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GUIDANCE NOTE FOR OCCUPATIONAL MEDICAL PRACTITIONERS

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LUNG FUNCTION TESTING

Mine Health and Safety Inspectorate

Minerals and Energy for Development and Prosperity

5.3.1.2 Biological false positive results

The important causes of biological false positives in spirometry differ at baseline from subsequent tests.

- False positives on baseline testing

Occupational medical practitioners are cautioned to be aware of the contribution of ethnic factors in determining lung function. It has been repeatedly observed in studies of populations of African ethnic origin that observed spirometric values are 5 - 13% lower than in comparable populations of European ethnic origin. Although this phenomenon is well known, there is no reliable method of taking such differences into account in a fair and systematic fashion. It can be expected that 10 - 15% of otherwise healthy persons of African ethnic origin will record a mild restrictive abnormality in spirometric testing when ECCS reference values are used without an ethnic correction factor, even though these individuals have no objective respiratory abnormality detectable and have normal exercise capacity. Consequently the presence of a mild restrictive abnormality in the correct context is not a sufficient basis for considering a person unfit. Spirometry must always be interpreted clinically. The purpose of documenting a person's level of lung function at an initial examination is in order for any future health events to be measured against a baseline. This is the most reliable and informative manner in which to interpret spirometry and has the advantage of minimizing the problems inherent in a choice of any particular set of reference values.

- False positives on periodic testing

In medical surveillance using spirometric testing the signal of interest is the contribution of occupational exposures to declining lung function. All other causes of accelerated decline in lung function can therefore be regarded as noise or false positives, for example the progressive onset of obesity will influence spirometry as would intercurrent illnesses or events such as chest infections or chest trauma.

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Chief Inspector of Mines

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Table 1: Guide for Grading Pulmonary Impairment According to Percent of Predicted Spirometry

	Normal	Mildly Impaired	Moderately Impaired	Severely Impaired
FEV_1	>80%	60-79%	41-59%	<40%
FVC	>80%	60-79%	51-59%	<50%
FEV_1/FVC	>75%	60-74%	41-59%	<40%

5.3 False positive causes of abnormal results

5.3.1 Before acting on an apparently abnormal spirometric test, the occupational medical practitioner needs to consider again the possibility of a false positive test. Causes of false positives are technical or biological.

5.3.1.1 Technical false positive results

The causes of these include incorrect entering or measurement of data such as age, height or ambient temperature; differences in head or body position; a different or malfunctioning spirometer or person administering the test; differing amounts of effort from the person being tested. The FEV1 is usually underestimated because of insufficient or poorly coordinated effort in early expiration. The FVC is usually underestimated because not enough time is allowed for lung emptying. This is particularly the case when airflow obstruction is present and there is a low flow rate at the end of expiration. In this instance the severity of airflow obstruction will be underestimated.

5.2.4 Accelerated Annual Decline in FEV1 or FVC:

This is interpreted when the decline in an individual's FEV1 or FVC exceeds an annual average of 200-ml (0.2L) between tests. The normal rate of annual decline in these parameters is about 40 ml per year. Normal people can be expected to show a 10%, but less than 15% decline in observed lung volumes during the 20 years from age 20 to 40. There are percentile charts in existence that enable more precise estimations of annual decline in lung function.

5.2.5 Grading the Severity of Spirometric Abnormality:

5.2.5.1 Spirometry has a modest correlation with ability to perform work as indicated by performance in formal exercise testing. Spirometry should therefore be viewed as a broad, rather than as a precise indicator of fitness to perform work.

5.2.5.2 Spirometric abnormalities can be graded as mild, moderate or severe. Abnormalities are graded according to the index (FEV1, FVC or FEV1/FVC) indicating the most impairment of lung function. A guide to the grading of abnormality, as recommended by the ATS is contained in the Table 1 below. In general terms the severity of implied impairment in spirometric abnormalities is:

5.2.5.2.1 Mild Impairment: Not usually associated with diminished ability to do most jobs.
5.2.5.2.2 Moderate Impairment: Progressively lower levels of lung function associated with diminished ability to meet the physical demands of many jobs.
5.2.5.2.3 Severe Impairment: Unable to meet the physical demands of most jobs, including travel to work.

