



Biological Substances Export / Import Permits

Information Booklet



The Biological Substances Export / Import Permits Information Booklet comes to you in collaboration between TNT and SACRA.

We would like to thank the Export / Import section of the Department of Health for their input and support with this initiative.

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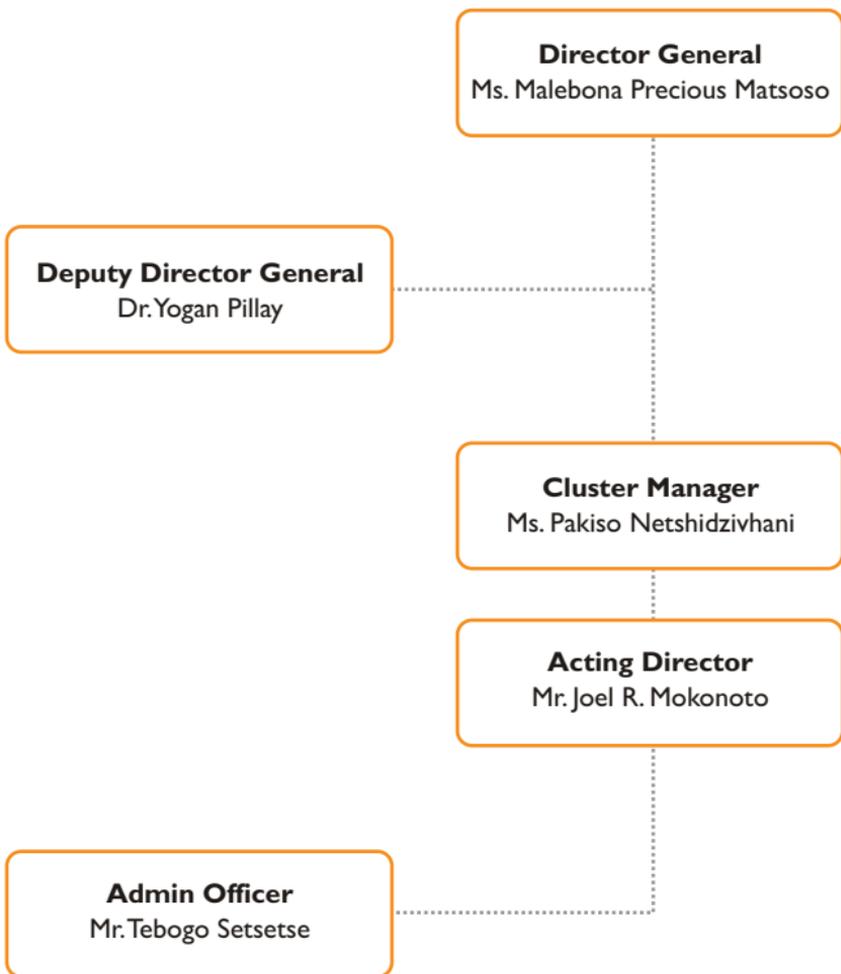
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Section I

Department of Health Export / Import Permit Organisational Line Structure.



Section 2

2.1 Annotated Application for an Export Permit for Biological Substances.



DEPARTMENT OF HEALTH
Private Bag X828 PRETORIA 0001

Inquiries: Mr JR Mokonoto Tel.: (012) 395-9063 Fax: 086 6327733

APPLICATION FOR AN EXPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Export Permit: NB:			
NAME	1		
RANK / POSITION	2		
Organisation:			
NAME	3		
ADDRESS	4	NO. P.O. BOX ADDRESS	
		ONLY PHYSICAL ADDRESS	
TEL. NO.	5	FAX. NO.	6
Specific substance(s) for which an export permit is required:			
SUBSTANCE		QUANTITY	
7			8
Period during which export will take place:			9
Contact person and organisation to which the substance(s) is(are) exported:			
NAME: PERSON	10		
NAME OF ORGANISATION	11		
ADDRESS	12	NO. P.O. BOX ADDRESS	
		ONLY PHYSICAL ADDRESS	
TEL. NO.	13	FAX. NO.	14
Purpose(s) for which substance(s) is(are) to be used. Although detail is not required, the specific purpose(s) must be clearly stated:			
15			
SPECIFIC PURPOSE MUST BE DEFINED			

