

DEPARTMENT OF HEALTH

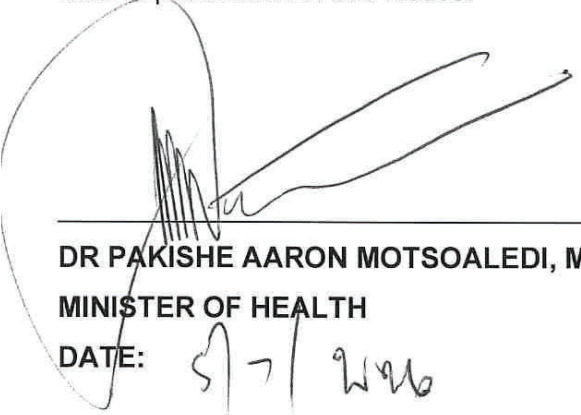
NO. 7782

7 August 2026

**REGULATIONS REGARDING FEES PAYABLE IN TERMS OF THE PROVISIONS OF
THE HAZARDOUS SUBSTANCES ACT, 1973 (ACT No. 15 of 1973)**

The Minister of Health intends, in consultation with the Minister of Finance and the South African Health Products Regulatory Authority, in terms of Section 29(1)(r) read together with Section 29(2)(a) and (4) of the Hazardous Substances Act, to make the Regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations, to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities and Relations Management, mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za), within three months of the date of publication of this Notice.



DR PAKISHE AARON MOTSOLEDI, MP
MINISTER OF HEALTH

DATE:

5/7/2026

SCHEDULE

1. Definitions In these Regulations, any word or expression to which a meaning has been assigned in the Act shall bear such meaning and, unless the context otherwise indicates-

“Authority” means the South African Health Products Regulating Authority

“MBq” means Megabecquerel;

“MRI” means Magnetic Resonance Imaging; and

“the Act” means Hazardous Substances Act, 1973, as amended (Act No. 1 of 1973).

Group IV Hazardous Substances

2. The fees payable, for the production, acquisition, disposal, importation and exportation, possession of or use or convey Group IV hazardous substances, for which an application for written authorisation is submitted as contemplated in Section 3A of the Act, are:

- (a) In respect of the submission of an application for authorisation to produce, possess, convey, cause to convey, use and distribute, including temporary use per authorisation:
 - (i) Category 1: **R41 200.00**
 - (ii) Category 2: **R33 000.00**
 - (iii) Category 3: **R29 000.00**
 - (iv) Category 4: **R14 000.00** and
 - (v) Category 5: **R11 200.00**.
- (b) In respect of the submission of an application for authorisation to export, import and other activities related to the authorisation, including monthly reporting:
 - (i) Once off export authorisation and confirmation: **R1 000.00** per sealed source,
 - (ii) Once off export authorisation and confirmation: **R1 000.00** per unsealed source of activity of 370 MBq,
 - (iii) Once off import authorisation and confirmation: **R1 300.00** per sealed source,

- (iv) Once off import authorisation and confirmation: **R1 300.00** per unsealed source activity of 370 MBq,
 - (v) Import and export of open authorisation and confirmation: **R980.00** per sealed source,
 - (vi) Import and export of open authorisation and confirmation: **R980.00** of unsealed source up to activity of 370 MBq provided that every additional 370 MBq, **R980.00** will be chargeable,
 - (vii) Transfer of sealed sources (buy/add/loan and sell/discard): **R700.00** per source,
 - (viii) Transfer of unsealed sources: **R700.00** per 370 MBq and
 - (ix) Closure of an existing authorisation: **R4 800.00**.
- (c) In respect of submission of exchange forms: **R2300.00** per Form.
- (d) In respect of the submission of an application to re-issue an existing authorisation or to amend an authorisation approved by the Authority:
- (i) Re-issuing of an authorisation: **R1 000.00**,
 - (ii) Change of office bearers, Radiation Protection Officer, Medical Physicist and other: **R4 000.00**,
 - (iii) Addition of facility: **R7 000.00** per facility; and
 - (iv) Increment of an activity: **R3 500.00** per 370 MBq.
- (e) In respect of the submission of an application for a certificate relating to a container:
- (i) Type container with multilateral approval and type container with unilateral approval certification: **R19 000.00** and
 - (ii) Type container with unilateral approval validation : **R5 000.00**.
- (f) Annually, in respect of the returns of an authorisation in accordance with Section 3A of the Act to produce, acquire, dispose, import, and export, possess, use, or convey Group IV hazardous substances: **R 2 150.00** provided that the fee is payable on or before the last working day of June that year, failing which the authorisation given may be revoked.
- (g) In respect of the renewal of an authorisation to produce, acquire, dispose, import, and

export, possess or use or convey Group IV hazardous substances (excluding open authorisation): **R5 300.00.**

Group III Hazardous Substances

3. Fees payable for licences to sell, let, use, operate and install any group III hazardous substances as contemplated in terms of section 4 of the Act, are as follows:

