health symptoms. An updated health questionnaire enquiring about symptoms should be administered annually thereafter.

Specific tests for detecting diseases induced by mineral dust (i.e. silica) are also included in the WHO document, with emphasis on the chest radiograph as the most important tool for detecting pneumoconiosis (including silicosis), and that a standardised method of radiograph interpretation such as the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses (1980) is used to recognise and classify disease

Full size radiographs are recommended, in keeping with the ILO classification system, also based on full sized radiographs. The WHO suggests that interpretative variability can be reduced if readers are trained, tested and certified (as typified by the NIOSH B Reader programme in the USA).

The WHO recommends periodic chest radiographs for silica-exposed workers, leaving the interval between examinations to the discretion of the healthcare professional carrying out the surveillance. However, general guidance is given; if the worker is symptom-free and exposure controls are in place in the working environment, then it is recommended that a baseline chest radiograph should be obtained at the start of employment, then after 2 - 3 years of exposure, and every 2 - 5 years thereafter.

The WHO also recommends that lung function (spirometry to measure FEV₁ and FVC) is measured annually and this should be carried out using a standardised method, adopting equipment testing and procedures recommended by either the European Respiratory Society (ERS) or the American Thoracic Society (ATS). Comment is also made that the individual worker should be used as their own control, as opposed to relying on population data to define abnormality. If lung function cannot be performed annually, a recommendation is made that it should be performed at the same time as the periodic chest radiograph examination.

iii In 1980, the ILO created standard radiographs to assist with accurate diagnoses of pneumoconiosis and other interstitial lung diseases. The ILO system uses a step-by-step method to describe the lesion on a chest x-ray (CXR). The shape, size, location, and number of opacities are taken into account. The CXR is then classified once it has been compared with the standard CXRs. However, despite efforts to standardise the interpretation of chest x-rays with this system there still remains significant inter-reader and intra-reader variability.
Mention is also made of the potential inclusion of tuberculin skin testing within health surveillance programmes unless workers have been immunised with BCG, although intervals between testing are not proscribed.

Finally, a physical examination should be included, with focus on the respiratory system.

The WHO recognises that resources will also have an impact on frequency of any health surveillance carried out, particularly being true when assessing former workers who have left the industry.

The WHO also gives certain guidance on definitions of abnormal test results:

- An abnormal chest radiograph would be one consistent with the presence of pneumoconiosis (ILO category 1/0 or higher) or PMF;

- Abnormal spirometry would be that showing values below the lower boundary of the 95% confidence interval for the worker’s age, height and gender, or a drop in 15% from baseline spirometry data (as there can be considerable variability in FEV₁ values a year to year change of less than 15% should not be considered significant).

The WHO believes that workers should be notified of their test results in writing and, if required, counselling should be given.

Any legal implications should be discussed, as should any changes in working practice. If removal from the workplace is recommended, then alternative employment options should be discussed as part of the health surveillance programme.

6.3 NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH (NIOSH) USA

The National Institute of Occupational Safety and Health (NIOSH; USA) carries out research, develops guidance and recommendations, and disseminates information relating to prevention of work-related illness, and in 2002 published a hazard review on health effects of occupational exposure to RCS.

In this hazard review, NIOSH recommends that the risk of exposure to RCS is kept to a minimum, and that when feasible RCS is replaced with less hazardous materials. NIOSH also recommends that appropriate respiratory protection is used when working with RCS, and when source controls cannot keep levels below the recommended exposure limit (REL), that medical examinations are made available to RCS-exposed workers.²⁷

NIOSH currently has cooperative agreements with various American state health departments to develop models for state-based prevention and surveillance for silicosis. There are currently 15 states involved in this silica
awareness programme. Some of these states are concentrating on education and prevention of exposure to silica; others are using surveillance to monitor and record disease process and some are using passive surveillance, for example, monitoring reported cases of silica-induced disease by physicians to state reporting schemes. 28

NIOSH believes it is critically important to detect early signs of disease and take action to reduce further exposure in these individuals in order to prevent significant medical conditions such as silicosis.

Although specific guidance on health surveillance for silica-exposed workers is not given within the document, education and guidance on general health surveillance tools, including radiography, spirometry, questionnaires, and biomarkers are included.

NIOSH also operates the B-reader programme29, designed to test proficiency in reading chest radiographs for pneumoconioses (including silicosis) according to the International Labour Office (ILO) criteria. They also offer the NIOSH approved spirometry training course, which reviews and certifies training of health care workers who are responsible for carrying out spirometry.30

6.4 DIVISION OF LABOR AND INDUSTRY. MARYLAND OCCUPATIONAL SAFETY AND HEALTH (MOSH) USA

The primary objective of the Maryland Occupational Safety and Health (MOSH) programme is to assure, as far as possible, that “every Maryland worker has a safe and healthy workplace”. It monitors work sites and can, when required, measure levels of airborne RCS.

MOSH recommends that RCS-exposed workers should have a chest radiograph every two or three years and a lung function test once a year. They state that medical examinations are helpful, but cannot be relied upon as a primary protective measure. MOSH also emphasises that preventive measures are essential as silica-associated complications are often well advanced before detection with health surveillance occurs.

6.5 NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES

The New Jersey Department of Health and Senior Services (NJHSS) Surveillance Unit collects medical and demographic information from health care providers on sick and injured workers, analysing this information to allow them to work with employers to find practical solutions to improve health and safety at work. It also develops educational and training materials for workers and employers, and conducts educational outreach to high-risk industries in collaboration with stakeholders. It also evaluates educational outreach and industrial hygiene intervention activities to improve the effectiveness of the surveillance systems, and tracks patterns of work-related illness and injury in
New Jersey, sharing this information with policy makers and other interested parties.