NB: Incomplete application forms will not be processed

SIGNATURE OF APPLICANT: _____ 16 _____ DATE: _____ 17 _____

Section 2

2.2 Instruction for Completion of the Application for an Export Permit for Biological Substances

1.	Name	Fill in the full name (title, first, middle, surname) of the applicant. The applicant should be an investigator / lab and should not be the sponsor / CRO / courier / lab applying on behalf of the investigator site.
2.	Rank / Position	Fill in the designation of the applicant (i.e. principal investigator).
3.	Name	Fill in the applicant's complete company name.
4.	Address	Fill in the applicant's complete company physical address. No P.O. Box addresses are allowed.
5.	Tel No.	Fill in the applicant's complete company contact number.
6.	Fax No.	Fill in the applicant's complete company facsimile number.
7.	Substance	Fill in the complete description of the substance / commodity / product (i.e. serum; blood; plasma etc.).
8.	Quantity	Fill in the liquid quantity per sample and the number of samples (i.e. 10ml 2 samples).
9.	Period of Export	Fill in the time period that samples will be exported for.
10.	Name: Person	Fill in the complete receiver's name.
11.	Name of Organisation	Fill in the receiver's complete company name.
12.	Address	Fill in the receiver's complete physical address. No P.O. Box addresses are allowed.
13.	Tel No.	Fill in the receiver's complete contact number.
14.	Fax No.	Fill in the receiver's complete facsimile number.
15.	Purpose of substance use	Fill in the specific purpose (i.e. clinical research) including the protocol number.
16.	Signature of Applicant	This must be the physical signature of the actual applicant.
17.	Date	Fill in the date the application is signed.

Section 2

2.3 Example of Completed Application for an Export Permit for Biological Substances.



DEPARTMENT OF HEALTH
Private Bag X828 PRETORIA 0001

Inquiries: Mr JR Mokonoto Tel.: (012) 395-9063 Fax: 086 6327733

APPLICATION FOR AN EXPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Export Permit: NB:			
NAME	Dr. John Smith		
RANK / POSITION	Principal Investigator		
Organisation:			
NAME	The Cross Hospital		
ADDRESS	Private Practice		
	1 Cross Street, Centurion		
	Pretoria, 0157		
	South Africa		
TEL. NO.	012 221 1331	FAX. NO.	012 221 1344
Specific substance(s) for which an export permit is required:			
	SUBSTANCE	QUANTITY	
	Serum	10 ml (2 samples)	
	Plasma	10 ml (2 samples)	
	Whole Blood	10 ml	
Period during which export will take place:	12 months i.e. 01 August 2011 - 31 July 2012		
Contact person and organisation to which the substance(s) is(are) exported:			
NAME: PERSON	Mrs. Rebecca Nurse		
NAME OF ORGANISATION	Green Central Laboratory		
ADDRESS	24 Green Street		
	London, WC 1N 3QS		
	United Kingdom		
TEL. NO.	+44 (0) 20 72243 2538	FAX. NO.	+44 (0) 20 7243 2539
Purpose(s) for which substance(s) is(are) to be used. Although detail is not required, the specific purpose(s) must be clearly stated:			
Human biological substances UN3373 (blood or serum or urine or other body fluids or biopsies).			
Packed in accordance with IATA Packaging Instruction 650. Transported for diagnostic testing as part of a clinical trial.			
Protocol ABC456.			

