

Quarterly Bulletin

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Volume 4

The OHSC releases its Certification and Enforcement Bi-Annual report for April to September 2023

The Office of Health Standards Compliance (OHSC) is a public entity created by Parliament through an amendment to the National Health Act to protect and promote the health and safety of health workers and users of health establishments across South Africa. The OHSC is required in terms of Section 79 (1) (b) to inspect and certify the public and private health establishments as compliant or non-compliant with norms and standards regulations, prescribed by the Minister of Health. The Office is further obliged to take enforcement action against the persons in charge of health establishments found to be non-compliant with norms and standards regulations after additional inspections conducted by the OHSC.

The number of certificates of compliance issued from the 2020/21 and 2023/2024 financial years till the end of the reporting period 30 September 2023.

The OHSC commenced the process of implementing its certification and enforcement framework for the first time in the 2020/21 financial year. A total of 647 health establishment inspections were conducted between July 2019 and March 2020 which led to the issuing of 33 certificates to compliant health establishments during the reporting period. Subsequently, during the 2021/22 financial year, 189 compliant health establishments were issued with certificates of compliance, and 222 health establishments in the 2022/23 financial year. Overall, a total of 787 certificates of compliance were issued in the previous financial years, including the period 1 April to 30 September 2023.

Table 1 below illustrates the number of certificates of compliance issued by the OHSC from 2019/2020 to date.

Financial Year	Number of Health Establishments Inspected	Number of Certified Health Establishments
2019/2020	647	N/A
2020/2021	387	33
2021/2022	544	190
2022/2023	832	222
2023/2024	292	*342
Total	2 702	787

* Some of the health establishments certified in the 2023/2024 financial year were inspected in the previous financial years.

Enforcement action taken against non-compliant health establishments

From April to 30 September 2023, all non-compliant health establishments recommended for enforcement action were issued with Compliance Notices stating the norms and standards regulations that have not been complied with, the nature and extent of non-compliance, Action to be undertaken by the health establishment to remedy non-compliance, and time-frame within which to remedy the identified breaches.

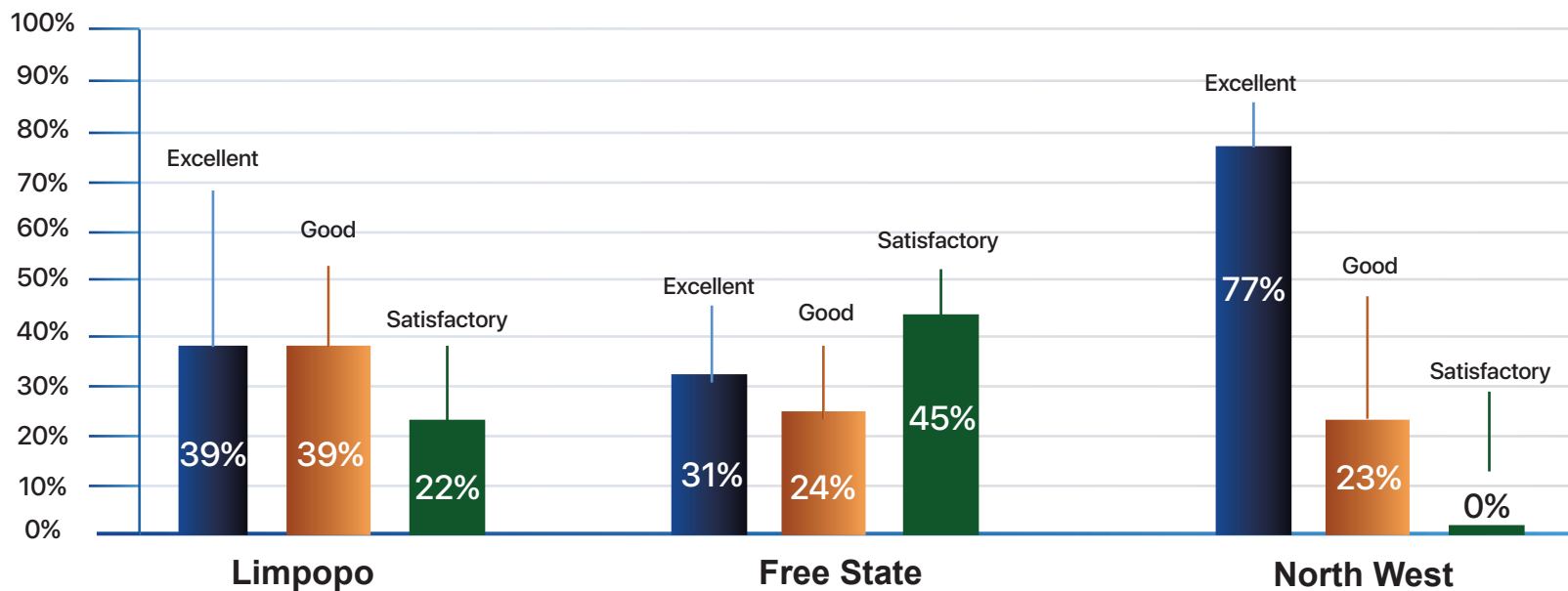
Additional inspections were conducted to determine whether the health establishments have remedied identified breaches. Health establishments that were found non-compliant following additional inspections were recommended for enforcement actions by the OHSC inspectors. During the 2021/22 financial year, 24 health establishments were recommended for enforcement actions, and the written warnings were issued against 100 health establishments after additional inspections in the 2022/23 financial year