It recommends that the following health surveillance is recorded as a baseline for all workers with potential exposure to RCS and periodically (as stated below) thereafter:

- Annual occupational exposure history. This should enquire about materials used, tasks performed, occupations and industries the workers have previously worked in.
- Annual medical examination concentrating on the respiratory system
- Annual lung function (forced expiratory volume in 1 second; FEV₁) FVC (forced vital capacity), and DL_{CO} (diffusion capacity of the lungs) to look for signs of respiratory impairment. It is also noted that all pulmonary function testing should follow recommendations issued by the ATS (American Thoracic Society) and be administered by a technician who has successfully completed NIOSH-certified training.
- A baseline purified protein derivative (PPD) screening skin test for pulmonary tuberculosis (pTB). This should be repeated annually if there is radiograph evidence of silicosis (ILO grading 1/0 or greater, or if the workers has 25 years or more exposure.
- Chest radiograph assessed by a B Reader to look for evidence of abnormality.

Although this guidance notes the potential for excessive radiographs (if, for example, workers have also worked with asbestos or other hazards for which this is an additional requirement), the following guidelines for the frequency of chest x-rays for RCS exposed workers are proposed:

- Every 3 - 5 years with normal radiograph, low exposure, and less than 20 years exposure.
- Every 1 - 3 years with normal radiograph, high exposure, or greater than 20 years exposure.
- Annually with radiographic evidence of silicosis (ILO 1/0 or greater or ILO results A, B, or C large opacities), massive exposure, or positive PPD test.

**6.6 NATIONAL PROGRAMME FOR THE ELIMINATION OF SILICOSIS, DEPT OF LABOUR, REPUBLIC OF SOUTH AFRICA**

This programme outlines the commitment of the South African (SA) government to significantly reduce the prevalence of silicosis by 2015 and to totally eliminate silicosis in SA workplaces by 2030, in line with the ILO and WHO Global Programme for the Elimination of Silicosis. Encouraged by the fact that countries such as Finland, Sweden and Switzerland have all but eliminated silicosis, the SA government feels that this is an achievable aim.
As well as regulatory enforcement, which focuses on the prevention of exposure to silica, the SA government is striving to raise awareness and to provide education and training at all levels, emphasising that early detection of asymptomatic RCS-related respiratory disease is crucial in this programme, as is prompt intervention to prevent disease progression.

It advises that health surveillance consists of a chest radiograph and lung function testing, stipulating that the former should be read by specialists in pneumoconiosis who are competent to do so (ILO trained). No guidance is given on the frequency or duration of the health surveillance programme.

6.7 AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE (ACOEM)

The ACOEM, a US-based medical professional society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education, published a guideline on the Medical Surveillance of Workers Exposed to Crystalline Silica in 1995. The aim of this guidance was to recommend objectives, key elements and implementation strategies for a medical surveillance programme. This is the most comprehensive evidence based guideline reviewed for inclusion within this report, recommending that the following components are available when assessing the health of workers exposed to RCS.

- **Occupational and Medical History.** A specific questionnaire should be used, focusing on the risk associated with the workers' exposure to RCS, and able to identify symptoms that relate to silicosis, chronic obstructive pulmonary disease (COPD), tuberculosis, connective tissue disease and lung cancer. It is also stressed that wherever possible, questions used should be standardised and validated. This questionnaire should be administered as a baseline record when a worker commences work, and repeated after one year to take into consideration individual worker RCS exposure. With this in mind the questionnaire should include some form of risk characterisation, such as onset and duration of RCS exposure, intensity of exposure, descriptions of all jobs associated with such exposure, and whether the individual has used any respiratory protective equipment. If possible, any exposure data collected from hygiene measurements should also supplement this questionnaire.

- **Physical examination.** This should focus on the respiratory and general health status of the worker; again a baseline examination should be carried out and repeated after one year, to monitor for any signs of acute silicosis.

- **Purified protein derivative (PPD) tuberculin skin test.** It is recommended that all workers have a baseline tuberculin skin reactivity test using the Mantoux technique and that this is reassessed periodically. However, ACOEM does not give a timeframe or frequency for reassessment.
• **Chest Radiographs.** ACOEM states that it is understood that chest radiograph changes can often precede symptoms and lung function changes in silicosis, but that there is evidence to suggest detection of simple silicosis, followed by removal from silica exposure, can decrease the risk of progression of the disease\textsuperscript{35}. As a chest radiograph is a useful tool for monitoring silicosis progression, it is stressed that the physician interpreting this does so in accordance with ILO criteria.

• **Spirometry.** The point is made that a reduction in lung function is not frequently observed in early silicosis, although the prevalence of obstructive defects is higher in silica-exposed workers even after taking into account smoking history\textsuperscript{36} \textsuperscript{37}. To monitor this FEV\textsubscript{1}, FVC, FEV\textsubscript{1}/FVC ratio are recommended to be recorded as a baseline measurement and then longitudinally thereafter, to determine whether there is excessive lung function decline.

### Follow up

ACOEM advises that if questionnaire data suggests that workers have low exposure to RCS (< 0.05 mg/m\textsuperscript{3}) then follow up frequency can be reduced, but does not offer specific interval advice here. It is recommended that workers with less than 10 years overall RCS exposure should be followed up and re-evaluated every 3 years. For those with greater than 10 years exposure, follow up frequency should be every 2 years. Exit medical evaluations are recommended for all RCS-exposed workers.

The ACOEM also advocates that there is an education component to any RCS health surveillance programme, including:

- Adverse health effects from exposure to RCS;
- Methods of prevention;
- Exposure limits;
- Why health surveillance is carried out
- Associated risk (e.g. cigarette smoking).

ACOEM also recommends that health surveillance programmes should be supervised by a physician with good knowledge of the health effects of RCS, tuberculosis and the interpretation of lung function tests and chest radiography, including ILO classification.

### Reporting

The ACOEM recommends that the results of any health surveillance should be reported back and explained to the worker. If the worker then gives permission, their primary health care provider should be also sent a copy of the results. If the surveillance results suggest that the worker is developing any silica-related ill health, then they should be referred to a specialist in this field. Additionally, summary of the surveillance results for all workers should also be anonymously reported back to the employer.
Smokers

6.8 ANY WORKERS WHO SMOKE SHOULD BE ENCOURAGED TO STOP SMOKING BY SUPPLYING ADVICE AND NECESSARY SUPPORT.

NEWFOUNDLAND LABRADOR SILICA CODE OF PRACTICE

This is an updated silica code of practice published in August 2006\(^{38}\) (the previous being in effect since 1984), which was developed by a committee, including government, management and union representation of two mines in Newfoundland.