NB: Incomplete application forms will not be processed

SIGNATURE OF APPLICANT: Dr. John Smith DATE: 01 August 2011

Section 3

3.1 Annotated Application for an Import Permit for Biological Substances.



DEPARTMENT OF HEALTH
Private Bag X828 PRETORIA 0001

Inquiries: Mr JR Mokonoto Tel.: (012) 395-9063 Fax: 086 6327733

APPLICATION FOR AN IMPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Import Permit: NB:			
NAME	1		
RANK / POSITION	2		
Organisation:			
NAME	3		
ADDRESS	4	NO. P.O. BOX ADDRESS	
		ONLY PHYSICAL ADDRESS	
TEL. NO.	5	FAX. NO.	6
Specific substance(s) for which an import permit is required:			
SUBSTANCE		QUANTITY	
7			8
Period during which import will take place:			9
Contact person and organisation supplying the substance(s):			
NAME: PERSON	10		
NAME OF ORGANISATION	11		
ADDRESS	12	NO. P.O. BOX ADDRESS	
		ONLY PHYSICAL ADDRESS	
TEL. NO.	13	FAX. NO.	14
Purpose(s) for which substance(s) is(are) to be used. Although detail is not required, the specific purpose(s) must be clearly stated:			
15			
SPECIFIC PURPOSE MUST BE DEFINED			

NB: Incomplete application forms will not be processed

SIGNATURE OF APPLICANT: _____ 16 _____ DATE: _____ 17 _____

Section 3

3.2 Instruction for Completion of the Application for an Import Permit for Biological Substances

1.	Name	Fill in the full name (title, first, middle, surname) of the applicant. The applicant should be an investigator / lab and should not be the sponsor / CRO / courier / lab applying on behalf of the investigator site.
2.	Rank / Position	Fill in the designation of the applicant (i.e. principal investigator).
3.	Name	Fill in the applicant's complete company name.
4.	Address	Fill in the applicant's complete company physical address. No P.O. Box addresses are allowed.
5.	Tel No.	Fill in the applicant's complete company contact number.
6.	Fax No.	Fill in the applicant's complete company facsimile number.
7.	Substance	Fill in the complete description of the substance / commodity / product (i.e. serum; blood; plasma etc.).
8.	Quantity	Fill in the liquid quantity per sample and the number of samples (i.e. 10ml 2 samples).
9.	Period of Import	Fill in the time period that samples will be imported for.
10.	Name: Person	Fill in the complete contact name of the person supplying the substance (shipper).
11.	Name of Organisation	Fill in the complete company name supplying the substance (shipper).
12.	Address	Fill in the shipper's complete physical address. No P.O. Box addresses are allowed.
13.	Tel No.	Fill in the shipper's complete contact number.
14.	Fax No.	Fill in the shipper's complete facsimile number.
15.	Purpose of substance use	Fill in the specific purpose (i.e. clinical research) including the protocol number.
16.	Signature of Applicant	This must be the physical signature of the actual applicant.
17.	Date	Fill in the date the application is signed.

Section 3

3.3 Example of Completed Application for an Import Permit for Biological Substances.



DEPARTMENT OF HEALTH
Private Bag X828 PRETORIA 0001

Inquiries: Mr JR Mokonoto Tel.: (012) 395-9063 Fax: 086 6327733

APPLICATION FOR AN IMPORT PERMIT FOR BIOLOGICAL SUBSTANCES

Person applying for an Import Permit: NB:	
NAME	Dr. John Smith
RANK / POSITION	Principal Investigator

Organisation:			
NAME	The Cross Hospital		
ADDRESS	Private Practice		
	1 Cross Street, Centurion		
	Pretoria, 0157		
	South Africa		
TEL. NO.	012 221 1331	FAX. NO.	012 221 1344

Specific substance(s) for which an import permit is required:	
SUBSTANCE	QUANTITY
Serum samples	10 ml (30 samples)
Urine samples	10 ml (30 samples)
Period during which import will take place: 12 months i.e. 01 August 2011 - 31 July 2012	

Contact person and organisation supplying the substance(s):			
NAME: PERSON	Dr. Karen Ralph		
NAME OF ORGANISATION	Ghana Centre for Diseases Control		
ADDRESS	Ring Road East		
	Osu		
	Accra - Ghana		
TEL. NO.	+(233) 0302 736911	FAX. NO.	+(233) 0302 736912

Purpose(s) for which substance(s) is(are) to be used. Although detail is not required, the specific purpose(s) must be clearly stated:
Human biological substances UN3373 (blood or serum or urine or other body fluids or biopsies).
Packed in accordance with IATA Packaging Instruction 650. Transported for diagnostic testing as part of a clinical trial.
Protocol ABC456.

