Share this with those who need to know



COVID-19 news from SAMED, Government and Abroad.

LEVEL THREE REGULATIONS: WHAT IS IN IT?

Chapter 3 is a new part of the existing 29 April 2020 "Lockdown" regulations. The new regulations can be summarised as follows:

- **Hotspot areas** have been formally declared, and regulation 3(5) and (6) state that additional measures may be put in place by the Ministers of COGTA and Health.
- **New permits** are prescribed for children and students (and those transporting them) who may need cross districts or metropolitan areas or provinces to go to educational institutions, as well sinter-provincial travel by persons who are moving house (in the form of a sworn affidavit)
- Persons may **only leave their houses to** perform service or work permitted under level 3, to buy permitted goods or services, to attend school, and to attend places of worship.
- Cloth face masks must be worn in all public places and also when entering any building, transport, etc.
- No inter-provincial movement, unless doing permitted work and having a permit issued by the employer, or, with the affidavit prescribed, to move house, or to care for an immediate family member.
- Persons may also move for funerals (details in reg 35), to obtain medical treatment (reg 33(4) (g)), or to return to home after isolation/quarantine, etc.
- There are detailed regulations on children and parental responsibilities (reg 34).
- "Gathering" at work is permitted (obviously subject to regs 5, 16(5), 46; Annexure E; the Health & Safety Directive; as well as the various NICD and DoH Guidelines)
- "Professional non-contact sports" marches are permitted, without spectators.
- No initiation practices may take place (reg 38).
- Closed to the public (reg 39), are gyms, bazaars, night clubs, casino's, accommodation establishments (save where they house those for permitted work or persons in isolation/quarantine), conference facilities, etc., but maintenance and security at these places may be rendered.
- Visits by the public to health establishments and facilities are prohibited, save to obtain treatment and medicine (reg 40(e)) (note: this raises the question whether medical reps would be deemed to be "members of the public")
- Cross-border travel is overall prohibited, with some exceptions as set out in reg 41. Cargo to and from other countries are permitted, and directions will be issued on the prioritisation of imports and exports.
- Public transport will be subject to Directions.
- Liquor sales etc permitted as per reg 44 and tobacco prohibited as per reg 45.
- All businesses and public service may operate, but not those listed in Table 2. If a workplace has more than 100 staff, all staff may not be there at the same time, etc. See reg 46(2)).
- The over 60's and co-morbidities rules still apply, and the health guidelines (i.e. doctor's notification to the employer) must be followed.
- More details are provided on the COVID-19 Compliance Officer.

Download the changes to the regulations here.



BUSINESS FOR SA | COVID-19

TEMPORARY EMPLOYER/EMPLOYEE RELIEF SCHEME APPLICATION (TERS) PROCESS AMENDED FROM MAY 2020 Employers will be entitled to receive payment if they require a refund from the UIF, which would be the case where the employer has paid the benefit to the employees, or where the employees have been required to take annual leave. In other circumstances, the UIF will make payment directly to the employees.

The addition of this second option has essentially been introduced with the intention of ensuring that the payments of the UIF Covid19 TERS benefits are smoother for May and June.

Anyone with queries should be directed to the UIF call centre at 0800 843 843 or visit https://uifecc.labour.gov.za/covid19/

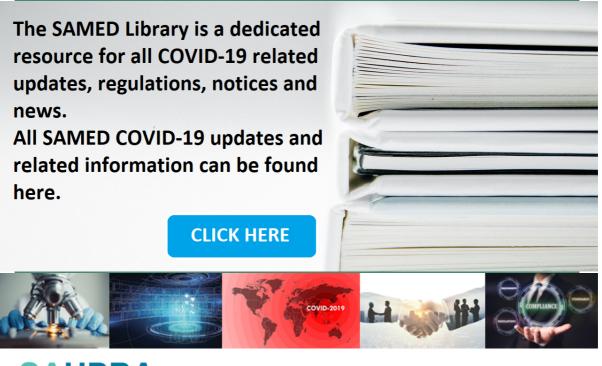
MINIMUM PRACTICE GUIDELINES FOR EMPLOYERS TO ENSURE A SAFE RETURN TO WORK – UPDATED

Every employer will, during each of the levels of lockdown and for the foreseeable future, have to adhere to detailed occupational health and safety protocols. This means that all employers must re-examine their activities, work environment and policies in the light of the COVID-19 pandemic and may need to change, adapt or enhance these in order to operate.