A total of 28 health establishments were issued with written warnings, outlining specific time-frames for responses from April to September 2023. Thirteen health establishments in the Free State were issued with enforcement actions, two from Mpumalanga, three in the Northern Cape, one in the North West, and two in the Western Cape. Further enforcement actions will be considered should health establishments fail to address the breaches or respond to the written warnings issued by the OHSC. There were no formal hearings held by the OHSC for the revocation of any certification of compliance from April to September 2023. There were no recommendations made to relevant authorities for action to be undertaken against persons responsible for non-compliance within health establishments. These steps will be undertaken and implemented by the OHSC at the appropriate time.

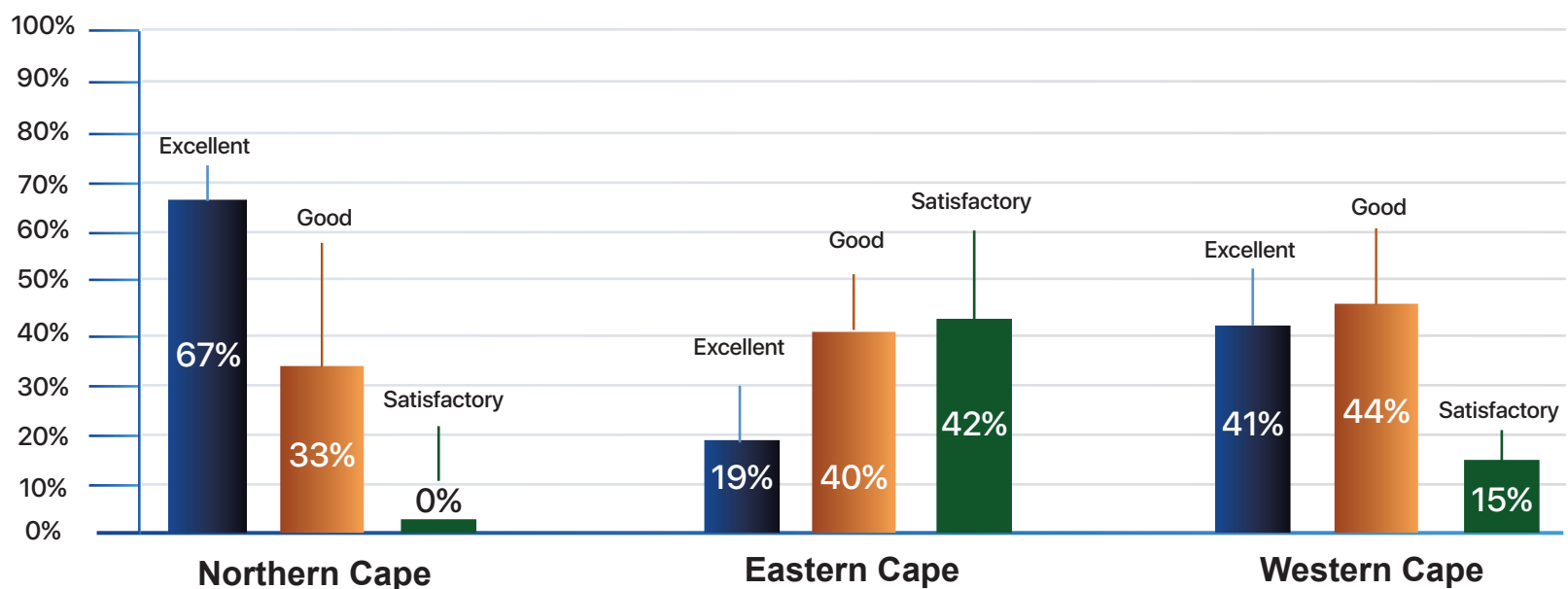
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Compliant health establishments per province issued certificates of compliance during the reporting period - 01 April 2023 to 30 September 2023.

