Black Mountain Mining

BMM-HSE-VOH-SOP-0028 Management and Control of TB in SAMI

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❖ Change History

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2024/11/06	1	Charles William Klopper	New document, extracted “Management & Control of Tuberculosis” from SOP for Medical Surveillance

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❖ Definitions and Abbreviations

Word / Phrase / Abbreviation	Definition
3HP	Three months of once-weekly INH plus Rifapentine.
4R	Four months of daily rifampicin.
Adherence	The extent to which the behaviour of a person corresponds with agreed recommendations from a healthcare worker for taking medication, following a diet and/or making lifestyle changes.
AIDS	Acquired Immunodeficiency Syndrome.
AMR	Annual Medical Report.
ART	Antiretroviral Therapy.
Case of tuberculosis	Either a definite case (as defined below) or a patient that has been diagnosed with TB by a health worker based on clinical picture, x-rays or other tests, and who has started on a full course of TB treatment.
Clinician	A health professional, such as a doctor or nurse, who is directly involved in patient care.
Close contact	A person who shared the same enclosed living or working space for at least eight continuous hours with the index case during the 3 months before commencement of the current treatment episode.
COIDA	Compensation for Occupational Injuries and Disease Act, Act No. 130 of 1993.
Contact	A person who has been sharing the same environment with a person who has confirmed infectious TB disease (index case).
DMRE	Department of Mineral Resources and Energy.
DR-TB	Drug-resistant TB.
DST	Drug Susceptibility Testing.
GXP	GeneXpert.
Health worker	All people primarily engaged to enhance health by providing preventative, curative, promotional or rehabilitative health care services.
HIV	Human Immunodeficiency Virus.
INH	Isoniazid.
LTB	Latent TB.
LTBI(s)	Latent TB infection(s) which is a state of persistent immune response to stimulation by the Mycobacterium TB antigens without evidence of clinically manifested active TB.
MBOD	Medical Bureau for Occupational Diseases.
MCOP	Mandatory Code of Practice.
MDR-TB	Multidrug-Resistant Tuberculosis, which has the following categories:

Word / Phrase / Abbreviation	Definition
	a) "New case of MDR-TB" means a patient who has received no anti tuberculosis treatment for TB, MDR—TB or Extensively Drug-Resistant Tuberculosis (XDR-TB) or received less than 4 weeks anti-TB drugs. b) "Previously treated with first-line drugs only" means a patient who has been treated for 4 weeks or more with first line drugs.
MHSA	Mine Health & Safety Act, Act 29 of 1996 (as amended).
MHSC	Mine Health and Safety Council.
Monitoring	The tracking of key elements of programme performance (inputs, activities and results) on a regular basis to provide continuous information on the progress towards achieving goals, and alert staff and managers to problems, providing an opportunity for these to be resolved early.
NAT	Nuclear Amplification Test.
NDOH	National Department of Health of South Africa.
New case of TB	in cases of TB, other than MDR-TB, a patient who has never had treatment for TB or who has taken anti-tuberculosis drugs for less than 4 weeks and possibly having smear positive/ negative PTB or Extra Pulmonary TB (EPTB).
NIOH	National Institute for Occupational Health.
NTBMG	National Tuberculosis Management Guideline issued by NDOH.
ODMWA	Occupational Diseases in Mines and Works Act, Act No.78 of 1973 (as amended).
OMP	Occupational Medical Practitioner
OHC	Occupational Health Clinic
Peri-mining communities	The people who live in the vicinity of mining operations and who have been, or could be directly affected by mining-exploration, construction, operational or divestment activities.
PLHIV	People living with HIV.
PPD	Purified protein derivative standard; TB skin test; T ST; Mantoux TST.
PTB	Pulmonary TB.
Relapse	A pulmonary TB patient who received treatment and was declared cured or treatment completed at the end of the treatment period and has now developed sputum smear or culture positive pulmonary TB again.
SAMI	South African Mining Industry
Significant TB	A known exposure to a person with PTB who shared the same enclosed space for one or more nights, or for frequent or extended daytime periods during the three months before the index patient starting their TB treatment.

Word / Phrase / Abbreviation	Definition
Silicosis	A lung fibrosis caused by the inhaling of silica-containing dust.
SOP	Standard Operating Procedure
TB	Tuberculosis.
TB contact	All people (family members, colleagues and other individuals, regardless of age and/or HIV-status) who have had a significant TB exposure.
TB disease	A disease caused by the Mycobacterium tuberculosis bacterium, either bacteriologically confirmed or clinically diagnosed.
TPT	TB preventive treatment.
TST(s)	Tuberculin skin test(s).
VOH	Ventilation & Occupational Hygiene
WHO	World Health Organization.

1. Purpose

The purpose of the Management & Control of Tuberculosis procedure is to maintain a tuberculosis program at the mine to reduce the burden of TB, the prevention of disability and mortality, through the prevention, early detection and successful treatment of cases as well as to reduce the incidence of TB by preventing progression from Latent TB to TB disease.

2. Scope

The main target population for this guidance note is the BMM employees (Direct & Business Partners), Aggeneys town community and peri-mining communities who are exposed to TB, including those that may require TPT once the disease has been excluded through testing and the exclusion criteria has been considered.