The <u>Return2Work</u> website provides valuable tools and guidelines to expedite a safe, effective and structured return to work plan.

The **Minimum Practice Guidelines** for all employers operating in South Africa including all types of businesses have now been updated. Each employer is unique in its activities, environment and workforce demographics and should, where reasonably practicable, apply these minimum controls as well as any additional controls appropriate for its organisation, workspaces and commuting arrangements. This practice note provides guidance to employers on the application of the Occupational Health and Safety Act ("OHSA") and the regulations and Disaster Management Regulations and the Ministerial Directives. https://www.return2work.co.za/wp-content/uploads/2020/05/Practice-Note-Workplace-readiness 27May.pdf

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REPORT UNLICENCED COMPANIES TO SAHPRA

Several members have contact SAMED about companies trading medical technologies without a SAHPRA Medical Device Establishment License. These companies are trading illegally and it is essential that they be reported to SAHPRA for investigation.

sending a report. You can download this list as at 26 May 2020, <u>here.</u> Please ensure that you visit the SAHPRA website to obtain updates as this is an evolving list.

Report unlicensed companies by emailing: mokgadi.fafudi@sahpra.org.za

IMPORTANT SAHPRA MEDICAL DEVICE NOTICES

- <u>MD010_Guidance_Rapidly developed ventilators_26May2020_v1</u>
- PCR Tests Authorised for Listing by SAHPRA 19.05.2020Specification criteria for COVID-19 serological test kits
- Joint Communication-Regulatory Status of Equipment Used to Help Prevent COVID-19
- <u>NRCS media Release Standards for Masks and Disinfectants</u>
- <u>Regulatory Requirements for the manufacture, distribution or wholesale of Serological</u>
 <u>COVID-19 Rapid Test Kits</u>
- SAHPRA clarifies the issue of COVID-19 Rapid Test Kits
- MEDICAL DEVICES INCLUDING IN-VITRO DIAGNOSTICS (IVDS) REQUIREMENTS FOR SUPPLY OF MEDICAL DEVICES IN LIGHT OF THE COVID-19 PANDEMIC

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SAHPRA MEDICAL DEVICE CONTACTS

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.

- 084 220 8037
- 072 993 2273
- 078 281 6334

For queries on COVID-19 please email <u>mdcovid.@sahpra.org.za</u> and all other regular medical device queries can be sent to <u>MDnotifications@sahpra.org.za</u>

For general licensing queries: June Searela june.searela@sahpra.org.za / 072 828 2416 For COVD-19 related applications: Matlapeng Shabalala Matlapeng.Shabalala@sahpra.org.za / 071 302 0409 or

Khanyisile Nkuku Khanyisle.Nkuku@sahpra.org.za / 081 854 7109

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What must I do to prepare my workplace and have staff return to work? There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down.

Download the directive here

You can also find useful tools on the Return2Work website.

Subscribe

Past Issues

The information collected on the B4SA <u>covid19manager.co.za</u> platform will be used to ensure supplier verification, regulatory compliance, product availability, reasonable pricing and providing the accurate and most up-to-date logistical information to the procurement department division at BSA to place orders from you and/or assist with ramping up local production. It is an automated process to help facilitate the overwhelming demand currently being experienced in South Africa during the weeks to come.

NOTE: THIS IS A LIVE SYSTEM SO PLEASE UPDATE YOUR STOCK QUANTITIES AND LEAD TIME AS AND WHEN THEY CHANGE.

Please see the following <u>link to the video</u> for an explanation of how to use the portal and click on <u>https://covid19manager.co.za/</u> to add your company and product information.