The code includes detailed hazard assessment, dust control management strategies and recommendations for medical surveillance for workers. Although the code is only in effect for two mines, it is their stated goal to extend the code to other mines, as an example of best practice in preventing silicosis in future generations of mine workers.

Recommendations are made that the employer establishes and maintains a system for the surveillance of the health of their employees exposed to RCS and that the International Commission on Occupational Health (ICOH) ‘International Code of Ethics for Occupational Health Professionals’\(^{39}\) and the ILO document ‘Technical and Ethical Guidelines for Health Surveillance’\(^{40}\) are adopted to form the basis of the recommended health surveillance programme.

It is understood that not all workers will require health surveillance. Examples given include those working in an office with no potential exposure to silica, contractors who are self-employed who work for a cumulative period not exceeding 3 months during a 12 month period, or employees who work for a cumulative period not exceeding 3 months during a 12 month period.

An initial health assessment is recommended to be carried out under the direction of a physician and must include:

- **An occupational history** to determine years of exposure, including questions about materials used, tasks performed, and previous occupations. This should be updated annually.

- **A respiratory questionnaire** which is nationally or internationally accepted (e.g. American Thoracic Society).

- **Pulmonary function tests** (FEV\(_1\), FVC, DL\(_{CO}\) standardised for alveolar volume) in accordance with criteria established by the ATS or ERS, carried out by a competent technician.

- **A chest radiograph** (full size PA view) classified according to ILO Classification, B Reader recommended.

- **A medical history and physical examination** concentrating on the respiratory system. This examination shall consider the need for PPD skin testing for tuberculosis.
An Australian Safety Bulletin published by the Queensland Government in February 2010 reported results from a questionnaire aimed at assessing the potential exposure to excessive levels of RCS in small and medium sized mines, quarries and exploration sites in Queensland.

This survey concluded that there still remained a risk to workers exposed to RCS, and that silica-related diseases may develop in this group of workers even after leaving the industry. As well as recommending control strategies and monitoring of RCS, health surveillance is recommended to include:

- Recording of demographic data and information regarding occupational history and medical history;
- Information for the worker about the potential health risks associated with working with RCS;
- A physical examination, concentrating on the respiratory system;
- A respiratory questionnaire;
- Respiratory function tests;
- A full size PA chest radiograph;
- Records of personal monitoring exposure.

It is recommended that health surveillance should be carried out when the worker commences work with RCS, and that frequency of health surveillance will depend on the worker’s exposure to RCS.

The same levels laid down in the ACOEM document are adopted, with a follow-up evaluation within 12 months, evaluating the need for a repeat chest radiograph at this time.

- If exposure is < 0.05 mg/m³, assess need for frequency of future follow-up evaluations.
- If exposure is equal to or greater than 0.05 mg/m³ for less than 10 years, follow-up evaluation every 3 years.
- If exposure is equal to or greater than 0.05 mg/m³ for 10 or more years, follow-up evaluation every 2 years.
- An exit evaluation should be conducted when the worker leaves their job.

The evidence for these recommendations comes from the WHO, ACOEM and the Safe Work Australia guidelines for health surveillance. 41
Various other relevant points emerged from the generality of the evidence assessed, and these are briefly summarised for completeness in this section.

### 7.1 PULMONARY FUNCTION TESTING

Spirometry carried out using generally portable equipment can measure FEV$_1$, FVC, VC in addition to mid-expiratory flow rates, and as such is a useful assessment within a health surveillance programme to detect airflow obstruction and/or restriction. Serial spirometry can be used to monitor the rate of FEV$_1$ decline, enabling the health care professional to document whether there is excessive decline in a single worker or group of exposed workers.

Previous studies have shown that the prevalence of obstructive ventilatory defects is higher in silica-exposed workers, even in the absence of silicosis and after accounting for smoking. These measures, therefore, can be used both in a cross-sectional and longitudinal manner to assess absolute lung function values in comparison to predicted individual values, and prospectively with time to assess year on year change in RCS-exposed workers.

SPIROLA, a NIOSH-based software, has been specifically developed to assess changes in lung function with time, and could be easily adopted for use within a health surveillance programme.$^{42}$

### 7.2 TUBERCULIN TESTING

The ATS recommends that workers with silicosis undergo tuberculin testing in addition to workers without silicosis who have had 25 years of occupational exposure to RCS$^{43}$, given the higher risk of developing pTB in these groups of workers.

The evidence for this comes, in part, from two studies: (i) a Danish study$^{44}$ which noted a threefold incidence of pTB in non-silicotic silica-exposed workers compared to the general population and (ii) a South African study$^{45}$ which noted almost a tenfold increase in pTB within black South African goldminers who did not have silicosis, who had worked underground for a median of 26 years.

Ex-silica workers are also at risk from TB$^{46}$, with a study of incidence in white South African gold miners concluding that pTB was diagnosed at a mean 7.6 years following the end of exposure to RCS and mine dust, and following a mean of 6.8 years after radiological appearances of silicosis appeared.
7.3 RADIOLOGY

7.3.1 International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses

In 1980, the ILO International Classification of Radiographs of Pneumoconioses created standard radiographs to assist with accurate diagnoses of pneumoconiosis and other interstitial lung diseases. The ILO system uses a step-by-step method to describe lesions seen on a chest radiograph, taking the shape, size, location, and number of opacities into account, and using standard radiographs for comparison. Despite high resolution CT scanning now being a preferred and more sensitive method for such assessment, no ILO guidance is based on this imaging technique as yet.

7.3.2 Chest radiography

The chest radiograph is a relatively insensitive and non-specific tool for diagnosing silicosis, as a normal examination does not exclude the presence of silicosis or pulmonary fibrosis. Their use continues largely as a function of their simplicity, relative inexpense, rapid access and low radiation dose, making them the first choice in health surveillance and screening.\(^{47, 48}\)

Chest radiographs are not a useful screening tool for other occupational respiratory diseases including specifically bronchitis, emphysema and COPD.