The graphs depicted below illustrate compliant health establishments inspected per province issued with certificates of compliance during the reporting period



In Limpopo 18 health establishments were issued with certificates of compliance - 39% of health establishments inspected were graded as Excellent, 39% Good, and 22% Satisfactory. In the Free State, 29 health establishments were issued with certificates of compliance - 31% were graded as Excellent, 24% Good, and 45% Satisfactory, while in the North West, 13 health establishments were issued with certificates of compliance - 77% were graded as Excellent, 23% Good, and 0% Satisfactory

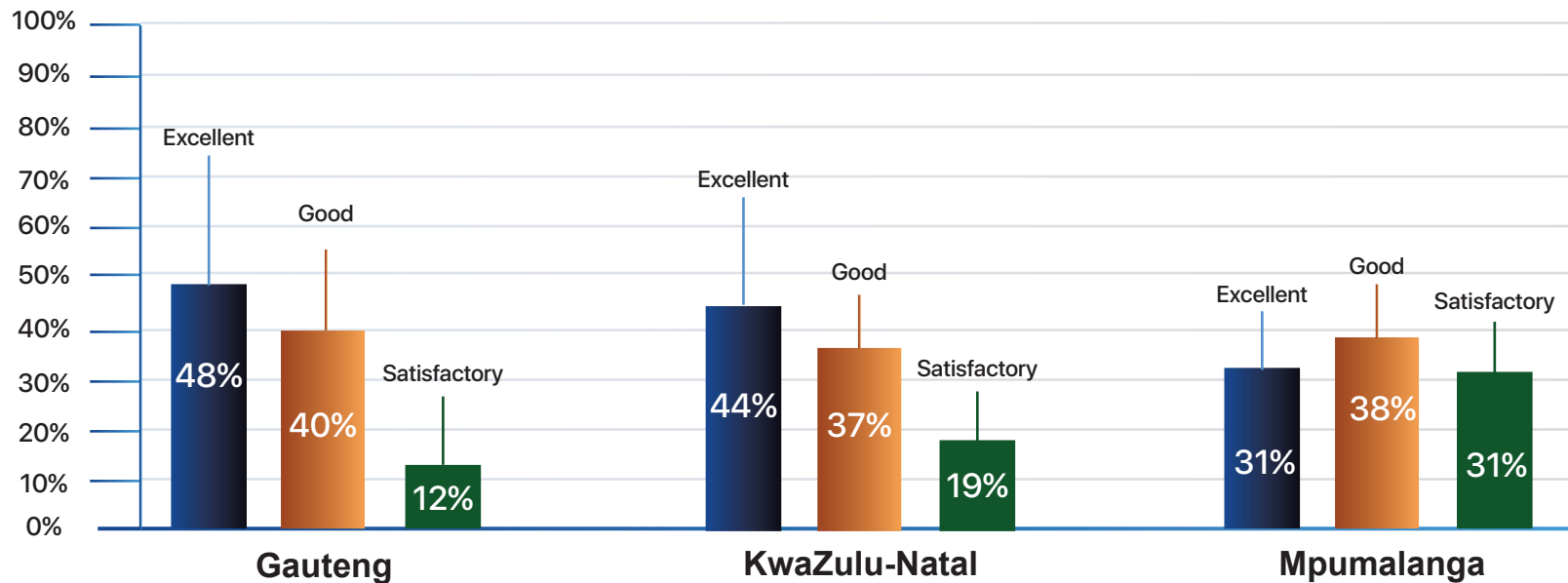


In the Northern Cape, 3 health establishments were issued with certificates of compliance - 67% of health establishments inspected were graded as Excellent, 33% Good, and 0% Satisfactory. In the Eastern Cape, 48 health establishments were issued with certificates of compliance - 19% were graded as Excellent, 40% Good, 42% as Satisfactory, while in the Western Cape, 41 health establishments were issued with certificates of compliance - 41% were graded as Excellent, 44% Good, and 15% Satisfactory



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In Gauteng 48 health establishments were issued with certificates of compliance - 48% were graded as Excellent, 40% Good, and 12% Satisfactory. In KwaZulu-Natal 107 health establishments were issued with certificates of compliance - 44% were graded as Excellent, 37% Good, and 19% Satisfactory; and in Mpumalanga, 29 health establishments were issued with certificates of compliance - 31% were graded as Excellent, 38% Good, and 31% Satisfactory

Challenges

The OHSC is concerned about the overall low compliance rate of health establishments in the inspected health establishments. The other concern for the OHSC is the high number of health establishments that did not provide any evidence of actions taken to address areas of non-compliance upon receiving their preliminary inspection reports. The OHSC urges the districts, sub-districts and provincial health authorities to actively assist health establishments issued with compliance notices to address the identified breaches in norms and standards regulations. During the bilateral meetings held between the OHSC and the National Department of Health's Quality Assurance directorate, the latter has indicated that it is in the process of assisting and mentoring non-compliant health establishments to develop and implement quality improvement plans to help health establishments to remedy areas of non-compliance as indicated in the compliance notices.

Recommendations

The OHSC has registered a significant increase in the rate of certificates during the reporting period. The increase in the rate of certificates is attributable to the reduced period of issuing preliminary reports by the Compliance Inspectorate. Despite this, the OHSC encourages all health establishments to observe and consistently comply with the prescribed norms and standards regulations applicable to different categories of health establishments.

Visit our website on www.ohsc.org.za for a detailed report.