You will most likely be contacted by a member of the BSA procurement team should your information provided need to be verified or an order need to be placed.

If you have any questions about the status of your registration, on the types of PPE and medical equipment that B4SA are procuring, if you are struggling to complete your application, or if you have any other queries, please get in touch with the B4SA support team via **covid19portal@businessresponsecovid19.co.za**. If you are not receiving feedback from the administrators, please check your spam/junk folders.

SAMED is appreciative of the support and commitment of our members in fighting this pandemic.

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THE SOLIDARITY FUND

The Solidarity Fund provided more details on its purpose and mandate of mobilising and coordinating efforts and resources from all South Africans and the international community to assist most vulnerable South Africans to deal with the impact of Covid19 and the consequences of measures intended to slow its rate of infection. One of its key focus areas is a Health Response with direct support for the healthcare system, augmenting both the private and government healthcare sectors to ensure they have what they need, as well as enabling emergency supplies.

Details on how to donate are available on the Fund's website <u>www.solidarityfund.co.za</u> For more information email <u>info@solidarityfund.co.za</u>

For offers of supply of Medicines and Medical Devices send to <u>covid19supplies@businessresponsecovid19.co.za</u> If you are seeking PPE for your hospital, clinic, or NGO please email your request to <u>covid19requests@businessresponsecovid19.co.za</u>

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COVID-19 EVENTS

PTCMA WEBINAR: INSIGHTS DURING COVID-19

Measuring the impact of COVID-19 on our healthcare environment - what about our economy?

- Where is the Ministerial Advisory Committee (MAC) coming from?
- A vaccine needs to be developed sooner rather than later for COVID-19 but what happens in between?
- Where do we stand with the treatment development for COVID-19?

Date: 5 June 2020, 09:45 - 12:30 For more information or to register, click here.

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OMMIA HEALTH COVID-19 VIRTUAL EXPO

Omnia Health Live are bringing together the global healthcare industry, for the largest virtual gathering ever seen before, a whole new concept planned from the ground up to be more diverse and accessible, **taking place 22-26 June 2020.**

Join the experience here

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Past Issues

LEVEL 3 DEVELOPMENTS

Nkosazana Dlamini-Zuma confirmed that level 3 of the national lockdown starts on Monday, 1 June 2020. The regulations governing it were published late on Thursday afternoon.

| Here's what | B lockdown is allowed under South Africa's d-19 restrictions. |
|-------------|--|
| WHAT'S | SALLOWED |
| | Domestic workers will be allowed to return to work |
| <u> </u> | Sales of hot food in stores will resume. People will also be allowed to pick up food from stores. Drive-throughs will also be open |
| H ø | Professional non-contact sports will be permitted |
| | Places worship including churches and mosques will be allowed to reopen, adhering to strict hygiene protocols and at maximum capacity of 50 people. |
| A. | Domestic air travel for business travel will be allowed |
| | Liquor sales will be permitted Monday to Thursdays from 09:00 to 17:00 |
| | All construction will now be allowed |
| | All clothing sales |
| j | All household appliances sales |
| | Exercise will be permitted between 06:00 and 18:00 - as long as does not take place in groups |
| | Wholesale and retail, including spaza shops, will be allowed to completely reopen |

Source: National Coronavirus Command Council

• There are more than one million domestic workers in SA - and many have been left without an income during the lockdown. All domestic workers can go back to work in Alert Level 3 and they will have to adhere to protocols, which will include physical distancing and wearing masks. While draft regulations included the proviso that domestic workers had to use private transport, this is not included in the final regulations. There are no restrictions on transport.