5.2.5.3 Limitations of spirometric grading of physiological abnormality: the major use of spirometry is that it can provide a precise and reproducible measurement of an individual's lung function. It cannot be relied on to always give a correct evaluation of the full degree of an individual's degree of cardio-respiratory fitness or impairment. In the event of discrepancy between an individual's symptoms and degree of spirometric impairment; or if more information is required to evaluate fitness to perform an occupation; or to support an application for compensation benefits, more detailed lung function testing or formal exercise testing may be appropriate as an adjunct to clinical evaluation.

GUIDANCE NOTE FOR OCCUPATIONAL MEDICAL PRACTITIONERS: LUNG FUNCTION TESTING

ACRONYMS

ATS	:	American Thoracic Society
BTPS	:	Body Temperature and Pressure at Sea Level
ECCS	:	European Community for Coal and Steel
MOHAC	:	Mining Occupational Health Advisory Committee
MHSA	:	Mine Health and Safety Act, 1996 (Act No. 29 of 1996)
OEM	:	Original Equipment Manufacturer

1. THE STATUS OF THIS GUIDANCE NOTE

1.1 This guidance note has been compiled by the MOHAC to assist employers preparing a comprehensive Lung Function Test Programme.

1.2 A guidance note sets out good practice and will be widely distributed by the Mine Health and Safety Inspectorate within the industry. As is the case with all other documents setting out accepted good practice, the application of inferior practices without justification could be regarded as negligence.

2. RELEVANT PROVISIONS OF THE MHSA

2.1 The establishment of a system of medical surveillance and the role of the risk assessment process therein is covered in some detail in the guideline for the compilation of a mandatory code of practice for the establishment of a system of medical surveillance. However, there are a few provisions of the MHSA dealing with these issues that are worth repeating:

2.1.1 Section 11 of the MHSA requires the employers to identify hazards, assess the health and safety risks to which employees may be exposed while they are at work and to record the significant hazards identified and risks assessed.

2.1.2 Section 11(2) requires every employer, after consulting the health and safety committee at the mine, to determine all measure, including changing the organisation of work and the design of safe systems of work, necessary to, first, eliminate any recorded risk; secondly, to control any recorded risk at source; thirdly, to minimise any recorded risk; and fourthly, in so far as the risk remains, to provide personal protective equipment and to institute a programme to monitor the risk.

2.1.3 Section 13(1) requires every employer to establish and maintain a system of medical surveillance of employees exposed to health hazards if it is necessary to do so in terms of the risk assessment, or if required to do so by regulation or notice in the Government Gazette.

2.1.4 Section 13(2) provides that every system of medical surveillance must be appropriate having regard to the health hazards to which employees are or may be exposed and must be designed so that it provides information that the employer can use in determining measure to eliminate, control and minimise the health risks and hazards to which employees are or may be exposed; or in determining measures to prevent, detect and treat occupational diseases.

2.1.5 Medical surveillance must consist of an initial medical examination and other medical examinations at appropriate intervals (section 13(2)(c)) and an exit examination (section 17(1)). A record of medical surveillance must be kept for each employee exposed to a health hazard (section 13(3)(c)) until the mine closes whereafter those records must be delivered to the Medical Inspector (section 13(8)).

5. CRITERIA FOR INTERPRETING SPIROMETRY RESULTS

5.1 Normal or acceptable results

5.1.1 Interpretation of spirometry results can only take place with the assurance that correct procedures have been followed and an acceptable test is being interpreted. If previous spirometric results or other medical facts are available the interpretation should be informed by reference to these facts.

5.1.2 A spirometric test is normal or acceptable if:

5.1.2.1 best FEV1/Best FVC > or = 75%; and

- best FVC > or = 80% predicted value; and
- there is a less than 200 ml averaged annual decline in FEV1 or FVC; or
- there is a less than 10% decline in FEV1 or FVC from the initial or baseline spirometric test.

