

## **REGULATORY GUIDE**

### **REGISTRATION/LICENSING AND ISSUANCE OF NOC TO THE EXPORTER(S) OF RADIOPHARMACEUTICALS**

**PAKISTAN NUCLEAR REGULATORY AUTHORITY  
P.O. Box 1912 Islamabad**

# Pakistan Nuclear Regulatory Authority

August 2005

PAK-9801  
Rev. 0

## REGULATORY GUIDE

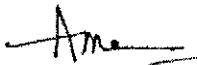
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### TITLE:

**REGISTRATION/LICENSING AND  
ISSUANCE OF NOC TO THE  
EXPORTER(S) OF  
RADIOPHARMACEUTICALS**

### ABSTRACT:

Pursuant to the requirements of the "Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s)-PAK/908", this document provide guidance to the applicant and describes the stepwise process for registration/licensing and issuance of NOC for the export of radiopharmaceuticals.

Prepared:   
(Samina Iftikhar)

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## **1. INTRODUCTION**

Pursuant to clauses 16 and 19 of "PNRA Ordinance III of 2001[1], PNRA has been entrusted with the responsibility for controlling, regulating and supervising all matters related to nuclear safety and radiation protection measures including the power to issue licence for export of any radioactive ores, radioactive material, nuclear substance or any other substance as the Pakistan Nuclear Regulatory Authority (PNRA) may, by notification in the official gazette specify. Moreover, under the provision of "Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s)-PAK/908, Clause (16)[2]", Pakistan Nuclear Regulatory Authority (PNRA) issues No Objection Certificates (NOC) to the license holders for the export of radioactive material and radiation apparatus. Keeping in view the provisions of the PNRA Ordinance and the requirements of PNRA Regulations and "Export Policy and Procedure Order 2000", Ministry of Commerce, this guide describes the various stages of process, which are obligatory for the licensee to comply for the export of radiopharmaceuticals.

## **2. OBJECTIVE**

The objective of this document is to provide step by step guidance to the applicant interested in registration and obtaining license/ NOC from PNRA as exporter of radiopharmaceuticals.

## **3. SCOPE**

This guide applies to exporters of radiopharmaceuticals. All activities covered in this guide are considered as part of a practice and meet the requirements for such practice.

## **4. GUIDELINES FOR MEETING REGULATORY REQUIREMENTS**

The guide comprises of the following **FIVE** steps:

### **Step 1: Application for the registration/licensing**

Any individual/company/institute desirous of exporting radioactive material/radiation apparatus is required to submit an application for the registration/licensing on the prescribed form along with the purpose, justification for the export, in broad way, and any other information/documents

required by PNRA as mentioned in the application form (ANNEXURE-I) and prescribed in "Regulations -PAK/908". Application forms either incomplete or containing incorrect information may not be accepted.

**Step 2: Submission of request for NOC**

After the registration by the PNRA, the applicant is required to submit the request for NOC to export the desired radiopharmaceuticals on prescribed application form (ANNEXURE-II). The applicant should be aware of the items exempted for the requirement of NOC from PNRA as described in "Regulations on Radiation Protection-PAK/904, (*annex-I*)[3]". The requirement for NOC may be exempted if the exemption criterion of clause 7 of PAK/904 is satisfied. PNRA requires at least (approx. 7 days) to process each request of NOC for export.

**Step 3: Completion of packaging/shipment requirements**

The packaging/shipment of each consignment of radioactive material for the export is required to follow the IAEA Safety Standards Series No. TS-R-1[4]. At the request of the applicant PNRA may provide the services to the manufacturer/consignee/exporter such as the issuance of certificate of package design validity, etc. PNRA may perform regulatory inspection of the premises before the shipment of consignment to verify the package design, type, category and to monitor the radiation doses and radioactive contaminations at the surface and around the package/container of the consignment.

**Step 4: Verification of the legitimacy of end user(s)**

Exporters are required to provide the documentary evidence about the end user(s) who should be a registered/licensed entity by their own national nuclear regulatory authority/radiation protection directorate etc., along with each request of the NOC for export. In addition, the exporter is also required to provide NOC/authorization for import of radiopharmaceuticals from the Government/Regulatory Authority of his country.

**Step 5: Provision of other essential certificate/ declaration/ documents**

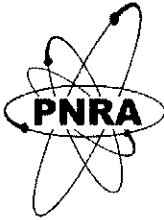
The exporter is required to provide a certificate/declaration from the end users, not to export a whole or part of the consignment to any other country in the world and to prohibit the free distribution of the radiopharmaceuticals within the country of export. The end user shall also declare that the consignment shall be utilized for the same purpose and shall be handled within the same premises, for which it has been procured.

**5. REFERENCES**

1. Pakistan Nuclear Regulatory Authority Ordinance No. III of 2001.
2. Regulations for the Licensing of Radiation Facility(ies) other than Nuclear Installation(s) (No. PAK/908).
3. Regulations on Radiation Protection (No. PAK/904).
4. IAEA Safety Standards Series No. TS-R-1(Safe Transport of Radioactive Material, 2003)

**ANNEXURE-I**

Form No. 4-A



# Pakistan Nuclear Regulatory Authority

Regional Nuclear Safety Directorate  
P. O. Box No. 1912, Islamabad

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(Please tick)

## APPLICATION FORM FOR REGISTRATION /LICENSING OF EXPORTER(S) OF RADIOACTIVE MATERIAL/RADIATION APPARATUS

1. Particulars of the applicant (hereinafter will be called the "Licensee") along with telephone number and Nationality (attach copies of the N.I.C/Passport)

Name:	NIC No.																		
Title (Owner, Director, etc):																			
Qualification:																			
Address (including Tehsil, District & Division):																			
Tel. No.:					Fax. No.:					e-mail:									

2. Particulars of the person(s) responsible for handling/packaging/shipment of radiation apparatus/radioactive material:

Sr. No.	Name	Designation	Qualification	Experience	Training in Radiation Protection

Provide the information on radiation personnel monitoring arrangements of the radiation workers.