7.3.3 Computerised Tomography (CT) and High Resolution CT (HRCT) Scanning

CT scanning is more sensitive and specific compared to standard radiology when identifying changes related to RCS exposure, also being more reproducible, with higher agreement between readers than a simple chest radiograph. Radiation dosage for even a limited CT scan is well in excess of that used for a plain chest radiograph.

High resolution CT images (HRCT) changes also have better correlation with pulmonary function tests, irrespective of smoking habit and the presence of chronic bronchitis, in workers exposed to silica dust.\(^{49}\) CT scanning is also superior for identifying other lung diseases such as lung cancer, emphysema, and atelectasis, which may coexist in patients at risk of silicosis.

Whilst HRCT is also a useful modality to identify fine lung parenchymal details, several papers disagree about the concordance between CT and the plain chest radiograph when evaluating parenchymal opacities in silicosis, particularly in the early stage of disease.\(^{50, 51, 52, 53}\)

As a consequence there is currently no standardisation of technique for scoring HRCT images relating specifically to silica exposure\(^{54}\), and HRCT is not recommended for routine health surveillance in silica-exposed workers.
7.4 MODELLING

The Institute for Risk Assessment Sciences (IRAS) in the Netherlands has recently developed a simple diagnostic model to estimate the probability of individual workers having pneumoconiosis using questionnaire and spirometry results\textsuperscript{55}, based on the detailed findings of a large cross-sectional study (n=1291) of Dutch stone and construction workers with potentially high RCS exposure.

A multivariable logistic regression model was developed using chest radiographs with an ILO category of greater than 1/1 as the reference standard. Following validation of the model, a score chart was developed allowing prediction of those workers had a low probability of having pneumoconiosis. This approach may be of practical use in terms of predicting which workers have a low probability of developing silicosis, with the potential to exclude certain groups from unnecessary health surveillance, including radiological assessment. To the knowledge of the study team at HSL, this model has not been externally validated, although it did undergo internal validation.
8 RECOMMENDATIONS FOR A STANDARD APPROACH TO HEALTH SURVEILLANCE FOR SILICA-EXPOSED WORKERS IN THE UK

The original aims of this project were to (i) identify existing recommendations for health surveillance for silica-exposed workers, (ii) to assess the evidence base for these recommendations and other relevant evidence in the scientific literature, and (iii) to make recommendations for a standard approach to health surveillance for silica-exposed workers in the UK.

Both (i) and (ii) have been dealt with in previous sections of this report.

In terms of making recommendations for a standard approach to health surveillance for silica-exposed workers, the following general and specific points are made.

8.1 GENERAL POINTS

There was general consensus from the specific surveillance approaches assessed that this should be implemented for all workers exposed to RCS where there is a risk to respiratory health\textsuperscript{56}.

Despite this consensus, it was not possible from the reviewed evidence base to define firm evidence based guidance for developing a high quality health surveillance programme in GB for workers exposed to RCS. Specifically, the detailed content and periodicity of regular health surveillance was not stipulated, although various examples of practice have been identified that can assist in the formulation of such guidance.

8.1.1 Risk assessments

Each workplace should carry out appropriate risk assessments to identify whether the hazard posed by RCS exposure carries with it significant risk to the individual worker (a generic example of which, adapted for GB from an Australian approach, is given in Appendix 1).

Risk assessments should be carried out at frequent intervals, the findings of which should be available to those carrying out health surveillance.

8.1.2 Pre implementation of health surveillance

Before implementation, the benefits of a health surveillance programme should be considered, with a focus both on the benefit to the individual worker and to the entire workforce. Methods of data collection should be discussed with the individuals at risk in order to gain an acceptance by all involved that health surveillance is valuable. If the individual worker does not understand the value
of the health surveillance programme or feels it is an inconvenience, then the importance of participating in such a programme may not be fully appreciated.

It should also be made explicitly clear how workers are handled if they have at baseline (or develop during the programme) abnormal results. This information should be contained within an associated comprehensive occupational health policy. This should also deal with how best to handle individual workers who ‘fail’ health surveillance. For example, ACOEM guidance advises that workers who develop health consequences from RCS exposure should be referred to a specialist in the field.

### 8.1.3 Health Surveillance records and evaluation

Results of health surveillance should be shared in writing with individual workers, kept separate from organisation human resource functions, shared with the worker’s primary care provider, and kept for a significant duration (30 years recommended due to the long latency nature of the silica related adverse health effects). It was also noted that group data fed anonymously back to the employer.

Certain authorities suggested the inclusion of previous or retired workers in workplace-based health surveillance programmes because of the generally long latent periods between exposure and the subsequent development of the respiratory complications associated with RCS exposure.

Health surveillance programmes should be evaluated annually, and should be able to detect if an individual worker is being exposed to unacceptable levels of RCS, assess whether control measures in the workplace are effective to minimise exposure to RCS, and also indicate to the employer if a reduction in exposure is required to prevent the development of further health effects.

A standard proforma should be used to collect all relevant data relating to health surveillance and a standard questionnaire should be administered.

### 8.1.4 Health surveillance personnel

Many of the current examples of health surveillance criteria for RCS-exposed workers highlighted the importance of adequate health care professional training, and specifically that OHPs carrying out and maintaining the programme should have knowledge of local and national rules and legislation relating to silica, in addition to expertise specifically relating to the adverse health effects of silica exposure.
8.2 \hspace{1cm} \textbf{SPECIFIC POINTS}

There were no comments or evidence that suggested that health surveillance in RCS exposed workers is not useful. Once the need for health surveillance is established, the following specific points are made, based on the review of literature, for consideration when defining a health surveillance programme for RCS-exposed workers.