NB: Incomplete application forms will not be processed

SIGNATURE OF APPLICANT: Dr. John Smith DATE: 01 August 2011

The Department of Health Export / Import Permit

Section 4

4.1 Department of Health Act Background

When did the National Health Act, 2003 (Act no. 61 of 2003) regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes come into being?

The Act came into being in 1983.

How did the regulation come about?

The regulations came about with the implementation of the Human Tissue Act no 65 of 1983.

Why did the Act come about?

To control & manage Health Ports of entry. All regulations are promulgated to govern and control certain activities e.g. The Human Tissue Act governs the Human Tissue Industry, hence the government identified a need for such an Act.

Who does this Act apply to?

The Act applies to all authorised individuals / institutions in South Africa i.e. people dealing with human biological specimens.

Where can a copy of the Act be obtained?

This is a very old Act and is not currently available on the website. A hard copy is available upon request from the Department of Health.

Where can a copy of the Act be collected?

Department of Health, Civitas Building, Room N315, 3rd Floor, Cnr Andries and Struben Streets, Pretoria

Prior arrangements need to be made with the Department of Health.

Why is this process being enforced now?

It has been in existence since 1983 and been in force from inception. It was only recently discovered that the Health Ports were not enforcing it .

The Department of Health Export / Import Permit

Section 4

4.2 Frequently Asked Questions and Answers

Would this process apply to all UN3373 Biological Substance, Category A and B samples being exported / imported?

Yes. This applies to all Biological Substance samples.

Who are automatically authorised?

Doctors, hospitals, universities and technicians.

What needs to happen if an organisation / institution are not authorised?

A letter needs to be addressed to the Minister of Health applying for authorisation.

Does each investigator site need to complete an export / import application form and obtain a permit?

Yes.

Is there a deadline for the investigator site/s to adhere to in terms of compliance with this regulation?

The deadline is for all applicants to make application before they export / import samples.

Will an export / import permit be needed for investigator sites that are already participating in current or old clinical trials?

Yes, if they do not yet have a permit

If so, would the export / import permit application process be the same?

Yes.

Is there a time frame or a sliding scale used i.e. Say that a study has three months left versus one that has eighteen months left?

No. A renewal of the application must be submitted.

The Department of Health Export / Import Permit

Section 4

4.2 Frequently Asked Questions and Answers continued

Does an investigator need to apply for an export permit if Biological Substance samples are sent to a local laboratory for analysis and then the laboratory exports the samples overseas?

No. The laboratory is responsible for applying for an export permit.

For what period of time is an export / import permit valid?

The period depends on what is being exported / imported and the purpose thereof. Normally the period is twelve months but it can be one month, three months, six months or one year.

What is a recommended example of a time period to be completed on the application?

Example: 01 August 2011 - 31 July 2012.

Can an export / import permit be issued for longer than a period of twelve months?

Yes, but this is not advisable especially on a longer term clinical trial. If there are any changes to the Act during the duration of the clinical trial then a new export/import application needs to be completed for a new permit to be issued.

If an investigator site is running multiple clinical trial studies going to the same destination, would they need to apply for separate export permits?

Yes. A separate export / import permit is required per study / protocol.

Can application be made for a combined export permit for more than one type of commodity (i.e. blood, urine etc.)?

Yes you can use one application for different types of samples per applicant and per study.