3. Objectives

The objectives of a TB control programme should be to:

i. Obtain at least 90% treatment success rate for all TB cases.

ii. Reduce defaulter rate to less than 5%.

iii. Implement Directly Observed Treatment course (DOTS) for 100% of TB cases on intensive and continuation treatment phases.

iv. Notify 100% of TB cases to the NDOH.

v. Report all TB cases to the DMR as per the Health Incident Report (HIR), Reporting on TB & HIV and the Annual Medical Report requirements.

vi. Submit 100% of TB cases reportable under ODMWA and COIDA.

vii. Screen all close contacts.

viii. Achieve 100% investigation of all symptomatic TB contacts.

ix. Conduct annual TB symptomatic screening of all employees.

x. Ensure continuity of care for patients on TB treatment.

xi. Promote access to HIV and AIDS prevention, treatment care and support services for all employees with TB by ensuring the following:

   a. Offer every TB patient with provider-initiated HIV counselling and testing.

   b. Put every TB and HIV co-infected patients on Highly Active Antiretroviral Therapy (HAART).

   c. Screen all HIV positive patients for TB with increased frequency.

xii. To reduce the incidence of TB in the mines by preventing progression from LTB to TB disease.

4. Related COPs, SOPs and Other Documents

a) A Management and Control Programme of Tuberculosis in SAMI, Reference DMRE 16/3/2/3-A8

b) The Management of Latent Tuberculosis Infections in SAMI, Reference DMRE 16/3/2/3-B5

c) Occupational Hygiene Baseline Risk Assessment

d) VOH-COP-005: Minimum Standards of Fitness to Perform Work at a Mine

e) VOH-COP-002C Prevention, Mitigation and Management of COVID-19

f) VOH-COP-006: Occupational Health Programme on Personal Exposure to Airborne Pollutants

g) VOH-SS-005A and B: Job Placement Medical Guide Matrix

h) VOH-BMF-005: Occupational Hygiene Exposure Profiles

i) HR policies, procedures, documents

j) Occupational Risk Exposure Profiles (OREPs)

5. Legislative Requirements

The following legislative requirements has reference:

a) MHSA - Act 13: Employers to establish system of medical surveillance.

b) MHSA - Act 14: Record of hazardous work

c) MHSA - Act 15: Records of medical surveillance

d) MHSA - Act 16: Annual medical reports

e) MHSA - Act 17: Exit certificates.

f) MHSA - Act 19: Employee's right to information

g) MHSA - Regulation 11: Occupational Health

6. Risk Management

An Occupational Health Baseline Risk Assessment was conducted. Periodic reviews and updates of the baseline risk assessment will be conducted as and when required.

7. Management & Control Programme for Tuberculosis in SAMI

7.1. Passive Case Finding

Passive case finding will be promoted through the following practices:

7.1.1. All TB education initiatives, which includes sessions by the Wellness Coordinator, and other formal practices such as peer educators or

presentations, and which will reach all employees at least once a year includes:

a) The signs and symptoms of TB.

b) Information to employees on the importance of early presentation and diagnosis, prevention of transmission and compliance with medication regimens.

7.1.2. A high index of suspicion for TB are inculcated in all health workers and are maintained through continuous training as well as regular awareness campaigns.

7.1.3. Access to good quality, diagnostic and treatment service for TB, and integrated TB and HIV treatment services are provided through the BMC Clinic and/or the NDOH clinic located in Aggeneys Town. Access to diagnostic and treatment services for TB is provided by the on-site State and Private Clinic facilities.

7.2. Active Case Finding

7.2.1. Where risk assessment indicates that employees should be screened by means of annual chest x-rays, a competent person will perform these x-rays as part of the periodical medical surveillance.

7.2.2. All employees will undergo symptomatic screening for TB at least once per year during periodical medical surveillance and when symptoms indicate (TB questionnaire).

7.2.3. Screening of close contacts of TB index cases will be initiated as per NTBMG.

7.3. TB Case Definitions

The case definition of TB is any patient with either of, or both, the following compatible clinical or radiological features:

7.3.1. Bacteriologically confirmed: A patient with Mycobacterium tuberculosis complex identified from a clinical specimen, either by smear microscopy, culture or molecular assays; and/or

7.3.2. Clinically diagnosed: A person started on TB treatment by a health worker based on clinical presentation, x-rays findings or other tests.

7.4. Diagnosis

7.4.1. In all suspected cases of TB, a chest x-ray and the following laboratory investigations will be conducted:

7.4.1.1. At least two sputum smear examinations; and

7.4.1.2. Sputum culture and first line DST or NAT (e.g. Gene-Xpert).

7.4.2. In all confirmed MDR-TB cases second line DST will be conducted.

7.4.3. Only laboratories accredited by the South African National Accreditation System (SANAS) will be used to conduct the tests contemplated in 4.1.1 and 4.1.2 above. The target for the turnaround time for smear and nuclear amplification test is to have the results back at the health facility within 48 hours. The target for the turnaround time for culture is to have the results back at the health facility within 2-8 weeks.

Note: Under ODMWA; pleural, inter-thoracic lymph nodes and pericardial TB is considered as occupational tuberculosis. Investigation and diagnosis of disease involving these sites may require additional investigations.

7.5. Treatment Category

Patients will be classified as either "new" or " previously treated" patients as follows:

7.5.1. New patients are those who are a new case of TB or a new case of MDR-TB; and

7.5.2. Previously treated patients are those who:

7.5.2.1. Have taken TB treatment for 4 weeks or more in the past and either relapsed, defaulted or had treatment failure and possibly having positive or negative smear microscopy and culture or extra pulmonary TB disease; or

7.5.2.2. In the case of MDR-TB, are previously treated with first-line drugs only.

7.6. Treatment Regiments

Treatment regiments will be as recommended in the NTBMG (as set out below).