- (a) An application for a new licence for a Group III hazardous substance, in terms of Section 4(1)(b) of the Act, per product:
 - (i) Import/Manufacture licence of a listed medical electronic product: **R11 700.00,**
 - (ii) Import/Manufacture licence of a listed non-medical electronic product: **R8 600.00**
and
 - (iii) Export licence (medical/non-medical product): **R8 600.00.**
- (b) An application for a new licence to install and the use of electronic generators for medical purposes, in terms of Section 4(1)(b) and (c) of the Act per product:
 - (i) Class 3B and 4 lasers: **R19 400.00,**
 - (ii) MRI: **R27 000.00,**
 - (iii) Computed Tomography Scanner: **R27 000.00,**
 - (iv) Mammography, interventional radiology, or fluoroscopy: **R9 000.00,**
 - (v) Conventional radiology: **R7 000.00,**
 - (vi) Dental radiology and bone dental scans: **R6 200.00** and
 - (vii) Component: **R4 100.00.**
- (c) Application for new licence to install and use any electronic product for medical purposes, employing radioactive nuclides: **R27 000.00.**
- (d) An application for a new licence to install and use of electronic generators for non-medical purposes, in terms of Section 4(1)(b) and (c) of the Act per product:
 - (i) Industrial and veterinary radiology: **R7 000.00,**
 - (ii) Well loggings: **R18 900.00,**
 - (iii) X-ray irradiators, Cargo scanners, Whole body scanners: **R33 000.00,**

- (iv) Class 3B and 4 lasers: **R19 400.00**,
 - (v) MRI: **R27 000.00**,
 - (vi) CT Scanner: **R27 000.00** and
 - (vii) Component: **R4 100.00**.
- (e) An application for a new licence to install and use of electronic generators of X-Ray and particle accelerator products, in terms of Section 4(1)(b) and (c) of the Act per product:
 - (i) Therapeutic machine: **R43 000.00**,
 - (ii) Cyclotron: **R43 000.00**.
- (f) An application for the movement or exchange of an existing product licenced in terms of Section 4(1)(b) and (c) of the Act:
 - (i) Movement or exchange of products in section 3(b)(i-vi) and (d)(i-vi): **R2 300.00** and
 - (ii) Dental X-ray: **R2 000.00**.
- (g) An application for the discontinuation, modification, or disposal of an existing product licenced in terms of Section 4(1)(b) and (c) of the Act: **R7 000.00**.
- (h) In respect of the submission of an application to re-issue an existing or to amend an existing Licence approved by the Authority:
 - (i) Re-issuance of a licence: **R1 000.00** and
 - (ii) Amendment of a licence: **R4 000.00**.
- (i) Annual submission of information compliance per licenced product: **R220.00** per product for applications under Section 3 (a) in terms of section 5 of the Act.
- (j) An application for the renewal of the products licenced in Section 3(b-d), with renewal dates ranging from 1 to 5 years since its issuance, in terms of Section 5 of the Act: **R5 300.00**.
- (k) In respect of the issuance of a letter, permit, or a certificate:
 - (i) Non-radioactive certificate: **R4 100.00** and

- (ii) Non licensable letters or inspection body certificate: **R4 700.00**.

Fees payable for inspections

4. Payable fees payable for inspections not relating to the issuing a licence are:
- (a) The charge out rate per inspector will amount to **R1 700.00 per** hour per inspector for all scheduled inspections conducted that do not relate to the issuing or renewal of a licence, the inspection hours and travel time will be charged for in accordance with the applicable guideline; and
 - (b) Desktop inspection after licence amendments: **R2 300.00** per day per inspector.

Forfeiture and disposal of goods recovery

5. The fees payable for anything forfeited under Section 21(1) of the Act:
- (a) Cost relating to the appointed inspector to oversee the disposal: **R34 000.00** and
 - (b) Actual cost of storage and disposal to be recovered from the offender.

Penalties

6. (1) The following are fines for the production, acquisition, disposal, importation and exportation, possession of or use or convey Group IV hazardous substances without an approved written authorisation in accordance with Section 3A of the Act:
- (a) Category 1-2: **R162 500.00**,
 - (b) Category 3-5: **R115 000.00**,
 - (c) Import and export: **R50 000.00**,
 - (d) Source transfers, exchange forms, disposal, or closure: **R21 000.00**,
 - (e) None or late submission of monthly reports: **R22 000.00**,
 - (f) Non submission of amendments to existing authorisations: **R16 500.00**,
 - (g) Non-renewal, fraudulent documents, or annual return submission: **R28 500.00** and
 - (h) Failure to report in line with the requirements: **R68 000.00**.

(2) The following are fines for operating without a licence to sell, let, use, operate and instal in accordance with Section 4(1)(b)(c):

- (a) Medical importations: **R58 500.00**,
- (b) Non-medical importation: **R45 000.00** and
- (c) Other use licences: **R100 000.00**.

(3) The following are fines for operating without a licence in accordance with Section 4(1)(b)(c) for:

- (a) Medical installations and use: **R115 000.00**,
- (b) Non-Medical installations and use: **R100 000.00**,
- (c) Movement, exchange, and discontinuation: **R78 500.00**,
- (d) Non submission for the amendment of an existing licence: **R20 500.00**,
- (e) Non submission to renew and existing licence: **R28 500.00** and
- (f) Failure to report in line with the requirements: **R68 000.00**.

Appeal against the decision of the Authority.

7. Fee payable in respect of an application in terms of Section 24 (3): **R54 180.00** per application.

Short title

8. These Regulations are called Regulations regarding Fees Payable in terms of the provisions of the Hazardous Substances Act, 1973 (Act No. 15 of 1973), 2026.