ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

Section

PART II

APPLICATION FOR REGISTRATION OF BIOTECHNOLOGY FACILITIES

PART III

GENERAL

Section

IT is hereby notified that the Minister of Higher and Tertiary Education, Innovation, Science and Technology Development has, in terms of section 23 as read with section 59 of National Biotechnology Authority Act [*Chapter 14:31*] of 2006 and after consultation with the Authority made the following regulations:—

Title

1. These regulations may be cited as the National Biotechnology Authority (Biotechnology Facility Registration) Regulations, 2026.

Interpretation

2. In these regulations—

"biosafety level" means a specific combination of biocontainment precautions (work practices, safety equipment and facilities) required to isolate biological agents in an enclosed facility and minimise the exposure of workers and the environment to infectious agents;

"biosafety committee" means a committee established in terms of section 30 of the National Biotechnology Authority Act [*Chapter 14:31*] of 2006;

"Institutional Biosafety Manual (IBM)" means an operating manual for the purpose of standardising safety and emergency procedures to be observed in connection with projects undertaken in the biotechnology facility;

"facility" in relation to these regulations means any premise that is used for the development, production, use or application of biotechnology;

"registered facility" means a facility registered in terms of section 4.

Application

3. These regulations shall apply to all facilities that carry out biotechnology undertakings, unless informed otherwise.

PART II

Application for Registration of Biotechnology Facilities

Application for facility registration

4. (1) Pursuant to section 24 of the Act any person wishing to register a facility carrying out the objects of subsection (1)(a) to (d) shall complete Form NB1 as specified in the First Schedule together with an application fee specified in the Second Schedule:

Provided that where an application is not successful the Authority shall refund half the fee within thirty days of notification of an unsuccessful application.

(2) On submission of an application in terms of subsection (1) a facility must ensure that it sets up an institutional biosafety committee in accordance with section 30 of the Act which committee shall develop an institutional biosafety manual, containment measures and contingency plans within 30 days of submitting the application for registration.

(3) On receipt of the institutional biosafety manual in subsection (2) the Authority shall review the IBM and generate a report with recommendations to the applicant within 14 days of such receipt.

(4) Upon receipt of the report and recommendations referred to in subsection (3) the applicant must immediately implement the IBM and any recommendations thereto.

(5) Within seven days of receiving the IBM review report from the Authority the applicant shall invite the Authority to audit the facility.

(6) The Authority will audit the facility for the purposes of—

(a) carrying out a safety assessment;

(b) verifying the biosafety level of the facility;

within seven days of receiving the audit notification from the applicant.

(7) The Authority shall generate an audit report within 14 days of the audit date.

(8) The applicant shall rectify anomalies noted in the audit report, if any, within 30 days of receiving the audit report and notify the Authority of such rectification.

(9) Upon completion of requirements in subsections (1) to (8) or where there are no anomalies at the completion of the audit reports, the Authority shall finalise consideration of the application within seven days from the date of notification in terms of subsection (8) or the date of completion of the audit report in terms of subsection (7), and shall within that period, make a decision on the application by remitting to the applicant a copy of the application whereon it shall be indicated whether the Authority—

(a) approves the application unconditionally; or

(b) approves the application subject to specified conditions; or

(c) rejects the application for specified reasons.

(10) Subject to section 5 every holder of a certificate of registration—

(a) shall at every approved facility, display or have available a copy of his or her certificate of registration; and

(b) on demand by any person who produces proof to the holder of a certificate of registration that he or she is—

(i) an inspector in terms of the Act; or

(ii) a police officer;

produce to that person a copy of such certificate.

(11) Any person who contravenes this section shall be guilty of an offence and liable to a fine not exceeding level 12 or to imprisonment for a period not exceeding five years, or to both such fine and imprisonment.

