

**SUBMISSION BY THE SOUTH AFRICAN MEDICAL TECHNOLOGY INDUSTRY ASSOCIATION**

On the  
Draft Employment Equity Regulations  
as published on 1 February 2024 in the Government Gazette No 50058, Notice No 4295

TO:  
The Department of Employment and Labour (“DoEL”)  
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2 May 2024

## 1. About SAMED

SAMED is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa. Its 152 members comprise large corporates, and smaller entities. It includes manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies, of medical devices, medical equipment and invitro diagnostics (collectively termed medical technologies). SAMED is committed to ensuring a sustainable, transformed and ethical medtech industry in South Africa.

Of relevance to the process of setting targets for the medtech sector, which supplies vital health products to the healthcare sector, are several unique considerations.

The medical technology industry is comprised of:

- both multinational affiliates and local companies;
- in employment equity terms, smaller employers, as well a large employers;
- manufacturers, based both locally and internationally;
- entities that assemble, repackage, or package products locally;
- a vast array of products types spanning product-sectors such as textiles, plastics, metals, electronics, radioactive materials, etc.;

- “high-tech”, as well as “low-tech” products and services;
- artificial intelligence, software and, also, robotic technologies;
- etc.

Medtech companies are also regulated by the South African Health Products Regulatory Authority (SAHPRA) under the Medicines and Related Substances Act, 1965, and the Hazardous Substances Act, 1974. The criteria set by SAHPRA includes mandatory requirements on staffing complements, required to be accountable to the authority, and to be able to provide the necessary scientific and technical input in the business and all its activities, requiring also oversight and professional accountability to SAHPRA.

## **2. SAMED’s commitment to transformation in the medical technology sector**

SAMED is committed to transformation in the medical technology sector, including in the ownership, and employment structures in business. To this effect, in 2013 SAMED established a committee to deal specifically with matters of transformation and diversity in the medical technology industry.

SAMED regards transformation as an economic and social imperative. It is committed to transformation and believes it has a responsibility to drive meaningful, impactful and sustainable change as an industry body.

SAMED wishes to state, in no uncertain terms, that it supports the Employment Equity Act, and the transformation agenda of the country, as is espoused in the Constitution of the Republic. Its comments below should be construed as pro-transformation and focusing on the practicalities of implementing real and lasting change.

## **3. The new Draft Regulations**

SAMED applauds the fact that the DoEL has issued this new set of draft regulations, which includes improved explanation of the targets being set, such as the timeframe for a target, and the justifications for possible non-compliance.

Some concerns do remain, many of which relate to the business of the members of SAMED, the need to fairly compete, especially as the Compliance Certificates will be a requirement in government tenders.

Furthermore, the broadness of the classification means that SAMED members will, in spite of its fundamental differences with others in the same class, be subjected to targets set for businesses with significantly different staff profiles (e.g. textiles in general, and textiles as wound care products are significantly different businesses in terms of staff and staffing requirements). The same applies to the plastics sector, and so forth.

It is important that the setting of these targets is done in a manner that is compliant with the empowering section 15A,<sup>1</sup> namely that the Minister:

- “may have regard” to the Standard Industrial Classification (“SIC”),
- may consult different sectors;
- may set differential targets; and
- may set targets per sub-sector.

Although not peremptory, in compliance with the principles of administrative justice, the decision relating to the classification of sectors, and the setting of appropriate targets per sector, necessitates such consultation and consideration of setting targets that are not overly broad in the industries captured under a single set of targets.

In its previous submission in June 2023 (attached hereto for ease of reference), SAMED pointed out:

*“...SAMED members undertaking comparable services, with similar employee requirements, could face vastly different targets, e.g. the target for “Professionally qualified” employees in health is at 91% black employees, but in manufacturing, it is 62%, in professional and scientific, it is 65% and in wholesale and retail 75%. This means that unless the economic sub-sectors are set in a manner that is fair, and rational, the impact would be vastly different on similarly situated employers.”*

The most recent SAMED survey reveals that SAMED’s members are in the following SIC categories:

- Human Health and Social Work;
- Wholesale and Retail;
- Manufacturing; and
- Professional, Scientific and Technical Activities

**SAMED urges that the medtech industry be consulted, pursuant to section 15A.** This is so that the targets are set in a manner that is fair towards competitors for state tenders. Fairness in procurement is a constitutional requirement in section 217 of the Constitution, 1996. For example, medtech employers should not be (inadvertently) included in broad industrial categories where staffing requirements are different to those required from SAMED members, such as those required through the application of the Medicines and Related

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<sup>1</sup> **15A.** (1) The Minister may, by notice in the Gazette, identify national economic sectors for the purposes of this Act, having regard to any relevant code contained in the Standard Industrial Classification of all Economic Activities published by Statistics South Africa.