8.2.1 \hspace{1cm} \textbf{Health surveillance data to collect}

1. Collection of demographic data, including:
   - Name and unique identification, date of birth and gender
   - Home address
   - Date started at company
   - Job title and current job profile

2. Occupational history
   - Current potential exposure to RCS and relevant measures
   - Current job profile and tasks
   - Use of current RPE
   - Use of previous RPE
   - Previous estimate of years worked with RCS (broken down where necessary by duration and job title/task)
     (i) Occupational and non-occupational exposures
   - Previous exposures to other dusts/gases/fumes/vapours (broken down where necessary by duration and job title/task)
     (i) Occupational and non-occupational exposures
   - Inclusion in previous health surveillance
     (i) Previous chest radiographs and results, if known
     (ii) Previous lung function estimates and results, if known

3. Medical History
   - Past medical history
     (i) Respiratory: asthma, COPD, silicosis, other respiratory with dates diagnosed
     (ii) Non-respiratory
   - Smoking history
     (i) Pack year estimate and current status of smoking
4. Health questionnaire

- Use of a validated respiratory questionnaire (certain examples are given in Appendix 2) that should include the following:
  (i) General respiratory symptom enquiry
  (ii) Enquiry about symptoms related to silicosis, COPD, pulmonary TB, lung cancer
  (iii) Enquiry about symptoms suggestive of connective tissue disorders
  (iv) Enquiry about general health issues, including ‘feeling unhealthy’, the latter identified as one useful predictor of workers requiring more frequent radiological assessment in the Dutch modelling study of construction workers [56]
  (v) Other complaints in memo format

5. Physical examination

- Concentrating on respiratory system, assessing for signs of silicosis (including acute silicosis) and progressive airways obstruction (COPD).

6. Lung function tests

- No consensus view is identified relating to the exact role of lung function testing in RCS health surveillance, although all reviewed documents commented on its desirability.
- Testing should be carried out as part of a quality assured programme, with calibration and other quality relevant data also stored in the individual patient health surveillance record.
- Whilst one authority suggested the measurement of transfer factor and coefficient, the majority recommended measuring the following:
  (i) FEV$_1$ (forced expiratory volume in one second)
  (ii) FVC (forced vital capacity).
- Training of personnel carrying out these tests was highlighted as important (e.g. NIOSH-certified training).
- Reference of measured to predicted values should be made, with ERS and ATS prediction equations cited.

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iv Certain authorities mention the use of a validated questionnaire, but no consensus has been developed concerning the content of such a questionnaire

v Recognising that physical examination may be a relatively insensitive for identifying early silicosis and early COPD
7. Chest Radiology

- No consensus view is identified from the reviewed literature as to the exact role of chest radiology in health surveillance programmes for RCS-exposed workers.
- A full sized PA chest radiograph should be used, reported according to ILO classification.
- CT scanning has no current practical role in health surveillance, although its role is of a research interest.
- Specialists reporting such radiology should be able to demonstrate specific competence to do this (e.g. NIOSH B reader programme).
- Abnormal chest radiograph needs a definition within a health surveillance programme (e.g. ILO 1/0, PMF, or large opacities A, B or C).

8. Health advice

- Workers should be given advice and information concerning the potential health effects of exposure to RCS as part of a health surveillance programme. This should include knowledge of previous methods to reduce RCS exposure, exposure limits and the need for health surveillance.
- Workers should be given smoking cessation advice and support within such a programme should they require this, given the potential interaction between smoking and the occupational causes of COPD and lung cancer.

9. Tuberculin testingvi

8.2.2 Periodicity of health surveillance

Few data exist here to guide an evidence-based view concerning frequency of health surveillance required for RCS-exposed workers in GB.

The following themes emerged from the reviewed literature:

1. Periodic health questionnaires, physical examinationvii findings and occupational history should be recorded annually, the findings of which are also triangulated to the outputs of risk assessments and exposure estimates.

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vi Included here for completeness, tuberculin testing is discussed within many of the evidence documents identified. Given the relatively low levels of RCS exposure, alternate diagnostic strategies emerging and relatively low prevalence of pTB within this population, tuberculin testing may no longer be a central requirement.

vii Specific differential comments about physical examination are not made in the evidence, and it is therefore assumed that these are carried out with each annual questionnaire. Given the current levels of RCS exposure and insensitivity of examination findings, these may be deemed less important by individual OHPs.
2. Periodic spirometry should be recorded on an annual basis, in order to detect both progressive restrictive and obstructive abnormalities.\textsuperscript{viii}

3. Periodic chest radiology. This area represents that with least consensus.

Each organisation appeared to handle the indication for chest radiology in differing ways, although central to many schemes was the view that shorter term, lower level exposures required a baseline radiograph and less surveillance, whereas those workers with more intense exposures or longer duration of exposure required more frequent surveillance.

### 8.2.3 Development of a GB RCS health surveillance approach

It is recommended that a standard approach to health surveillance for RCS-exposed workers should be developed and should include the components listed in 8.2.1, with the possible exception of tuberculin testing.

With regards to achieving the best relative contributions of these components to allow optimal early identification of both silicosis and COPD, little data are available for guidance. Consequently, additional consideration should be given to the following:

1. Use of existing health surveillance data collected within sectors with RCS health surveillance already up and running, in order to retrospectively identify factors associated with the development of silicosis.

2. Use of existing health surveillance data collected within sectors with RCS health surveillance already up and running, in order to retrospectively identify factors associated with the development of either COPD, or accelerated lung function loss.

3. Use of these data, and other published modelling approaches, to develop a set of rules designed to stratify workers into those requiring and not requiring chest radiology.