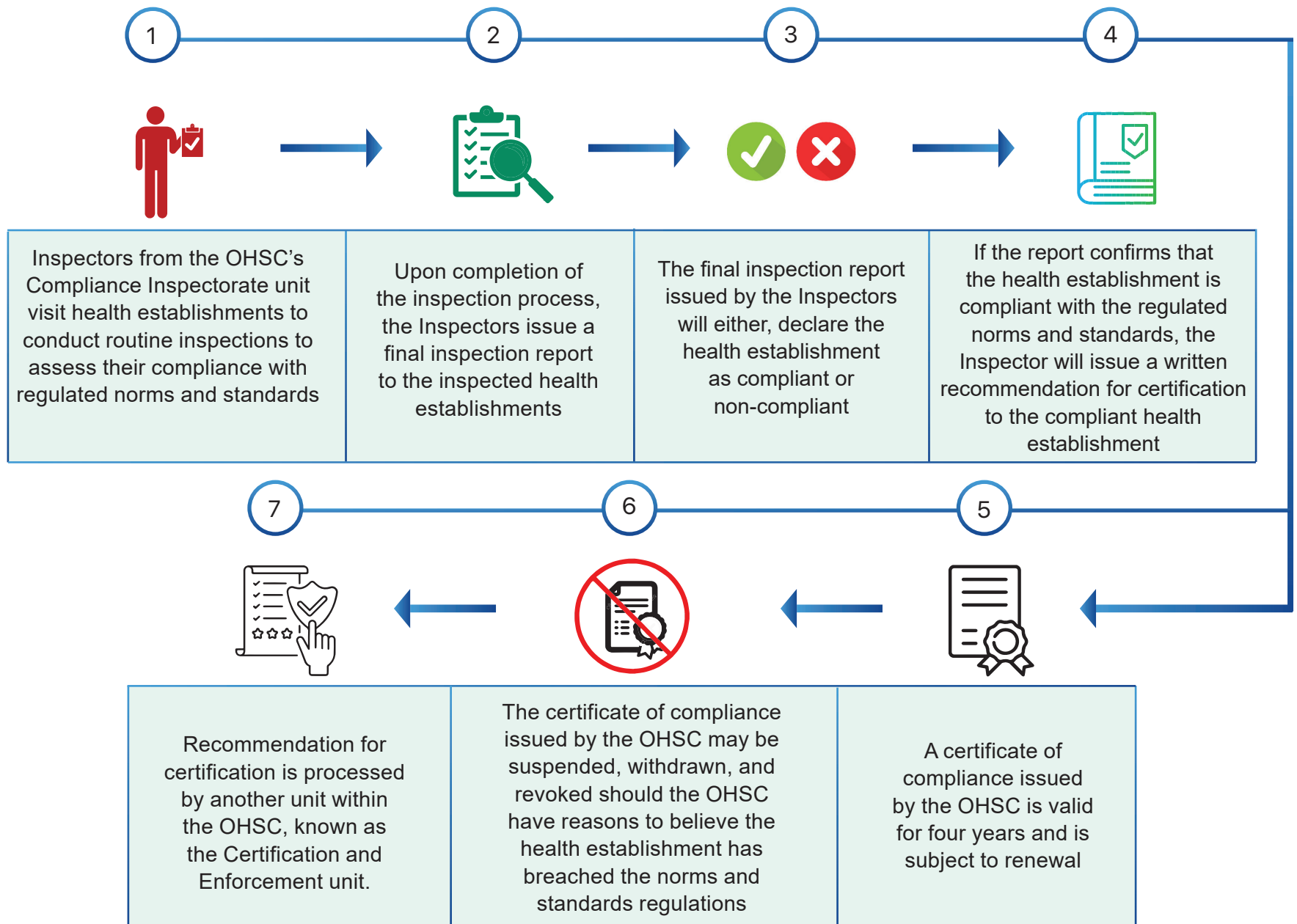


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2 What do you need to know about the Certification and Enforcement functions of the OHSC?

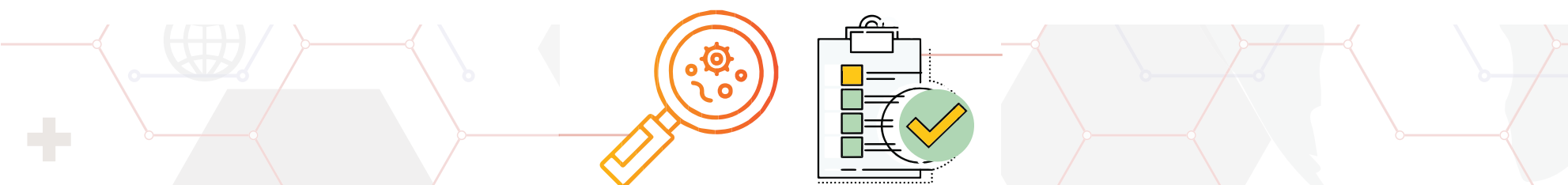
In 2013, Parliament amended the National Health Act to establish the OHSC and to make laws incidental thereto. Section 78 of the Act provides that the objectives of the OHSC are to protect and promote the health and safety of users of health services. The entity performs its functions by monitoring and enforcing compliance by health establishments with norms and standards regulations prescribed by the Minister of Health in relation to the National Health System. Section 79(1) (b) provides that one of the functions of the OHSC is to inspect and certify health establishments (private and public) as compliant or non-compliant with prescribed norms and standards regulations.