(2) The Minister may, after consulting the relevant sectors and with the advice of the Commission, for the purpose of ensuring the equitable representation of suitably qualified people from designated groups at all occupational levels in the workforce, by notice in the Gazette set numerical targets for any national economic sector identified in terms of subsection (1).

(3) A notice issued in terms of subsection (2) may set different numerical targets for different occupational levels, sub-sectors or regions within a sector or on the basis of any other relevant factor.

(4) A draft of any notice that the Minister proposes to issue in terms of subsection (1) or subsection (2) must be published in the Gazette, allowing interested parties at least 30 days to comment thereon.

Substances Act, 1965, and the Medical Device Regulations, 2016, as well as the ISO13485 requirements.

To illustrate this point, SAMED, in its previous submission, made clear:

*“SAMEDs preliminary analysis shows that members are in different categories, such as manufacturing, wholesale/retail, human health, etc. Even whilst most respondents are in “manufacturing”, members are in different categories, ranging from pharmaceuticals and plastics to food products, to wood and paper. The same applies to the wholesale and retail sector.”*

#### **4. Process and timelines: the annual targets and the section 53 certificate**

SAMED welcomes the fact that employers would be able to set their own targets for years 1 to 4, and then by year 5 would have to achieve the ministerially-set targets.

This, however, leaves uncertainty as to the criteria and process through which the section 53 certificate would be issued. In terms of criteria, it is assumed (but not clear in the draft regulations) that employers would be measured against their own targets for years 1 to 4. Then, in terms of the process, the start-date for “year 1” has to be clear and uniform, so as to ensure fairness between competitors.

Also, there are no clear process and timelines for the “measurement” (in par 3.4.3) and “compliance analysis” (in par 4.4), and consideration of the justifications of non-compliance (in par 4.5). In addition, opportunities have to be created for disputes on the acceptability of justifications. These timelines and processes are vital to the fairness of the process. A system that is easy to navigate and expeditious are critical for those who require such certificates in order to participate in state tenders.

**SAMED urge the inclusion of processes and timelines relating to the implementation of section 53, in order to create a predicable, consistent system of compliance monitoring and certification.**

#### **5. The proposed targets**

SAMED, as a member of BUSA, supports BUSA’s submission and includes by reference the comments relating to the absolute barriers placed by implication on non-designated, or equitably-represented groups.

In addition, SAMED reiterates, from its previous submission, the mathematical impossibility of achieving targets that cater for all designated groups in smaller workplaces, where the numerical targets, per designated group, imply a sufficiently large employee group in that employment level:

At senior management level, for a company in manufacturing with 18 positions at senior management level, the following numbers would be needed to achieve the targets:

	<b>AF</b>	<b>CF</b>	<b>IF</b>	<b>WF</b>
<i>Female Target</i>	14.8%	1.7%	0.5%	3.5%
<i>Numbers needed</i>	2.7	0.3	0.09	0.6
	<b>AF</b>	<b>CF</b>	<b>IF</b>	<b>WF</b>
<i>Male Target</i>	28.7%	3.3%	1%	4.5%
<i>Numbers needed</i>	5.2	0.6	0.2	0.8

The most recent SAMED survey shows that most employers regard the five-year targets as either “highly unlikely or impossible” to achieve, or “difficult but possible” to achieve. A minority stated that it would be achievable, and a few indicated that it would depend on various factors, such as organisational changes and the availability of suitably qualified staff or scarcity, salary expectations, etc.

## 6. Justifications

Paragraph 4.5 refers to the Draft 2018 EE Regulations. As not being in force, its finalisation would be peremptory prior to the finalisation of these draft targets. Those regulations also propose provisions on the determination of numerical targets and the issuance of the section 53 certificate.