REGIMEN 1: For new patients and previously treated			
Pre-treatment body weight	**Intensive Phase** 7 days a week for 2 months	**Continuation phase** 7 days a week for 4 months	
	RHZE (150,75,400,275)	**RH (150,75)**	**RH (300,150)**
30-37 kg	2 tabs	2 tabs	
38-54 kg	3 tabs	3 tabs	
	4 tabs		2 tabs
>70kg	5 tabs		2 tabs

Note: Where NAT is used, and the result is Rifampicin susceptible then Regimen 1 should be used for both new and previously treated patients. Where the NAT result is Rifampicin resistant, the patient should be started on MDR-TB treatment. All Rifampicin resistant patients should have a culture, and first line DST conducted to confirm MDR-TB. The dosages may be adjusted based on changes in weight. Treatment instituted at DOH clinic and follow-up done at both DOH clinic for treatment and clinical follow-up at Mine Clinic if employee.

7.7. Fitness to Perform Work

Evaluation of fitness to return to work will be individualised and aligned with the requirements of the MCOP for Minimum Standards of Fitness to Perform Work. The focus is to ensure the employee be clinically well and smear negative. An assessment for fitness to perform work will be conducted prior to return to work to determine whether the employee is fit to perform their previous work. Other reasons for return to work will be at the OMP discretion.

NOTE: Loss of income and disability will be managed in accordance with the relevant legislation and collective agreements.

7.8. Case Monitoring

7.8.1. Smear positive patients should be kept isolated in the ward where possible, until they are smear negative.

7.8.2. A holistic package of TB care will include: HCT; adherence counselling; psychological support; nutritional assessment and education; and integration with the HIV prevention and management programme.

7.8.3. A treatment adherence programme will be implemented for all TB cases and will cover the following:

7.8.3.1. Education about the disease.

7.8.3.2. Duration of treatment.

7.8.3.3. Medication to be taken and possible side effects.

7.8.3.4. Importance of adherence to prescribed treatment regime.

7.8.3.5. Psychological support when required.

7.8.3.6. Treatment support and monitoring.

7.8.4. The response to treatment will be assessed at the end of the intensive and continuation treatment phases in accordance with the NTBMG.

7.8.5. For assessment and reporting of possible disability, a clinical examination, chest-x-ray and lung function test will be performed six to twelve months after completion of therapy.

7.8.6. Leave arrangements for employees on TB treatment will take account of the following:

7.8.6.1. Taking leave during the initial phase of treatment is not encouraged.

7.8.6.2. When leave is taken, there must be counselling and provision of sufficient medication.

7.9. Treatment Outcomes

Treatment outcomes will be classified as follows:

Cured	Patient whose baseline smear (or culture) was positive at the beginning and who is smear-negative (or culture negative) in the last month of treatment and on at least one previous occasion at least 30 days prior to the last month of treatment.

Treatment completed	Patient whose baseline smear (or culture) was positive at the beginning and has completed treatment but does not have a negative smear/culture in the last month of treatment and on at least one previous occasion more than 30 days prior.
Treatment failure	Patient whose baseline smear (or culture) was positive and remains or becomes positive again at 5 months or later during treatment.
Died	Patient who dies for any reason during the course of TB treatment (see note below).
Treatment default	Patient whose treatment was interrupted for more than two consecutive months before the end of the treatment period.
Transferred out	Patient who has been transferred by the employer to another reporting unit (e.g. district, province or country) and for whom the treatment outcome is not known.

NOTE: In addition, deaths while on treatment should be sub-classified as:

i. Those due to TB;

ii. Those due to other causes; and

iii. Those in which the cause of death could not be determined.

Where autopsies are requested, these will be performed with appropriate consent of the relatives. Autopsy results should be requested from the NIOH in order to determine compensation where indicated.

7.10. Treatment Follow-up

7.10.1. Where a patient is separated from work while on treatment the employer will make reasonable efforts to ensure continuous treatment and determine the final outcome. The employer will, as far as reasonably practicable, try to arrange for the patient to return for assessment (at the end of treatment). If this is not possible, alternative arrangements will be put in place to determine the outcome.

7.10.2. For those patients who interrupt treatment for less than two months refer to the protocol below (NTBMG):

Timing of Sputum Examination	Aim	Action	Comments
End of Intensive Phase			
One week before the end of the two months' intensive phase of treatment (at seven weeks)	To determine smear conversion a sign of good clinical progress. To guide the **health worker** on whether to change the	1) **If negative**, change 2) to the continuation phase of treatment at the end of the 8th week of intensive phase treatment. Register the patient as "negative".	This means the patient is responding well to treatment. Educate and counsel patient about importance of treatment compliance.

Timing of Sputum Examination	Aim	Action	Comments
	patient to continuation phase of treatment or extend the intensive phase.		
		3) a) **If positive**, check for treatment compliance, reassess patient clinically: Conduct LPA (or culture and DST, if LPA is not available).	This indicates the following: • That the initial phase of therapy was poorly supervised and that patient's compliance to treatment was poor.

Timing of Sputum Examination	Aim	Action	Comments
		b) Continue with the intensive phase treatment for one month. c) Register the patient as "positive". d) Review the drug susceptibility results when available.	• That there is a slow rate of progress with smear conversion, which is common in patients with extensive cavitations and a high bacillary load at diagnosis. • That the patient may have resistance to the other TB drugs i.e. Isoniazid (since only Rifampicin resistance was excluded upfront) or may have been reinfected with a drug resistant strain. • The patient could have non-tuberculous mycobacterial infection. • The patient may have another condition or taking other medication that affects the absorption or effectiveness of the **TB** drugs. • Patient may have been infected with mixed strains with amplification of resistant strains due to treatment. Address treatment compliance by counselling the patient and identifying a treatment supporter where necessary.
For Those Remaining Positive at 2 Months			
Repeat smear one week before the end of the third month (11 weeks)		4) **If negative and drug susceptible**, change to continuation phase of treatment at the end of the 12th week. Register the patient as "negative". 5) **If negative and Isoniazid mono resistant TB is confirmed**, continue	The intensive phase treatment is not extended beyond three months in patients with drug susceptible TB.