Inspection and certification of health establishments



Enforcement action against non-compliant health establishments

Should the final inspection report indicate that the health establishment is non-compliant, the Inspector will issue the report to the health establishment together with a Compliance Notice. A Compliance Notice is a document issued by an Inspector in terms of section 82A (1) of the Act to the Person in Charge of a health establishment found to be non-compliant during a routine inspection. The notice indicates all the areas of non-compliance identified during the inspection, the extent and nature of such non-compliance, as well as the measures that the health establishment should implement to achieve compliance status. The notice also prescribes time-frames within which the health establishment is required to achieve compliance in respect of the identified areas of non-compliance. Upon the lapse of the time-frames prescribed in the Compliance Notice, the OHSC will reschedule another inspection (additional inspection) of the health establishment to verify whether the areas identified in the Compliance Notice have been addressed. If re-inspection confirms that those areas have been addressed, the Inspector will then recommend the health establishment be issued with a Certificate of Compliance. In cases where the re-inspection report states that the health establishment has failed to address the areas of non-compliance as listed on the Compliance Notice, the Inspector will then recommend enforcement actions against the Person in Charge of the health establishment in terms of section 82(4).



The following are enforcement actions that the OHSC may appropriately take considering the nature, extent, gravity, and severity of the contravention by health establishments that remain non-compliant after re-inspection:

1. Issue a written warning to achieve compliance within a set period in the manner prescribed.
2. Require a written response from the health establishment regarding the continued non-compliance.
3. Recommend to the relevant authority any appropriate and suitable action to be undertaken, including the institution of disciplinary proceedings against persons responsible for the non-compliance or continued non-compliance.
4. Revoke the compliance certificate and recommend to the Minister the temporary or permanent closure of the health establishment or part thereof that constitutes a serious risk to public health or health service users.
5. Impose upon that person or health establishment a fine as determined by the Minister in the Gazette from time to time; or
6. Refer the matter to the National Prosecuting Authority for prosecution.

The Chief Executive Officer of the OHSC must inform the head of a national or provincial department, the municipal manager, or the head of a health establishment of any persistent non-compliance.

Pre-enforcement consultation

Regulation 22 (1) of the Procedural Regulations Pertaining to the Functioning of the OHSC and the Handling of Complaints by the Ombud requires the OHSC to develop and gazette an enforcement policy which sets out the OHSC's approach to enforcing compliance. Over and above the enforcement policy, the OHSC introduced an administrative process known as the pre-enforcement consultation. The purpose of the pre-enforcement consultation is to afford health establishments that are still found to be non-compliant after re-inspection an opportunity to furnish the OHSC with sufficient reasons and mitigation measures in support of their status of persistent non-compliance. The test is proof that non-compliance occurs as a result of situations that are beyond the control and capacity of the health establishments. In applying its mind, the OHSC is expected to apply compliance enforcement in a progressive manner that considers the following:

- The nature and severity of non-compliance by individual health establishments with the norms and standards and the consequences thereof;
- The compliance history of the health establishment;
- Frequency of transgressions in relation to the norms and standards;
- Any offenses by the health establishment in terms of section 89(1) of the Act; and
- Any mitigating or aggravating factors.



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What does the Early Warning System mean for health establishments in South Africa?

The OHSC as the health regulator monitors and enforces healthcare safety and quality standards in health establishments - independently, impartially, fairly, and fearlessly on behalf of healthcare users. The Office has a responsibility in terms of the National Health Act to monitor indicators of risk as an Early Warning System (EWS) related to serious breaches of norms and standards regulations and report any breaches to the Minister without delay.

In accordance with procedural regulations on the functioning of the OHSC and handling of complaints by the Office of the Health Ombud (OHO), the Office guides health establishments on the indicators of risk by category of health establishment; the approach to measure and calculate the indicators of risk, and the frequency of collection of the indicators of risk and the reporting of such indicators. Furthermore, the OHSC is required to identify areas and make recommendations for intervention by relevant authorities to ensure compliance with prescribed norms and standards. The information provided by the EWS is key in identifying gaps in patient safety within health establishments. As the regulator mandated to promote and protect the health safety of users in South Africa, the monitoring of compliance through the EWS is a critical mechanism used by the OHSC in ensuring that areas of concern are identified and addressed, to avoid and reduce harm as well as prevent recurrence of adverse events.