\textsuperscript{viii} Inclusion of annual spirometry assumes that a workplace wishes to identify workers developing rapid annual lung function decline, and also that an appropriate occupational health policy is in place to deal specifically with any health surveillance failures. It is not within the remit of this report to discuss annual decline in FEV1 in detail, although good profiling software and advice is available from NIOSH (Spirola programme).
APPENDIX A

Flow Diagram for Silica Health Surveillance in the UK

Is RCS used or expected to be used in GB?  
Yes

Is RSC hazardous to health?  
Yes

Is there evidence that RCS is injuring the health of workers or could do so under the anticipated conditions of use?  
• Consider the population at risk, is there a susceptible population  
• What is the level of exposure  
• Assess the ability to control exposure  
• Consider hazards from all routes of exposure  
Yes

Is atmospheric monitoring, without health surveillance, sufficient to evaluate exposure to RCS?  
• Is current monitoring sufficient to evaluate control?  
• Can ability to monitor substance in workplace be related to the anticipated health effects?  
Yes

Are there health surveillance techniques available to monitor the health effects of exposure to RCS?  
Yes

Would health surveillance be beneficial for those at risk?  
Yes

Are the methods of health surveillance likely to be acceptable to those at risk?  
Yes

Are the methods of health surveillance practical and ethically acceptable?  
Yes

Commence health surveillance programme as per recommendations
**Table A1 Evidence Table**

<table>
<thead>
<tr>
<th>Evidence/Year/Author</th>
<th>Health Surveillance</th>
<th>Comments</th>
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<tbody>
<tr>
<td>NEPSI -Signature of the Agreement on Workers Health protection through the Good Handling and Use of Crystalline Silica and Products containing it. (2006) <a href="http://www.nepsi.eu/agreement.aspx">http://www.nepsi.eu/agreement.aspx</a></td>
<td><strong>Annex 8 from Social Dialogue Agreement</strong>&lt;br&gt;Risk assessment to assess health hazards related to RCS&lt;br&gt;<strong>If at risk:</strong>&lt;br&gt;Medical file (kept for 40 years) – id data, demographics, family, personal history, job profile, occupational history, past exposure to dusts/chemicals/harmful agents, respiratory symptoms, smoking habit&lt;br&gt;Medical examination&lt;br&gt;Spirometry&lt;br&gt;Full size posterior anterior (PA) CXR read by a trainer interpreter. Classified using ILO guidelines. Frequency decided by occupational health practitioner based on the risk assessment&lt;br&gt;Follow up available for those who have left the industry/retired&lt;br&gt;Confidentiality/good communication with employee</td>
<td>All HS should be conducted by a competent medical professional and in accordance with national legislative requirements</td>
</tr>
<tr>
<td>Wagner GR. Screening and surveillance of workers exposed to mineral dust. 1996 World Health Organisation (WHO), Geneva</td>
<td>The difference between health screening and health surveillance is defined&lt;br&gt;Chapter 6 describes the tests for detecting diseases induced by exposure to <strong>mineral dust</strong>&lt;br&gt;<strong>Conventional chest radiography</strong> (X-rays)&lt;br&gt;A standard method for chest x-ray interpretation published by the International Labour Office (ILO) in 1980 should be used. Exposure to crystalline silica dust can result in development of opacities greater than 1cm diameter. Despite the ILO system, the detection of abnormalities is subject to inter-reader and intra-reader variability, manifested as disagreement between readers, or the same reader at different times. Radiographs may be insensitive to early changes resulting from exposure to dust. Physicians lacking in the required skills may miss subtle abnormalities. However, at higher profusions of silica-induced lesions the correlation between lung pathology and radiography has been found to be reasonable&lt;br&gt;<strong>Periodic chest x-rays</strong> are the primary means of screening. Periodic chest radiographs conducted in the absence of other screening</td>
<td></td>
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Methods have not been found to identify lung cancers at a sufficiently early stage to improve the outcome of therapy.

**Measures of lung function** – the standard lung function tests are described (FEV₁ (forced expiratory volume in 1 second), FVC (forced vital capacity) and FEV₁/FVC ratio). There is no clear or absolute separation between ‘normal’ and ‘abnormal’ values. The utility of periodic testing of lung function in workers exposed to mineral dust has not been fully investigated. Longitudinal comparison of an individual’s values is likely to yield more meaningful results than comparison with the total population. There should be a point at which accelerated decline can be recognised. However, the interpretation of longitudinal results can be confounded by individual variability leading to test results exceeding the expected annual decline due to age.

**Questionnaires** – respiratory function questionnaires provide the usual first step in health screening or surveillance. They provide smoking, work and exposure histories and can provide useful information when used in conjunction with health screening tests. Their value as an independent tool for early identification of disease attributable to mineral dust exposure is unproven. Technical guidance concerning questionnaire use should be followed.

**Physical examination** – as with other screening tests, physical examination can provide useful information but are not recommended as an independent tool for screening or surveillance of workers exposed to mineral dust.

**Sputum examination** – sputum can be examined for *Mycobacterium tuberculosis* or other infectious agents or malignant cells. The weight of evidence does not support the general use of sputum cytology for the early detection of lung cancer in workers exposed to silica dust.

**Tuberculin skin testing** – is recommended in countries where tuberculosis incidence is low. The increased risk for developing tuberculosis in workers exposed to silica should increase the benefit to be derived from testing and intervention in this population.

Chapter 7 describes the recommendations for screening and the complex range of variables.
that influence the development of screening and surveillance programmes. The factors include “medical, economic, legal and political factors in the country, region or industry where the programme will be conducted”. No single set of guidelines is applicable to the development and implementation of a screening/surveillance programme. The potential level of workplace exposure to hazardous dust and the exposure controls that are currently in place will affect the design of screening programmes. Also “eligibility for and frequency of medical examination, the specific examination used, methods of interpretation and analysis of results, procedures for the reporting of data, the interventions that may be recommended, and the means of evaluation will all reflect local priorities, resources, laws, customs, language and public health infrastructure”.

Having stated these constraints, the chapter makes the following recommendations for workers exposed to crystalline silica or coal mine dust:

A chest x-ray should be obtained at the start of employment (baseline), then after 2 - 3 years of exposure and every 2 - 5 years thereafter, for workers with <10 years since first exposure; 1-2 years for workers >10 years’ exposure, annually for workers with >20 years since first exposure. Frequencies may be adjusted depending on worker age and intensity and duration of exposure.

Respiratory questionnaire, physical examination and spirometry should be performed annually, or at the same frequency of chest x-rays.

Annex 2 of the book provides examples of screening and surveillance programmes from 7 countries, including the British Coal Corporation OH Service in the UK. The frequency of X-rays and lung function tests for silicosis workers is stated as “usually at 2-, 3-, or 4-year intervals” (p48). Questionnaire and physical examination were also part of the screening tests conducted on this group of RCS exposed workers. Programme effectiveness was reported periodically through SWORD.