Timing of Sputum Examination	Aim	Action	Comments
		intensive phase treatment and refer patient to **MDRTB** for assessment and registration in DR-**TB** register. Register the patient as "Isoniazid mono-resistant **TB**" in the **TB** register. 6) **If still positive and** RRTB **or MDR-TB is confirmed**, stop treatment and refer patient to the **MDR-TB** treatment initiation site for assessment and treatment initiation. Register the patient as "RR-TB or **MDR-TB**" in **TB** register.	
End of Continuation Phase			
One week before the end of the four months' continuation phase (at 23 weeks)	To determine the final outcome of treatment for the patient.	1) **If negative**, stop treatment at the end of the 24th week of treatment. Register the patient as "cured".	Educate the patient about TB prevention and healthy lifestyle.
		2) **If positive**, stop TB treatment. Register patient as "treatment failure". a) Conduct LPA and DST for pyrazinamide and ethambutol. b) Review the results when available.	This indicates the following: • That the patient was reinfected with a sensitive or resistant strain. • The treatment during the continuation phase was unsupervised and patient compliance was poor.
For Those Remaining Positive at 6 Months			
	To determine further management of the patient.	1) **If drug susceptible**, restart TB treatment, counsel the patient and provide treatment support.	

Timing of Sputum Examination	Aim	Action	Comments
		2) **If DR-TB** RR-TB**,** Isoniazid **Mono resistant, MDR-TB,** Other resistance**,** refer to the **MDR-TB** treatment initiation site hospital for assessment and treatment.	

7.10.3. Referral to another facility for TB care beyond employment:

Note: *Where required/appropriate, referrals to other facilities will be done in conjunction with the local NDOH clinic.*

7.10.3.1. Where a patient's employment is terminated while on TB treatment, the patient will be referred to an appropriate TB care facility where the patient can continue with treatment.

7.10.3.2. The TB care facility concerned will be contacted and alerted of the patient referred to it. The TB care facility will also be provided with contact details of the patient. If the TB care facility concerned is in another country, the National TB Manager of that country will be contacted.

7.10.3.3. The patient will be provided with a letter or form detailing the diagnosis, bacteriological investigations conducted (including dates), treatment regimen dosages and other chronic medication or ancillary medication that the patient is taking. The letter should also indicate the expected date for follow up at the mine health centre/one stop services during and post treatment (12 months after treatment completion). The referral will should be accompanied by:

a) GW 20/14 Referral Form prescribed by the NDOH;

b) The patient's health record (green card); and

c) MBOD guideline/COIDA (first, progress and final report) for benefit examination and compensation.

7.10.3.4. The patient will be provided with a counselling package which includes:

a) the available information on the receiving facility; and

b) Importance of presenting to the receiving facility to his home and continuation and when they should present to the clinic/ hospital

Note: A copy of the GW 20/14 Form will be forwarded to the province/country where the patient resides to ensure continuum of treatment and care. The acknowledgement slip on the form must be completed by the receiving facility and returned to the referring mine health facility.

7.10.4. Provision of TB services where employer does not have a health care facility. Where the employer does not provide access to health services, it will refer employees to the nearest local health care facility for diagnosis and treatment.

7.10.5. Infection control

The TB management control programme will include appropriate infection control measures, covering at least:

7.10.5.1. Workplace and administrative controls;

7.10.5.2. Environmental control measures;

7.10.5.3. Measures to protect health workers and staff; and

7.10.5.4. An implemented written infection control plan for each facility

7.11. Reporting & Monitoring

Reporting and monitoring initiatives will include:

Note: Where required/appropriate, parts of the required reporting and monitoring will be done in conjunction with the local NDOH clinic.

7.11.1. NDOH will be notified of all TB cases using the Notifiable Medical Conditions Form (GW 17/5);

7.11.2. The monthly report for the District Health Information System (DHIS) and quarterly report for the Electronic TB Register (ETR.net) should be submitted to the district health authorities;

7.11.3. Reporting will be done as per the MHSA requirements, including the Reporting on TB & HIV (DMR 164), Annual Medical Report (DMR 165) and Health Incident Report (DMR 231);

7.11.4. All possible Occupational TB cases will be reported to the Director: MBOD at the time of diagnosis and after the post treatment completion examination using the MBOD prescribed form;

7.11.5. All deaths presumed to be due to TB will be notified on the death form BI-1663 from Department of Home Affairs;

7.11.6. In cases of deaths due to other causes, cardiorespiratory organs will be sent to the NIOH for postmortem and Consent Form for a post-mortem will be filled. These will be performed with appropriate consent of the next of kin; and

7.11.7. The MHSC TB Programme Review Tool for the mining industry will be used as a standard tool for monitoring and evaluating the TB control programme.

7.12. Training & Support

The BMC TB control programme will include the following training initiatives:

7.12.1. Health Workers will be specifically trained in all aspects of TB management in accordance with the NTBMG, DMR Guidance Note and the MHSC TB Review Tool;

7.12.2. All mine health and safety representatives will be trained about the signs and symptoms of TB, the importance of early presentation and diagnosis, and on prevention of transmission; and

7.12.3. Data managers involved in the TB control programme will be trained in the collection, recording, analysis and reporting of TB data.