In order to avoid two different sets of rules applicable to the same issue, consultation would again be required prior to finalising the 2018 Draft Regulations. Such consultation is necessary given the substantial changes in the economy and in the employment sector since 2018 and post-Covid.

The correct sequencing of EE Regulations, Ministerial Targets and the proclamation to bring the Employment Equity Amendment Act into effect, is important to avoid legal challenges relating to the targets or regulations being authorised by the empowering Act and all provisions accompanying the targets, being aligned to the Act.

## 7. Conclusion

The Employment Equity system set through the system of 5-year goals, with own targets being set for years 1 to 4, provided that the “start date” of year 1 is uniform, should be achievable, practical, and fair between various employers.

SAMED supports the acceleration of transformation in the medtech sector, which must be achieved. SAMED believes this can happen, with consultation with the sector and by creating

a clear and timeous system for certification that creates certainty for the sector, especially when the EE Compliance certificate is a mandatory criterion for state tenders.

SAMED would welcome the opportunity to engage with the Department and Minister on the matters set out in the Amendment Act. SAMED can be contacted at:

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**SUBMISSION BY THE SOUTH AFRICAN MEDICAL TECHNOLOGY INDUSTRY ASSOCIATION  
(SAMED)**

On the  
Draft Employment Equity Regulations  
as published on 12 May 2023 in the Government Gazette No 48589, Notice No 3407

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12 June 2023

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## **2. SAMED’s commitment to transformation in the medical technology sector**

SAMED is committed to transformation in the health sector, including in the ownership, and employment structures in business. To this effect, in 2013 SAMED established a committee to deal specifically with matters of transformation.

SAMED regards transformation as an economic and social imperative. It is committed to transformation and believe it has a responsibility to drive meaningful and sustainable change as an industry body.

SAMED wishes to state, in no uncertain terms, that it supports the Employment Equity Act, and the transformation agenda of the country, as is espoused in the Constitution of the Republic. Its comments below should be construed as pro-transformation and focusing on the practicalities of implementing real and lasting change.

## **3. SAMED’s understanding of the Employment Equity Amendment Act, 2022 and the implications for the Notice**

SAMED understands that the Employment Equity Amendment Act, No. 4 of 2022, as published in the *Government Gazette No 48418* dated 14 April, 2023, has not been proclaimed yet, meaning that the provisions have not been brought into effect. In terms of section 16 of Act 4 f 2022: “This Act is called the Employment Equity Amendment Act, 2022, and takes effect on a date fixed by the President by proclamation in the *Gazette*.” No such date has been proclaimed yet.

Once proclaimed, the Minister is able to exercise the powers afforded in terms of section 15A to issue notices. Such notice cannot be done without the Minister having those powers, and such powers are dependent on the aforementioned proclamation.

Furthermore, to be lawful, the notice has to be in full compliance with section 15A:



**15A.** (1) *The Minister may, by notice in the Gazette, identify national economic sectors for the purposes of this Act, having regard to any relevant code contained in the Standard Industrial Classification of all Economic Activities published by Statistics South Africa.*

(2) *The Minister may, after consulting the relevant sectors and with the advice of the Commission, for the purpose of ensuring the equitable representation of suitably qualified people from designated groups at all occupational levels in the workforce, by notice in the Gazette set numerical targets for any national economic sector identified in terms of subsection (1).*

(3) *A notice issued in terms of subsection (2) may set different numerical targets for different occupational levels, sub-sectors or regions within a sector or on the basis of any other relevant factor.*

(4) *A draft of any notice that the Minister proposes to issue in terms of subsection (1) or subsection (2) must be published in the Gazette, allowing interested parties at least 30 days to comment thereon.*

Based on the above, the following must be undertaken:

- (a) The **setting of “economic sectors,”** not on the Standard Industrial Classification (SIC), but **“having regard”** to the SIC. This is, for SAMED a critical point. A snap survey amongst SAMED’s members show that members are dispersed across a variety of SIC categories, even where their business profiles and requirements would be similar. Being in different classifications mean that different targets would apply to entities that are similarly situated. This would obviously produce unfair results.

SAMEDs preliminary analysis shows that members are in different categories, such as manufacturing, wholesale/retail, human health, etc. Even whilst most respondents are in “manufacturing”, members are in different categories, ranging from pharmaceuticals and plastics to food products, to wood and paper. The same applies to the wholesale and retail sector.