5.2 Characterizing abnormal spirometric results

5.2.1 Obstructive Abnormality:

This is interpreted when the FEV1/FVC ratio is below the normal range. This indicates airflow limitation through the airways. The severity is graded on the basis of best FEV1 as a % predicted.

5.2.1.1 *Reversibility*: an obstructive abnormality is deemed reversible if there is 15% or greater increase in the FEV1 following administration of salbutamol (see 4.3.5).

5.2.2 Restrictive Abnormality:

This is inferred if there is a reduction of FVC without a reduction of the FEV1/FVC ratio. This may indicate lung tissue or chest wall problems or may be a non-specific finding. The severity is graded on the basis of best FVC as a % predicted.

5.2.3 Mixed Obstructive And Restrictive Abnormality:

This is interpreted when there is both a reduced FEV1/FVC ratio and a reduction of FVC. This may indicate problems both in the airways and the lung tissue. The severity is graded on the basis of either best FEV1 or best FVC as a % predicted, with the worst of the two results determining the grade.

4.4 Predicted or reference values for spirometry

4.4.1 At the present time there is no universally accepted practice for spirometric reference values in South Africa. This lack of uniform practice relates partly to observed ethnic differences in spirometric performance. Trying to take such observed differences into account presents practical difficulties in an ethnically heterogeneous country such as South Africa.

4.4.2 Any of the following practices could be considered acceptable. The occupational medical practitioner is advised to use informed judgement in deciding which practice to use.

4.4.3 One reference value for all persons

The recommended practice is to use reference values from the ECCS - a metastudy of European industrial workers that is universally available in spirometers with inbuilt software. The relevant equations for males are:

- FEV1 (litres)=0.058 x height (cm) - 0.026 x age (years) - 4.34
- FVC (litres)=0.043 x height (cm) - 0.029 x age (years) - 2.49

This method has the advantage of uncomplicated usage. The main disadvantage is mentioned in 5.3.2 - Biological false positives.

4.4.4 Ethnically specific reference values

It is recommended that the ECCS values always be used for people of European ethnic origin. For people of African ethnic origin it is acceptable to make use of:

4.4.4.1 References values for African males based on a study conducted in South Africa where:

- FEV1 (litres)=0.029 x height (cm) - 0.027 x age (years) - 0.535
- FVC (litres)=0.048 x height (cm) - 0.024 x age (years) - 3.08

OR

4.4.4.2 Correction factors for ethnic variation in spirometry: this is usually provided for in computer software systems. The correction factor for persons of African origin in relation to the ECCS values should be between 5% and 13%. A figure of 5% is recommended.

4.4.4.3 For persons of race or Indian origin: the practice outlined in either 4.4.3 or 4.4.4.2 is acceptable.

3. SPIROMETRY

3.1 Definition of spirometry: spirometry is the measurement of the volume of air inspired and expired over a period of time.

3.1.1 Spirometry is an objective test of lung function that is required as a part of medical surveillance for miners exposed to respiratory health hazards. For spirometry to add value to a medical surveillance programme, careful attention must be given to testing procedures. The occupational medical practitioner must be familiar with the physiological and pathophysiological principles that underlie spirometry in order for tests to be correctly interpreted.

3.2 General description of test: individual exhales forcibly from total lung capacity (maximal inspiration) to residual volume (complete exhalation). This procedure is repeated until test acceptability criteria are met, or eight adequate attempts have been made.

3.3 Physiology: spirometry is a test of the dynamic properties of the chest wall, lung and airways. The maximum amount of air entering the lungs is determined by alveolar size and number, inspiratory muscle strength and effort, and lung elastic recoil.

3.4 Physics: in order to standardise gas volumes for temperature and barometric pressure the appropriate BTPS correction must be made.

3.5.Spirometry measures will include:

3.5.1 • FEV1 : forced expiratory volume in one second.
3.5.2 • FVC : forced vital capacity is the maximum volume of air exhaled with forced effort from maximal inspiration.
3.5.3 • FEV1/FVC : expressed as a percentage.