7.13. Liaison with the Public Sector

A working relationship is in place with the local, regional and provincial NDOH. Interaction between medical and nursing staff involved with the management of patients with TB and district health staff occurs on a regular basis.

7.14. Documentation to be Available

The following documents will be available:

7.14.1. Copies of the latest NTBMG and this guidance note will be available in all clinics and centres where TB is treated.

7.14.2. A copy of the mine's TB control programme will be available at the mine.

7.15. Performance Indicators

Reporting and monitoring initiatives includes:

7.15.1. The mine's TB control programme will provide for the collection of data that will allow calculation of the following:

7.15.1.1. Percentage of TB, MDR-TB and XDR TB patients started treatment;

7.15.1.2. Percentage of TB patients tested for HIV;

7.15.1.3. Percentage of TB/HIV co-infected patients on ART (not started);

7.15.1.4. Percentage of TB patients with known HIV status;

7.15.1.5. Percentage of all employees screened for TB;

7.15.1.6. New Smear Positive Cure Rates;

7.15.1.7. New Smear Positive Death Rates;

7.15.1.8. New Smear Positive Defaulter Rates;

7.15.1.9. Treatment success for all TB;

7.15.1.10. Defaulter rate for all TB; and

7.15.1.11. Death rate for All TB.

Indicator definitions and targets (as per NTBMG)

No	Indicator	Description	Source	Collection	Target
1	New smear positive cure rates.	**Numerator:** Number of new smear positive cases cured. **Denominator:** Total number of new smear-positive cases started on treatment.	Electronic TB Register (ETR.net)	Quarterly	More than 90%
2	New smear positive death rates.	**Numerator:** Number of new smear positive cases that died. **Denominator:** Total number of new smear-positive cases started on treatment.	ETR.net	Quarterly	Less than 5%
3	New smear positive defaulter rate.	**Numerator:** Number of new smear positive cases that defaulted treatment. **Denominator:** Total number of new smear-positive cases started on treatment.	ETR.net	Quarterly	Less than 5%
4	Treatment success for all TB	**Numerator:** Number of all TB cases cured and completed treatment. **Denominator:** Total number of all TB cases started on treatment.	ETR.net	Quarterly	More than 90%
5	Death rate for all TB	**Numerator:** Number of all TB cases that died. **Denominator:** Total number of all TB cases started on treatment.	ETR.net	Quarterly	Less than 5%
6	Defaulter rate for all TB cases	**Numerator:** Number of all TB cases that defaulted treatment. **Denominator:** Total number of all TB cases started on treatment.	ETR.net		Less than 5%
7	Percentage of **TB** patients started on treatment	**Numerator:** Number of TB patients started on treatment. **Denominator:** Number of patients diagnosed with TB the ratio multiplied by 100.	ETR.net	Monthly	100%
8	Percentage **MDR-TB** and patients started on treatment	**Numerator:** Number of MDR-TB patients started on treatment. **Denominator:** Number of patients diagnosed with TB the ratio multiplied by 100.	ETR.net	Monthly	100%

No	Indicator	Description	Source	Collection	Target
9	Percentage of **TB** patients tested for **HIV**	**Numerator:** Number of TB patients tested for HIV. **Denominator:** The number of TB patients. The ratio multiplied by 100.			90%
10	Percentage of **TB** patients with known **HIV** status	**Numerator:** Number of TB patients with known **HIV** status. **Denominator:** Number of all TB cases. The ratio to be multiplied by 100.			90%
11	Percentage of **TB/HIV** coinfected patients on **ART** (not started on TB treatment)	**Numerator:** The number of TB/HIV coinfected patients on **ART**. **Denominator:** The number of all TB cases. The ratio to be multiplied by 100.			90%
12	Percentage of all employees screened for TB	**Numerator:** Number of employees screened for TB. **Denominator:** Number of all employees. The ratio multiplied by 100.			100%

7.16. Programme Performance Reviews

Reporting and monitoring initiative reviews will include:

7.16.1. An annual internal review of the mine's TB control programme using the MHSC TB Review Tool to enable health workers to analyse their performance. Groups of mines (i.e. corporations, or mines of a certain type and in a certain area) may also gain insight through pooling their data for analysis, especially if the numbers of cases on individual mines are low.

7.16.2. An external review of the mine's TB control programme will conducted once every five years, where appropriate.

8. Management of Latent Tuberculosis in SAMI

8.1. Target Population

8.1.1. The main target population for this guidance note is the BMM employees (Direct & Business Partners), Aggeneys town community and peri-mining communities who are exposed to TB, including those that may require TPT once the disease has been excluded through testing and the exclusion criteria has been considered.

8.1.2. Eligibility for TPT are guided by the risk assessment of the mine, considering the risk populations.

8.1.3. Guidance Note for the Management of Latent Tuberculosis in SAMI, Annexure B refers: Algorithm for managing the population at risk of developing LTBIs in the South African mining industry.

8.1.4. The following are identified as risk populations for developing LTBIs:

8.1.4.1. Mine employees exposed to silica dust and those with silicosis.

8.1.4.2. Mine employees with compromised immune systems e.g. HIV disease, cancer, diabetes, etc.

8.1.4.3. Pregnant women with significant TB exposure irrespective of age, HIV status or TB exposure.

8.1.4.4. Healthcare workers exposed to employees with TB disease and those at the highest risk with compromised immune systems e.g. HIV disease, on cancer therapy, diabetes, etc.

8.1.4.5. Families of mine employees, mining communities and peri-mining communities where the contacts of mine employees with TB disease should be assessed for eligibility for LTB treatment. The high-risk groups include children under the age of five years, those living with HIV and the elderly.