<p>| NIOSH hazard review. 2002. Health effects of occupational exposure to respirable crystalline silica | Significant risk of chronic silicosis for workers exposed to respirable crystalline silica over a working lifetime at the current OSHA permissible exposure limit (PEL), MSHA PEL or the NIOSH recommended exposure limit (REL) | This document focuses on analytical and sampling methods for silica containing dust |</p>
<table>
<thead>
<tr>
<th>Source</th>
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<tr>
<td>Dept of health and human resources NIOSH</td>
<td>NIOSH continue to recommend a REL of 0.05mg/m³ as a TWA for 10hr working day, during a 40hr working week. NIOSH recommend substitution as the highest level of control and recommend ‘making medical examinations available’ to workers exposed at the NIOSH REL. and epidemiological evidence of silicosis and other related morbidity. No relevant description of physiological/pathological tests.</td>
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<td>Division of Labor and Industry. Maryland Occupational Safety and Health (MOSH) - Occupational Health Hazards - Silica <a href="http://www.dllr.state.md.us/labor/silica.htm">http://www.dllr.state.md.us/labor/silica.htm</a></td>
<td>Exposed workers should have an x-ray every two or three years and a lung function test once a year. Medical exams are helpful but cannot be relied upon as a primary protective measure. Preventive measures are essential because the disease is often well advanced before detection. The primary objective of the Maryland Occupational Safety and Health (MOSH) program is to assure, as far as possible, every Maryland worker a safe and healthful workplace. To protect workers from overexposure to silica, the Commissioner of Labour and Industry has adopted a permanent standard, which establishes limits based on the percent of free silica in the workplace atmosphere. Maryland's standard is consistent with the Federal OSHA standard regarding silica exposure. MOSH will respond to worker complaints and will monitor work sites to measure the amount of silica in the air. Overexposure will result in citations requiring corrective action.</td>
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<tr>
<td>New Jersey Department of Health and Senior Services. What physicians need to know about occupational silicosis and silica exposure sources. Aug 1998 <a href="http://www.state.nj.us/health/surv/documents/silicosis.html">http://www.state.nj.us/health/surv/documents/silicosis.html</a></td>
<td>A baseline before exposure, then periodically as noted: Annual occupational exposure history Annual medical exam Chest x-ray to look for evidence of abnormality, posteroanterior 14&quot; x 17&quot; or 14&quot; x 14&quot;, classified according to the 1980 Guidelines for the Use of ILO International Classification of Radiographs of Pneumoconiosis by a certified class B reader, is recommended. The ILO</td>
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<td><strong>b.pdf</strong></td>
<td>System has the distinct advantage of a standardised set of comparison x-ray films. <strong>Note</strong> the potential for excessive x-rays if the employee has also worked with asbestos or other hazards for which OSHA may require employers to provide x-rays. <strong>Frequency of Chest X-rays for Silicosis</strong> Every 3 - 5 years with normal x-ray, low exposure, and less than 20 years exposure. Every 1 - 3 years with normal x-ray, high exposure, or greater than 20 years exposure. Annually with x-ray evidence of silicosis (ILO 1/0 or greater or ILO results A, B, or C large opacities), massive exposure, or positive PPD test. <strong>Lung Function</strong> FEV1 (forced expiratory volume in 1 second), FVC (forced vital capacity), and DLCO (diffusion capacity of the lungs) annually. All PFT should use equipment and follow recommendations issued by the ATS (American Thoracic Society) and be administered by a technician who has successfully completed NIOSH-certified training. A baseline PPD skin test for tuberculosis as people who have silicosis have increased susceptibility. <strong>National Programme for the Elimination of Silicosis, Dept of Labour, Republic of South Africa</strong> also Silica Exposure and its effect on the physiology of workers. Dept. of Labour Republic of South Africa <a href="http://www.labour.gov.za/documents/useful-documents/occupational-health-and-safety/silica-exposure-and-its-effect-on-the-physiology-of-workers/">http://www.labour.gov.za/documents/useful-documents/occupational-health-and-safety/silica-exposure-and-its-effect-on-the-physiology-of-workers/</a> This programme outlines the commitment of the South African (SA) government to significantly reduce the prevalence of silicosis by 2015 and to totally eliminate silicosis in SA workplaces by 2030. <strong>ACOEM (2005) Medical Surveillance of Workers Exposed to Crystalline Silica</strong> <a href="http://www.acoem.org/guidelines.aspx">http://www.acoem.org/guidelines.aspx</a> <strong>TARGET POPULATION:</strong> those individuals exposed to levels of crystalline silica that place them at risk for silicosis. Inclusion criteria are conservative <strong>COMPONENTS OF THE EVALUATION</strong> Occupational and medical history (questionnaire) Using a directed questionnaire focusing on</td>
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characterisation of risk and identification of symptoms related to silicosis, tuberculosis, obstructive pulmonary disease, connective tissue disease, and lung cancer. This questionnaire can be useful for the early detection of chronic obstructive pulmonary disease, active mycobacterial disease, and connective tissue disorders.

Physical examination
Physical examination should be focused on the general condition and respiratory status of the worker.

Purified protein derivative (PPD) tuberculin skin test
Baseline tuberculin skin test reactivity status of all silica-exposed workers should be established at job entry using the Mantoux technique.

Chest radiography
Radiographic manifestations of this disease often precede the development of symptoms and clinically significant pulmonary function loss. The interpretation should be performed by a physician.

Spirometry
Clinically significant decrements in spirometry are not typically observed in the early stages of simple silicosis, previous studies have shown that the prevalence of obstructive ventilatory defects is higher in silica-exposed workers, even in the absence of silicosis and after accounting for smoking. Therefore, spirometry is useful in this worker population. FVC, FEV1 and FEV1/FVC ratio should be evaluated cross-sectionally relative to predicted values. FVC and FEV1 can also be evaluated longitudinally, to determine whether a worker’s change over time is excessive.

Frequency of Surveillance Evaluations

Baseline Evaluation
An evaluation should be done on each worker, when he/she accepts a position involving exposure to a work site where silica is present and the concentration is either unknown or above 0.05 mg/m3. Such an evaluation would both establish baseline lung function and TB skin status plus identify the presence of pre-existing lung disease.