3.6 Purpose of test: to demonstrate the maximal volume of air and the rate that air can be moved into and out of the lungs.

3.7 Equipment: Spirometer. Many types with various properties are available.

3.8 Consumables: chart paper for permanent trace, single use cardboard mouthpieces, bacteriological filter (particularly if a forced inspiratory manouvre is performed).

4. PROCEDURES

4.1 Prior requirements for spirometry

4.1.1 A person competent to do so must conduct spirometry.

4.1.2 Read the spirometer manual and follow the manufacturer's instructions appropriately.

4.1.3 Collect data for BTPS correction:

4.1.3.1 Record ambient temperature using a room thermometer (repeat measures, in accordance with the OEM's instructions, are required as the temperature changes during the day).
4.1.3.2 Determine ambient barometric pressure from nearest weather station (usually 625 mm Hg in Johannesburg).

4.1.4 Calibration of instrument:

4.1.4.1 Leak test (if appropriate to the instrument) - every 50 tests.
4.1.4.2 Volume calibration with a 3 liter syringe - before and after every testing/monitoring session (should remain + 3% accurate).
4.1.4.3 Flow calibration - should be calibrated in accordance with OEM's instructions.

4.1.5 Explain test procedure to individual, including:
- full inspiration;
- mouthpiece inside mouth, avoiding leaks and blowing as if into a trumpet;
- keep exhaling forcefully from the beginning until instructed to stop;
- two practice efforts;
- standing or sitting (always follow the same practice);

4.1.6 Make provision for good hygiene (disposable mouthpieces, gloves and well-ventilated rooms). Follow the manufacturer's instructions for disinfection.

4.1.7 Precise, calibrated instruments are required to measure height and weight (barefoot in light clothing).

4.1.8 If the test shows an obstructive abnormality (see 5.2.1) then it should be repeated 15 minutes after administration of 400 micrograms of salbutamol per inhaler. This test is performed as a means of evaluating the reversibility of the obstructive abnormality.

4.2 Criteria for test acceptability

4.2.1 Acceptability criteria: a minimum exhalation time of 6 seconds. If greater than 0.05L is exhaled in the last second (ie between 5 and 6 seconds), then exhalation time should continue; the test should demonstrate a satisfactory start, smooth, continuous exhalation, with maximal effort and without coughing, early termination, leak or obstruction to mouthpiece.

4.2.2 Reproducibility criteria: a minimum of three acceptable efforts should have FEV1 and FVC within 5% of the best effort.

4.2.3 A maximum of 8 expiratory efforts per session; and

4.2.4 BTPS correction factor should be applied (to correct for the influence of altitude and temperature on gas volumes). The method for doing this is explained in the spirometer manual.

4.2.5 People incapable of performing reproducible spirometry: from various studies it is known that about 5% of any population is incapable of performing an acceptable test, even after eight efforts. There are many reasons for this phenomenon. If a person fails to perform an acceptable test because of failure to meet the reproducibility criteria alone, then the test should be repeated again after two weeks. If the person still fails to produce an acceptable test then the best values achieved should still be recorded with a comment - poor reproducibility. Clinical judgement must be used in the evaluation of such persons.

4.3 Results and records

4.3.1 On the occasion of each test record the best value achieved for FEV1 and FVC in acceptable tests. The two values do not need to come from the same effort.

4.3.2 Record the value in liters to two decimal places. A copy of the test print out must be placed in the employees' medical record and should include the person's name, the date, height and, if available, BTPS factor used.

4.3.3 The best value obtained should also be compared to a predicted or reference value, accounting for age, gender and height:

- Best FEV1 measured / FEV1 predicted expressed as a percentage
- Best FVC measured / FVC predicted expressed as a percentage

4.3.4 A baseline spirometric test is a spirometric test performed on initial examination, or on initiation of spirometry as a part of medical surveillance, or any other test at which the values for spirometry are the best ever recorded from that employee.

4.3.5 If subsequent spirometric tests show evidence of an accelerated annual decline in lung function (see 5.2.4.) from the baseline spirometric test, then clinical evaluation is required.