8.2. Identifying LTB Cases (case finding)

8.2.1. Screening for active TB will be done on all high-risk populations before LTB testing and assessing for TPT eligibility.

8.2.1.1. TB screening

- Guidance Note for the Management of Latent Tuberculosis in SAMI, Annexure C refers: TB symptom screening tool for adults and children (adopted from the NDOH TB screening and testing standard operating procedure 2022)

8.2.1.1.1. All mine employees will be screened, refer to Annexure A of this SOP,for TB symptoms at each clinic visit (at least once per annual during periodical medical surveillance) and all the points of care, and those that are symptomatic, will be tested and treated for active TB.

8.2.1.1.2. Employees who have been previously treated for TB will be screened and tested after each exposure to a person with TB, forming part of contact tracing.

8.2.1.1.3. Employees newly diagnosed with HIV will be screened and tested for TB at the HIV diagnosis.

8.2.1.1.4. PLW-HIV in care should be tested annually for TB and this should be linked to the viral load follow up visit. In between the testing, PI-HIV should be screened,

tested and offered T PT where TB disease has been ruled out.

- Guidance Note for the Management of Latent Tuberculosis in SAMI, Annexure C refers: TB symptom screening tool for adults and children (adopted from the NDOH TB screening and testing standard operating procedure 2022)

8.2.1.1.5. All contacts of people with TB disease will be screened, tested - irrespective of symptoms - and treated for TB.

8.2.1.1.6. The identified risk populations for LTB will be screened for TB symptoms, TB radiological changes (chest X-ray) and TB sputum to exclude active TB disease.

- See Annexure C: TB symptom screening tool for adults and children (adopted from the NDOH TB screening and testing standard operating procedure 2022)

8.2.1.1.7. Risk populations who have completed TB treatment and have bacteriological proof of cure will be screened for TB symptoms and assessed for TPT eligibility. If a bacteriological cure is not demonstrated after the completion of treatment, reassess the patient for TPT eligibility three months after completion of the TB treatment.

8.2.1.1.8. People with a history of silica dust exposure and those living with silicosis, may present with similar symptoms and signs of TB. Therefore, it is imperative to exclude active TB disease and offer TPT.

8.2.1.2. Diagnosis and confirmation of LTBI

8.2.1.2.1. TST may be used to identify those infected with LTB.

- Guidance Note for the Management of Latent Tuberculosis in SAMI, Annexure D refers: Tuberculin Skin Test

8.2.1.2.2. The unavailability of TST should not be a barrier to the provision of TPT (once active TB disease has been adequately excluded).

8.3. Management

8.3.1. It is essential that TPT is scaled up to reduce the burden of TB in South Africa. Previously, TPT was offered only to people who were at the highest risk of progressing to TB disease after exposure (i.e. children younger than five years of age and all PLHIV, regardless of age). However, to achieve TB

elimination, it is crucial to implement TPT more comprehensively for everyone with significant TB exposure and all other individuals at high risk of TB disease.

8.3.1.1. Those that are eligible for TPT:

- See Annexure B: Algorithm for managing the population at risk of developing LTBIs in the South African mining industry,

8.3.1.1.1. All people, regardless of age and HIV-status, after significant TB exposure.

8.3.1.1.2. Those who are immune compromised, regardless of known exposure, after TB disease has been ruled out.

8.3.1.1.3. People living with silicosis regardless of whether they have a known significant exposure, regardless of prior TB treatment or TPT unrelated to silicosis.

8.3.1.1.4. Pregnant women living with HIV should be provided with TPT irrespective of the clusters of differentiation (CD4) cell count.

8.3.1.2. Other risk groups that may be considered for TPT based on risk assessment and selection criteria:

- Guidance Note for the Management of Latent Tuberculosis in SAMI, Annexure B refers: Algorithm for managing the population at risk of developing LTBIs in the South African mining industry.

8.3.1.2.1. Healthcare workers to be considered during a routine occupational TB screening programme.

8.3.1.2.2. People who have previously had TB and those who previously completed TB treatment since they are at higher risk of getting TB again. Some may experience multiple significant exposures or, acquire or develop immune-compromising conditions over the course of their lives. TPT is indicated at each new TB exposure to a TB contact or each period of immuno-compromise.

8.3.1.3. Those that are not eligible for TPT:

8.3.1.3.1. Individuals diagnosed with TB disease.

8.3.1.3.2. Individuals that have active liver disease (acute or chronic).

8.3.1.3.3. Individuals that have signs or symptoms of severe peripheral neuropathy (could consider 4R).

8.3.1.3.4. Individuals that have a history of adverse reactions to any of the medication used for TPT.

8.3.1.3.5. Individuals that drink alcohol excessively and are unwilling, or unable, to scale down. Use the following measures:

a) For men: more than five standard drinks on any day or 15 drinks per week.

b) For women: more than four standard drinks on any day or eight drinks per week.

8.3.1.4. For individuals with abnormal baseline liver function test results, sound clinical judgement is required to ensure that the benefit of T PT outweighs the risks, and these individuals should be tested routinely at subsequent visits.

8.3.1.5. Treatment:

8.3.1.5.1. Initiation

a) If TB symptoms appear, the employee needs to be tested for TB to exclude TB disease.

b) People offered TPT will be offered appropriate education (including information on adverse events), counselling prior to TPT initiation and support throughout the TPT journey. This is also for adherence purposes.

c) Education on TPT will include the following:

i. Adverse drug reactions.

ii. Duration of the treatment.

iii. Distance from a health facility.

iv. Absence of the perception of the risk.

v. Presence of stigma.

vi. Alcohol and drug use.

vii. Socio-economic factors.

viii. Time lag between diagnosis and treatment.