Must a separate application be made per type of commodity, per applicant and per study?

No. Please refer above.

The Department of Health Export / Import Permit

Section 4

4.2 Frequently Asked Questions and Answers continued

From which National Authority must the approval of a shipment be obtained?

National Department of Health.

Does a physical copy of the export permit have to be attached to the shipment when it is being exported?

Yes, otherwise the goods won't be allowed to go through the Port of Health.

Can an electronic copy of the export permit be filed instead of being physically attached to the shipment?

No. A physical copy is required at the Port of Health. They have been instructed to ask for the permit with regards to all shipments.

How can one determine if an organisation / institution is authorised to export / import?

The Department of Health has records of all authorised institutions.

How can one determine who within an organisation / institution (i.e. lab) is authorised to apply for permits?

Laboratory Manager, Quality Manager, Doctors.

Do people within an organisation / institution need to be on a specific level to be authorised? If so, who would normally be authorised in terms of titles?

Laboratory Manager; Quality Manager; Doctors.

How many people per organisation / institution can be authorised to export / import?

There is no limit.

Can a blanket authorisation be issued to an organisation that has multiple people working with the export / import of biological samples?

The Department of Health do not issue blanket authorisation for permits.

The Department of Health Export / Import Permit

Section 4

4.2 Frequently Asked Questions and Answers continued

If so, what process needs to be followed and with whom should it be addressed?

Not applicable.

If not, then instead of applying for a new permit can an addendum of change be attached with a change in applicant information on the current valid permit?

Yes, provided the valid permit is attached.

In the case of staff turnover or changes within an organisation, how is it determined which positions can be authorised?

The organisation should decide on who can be given the responsibility for applying for permits.

If a sponsor requests that samples be sent from an investigator to a lab for storage purposes, where they are stored over a period of time (say three to six months) before an instruction is received to ship them overseas but no local lab analysis takes place, who would be responsible for making application for the permit?

The laboratory exporting the samples would be responsible.

The Department of Health Export / Import Permit

Section 5

5.1 Getting to Know the Department of Health

Can the Department of Health provide a copy of the organisational structure for the complete export / import permit process?

Yes. It is included in the information pack.

Can the Department of Health provide a completed contact list in terms of export / import permit applications for biological substances and medicines?

Our contact details are as follows:

Mr. Tebogo Setsetse (Admin Officer)

Tel: +27 12 395 9197

Fax: +27 86 211 4903

E-mail: tsetset@health.gov.za

Mr. Joel R. Mokonoto (Acting Director)

Tel: +27 12 395 9063

Fax: +27 86 211 4903

Emergency: +27 82 412 5673

E-mail: mokonj@health.gov.za

Ms. Pakiso Netshidzivhani (Cluster Manager)

Tel: +27 12 395 8856

E-mail: netshp@health.gov.za

Dr. Yogan Pillay (Deputy Director General)

Tel: +27 12 395 8078

Fax: +27 86 632 3053

E-mail: pillay@health.gov.za

The PA needs to be copied in on all correspondence to Dr. Yogan Pillay.

Details of which are as follows (the same contact details apply):

Selokela Leshabane

E-mail: leshas@health.gov.za

The Department of Health Export / Import Permit

Section 5

5.1 Getting to Know the Department of Health continued

Ms. Precious Matsoso (Director General)

Tel: +27 12 395 9150

Fax: +27 12 395 9019

E-mail: matsop@health.gov.za

What is the Department of Health escalation process?

Technical Enquiries:

Mr. Joel R. Mokonoto

Administrative Enquiries:

Mr. Tebogo Setsetse

Mr. Joel R. Mokonoto

Complaints:

Mr. Joel R. Mokonoto (Acting Director)

Ms. Pakiso Netshidzivhani (Cluster Manager)

Dr. Yogan Pillay (Deputy Director General)

Ms. Precious Matsoso (Director General)

What are the Department of Health operating hours?