3. Particulars of radioactive material/radiation apparatus to be exported:

i. Name of radioactive material/ radiation apparatus	
ii. Specification (Atomic weight, Atomic Number, Type, Model, mA/kV etc.	

4. Reason/justification of the export of radioactive material/radiation apparatus:

i. Purpose of the export (in detail)	
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ii. Justification of the export	
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5. Location of Premises for handling/packaging/shipment of radiation apparatus/radioactive material for the export

Address (including Tehsil, District & Division):
Premises Owned or on Lease (attach documents)
Plan/map and brief description of the building including shielding design (attach documents)

6. Remittance of license fee in the form of Bank Draft only:

Bank Draft Number	
Bank Draft In favor of	<b>“Director (Finance), PNRA, Islamabad”,</b>
Payable	<b>at Islamabad (state amount, date and name of th bank)</b>

7. Whether a radiological emergency plan has been prepared, if exists then submit a copy of that.

I, hereby, affirm that all the particulars given above are correct to the best of my knowledge and belief. I undertake to abide by the provisions of PNRA Ordinance-2001 and PNRA Regulations-Pak/908 & Pak/904 including any guidelines or amendments/revisions issued thereto.

Dated: \_\_\_\_\_

Signature of the Applicant \_\_\_\_\_

Seal of Office \_\_\_\_\_

Please check the following:-

- |  |         |
|--|---------|
| i. Copy of N.I. Card                     | Yes/ No |
| ii. Ownership/Lease documents attached   | Yes/ No |
| iii. Plan/Map of the building attached   | Yes/ No |
| iv. Arrangements of personal monitoring  | Yes/No  |
| v. Documents for justification           | Yes/No  |
| vi. Copy of radiological emergency plan. | Yes/No  |
| v. Bank draft attached.                  | Yes/No  |



### LICENSE FEE SCHEDULE

**License and Renewal Fees as per S.R.O. 901(I)/2003 dated September 11, 2003**

Facility	License fee (Rs.)	Annual Renewal Fee (Rs.)	License amendment Fee (Rs.)
Importers/exporters/manufacturers of radioactive material or radiation apparatus.	50,000.00	25,000.00	12,500.00

Note:- (The requirement of licensing is in effect from 01.01.1992. For details please contact your respective RNSD).  
RNSD-I, Islamabad 051-9204233, RNSD-II, Kundian 04592-41535, RNSD-III, Karachi 021-5800867



**ANNEXURE-II**  
**Form No. 2-D**

**Pakistan Nuclear Regulatory Authority**

Regional Nuclear Safety Directorate  
P.O. Box No. 1912 Islamabad

I	II	III
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(Please tick)

**APPLICATION FORM TO OBTAIN NO OBJECTION  
CERTIFICATE (NOC)\* FOR THE EXPORT OF  
RADIOACTIVE SOURCE(S)/MATERIAL/CONTAINER**

**1. PERSONAL DATA**

i. Name:		ii. NIC No.:	
iii. Title (Owner, Director, etc):			
iv. Tele. No.:	v. Fax. No.:	vi. e.mail:	
vii. Mobile No.:	viii. Address:		

**2. LICENSE INFORMATION**

i. Date of registration and licensing with PNRA:	
ii. License No.:	iii. Date of issue:
iv. Validity of License:	

*\* NOC will be granted to registered/valid license holder with PNRA*

**3. TECHNICAL INFORMATION**

i.	Name of radioactive source(s)/material	
ii.	Radioactive Source(s) Identification No(s). along with copy of manufacturer certificate(s)	
iii.	Sealed or unsealed	
iv.	Physical form of source(s)/material	
v.	Chemical Composition	
vi.	Number of radioactive source(s) along with radioactivity of each source or total quantity of radioactive material at the time of import	
vii.	Present radioactivity of source(s)/material being exported	
viii.	Identification number of the package/container	
ix.	Radiation level at the surface of package/container	
x.	Transport Index	
xi.	Category of the package/container	

xii.	Type of the package/container	
xiii.	Design validity certificate of the package/container	
xiv.	United Nations Number with proper Shipping Name	
xv.	Wipe test (Bq/cm <sup>2</sup> ) a. Dry b. Wet	

### 3. ADMINISTRATIVE INFORMATION

i.	Purpose of export	
ii.	Expected date of export	
iii.	Recipient	
iv.	Country of destination	
v.	Name and address of carrier/agent	
vi.	Mode of shipment (Air/Sea/Land)	
vii.	Arrangements for safe transportation of radioactive source(s)/material from the establishment to the port of exit	

### 4. ANY OTHER INFORMATION

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I hereby confirm that all the particulars given by me in this application are true and correct.

Dated:

Signature of the Applicant \_\_\_\_\_

Seal of Office \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_