Note:

- All healthcare providers will be trained and updated on TPT guidelines.

- Education will include that subsequent TPT will be required following completion of the treatment.
- If another significant TB exposure occurs, they need to access care for TB evaluation.

8.3.1.5.2. Treatment options

a) As per the guideline for TPT of the NDOH, the treatment regimen chosen will depend on:
   i. The weight (for children)
   ii. The HIV-status.
   iii. The type of patient.
   iv. The circumstances.
   v. Household or family considerations.
   vi. Other medications including anti-retroviral therapy (ART).
   vii. The availability of formulations.
   viii. Current evidence.

Note: Refer to the prevailing National Guidelines on the Treatment of LTBIs of the NDOH.

b) It is recommended that where possible, individuals in one household or a group receive the same treatment regimen to lessen the burden and complexity of TPT on the individuals.

c) Treatment options in South Africa as recommended by the NDOH include:
   i. Six months INH.
   ii. 12 months INH.
   iii. 4R; or
   iv. 3 - 4 months of daily INH plus Rifampicin (3HR).

d) A short course treatment regimen such as 3HP and 4R are considered safer and effective since it has higher completion rates and lower risks of adverse effects than the longer regimens. Therefore, where feasible, shorter treatment options should be offered.

e) Options for TPT regimens may be revised as new evidence regarding safety, efficacy, appropriate

dosing and the required patient friendly formulations become available.

f) Prevailing approved regimens may be undertaken by the mine as per the prevailing NDOH recommendations.

g) The employer will familiarise themselves with the health benefits and possible adverse health effects of each regimen.

8.3.1.5.3. Treatment under special conditions

a) Pregnant and breastfeeding women will be treated as per the national guidelines on the treatment of LTBIs of the NDOH.

b) Contacts of people with DR-TB to be treated as per the national DR-TB guidelines.

8.3.1.5.4. Clinical monitoring and outcomes

a) For the duration of the treatment, employees must be monitored for the emergence of TB symptoms and any adverse health effects for safety, support and adjusting the dose as needed.

b) In the event that the employee who is on treatment for LTBI, is diagnosed with active TB, they must be treated for TB as per existing South African mining industry TB management guidelines and prevailing NDOH guidelines.

8.3.1.5.5. Management of individuals who decline treatment

a) Contacts who are eligible for TPT but decline treatment despite counselling, will be counselled further regarding TB symptoms and will be offered TPT again at the next opportunity.

b) If individuals develop symptoms suggestive of TB, they will be evaluated for TB disease again and be offered TB treatment if they test positive for TB. Alternatively, they will be offered TPT once more if TB disease has been excluded.

8.3.1.5.6. Management of individuals who miss doses of TPT

a) Adherence and completion of TPT treatment are important for ensuring the successful prevention of TB. It is important to be incorporated into the

education and counselling provided to employees. Table 1 below provides guidance on how to manage individuals who interrupt TPT.

Table 1: Management of individuals who miss doses of treatment, NDOH guidelines TB Preventive Therapy-2021

Duration of Interruption	Management
If an individual misses one dose	• The individual should take the missed dose(s) as soon as they remember within the same day. If the day's dose is missed, take the next scheduled dose and continue with the regular schedule. Do not take two doses on the same day. • For the weekly doses, take the missed dose as soon as they remember. If this is on the following day, continue with the next dose on the new day.
If an individual interrupts treatment for: Less than one month for a short regimen or Three consecutive months for a longer TPT regimen	• Enquire about the reasons for the treatment interruption. • Address the concerns of the individual. Counsel the individual on the importance of adherence. • Screen clinically for TB symptoms. • Conduct investigations to exclude T B, if signs and symptoms of TB are resent. • If asymptomatic and there are no signs of TB disease, continue TPT to complete the remaining treatment.
If an individual interrupts treatment for more than one month for a short regimen or three consecutive months for a longer TPT regimen	• If this is the first interruption, the individual returns at any point and commits to taking treatment. • The individual may be reassessed for eligibility, counselled and restarted on treatment and referred to relevant health workers (psychologist, dietitian, social worker, pharmacist. Etc.)
If an individual interrupts treatment for a second time regardless of the duration of interruption, despite adherence counselling.	• Do not consider for treatment.

b) Should there be situations where treatment is not adhered to, the prevailing NDOH adherence guidelines for TB will be followed.

8.3.1.5.7. Completion of treatment

c) RR10215390It is important to ensure that individuals who start TPT, complete it. Monitoring and support are important throughout the course of the treatment. The clinician is to determine the outcomes at the completion.

8.3.1.6. Management of adverse health effects:

8.3.1.6.1. While most adverse drug reactions are minor and occur rarely, it must be noted that maximum attention should be paid to the prevention of drug-induced hepatotoxicity.

8.3.1.6.2. Drug-specific adverse reactions can occur with:

a) Isoniazid (asymptomatic elevation of serum liver enzyme concentrations, peripheral neuropathy and hepatotoxicity).
b) Rifampicin and Rifapentine (cutaneous reactions, hypersensitivity reactions, gastrointestinal intolerance and hepatotoxicity).

8.3.1.6.3. Early identification and management of an adverse reaction is critical to ensure retention on treatment.

8.3.1.6.4. Employees will be furnished with information to identify and report signs and symptoms of adverse health effects to the clinician.

8.3.1.6.5. The clinician will carefully assess the employee and report all the adverse health effects using the standard reporting form as per the National Pharmacovigilance Centre guidelines.