Conditions attaching to every certificate of registration

5. (1) It shall be deemed to be a condition of every certificate holder that—

(a) no holder of a certificate, shall transfer his, her or its certificate of registration;

(b) a certificate of registration shall not be used for a facility other than the facility audited during the application process;

(c) the certificate will only be applicable for the biosafety level for which the certificate was issued;

(d) every holder of a certificate shall adhere to the relevant biosafety guidelines issued by the Authority in terms of section 22 of the Act.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level 10 or imprisonment for a period not exceeding two years or both such fine and such imprisonment.

Issuance, duration, surrender and renewal of certificate of registration

6. (1) Every certificate of registration shall be valid for a period of one year, unless it is earlier surrendered to or cancelled by the Authority for specified reasons.

(2) If an application for a registration is successful (whether approved with or without conditions) the Authority shall—

(a) inform the applicant accordingly in accordance with section 4(9); and

(b) issue to the applicant a certificate of registration of the facility; and

(c) make an appropriate entry in the Register of facilities and permits.

(3) Upon expiry of the certificate of registration the registered facility may renew it by making an application therefore no later than ninety days before the expiry of the existing certificate of registration by submitting—

(a) Form NB2 specified in the Third Schedule, where there has been no material change in the details of the application for the existing certificate together with the renewal fee specified in the Second Schedule;

(b) Form NB1 specified in the First Schedule, where there has been any material changes in the details supplied in the original application for the existing certificate, together with the application fee specified in the Second Schedule.

(4) Upon receipt of an application for the renewal of certificate of registration—

(a) in terms of subsection (3)(a) the Authority shall—

(i) conduct a safety assessment and satisfy itself that there has been no material change in the details of the existing certificate; and

(ii) if so satisfied shall renew the certificate by endorsing the existing certificate accordingly;

(b) in terms of subsection (3)(b) the same procedure as is prescribed in subsection (2) shall apply.

Suspension or cancellation of certificate of registration

7. (1) Subject to subsections (2) and (4), the Authority may at any time suspend (for a period not exceeding sixty (60) days) or cancel any certificate of registration if the Authority has reasonable grounds for believing that—

(a) the certificate of registration was issued in error or through fraud or misrepresentation or non-disclosure of a material fact by the holder of a certificate; or

(b) the holder of a certificate has contravened any provision of the Act or these regulations or any condition of its certificate of registration; or

(c) the holder of a certificate has ceased the licensed operations.

(2) The Authority shall notify the holder of a certificate in writing of its intention to suspend or cancel its certificate of registration and the reasons for doing so, and shall call upon the holder of a certificate to show cause, within 14 days from the date of the notice, why the certificate of registration should not be suspended or cancelled, as the case may be:

Provided that if in the opinion of the Authority the certificate of registration needs to be immediately suspended or cancelled in the public interest or to avert an accident, the Authority may issue the notice requiring the holder of a certificate to show cause after suspending or cancelling the certificate of registration.

(3) If, at the expiry of the period specified in the notice given in terms of subsection (2), and after considering any representations made by the holder of a certificate of registration, the Authority is satisfied for any reason specified in subsection (1) that the certificate of registration concerned should be suspended or cancelled, the Authority shall, by notice in writing to the holder of a certificate, suspend or cancel the certificate of registration or take such other action as it considers appropriate.

(4) The penalty of suspension is only available where there has been a contravention of any provision of the Act or these regulations or any condition of a certificate of registration which, in the opinion of the Authority, is a contravention that can be easily or speedily remediated by the holder of a certificate:

Provided that—

(a) if after the expiry of the period of suspension the holder of a certificate has not taken the remedial action, the Authority shall forthwith cancel the certificate of registration; or

(b) on good cause shown by the holder of a certificate, the Authority may extend the suspension for a period not exceeding thirty (30) days to allow the holder of a certificate to take the required remedial action.

(5) The Authority shall immediately make an appropriate entry in the register of facilities and permits where it suspends or lifts a suspension of any certificate of registration or cancels it in accordance with this section.