Monday - Friday: 08h00 to 16h00

Weekends and public holidays: closed

Emergency enquiry contact: Available 24 hours, 7 days a week

The Department of Health Export / Import Permit

Section 5

5.2 Frequently Asked Questions and Answers

Does the Department of Health have representation in multiple regions?

The Department of Health operates on a National basis with the National office being based in Pretoria.

If so, please could the details of the other Department of Health offices be provided?

There are no offices in any of the other provinces.

Are there any planned changes in terms of roles and responsibilities with regards to the export / import permit sector of the Department of Health?

No.

If so, what are the planned changes?

Not applicable.

Will there be any planned changes for the export / import permit sector?

No. Mr. Joel R. Mokonoto will remain the main contact.

If so, what are the planned changes?

Not applicable.

How many export / permit application forms are processed by the Department of Health per day?

Between 70 - 200 on average, depending on Departments' man-power.

How can SACRA help the Department of Health in terms of expediting the process?

Feel free to approach the Department of Health (Deputy Director General) with member concerns and issues.

The Department of Health Export / Import Permit

Section 6

6.1 Export / Import Permit Application Process

Where can one obtain a copy of the export / import permit application document?

On the website - www.doh.gov.za

Department of Health Documents - Resource Centre - Forms

What is the export / import permit application process?

The authorised individual correctly completes and signs the application form and faxes it through to the Department of Health for processing.

What process other than that of the export / import permit application needs to take place?

There is no other process.

Can guidelines be provided as to the best method to complete the export/ import permit application form?

Simply follow the instructions on the form

Complete the correct information:

- Applicant details with full physical address; telephone and facsimile numbers.
- Product to be exported / imported and quantity.
- Protocol number.
- Period required for export / import.
- Full details (physical address, telephone and facsimile numbers) of whom the product is being exported to or imported from.
- Reasons for export / import.

What is the cost involved?

No cost involved.

What is the best method to use for submission of applications?

Send the export / import permit application directly to Mr. Joel R. Mokonoto on +27 86 211 4903 (fax to e-mail).

The Department of Health Export / Import Permit

Section 6

6.2 Frequently Asked Questions and Answers

Are there any institutions; investigator sites or organisations that have made special arrangements to expedite their export / import permit applications?

No. All clients are treated equally.

If so, please confirm what process needs to be followed to arrange the same for other organisations; investigators and organisations?

There is no special treatment for any client.

Are there any plans for an electronic application process to be made available by the Department of Health in the future?

Yes.

If so, when is this expected to take place?

This is to be advised.

Will an electronic signature system be implemented in the near future?

This is to be advised.

What is most important in terms of the applicant's signature?

The main issue is that the applicant themselves need to sign the application document and not the project coordinator.

Are P.O. Box address details acceptable on the export / import permit application?

No. Inspectors need the physical address for site inspection purposes. The original permits are also delivered to the applicant via the local postal system and a physical address is required.

Is a physical address required for both the sender and the receiver on the export / import permit application form?

Yes. Failure to comply could result in the application not being processed.

The Department of Health Export / Import Permit

Section 6

6.2 Frequently Asked Questions and Answers continued

What purpose / reason should be included on the export / import permit application form?

Include a specific purpose i.e. Human biological substances UN3373 (blood, serum or urine or other body fluids or biopsies) packed in accordance with IATA Packaging Instruction 650. Transported for diagnostic testing as part of a clinical trial. Protocol ABC456.

What level of detail is required for the product description on the export / import permit application form?

Keep it simple i.e. blood; plasma; serum etc. Please include number of patients and volume per shipment.

Please note:

Investigator may not export / import more than five litres at any given time. If there are too many patients participating on the clinical trial then the information will be split in order for multiple export / import permits to be issued.

It is the investigators responsibility to ensure that they monitor and manage the amount sent per shipment so the five litre limit is not exceeded.

Does a copy of the protocol need to be attached to the export / import permit application?

No. The Department of Health has requested that this not be attached.