9. Implementation (Part B)

9.1. Implementation Plan

9.1.1. The employer must prepare an implementation plan for a Guidance Note that makes provision for issues such as organizational structures, responsibilities of functionaries and programmes and schedules for the Guidance Note, which will enable proper implementation of the Guidance Note (a summary of and a reference to, a comprehensive implementation plan may be included).

9.1.2. Information may be graphically represented to facilitate easy interpretation of the data and to highlight trends for the purposes of risk assessment

9.2. Compliance with the Guidance Note

9.2.1. Measures for monitoring and ensuring compliance with the Guidance Note includes:

a) TB Screening

b) Occupational Medical Surveillance as per the requirements of the MCOP for Minimum Standards of Fitness

9.3. Access to the Guidance Note & Related Documents

9.3.1. The employer will ensure that a complete Guidance Note and related documents are kept readily available at the mine for examination by any affected person.

9.3.2. A registered trade union with members at the mine, or where there is no such union, a health and safety representative on the mine, or if there is no health and safety representative, an employee representing the employees on the mine, must be provided with a copy. A register must be kept of such persons or institutions with copies to facilitate the updating of such copies.

9.3.3. The employer will ensure that all employees are fully conversant with those sections of the Guidance Note relevant to their respective areas of responsibilities. This will include Induction/Annual Refresher training, education and awareness sessions by the Wellness Coordinator.

10. Monitoring & Evaluation (Part C)

10.1. The employer will ensure that:

10.1.1. Internal monitoring and evaluation of the TB management and control programme is conducted and recorded. This will be included in the Monthly Clinic Reports.

10.1.2. Annual monitoring of the TB management and control programme is conducted. Reporting will include the required reports as per the MHSA (DMR 164, DMR 165 & DMR 231).

11. Validity and Document Management

11.1. Document Validity

This SOP is effective from 2024/12/01 and was last reviewed on 01-12-2024. This SOP will be reviewed every 2 Years.

11.2. Document Management

11.2.1. This SOP replaces any other SOP issued earlier by VZI to the extent specifically covered here. This SOP should be followed in letter and spirit.

11.2.2. VZI is committed to continuously reviewing and updating policies and procedures, based on the Entity's risk assessment and shall incorporate for any regulatory requirement which is required to do so.

11.2.3. Any amendment to this SOP or issue of any guidance or circular etc. under this procedure must be approved in writing by the approving authority as listed in this document.

11.2.4. VZI reserves the right to withdraw, modify or revise the SOP as a whole / partial without providing any justification for the same. On revision, it should be duly communicated to the personnel involved.

11.2.5. If compliance with this SOP ever conflicts with the applicable law, regulation, directives issued by the statutory and or regulatory authority, then compliance must be ensured with the law.

11.2.6. In order to ensure compliance or to address any known conflicts with the law or to address any specific local requirements, VZI may adopt local sub-procedures which shall be by way of addendum to this SOP and which shall be approved by the approver of this SOP. Proposing of such addendum shall be the responsibility of the respective Entity’s competent authority who is at an equivalent level with the SOP owner as set out in this document.

11.2.7. Violation of the SOP

11.2.8. VZI follow a “Zero Tolerance Policy” with respect to non-compliance with this SOP and/or any other SOP / guidance issued by VZI and its constituent Entities.

11.2.9. Violation of this SOP is subject to appropriate disciplinary actions which may include but not limited to termination of employment. This determination will be based on the facts and circumstances of each situation. Any accused of violation of this SOP will be given an opportunity to present their case prior to any determination of appropriate disciplinary actions. Violation of this

SOP may also be subject to substantial civil damages, criminal fines and prison terms.

11.2.10. Each employee is responsible for ensuring that their conduct and the conduct of anyone reporting to them shall fully comply with this SOP. Compliances, both personal and by subordinates, will be a factor in periodic performance appraisals.

11.3. Disclaimer

11.3.1. This SOP issued by VZI is for internal compliance of within BMM, SZ and does not create, nor shall it be construed to create, directly or implicitly, any rights, duties or obligations of BMM/SZ to any person, body or legal Entity.

11.3.2. This document and its contents are the copyright property of VZI. The release of this document to any third party outside VZI is strictly prohibited without prior consent.

12. Review and Approval

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Catharina Kotze (Head of HSE | BMM) TimeStamp: 2025/02/17 9:43:38 AM ||

This document was approved (in sequence) by the individuals above using electronic approval in our Document Control System.

Final approval status: Approved

Approvals were done electronically.

❖ Annexures A: TB Screening Questionnaire

Life Occupational Health

TB Screening Questionnaire

Name & Surname:	Date:
Employee Number:	Site:

Do you suffer from any of the following complaints?	Yes	No
Cough for more than 3 weeks?		
Blood stained sputa?		
Weight loss of more than 3 kg in the past 4 weeks?		
Do you sweat excessively at night?		
Do you have frequent fever/chills lasting more than 3 days and feel tired easily?		
Do you have chest pains/rapid breathing/shortness of breath?		
Have you been treated for any form of TB before or are you currently on treatment for TB?		
If yes to the above, when were you treated for TB?		
Did you have any contact with a person/s diagnosed with TB at work/home?		
Do you have swelling in the neck, armpits or elsewhere?		

Clinical examination	Normal	Abnormal
Present weight		
Weight loss over past few months		
Neck and axillary glands		
Auscultation of the chest		

If "yes" to one or more questions, suspect TB and refer for further investigation for TB e.g. sputum collection etc.

If "no" to all questions, the patient is unlikely to have TB. Repeat screening in 3-6 months

Referral for :	No	Yes
CXR		
Sputum		

Comment

LOH-OM-Form-Resp-006 TB Screening Questionnaire Revision 0 March 2013