Application for permit

8. (1) No person may use a facility registered in terms of section 4 without a permit of utilisation.

(2) Any registered facility wishing to utilise such facility shall apply for a permit in Form NB3 specified in the Fourth Schedule together with a fee specified in the Second Schedule:

Provided that where an application is not successful the Authority shall refund half the fee within thirty (30) days of notification of an unsuccessful application.

(3) The Authority shall no later than 72 hours after receiving the application for a permit and after satisfying itself that Form NB3 specified in the Fourth Schedule has been properly completed—

(a) approve the application unconditionally;

(b) approve the application subject to specified conditions;

(c) reject the application for specified reasons.

(3) Any person who contravenes this section shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding five years, or to both such fine and imprisonment.

Conditions attaching to permit

9. (1) It shall be deemed to be a condition of every permit that—

(a) no registered facility shall transfer its permit to another person;

(b) no registered facility shall engage in any activities otherwise than those specified on the permit;

(c) it shall not be used for a facility other than the facility audited.

(2) Any person who contravenes subsection (1) shall be guilty of an offence liable to a fine not exceeding level 3 or to imprisonment for period not exceeding one month or to both such fine and such imprisonment.

Issuance, duration, surrender and renewal of permit

10. (1) Every permit shall remain valid for a period of one year subject to the validity of the certificate of registration unless it is earlier surrendered to or cancelled by the Authority for specified reasons.

(2) If an application for a permit is successful the Authority shall—

(a) inform the applicant accordingly; and

(b) issue to the applicant a permit for utilisation of the facility; and

(c) make an appropriate entry in the Register of facilities and permits.

(3) Upon expiry of the permit the registered facility may renew it by making an application thereof no later than thirty (30) days before the expiry of the existing permit by submitting—

(a) Form NB2 specified in the Third Schedule, where there has been no material change in the details of the application for the existing permit together with a renewal fee specified in the Second Schedule;

(b) Form NB3 specified in the Fourth Schedule, where there has been any material changes in the details supplied in the original application for the existing permit, together with a fee specified in the Second Schedule.

(4) Upon receipt of an application for the renewal of permit—

(a) in terms of subsection (3)(a) the Authority shall satisfy itself that there has been no material change in the

details of the existing permit and renew the permit by endorsing the existing permit accordingly;

(b) in terms of subsection (3)(b) or where a facility has not submitted any returns in terms of section 16, the same procedure as is prescribed in subsection (2) shall apply.

Suspension or cancellation of permit

11. (1) Subject to subsections (2) and (4), the Authority may at any time suspend (for a period not exceeding sixty (60) days) or cancel any permit if the Authority has reasonable grounds for believing that—

(a) the permit was issued in error or through fraud or misrepresentation or non-disclosure of a material fact by the registered facility; or

(b) the registered facility has contravened any provision of the Act or these regulations or any condition of its permit; or

(c) the registered facility has ceased to operate.

(2) The Authority shall notify the registered facility in writing of its intention to suspend or cancel its permit and the reasons for doing so, and shall call upon the registered facility to show cause, within 14 days from the date of the notice, why the permit should not be suspended or cancelled, as the case may be:

Provided that if in the opinion of the Authority the permit needs to be immediately suspended or cancelled in the public interest or to avert an accident, the Authority may issue the notice requiring the registered facility to show cause after suspending or cancelling the permit.

(3) If, at the expiry of the period specified in the notice given in terms of subsection (2), and after considering any representations made by the registered facility, the Authority is satisfied for any reason specified in subsection (1) that the permit concerned should be suspended or cancelled, the Authority shall, by notice in writing to the registered facility, suspend or cancel the permit or take such other action as it considers appropriate.

(4) The penalty of suspension is only available where there has been a contravention of any provision of the Act or these regulations or any condition of a permit which, in the opinion of the Authority, is a contravention that can be easily or speedily remediated by the registered facility:

Provided that—

(a) if after the expiry of the period of suspension the registered facility has not taken the remedial action, the Authority shall forthwith cancel the permit; or

(b) on good cause shown by the registered facility, the Authority may extend the suspension for a period not exceeding thirty (30) days to allow the registered facility to take the required remedial action.