For example, SAMED members undertaking comparable services, with similar employee requirements, could face vastly different targets, e.g. the target for “Professionally qualified” employee in health is at 91% black employees, but in manufacturing, it is 62%, in professional and scientific, it is 65% and in wholesale and retail 75%. This means that unless the economic sub-sectors are set in a manner that is fair, and rational, the impact would be vastly different on similarly situated employers.

- (b) The **Minister has to consult “relevant sectors”**. SAMED, as a very specific economic sector, recognised as such through, for example, the Industrial Policy Action Plans by the Department of Trade, Industry and Competition as a unique and distinct sector for economic development.<sup>1</sup> The medtech sector also services the health sector, which, in turn, is a priority in view of the envisaged National Health Insurance. SAMED has not been consulted by the Minister or the Department of

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<sup>1</sup> See the last IPAP, [https://www.gov.za/sites/default/files/gcis\\_document/201805/industrial-policy-action-plan.pdf](https://www.gov.za/sites/default/files/gcis_document/201805/industrial-policy-action-plan.pdf) at page 147ff.

Employment and Labour. Read with subsection (3), section 15A envisages consideration of “any other relevant factor”. These factors would be brought to light by the consultation process, and we allude to some of those in this submission.

- (c) Based on these consultations, the Minister then has to, for **sector and subsectors, set different numerical targets**. Section 15A also states that the Minister should give, at least 30 days to comment. During consultative processes, it will, as SAMED has now experienced during the past month, become apparent that the necessary research and analyses, which should underpin the setting of targets pertaining to “equitable representation of suitably qualified people from designated groups at all occupational levels” require a **longer time period**. It is imperative that the targets being set are grounded in the realities of the South African work force, and the needs of employers in the medtech sector and subsectors.

SAMED believes, that should these steps be followed, as empowered by the Act, the notice will be set in a manner that will lead to industry-wide buy in, and the achievement of transformation at an enhanced pace.

#### 4. The proposed targets and the section 53 certificate

SAMED’s preliminary analysis shows that members are unlikely to achieve the targets set for top and senior management. The reason for this relates to the fact that these levels of employment, in order to be representative, require significant numbers of staff. Classically, top management would include only a single, or small number of individuals (between 0 and 11, with the most around 3 or 4). This means that an employer would also fall short in most of the designated groups, even if it does have, for example, a black female country manager or CEO. For senior management, the range of number of employees was between 3 and 18. Mathematically, compliance with all the targets per job level would be impossible.

By way of example, at senior management level, for a company in manufacturing with 18 positions at senior management level, the following numbers would be needed to achieve the targets:

	<b>AF</b>	<b>CF</b>	<b>IF</b>	<b>WF</b>
Female Target	14.8%	1.7%	0.5%	3.5%
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Male Target	28.7%	3.3%	1%	4.5%
Numbers needed	5.2	0.6	0.2	0.8

Although the achievement of targets, mathematically, becomes more possible due to staff numbers in junior management / skilled technical level, smaller companies with less than 50 employees are at a disadvantage, as the achievement of targets in all designated groups would be impossible. When an Indian or coloured person is appointed, the employer will overshoot those targets, and then not achieve the African targets, or vice versa.

Most of SAMED's members participate in the supply of medical technologies to the public health sector, and public entities, such as the NHLS. Being able to participate in tenders, the issuing of the Certificate referred to in section 53 may be an essential requirement and a potential barrier to patient access. It remains unclear, with the targets being set at a five-year goal, what level of compliance would be required in order to obtain such a certificate. The process relating to the issuance of such certificates is also not yet outlined.

Given these uncertainties on the application of the targets, and the process of engaging in relation to a section, it would be difficult for companies to set their own targets for years one to four.

There must also be consideration for the right of access to healthcare, for companies to be able to compete to supply products to the health sector, through the process of competitive bidding.

## **5. Conclusion**

The Employment Equity system set through the system of 5-year goals, should be achievable, practical, and fair between various employers.

SAMED supports the acceleration of transformation in the medtech sector, which must be achieved. SAMED believes this can happen, with consultation with the sector, and by following the process outlined in section 15A, and creating a system for certification that creates certainty for the sector, on view of bidding of public health tenders.

SAMED would welcome the opportunity to engage with the Department and Ministers on the matters set out in the Amendment Act. SAMED can be contacted at:

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