Will the protocol number be included on the export permit?

The protocol number can be added on the same line as the doctors name.

Can an organisation / institution (i.e. laboratory; courier etc.) apply for the export / import permit on behalf of the investigator?

No. The investigator is responsible for applying for the permit. Organisations / institutions can assist with the export/import permit issue follow-up process.

The Department of Health Export / Import Permit

Section 6

6.2 Frequently Asked Questions and Answers continued

Can an organisation / institution semi-complete an export / import permit application form, send it to the investigator for signature, and receive it back confirming information is correct and signed and submit application to the Department of Health on behalf of the investigator?

Yes. It is critical that the applicant signs the application and not the organisation / institution.

Could the CRO (Central Research Organisation) complete the form and the investigator sign it?

Yes, provided all the information is correct and that the doctor realises that he / she is ultimately responsible if anything is incorrect.

Can an organisation / institution collect all the signed export permit applications from multiple participating investigators and submit directly to the Department of Health for processing in a batched format?

Yes, provided that the investigator has signed their own export permit application form as the actual sender.

Can a laboratory that is based overseas (i.e. Belgium) apply for the export permit on behalf of the local investigator in the case where biological samples are exported directly overseas for analysis?

No. Permits are only issued to South African citizens because the legislation is aimed at South Africans and is therefore only operational in South Africa.

How long does it take for an export / import application process to be completed?

It takes, on average three days to complete the process (submit; issue; fax back to client and post original to the applicant). Should take a maximum of seven working days.

The Department of Health Export / Import Permit

Section 6

6.2 Frequently Asked Questions and Answers continued

Do micro-organisms require an export permit?

Yes. Apply for the authority to export / import. Make use of the same Department of Health contacts.

Could an example of a correctly completed export / import permit application be made available?

Yes. It is included in this information pack.

What (if any) are the limitations / conditions related to the shipment of tumour samples?

There are no limitations or conditions.

Is an application and subsequent approval required before the shipment of tumour samples?

Yes.

Who needs to be the applicant in tumour samples shipment permission?

The doctor.

What documentation is required for the shipment permission application for tumour samples?

The same as other samples.

What is the duration of the shipment permission application process?

It depends on what the specimen is going to be used for.

Can an organisation apply for one export permit for multiple protocols with the same destination?

No. Each protocol must have its own permit.

The Department of Health Export / Import Permit

Section 6

6.2 Frequently Asked Questions and Answers continued

Can an organisation apply for one export permit for multiple protocols with the same destination?

No. Each protocol must have its own permit.

Can an organisation apply for one export permit for multiple protocols with the same destination with various sample sizes and containers put into one box (one type of commodity)?

No. Each protocol must have its own permit.

Can an organisation apply for one export permit for multiple protocols with the same destination with various sample sizes and containers put into one box (multiple types of commodities)?

No. Each protocol must have its own permit.

In Africa normally only P.O. Box addresses are available. Can this be used and what happens to these applications?

P.O. Box address is allowed for recipients outside of South Africa.

Can a concession be implemented to allow for P.O. Box addresses?

P.O. Box address is allowed for recipients outside of South Africa.

Often the facsimile number is not available in Africa. Can this section on the application document be left blank?

Yes. Leaving it blank is acceptable.

Can a concession be implemented to allow for the facsimile number to be left blank?

Yes. Leaving it blank is acceptable.

What application document would need to be used for tissue samples?

Same one used for biological substances.

The Department of Health Export / Import Permit

Section 7

7.1 Export / Import Permit Issue Process

What does the export / import permit issue process entail?

If the application form is completed properly, the export / import permit is processed, authorised and sent to the applicant

1. Application is received by Mr.Tebogo Setsetse and processed.
2. Once processed the permit application is submitted to Mr. Joel. R. Mokonoto for checking and verification.
3. Once checked and verified the permit application is submitted to the Cluster Manager (Ms. Pakiso Netshidzivhani) for signature.
4. Once signed the issued permits are faxed through to the applicants.
5. Copies of the permits are made by the Department of Health for record keeping.
6. The original export / import permit is posted to the applicant.