(5) The Authority shall immediately make an appropriate entry in the register of facilities and permits where it suspends or lifts a suspension of any or cancels it in accordance with this section.

Amendment and replacement of permit or certificate of registration

12. (1) The Authority may at any time amend a permit or a certificate of registration or any terms or conditions thereof—

(a) to correct any error in the certificate of registration or permit; or

(b) if the holder of a certificate or permit requests the amendment; or

(c) if the Authority considers the amendment necessary to reflect the true nature of the registered activities; or

(d) if for any other reason the Authority considers the amendment necessary or desirable in the interests of the environment or in the public interest.

(2) The Authority shall notify the registered facility in writing of its intention to amend a certificate of registration or permit on a ground referred to in subsection (1)(a), (c) or (d) and shall call upon the registered facility to show cause, within 14 days from the date of the notice, why the certificate of registration or permit should not be amended.

(3) Where a registered facility requests an amendment to its certificate of registration or permit, it shall make an application to the Authority thereof in Form NB4 specified in the Fifth Schedule, together with a fee specified in the Second Schedule.

(4) If in the opinion of the Authority the amendment sought by the registered facility is a material amendment the Authority shall advise the registered facility to make an application in terms of section 4.

(5) Where a certificate of registration or permit is lost or destroyed, the registered facility may apply to the Authority in Form NB5 specified in the Sixth Schedule, together with a fee specified in the Second Schedule, for a replacement certificate of registration or permit:

Provided that if the registered facility finds the lost certificate of registration or permit it shall forthwith surrender it to the Authority.

(6) Any person who contravenes the proviso to subsection (5) shall be guilty of an offence and liable to a fine not exceeding level 3 or imprisonment for a period not exceeding one month or both such fine and such imprisonment.

PART III

General

Register of facilities and permits

13. (1) The Authority shall establish and maintain a register for the purpose of—

(a) registering facilities utilised for the development, production, use or application of biotechnology; and

(b) recording permits issued for the utilisation of such facilities;

to be known as the Register of Facilities and Permits.

(2) The register of facilities and permits shall record the following—

(a) the name and address of every registered facility; and

(b) any permit issued to a registered facility; and

(c) the date of issue of the certificate of registration or permit and of any renewal thereof; and

(d) any special terms or conditions subject to which any certificate of registration or permit is issued or renewed; and

(e) the particulars of any suspension or cancellation or amendment of a certificate of registration or permit; and

(f) biosafety level and type of the facility; and

(g) name and contact details of the biosafety officer.

(3) Any person may inspect the register of facilities and permits free of charge at all reasonable times at the premises of the Authority or at such other place that the Authority may direct.

(4) The Authority shall keep and maintain the register in both material and electronic form.

Safety Assessments of facilities

14. (1) Any person who owns or operates facilities undertaking biotechnology activities, shall allow inspectors to carry out safety assessments during and after registration processes.

(2) Inspectors shall audit a facility by—

(a) assessing the adherence to biosafety guidelines and institutional biosafety manuals; and

(b) conducting a technical inspection of the facility; and

(c) reviewing of documents including but not limited to—

(i) personnel training records;

(ii) standard operating procedures;

(iii) facility equipment maintenance and calibration records;

(iv) facility safety manuals if any;

(v) waste disposal records;

(vi) accident reports if any.

(3) The Authority shall—

(a) generate an inspection observation report to be signed by a representative of the facility during the audit closing meeting;

(b) issue an audit report to the facility within 14 days of the audit date, which report will list the non-conformities noted, recommendations and verdict of the audit.

(4) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level 12 or to imprisonment for a period not exceeding five years, or to both such fine and imprisonment.