The entity started implementing EWS in March 2020 through a phased-in approach to allow progressive implementation of the system. To monitor breaches of the norms and standards, the OHSC enables reporting of incidents and events by health establishments as well as monitoring reports related to breaches of norms and standards from other sources.

The OHSC employs the system to collect information on specific indicators and uses it to monitor compliance with the norms and standards regulations. The system provides regular monitoring of indicators of risk to users' safety within health establishments. The system is further used to identify establishments posing significant risks to health users for prompt interventions aimed at addressing gaps to reduce the occurrence of adverse events. In addition to monitoring compliance with the norms and standards regulations done through inspections, an EWS is a mechanism that enables the OHSC to monitor health establishments regularly and remotely through the exchange of information to enable early identification of risk.

Incidents reported by health establishments

A total of 11 EWS indicators have been developed and health establishments are required to report on these.

Table 1 below provides a list of current EWS indicators that are reported by all health establishments. These incidents in the left column are proxy indicators that suggest possible breaches of the norms and standards regulations indicated in the right column of the Table.

	Indicator (Incident to be reported to the OHSC)	Norms and Standards Regulation
1	Missing minor	17(1) The health establishment must have systems to protect users, healthcare personnel, and property from security threats and risks
2	Abscondment of a user	
3	Suicide of an in-patient	
4	Acts of harm to healthcare personnel	
5	Acts of harm to the user	
6	Unavailability of Radiology services (CT scan, X-ray, and sonar service)	(1) The health establishment must ensure that diagnostic services are available and safe for users and for healthcare personnel involved in delivering these services 19(2) (a) The health establishment must, as appropriate to the size and type of health establishment, have and implement a human resource plan that meets the needs of the health establishment
7	Unavailability of hand washing soap	8(2)(a) A health establishment must ensure that there are hand washing facilities in every service area
8	Unavailability of water for > 24 hours	15(2) A health establishment must have 24-hour electrical power, lighting, medical gas, water supply, and sewerage disposal system
9	Retained foreign object in a user following a surgical/invasive procedure	7(2)(b) the health establishment must establish and maintain systems, structures, and programmes to manage clinical risk
10	Wrong-site surgery	
11	Procedure-related avoidable deaths	

Incidents reported by other sources

In addition to the 11 EWS indicators reported by health establishments to the OHSC, the Office has a mechanism to survey other sources to identify reports that may indicate a possible breach of the norms and standards regulations. The mechanism enables the OHSC to be alerted of other incidents within health establishments that could potentially or may have compromised the safety of health users. Sources of the incidents reported include media reports, complaints received through the entity's Call Centre, whistle-blowers (usually staff within the health establishments) as well as reports and referrals by other regulators. The report provides details of such incidents in the province and how the OHSC has addressed or attempted to address them.

Reporting on Early Warning System Indicators

An EWS information system is highly dependent on the availability of relevant data and information for monitoring activities and indicators within the health establishments. It is therefore imperative to ensure that all health establishments report on the EWS indicators as required. The EWS Online portal enables reporting on EWS indicators. Users who are registered on the OHSC Online system can access the portal and report on the indicators.

Root Cause Analysis

The reporting of indicators enables health establishments to identify trends in incidents occurring which provides an opportunity to study in detail the causes of the incidents. An effective patient safety mechanism should be aimed at reducing and avoiding the recurrence of similar incidents. Health establishments are encouraged to adopt a culture of systematically investigating the root causes for reported incidents to develop an effective remedial action plan to prevent the recurrence of similar incidents.

Reporting EWS Incidents

The EWS forum triggers risk-based inspection/investigation. Annually, the Office produces recommendations report. Health establishments are requested to provide the OHSC detailed incident reports for analysis and intervention where needed within the specified time through the dedicated EWS Online system on <https://www.ohsctool.org.za/>. The email reporting system ews@ohsc.org.za will be phased out on 31 December 2023, stakeholders are encouraged to report incidents on the dedicated EWS Online platform: <https://www.ohsctool.org.za/>.