Follow-up Evaluations
The initial follow-up examination should be performed within 12 months since acute silicosis and tuberculosis can occur in a
relatively short period of time. Repeating the chest radiograph after one year should be at the discretion of the health care provider, but under most circumstances would not be needed unless local circumstances so indicate.

For workers with exposures < 0.05 mg/m$^3$, the frequency of follow-up can be reduced, based on questionnaire responses and documented exposure data. For workers with < 10 years’ exposure, frequency of follow-up evaluation should be every three years. For workers with > 10 years’ exposure, follow-up evaluation should be every 2 years since workers with longer duration of exposure and time from initial exposure are at higher risk for silica-related abnormalities.

**Exit Evaluation**
A worker leaving a job with potential for silica exposure should be offered an exit medical evaluation. For workers with < 10 years exposure, a complete medical surveillance examination is indicted if the last evaluation was >12 months previously.

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<th>Newfoundland Labrador Silica Code of Practice, August 2006</th>
<th>This is an upgraded silica code of practice. It recommends that an initial health assessment is carried out under the direction of a physician and must include:</th>
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<tr>
<td><a href="http://www.gs.gov.nl.ca/ohs/silica_code_of_practice.pdf">www.gs.gov.nl.ca/ohs/silica_code_of_practice.pdf</a> - 2010-02-04</td>
<td><strong>An occupational history</strong> to determine years of exposure, including questions about materials used, tasks performed, and previous occupations. This should be updated annually</td>
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<td><strong>A respiratory questionnaire</strong> which is nationally or internationally accepted (e.g. American Thoracic Society)</td>
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<td><strong>Pulmonary function tests</strong> (FEV$_1$, FVC, DLCO standardized for alveolar volume) in accordance with criteria established by the ATS or ERS carried out by a competent technician</td>
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<td><strong>A chest x-ray</strong> (full size PA view) classified according to ILO Classification, B Reader recommended</td>
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<td><strong>A medical history and physical examination</strong> concentrating on the respiratory system. This examination shall consider the need for PPD skin testing for tuberculosis</td>
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</table>
This is a safety bulletin which recommends the following health surveillance for silica-exposed workers:

- Demographic data and information regarding occupational history and medical history
- Information about the potential health risks associated with working with RCS
- A physical examination, concentrating on the respiratory system
- A respiratory questionnaire
- Respiratory function tests
- A full size PA chest x-ray
- Records of personal monitoring exposure

This document recommends that health surveillance should be carried out when the worker commences work with RCS, and that frequency of health surveillance will depend on the workers exposure to RCS.

This document uses the same levels as the ACOEM:
- Follow-up evaluation within 12 months
- Evaluate need for repeat chest x-ray at this time

If exposure is < 0.05 mg/m³, assess need for frequency of future follow-up evaluations.
- If exposure is equal to or greater than 0.05 mg/m³ for less than 10 years, follow-up evaluation every 3 years.
- If exposure is equal to or greater than 0.05 mg/m³ for 10 or more years, follow-up evaluation every 2 years.

An exit evaluation should be conducted when the worker leaves their job.
REFERENCES


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19 Occupational health programme for exposure to crystalline silica in the industrial sand industry – National Industrial Sand Industry (NISA) – March 1997 http://ehp.niehs.nih.gov/cgi-bin/findtoc2.pl?tocinfo=Environmental Health Perspectives@106@11@1998

20 Wagner GR. Screening and surveillance of workers exposed to mineral dust. 1996 World Health Organisation (WHO), Geneva


22 Occupational health management in the quarry industry. Quarries joint national advisory committee. May 2004


27 NIOSH hazard review. 2002. Health effects of occupational exposure to respirable crystalline silica. Dept of health and human resources NIOSH

28 NIOSH State Health Department Surveillance Schemes for silica http://www.cdc.gov/niosh/topics/surveillance/ords/StateBasedSurveillance/Stateprograms.html

29 NIOSH B Reader Programme http://www.cdc.gov/niosh/topics/chestradiography/breader.html
30 NIOSH approved spirometry training guide
http://www.cdc.gov/niosh/docs/2004-154c/

31 New Jersey Department of Health and Senior Services. What physicians need to know about occupational silicosis and silica exposure sources. Aug 1998
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32 ACOEM (2005) Medical Surveillance of Workers Exposed to Crystalline Silica
http://www.acoem.org/guidelines.aspx?id=746#


37 Ng TP, Chan SL. Lung function in relation to silicosis and silica exposure in granite workers. Eur Respir J. 1992; 5 (8):986-91

38 www.gs.gov.nl.ca/ohs/silica_code_of_practice.pdf - 2010-02-04

www.icohweb.org/core_docs/code_ethics_eng.pdf


42 Spirometry Longitudinal Data Analysis (SPIROLA) Software;
http://www.cdc.gov/niosh/topics/spirometry/spirola-software.html last accessed 28.4.10


45 Cowie RL. The epidemiology of tuberculosis in gold miners with silicosis. Am J Crit Care Med. 1994; 150: 1460-1462


There is uncertainty in Great Britain (GB) about what constitutes appropriate health surveillance for silica-exposed workers, despite evidence that new cases of silicosis are occurring. The latter is supported by data from UK-based, HSE funded, national surveillance systems for work-related illness. There is also evidence to suggest that the risk of silicosis is finite at current permissible exposure levels.

Many of the industries in GB in which exposure to Respirable Crystalline Silica (RCS) may arise have signed up to a Social Dialogue Agreement (SDA), a pan-European initiative to improve the control of silica dust exposure. In part, this agreement is a commitment to undertake health surveillance where this is necessary because of a potential continuing risk of silicosis, even when recommended engineering and other controls are in place. The appropriate target population for this surveillance would likely include all workers who are exposed to levels of crystalline silica that place them at risk of developing silicosis or other silica-related lung diseases.

Consequently, the GB regulator wishes to establish a standard for the health surveillance of silica-exposed workers, in order to assess whether dutyholders are complying with their duties under appropriate legislation.

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