Graphic RUDI LOUM

 So far, only around 14,000 domestic workers received money from the Unemployment Insurance Fund (UIF) as part of the Covid-19 Temporary Relief scheme (TERS). Government has now issued new regulations that also include all employees who were not registered with UIF, as long as they worked for one employer for more than 24 hours per month. As the function of TERS is to support lost income, domestic workers should be eligible for a payment in April – as they weren't allowed to work during that stage of lockdown

ECONOMICS, POLITICS, EDUCATION, ENVIRONMENT, SOCIAL

Schools re-opening

• The SA Human Rights Commission has written to Basic Education Minister Angie Motshekga to recommend that she delay the return to school of Grade 7 and 12 pupils. They are set to return on

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|-----------|---|--|-------------|--|
| • | Teachers have started going back to school to get used to the new conditions from 1 June, which | | | |

- leachers have started going back to school to get used to the new conditions from 1 June, which
 include setting out wider spacing between desks, taping distancing marks on corridor floors, and
 receiving sanitisation packs.
- According to school governing bodies, about 3 500 schools did not have enough water.

Cigarette sales ban

- The acting director-general of the Department of Health, Anban Pillay, told the health committees of both Houses of Parliament on Thursday that empirical evidence would suggest smokers are "at risk of a negative outcome" with Covid-19, but a study in which smokers are exposed to the virus to prove this point cannot be done as it would be unethical. He added empirical evidence "would suggest smokers are at risk of a negative outcome" because smoking damaged the lungs' ability to fight viruses. Other viruses cause smokers much harm. We don't anticipate this virus to be any different."
- The Fair Trade Independent Tobacco Association served the government with court papers in early May to challenge its decision to retain the ban on the sale of cigarettes and tobacco products under Level 4 of the lockdown. Government responded: Government responded: "There is plenty of scientific evidence and it will all be aired in court as the matter is in court."

Government has fallen short

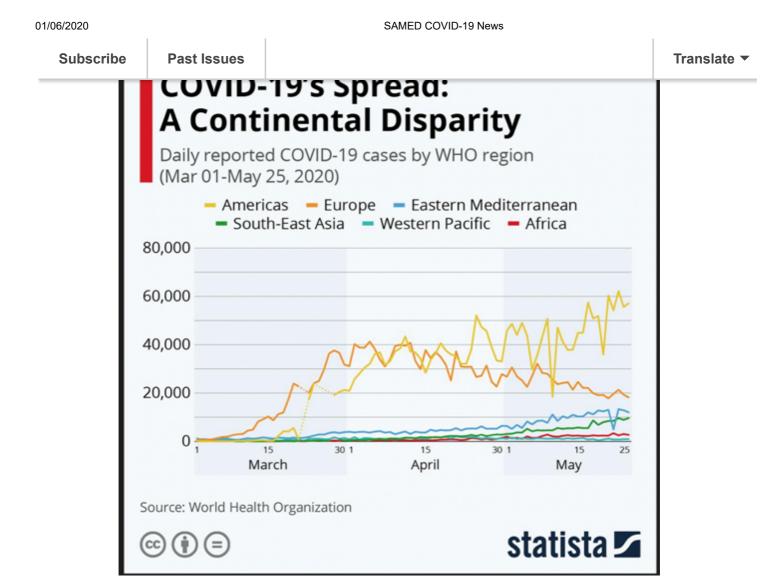
Minister Nkosazana Dlamini-Zuma conceded at a media conference on Thursday that the government
has fallen short in implementing its planned social and economic interventions. She said government
measures have at times not fully reached the intended recipients, adding "through collaboration and
concerted actions, we will better target our interventions, so that we see a brighter and better South
Africa, beyond the virus".

CLINICAL AND SCIENTIFIC

Test backlogs

• Following a week in which the availability of tests, and the backlog, was a hot topic the government gave three different figures for the Covid-19 testing backlog: 100 000, 80 000 and 30 000. EFF MP Naledi Chirwa demanded clarity, but chairperson Sibongiseni Dhlomo said the health department could write to the committee with the correct figure.

WHO figures for Africa



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SAMED is the voice of the South African medical technology industry. The not-for-gain was formed in 1985 and aims to provide members with a collective, objective and credible platform to engage with stakeholders. SAMED's members include individual medical technology companies, associate members and associations.

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