7.2 Frequently Asked Questions and Answers

How long does it take for an export / import permit to be issued?

It takes three days on average to complete the process. It should take a maximum of seven working days.

What problems are being experienced in terms of delays in the issuing of export / import permits?

During October, November and December the Department of Health receive many requests that generally lead to delays in finalising the permits, thus creating a backlog.

What steps can be taken to alleviate the backlog?

- It is advisable to spread the applications throughout the year instead of leaving them until the end of the year as this causes backlogs.
- Correct completion of the application.
- Correct signature on the application.

The Department of Health Export / Import Permit

Section 7

7.2 Frequently Asked Questions and Answers continued

When is the backlog expected to be cleared?

Many factors contribute to the backlog and delay and this varies from application to application. The Department of Health normally take a maximum of seven working days to finalise the applications, should the applicant have completed the form correctly.

What factors can contribute to causing a delay in the issue of export / import permits?

- Incorrect information completed on the application form.
- Incomplete application forms.
- Unauthorised person having signed the application form.
- Held awaiting authorisation from the Department of Health Cluster Manager.
- Backlog of applications.
- Department of Health currently only have one facsimile line.
- Non existence of the correct unit to deal with permit applications in the Department of Health (i.e. Laboratory Services versus. Clinical Forensic Medicine).

Should the protocol number appear on the export / import permit?

Yes. The protocol number should appear next to the doctor's name on the permit.

What happens if the Cluster Manager is not available to authorise the export / import permit applications?

Mr. Joel R. Mokonoto is only authorised to sign-off permits in the case of emergency and if written justification is presented in terms of the urgency. All other applications will be held awaiting the Cluster Manager's signature.

At the recent SACRA meeting it was agreed that an evaluation process is to take place to ascertain whether there has been an improvement in the permit issue process. Can the evaluation "test run" commence from the 10th of July 2011?

Yes.

The Department of Health Export / Import Permit

Section 7

7.2 Frequently Asked Questions and Answers continued

If so, what tool can be implemented in terms of measurement on the number of submissions received versus the number of export / import permits issued on a monthly basis?

The Department of Health is beginning to deal with the internal processes and systems to identify the bottlenecks. A proposal will be submitted to the Cluster Manager by Mr. Joel R. Mokonoto upon completion of the investigation. This is anticipated to take approximately two months to complete. The SACRA spreadsheet will be used in the interim as a measurement tool.

What is the Department of Health's contingency plan when export / import permit delays are experienced?

Mr. Joel R. Mokonoto will do the processing during the heavy backlogs.

Who can be contacted in the event that there is a delay in the signing of the export / import permit?

Enquiries can be referred to the Deputy Director General.

The Department of Health Export / Import Permit

Section 8

8.1 Export / Import Permit Follow Up Process

What is the application follow up process?

The applicant can phone the Department of Health to find out about the status of the permit request

Phone Mr.Tebogo Setsetse on +27 12 395 9197 with the following information on hand:

- Name of the applicant
- Type of permit applied for
- Date of application

or

Phone Mr. Joel R. Mokonoto on +27 12 295 9063 / +27 82 412 5673 or

E-mail mokonj@health.gov.za

or

Phone Ms. Pakiso Netshidzivhani on +27 12 395 8856

8.2 Frequently Asked Questions and Answers

What is the general response given by the Department of Health to the applicant enquiring about the status of their permit?

It will be faxed through to the applicant upon completion.



Need more assistance?

Customer Service Contact Centre

Sector: Clinical Express / Healthcare Booking Centre

Tel: +27 87 150 2443

Fax: +27 86 504 1465

After hours: +27 82 804 9899

E-mail: Healthcare.ZA@tnt.com

Operating Hours:

Monday - Friday

08h00 - 17h00

Saturdays

08h00 - 13h00

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