Containment measures and contingency plans

15. (1) An applicant shall apply the general principles and the appropriate containment and other protective measures set out in the Biosafety Guidelines and IBM corresponding to the biosafety level so that a high level of safety is ensured.

(2) The Authority shall ensure that before registration commences—

(a) the applicant draws up a contingency plan (immediate and delayed) for contained use to mitigate risks, to humans, animals and the environment within or outside the premises;

(b) information on such contingency plans, including the relevant safety measures to be applied, is outlined in the IBM for purposes of monitoring for compliance.

(3) In the event of an accident, a registered facility shall inform the Authority immediately and shall provide the following information—

(a) the circumstances and location of the accident;

(b) the identity and quantities of the biological and hazardous materials concerned;

(c) any information necessary to assess the effects of the accident on human, animal and environmental health; and

(d) emergency measures taken or needed to be taken to avoid or mitigate any adverse impacts.

(4) Where information is given pursuant to subsection (3), the Authority shall—

(a) ensure that all necessary measures are taken;

(b) where possible, collect information necessary for a full analysis of the accident, including the accident or incident report; and

(c) where appropriate, make recommendations to avoid a similar accident in the future and to limit the effects thereof.

(5) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level 12 or to imprisonment for a period not exceeding five years, or to both such fine and imprisonment.

Annual returns

16. Every registered facility shall annually submit returns to Authority concerning ongoing projects, accident reports, waste disposal records, facility equipment maintenance and calibration records, reports on trainings done within the period and any other information as maybe required by the Authority from time to time.

Appeals

17. (1) Any person who is aggrieved by a decision of the Authority, the Board, or the Minister may make an appeal in terms of section 58 of the Act.

Confidential information

18. (1) Subject to section 56 of the Act an applicant may indicate the information in the application which should be treated as confidential and shall give reasonable justification for such indication.

(2) The Authority shall not disclose to a third party any information considered to be confidential and shall respect the intellectual property rights related to the information received

regardless of whether the applicant has withdrawn the application or not.

(3) Any person who contravenes subsection (2) shall be guilty of an offence and liable to a fine not exceeding level 5 or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

FIRST SCHEDULE (*Sections 4 and 6*)

NB1

Application for Registration of Biotechnology Facility

This form must be completed legibly. Delay will be caused if this form is not completed properly, or if any of the questions below are not answered or if the declaration is not signed.

Biosafety Levels Applied For: *(Tick the applicable)*

Biosafety Level 1
Biosafety Level 2
Biosafety Level 3
Biosafety Level 4

Note: *Descriptions and work related with Biosafety levels outlined above are described in the Biosafety Guidelines.*

I hereby apply to be recognised as a Registered Biotechnology Facility in accordance with the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

Name and Address of Facility:	
Company Registration No.	
Contact Details (*Phone and Email*)**:**	
Number of Facilities to be registered:	
Scope of Biotechnology Activities:	
Contact Person (*Name and Designation*)**:**	*Signature: ….....*
Contact Details (*Phone and Email*)**:**	
Head of Company (*Name and Designation*)**:**	*Signature: ….....*

Declaration by applicant:

I declare that the particulars given by me, on behalf of the organisation, in this Form are true, to the best of my knowledge.

Date ……...…… Signature of applicant……

Checklist: *Have you attached the following—*

Completed Application Form	Yes / No
Institutional Biosafety Manual	Yes / No
Current Tax Clearance	Yes / No
Certificate of Incorporation	Yes / No
CR14	Yes / No
MoU/Proof of registration	Yes / No
Company Profile	Yes / No

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature: Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....
.....

(b) Approval recommended subject to the following conditions: .....
.....
.....
.....

(c) Rejection recommended for the following reasons: .....
.....
.....
.....
.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON..... SIGNED.....

SECOND SCHEDULE (*Sections 4, 6, 8,10 and 12*)

Fees

Section	Description	US$
(4)	Application for Facility Registration	800
(6) and (10)	Renewal of Certificate of Registration/ Permit	Half of the fee for certificate of registration/permit
(8)	Application for permit of utilisation	200
(12)	Amendment of Certificate of Registration/Permit	20
(12)	Replacement of Certificate of Registration/Permit	20

THIRD SCHEDULE (*Sections 6 and 10*)

NB2

Application for Renewal of Certificate of Registration or Permit

Name and Address of Facility:	
Contact Details (*Phone and Email*)**:**	
NBA Registration No.:	**Certificate No.:** **Permit No.:**
Date of issue:	
Classification	Biosafety Level ……....
Scope of Biotechnology Activities:	
Contact Person (*Name and Designation*)**:**	*Signature:*…..….....
Contact Details (*Phone and Email*)**:**	

Has there been a change in any of the following since the last registration

ITEM	YES/NO	IF YES DESCRIBE THE NATURE AND REASON OF CHANGE
BIOSAFETY LEVEL		
BIOSAFETY COMMITTEE		
BIOSAFETY MANUAL		
LOCATION OF FACILITY		
SCOPE OF WORK		
OTHER (please specify)		

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....
.....

(b) Approval recommended subject to the following conditions: .....
.....

(c) Rejection recommended for the following reasons: .....
.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON..... SIGNED.....

FOURTH SCHEDULE (*Sections 8 and 9*)

NB3

Application for Permit of Utilisation for Biotechnology Facility

This form must be completed legibly. Incomplete forms or unsigned declaration can delay processing time.

I hereby apply for a permit to operate a Biotechnology Facility in accordance with the National Biotechnology Authority Act [*Chapter 14:31*] of 2006.

Name and Address of Facility:	
Contact Details (*Phone and Email*)**:**	
NBA Facility Registration No.:	
Date of issue:	
Classification	Biosafety Level ……
Specific Biotechnology Activities Conducted on Site:	
Contact Person (*Name and Designation*)**:**	*Signature:*….....
Contact Details (*Phone and Email*)**:**	

Declaration by applicant:

I declare that the particulars given by me, on behalf of the organisation, in this Form are true, to the best of my knowledge.

Date …… Signature of applicant……

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.:.....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....

(b) Approval recommended subject to the following conditions:
.....

(c) Rejection recommended for the following reasons: .....
.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON ..... SIGNED.....

FIFTH SCHEDULE (*Section 12*)

NB4

Application for Amendment of Certificate of Registration or Permit

Name and Address of Facility:	
Contact Details (*Phone and Email*)**:**	
NBA Registration No.:	**Certificate No.:** **Permit No.:**
Date of issue:	
Classification	Biosafety Level ……
Reason for Amendment:	
Contact Person (*Name and Designation*)**:**	*Signature: ….*.....
Contact Details (*Phone and Email*)**:**	

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....
.....

(b) Approval recommended subject to the following conditions:
.....

(c) Rejection recommended for the following reasons: .....
.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON..... SIGNED.....

SIXTH SCHEDULE (*Section 12*)

NB5

Application for Replacement of Certificate of Registration or Permit

Name and Address of Facility:	
Contact Details (*Phone and Email*)**:**	
NBA Registration No.:	**Certificate No.:** **Permit No.:**
Date of issue:	
Classification	Biosafety Level ……
Reason for Replacement:	
Contact Person (*Name and Designation*)**:**	*Signature: ….…..*
Contact Details (*Phone and Email*)**:**	

FOR OFFICIAL USE OF REGISTERING AUTHORITY ONLY

....

Name of Officer Designation

.....

Signature Date and Stamp

1. Receipt No.: .....

2. Recommendation of registering authority (fill in where appropriate):

(a) Approval without conditions recommended: .....
.....

(b) Approval recommended subject to the following conditions: .....
.....

(c) Rejection recommended for the following reasons: .....
.....

NOTIFICATION PARTICULARS

The decision on this application was notified to the applicant:

ON..... SIGNED.....