NNRA/AUT/-021

NIGERIAN NUCLEAR REGULATORY AUTHORITY

GUIDE FOR FILLING AUTHORIZATION FORM

NIGERIAN NUCLEAR REGULATORY AUTHORITY

Plot 564/565 Airport Road Central Area

P. M. B. 559, GARKI, ABUJA

Tel: 09-2343123, 09-2343158
Fax: 09-2343122
e-mail: nnra@linkserve.com.
(www.nnra.gov.ng)

GUIDE FOR AUTHORIZATION FORM

PUROPSE OF THIS GUIDE

This document provides guidance to applicants in preparing an application for authorization to use radiation sources as well as Nigeria Nuclear Regulatory Authority (NNRA) criteria for evaluating the applications. It describes the information needed by the NNRA for new authorizations, amendments on existing authorizations, and renewal of authorizations for the use of radiation sources.

The Nigeria Basic Ionizing Radiation Regulations (NiBIRR) and other practice specific Regulations as issued by NNRA are to be used in conjunction with this guide. The applicant should read the applicable regulations carefully before filling the application form. This guide should not be considered as an all inclusive and complete substitution for understanding the regulations, training in radiation safety, or developing and implementing an effective radiation safety and protection programme.

THE APPLICATION FORM

Complete the form "Application for Authorization" form NNRA/AUT/-020 and the accompanying Table for List and Description of ionizing radiation sources. Submit the form with the radiation safety programme on supplementary sheets. All items are to be addressed in details for the NNRA to determine that the equipment, facilities, training and experience, and radiation safety programme provided are adequate to protect health and minimize danger to life and environment.

Name and Mailing Address of Applicant

Enter the applicant's name, mailing address including Town and State. Enter the official telephone number, fax number and e-mail if applicable.

The applicant must be the legal person with direct control over the use of the radiation sources for which authorization is sought. The NNRA considers this individual as having the authority to make commitments on behalf of the applying organization. Change of this applicant must be communicated to the Authority. If the Authority considers it an amendment it shall demand a re-application.

Type of Authorization

Indicate whether this is an application for a new authorization, an amendment, or a renewal. If this is an amendment or a renewal, please identify the authorization number. For an amendment or renewal, the applicant must identify the NNRA authorization number and give the business name. In all cases, the appropriate authorization fee must accompany the application in order to process the request. Choose the type of application you are making. If the type of Authorization you are applying for is not listed, indicate the type by describing clearly what you are applying for.

Purpose of Application

Specify the purpose for which the source will be used (e.g., for insect eradication through sterile male release programme, medical diagnosis, therapy, fixed industrial radiography, mobile, educational, etc.). Radiation sources and equipment should only be used for the purposes for which they are designed and in accordance with the

manufacturers recommendations. Applicants need to provide sufficient information to demonstrate that the proposed use will not compromise the integrity of the radiation source or source shielding, or other radiation safety-critical components of the device.

Business Name and Contact Address

This should be the business name with RC number and address where the facility is operated. The address should be descriptive (such as No. 2 Any Name Street, Any Area, Any Town, Any State). This descriptive address should be sufficient to allow an NNRA inspector to find the location. A Post Office Box is not acceptable. This address should also be the address where records concerning the radiation source(s) and or equipment are to be kept. The copy of certificate of registration with corporate affairs commission should be provided.

Radiation Safety Officer (RSO)

Enter the name and telephone number and qualification of the appointed Radiation Safety Officer (RSO). The qualification should be brief and should be only those connected with radiation safety training and other professional qualifications that have to do with use of radiation sources for which authorization is being sought.

This person is usually the contact person for this application and authorization and should therefore be familiar with the proposed radiation source(s) and be able to answer questions regarding the application. This is usually the person responsible for the radiation safety programme. The person must be a staff actively working in the facility and will serve as the point of contact during the application review process and after issuance of the authorization. Notify the NNRA if this contact person changes. This change may be considered as an amendment. The applicant can also be RSO if he has the required attributes.

Radiation Safety Adviser (RSA)

This should be an institution or a qualified professional or consultant with training and experience in radiation safety and protection. The institution or the person must be accredited by the NNRA. The RSA must be familiar with the organization's radiation safety programme and should preferably be resident in Nigeria and be available to defend the organization's radiation safety programme. The RSA may among others help in training of personnel and conduct radiation safety audit and review. Changes of RSA would not be considered as an amendment, but it must be communicated to the Authority.

Dosimetry Service Provider (DSP)

This should be an organization with proven capability to issue and interpret doses acquired by workers and the public. The service provider must have NNRA authorization to perform such service. Attach documentary evidence showing that a dosimetry contract has been entered with the provider. The NNRA can deny application of any type if the DSP is not accredited or the applicant and a DSP do not enter into a proper agreement.

Signature and Name of Applicant

This form NNRA/AUT/-20 must be duly signed and dated by the applicant. If the form is not properly signed, it will not be processed.

LIST AND DESCRIPTION OF SOURCES

The Table on page 2 for List and Description of Radiation Sources accompanying the application form NNRA/AUT/-020 should be used for listing the sources for inventory. Any source not listed on this form will be considered as not authorized. False declaration of sources is an offence and the penalties are prescribed in the Radiation Safety Act 19 of 1995. Use different rows on the table for each source. The categories of information on the form are:

- Identify each source by their names (e.g., Cobalt-60 for radioactive sources). For accelerators state the target source (e.g. H-3-Be). For machines state the type (e.g. X-ray Machine).
- **G**ive maximum strength (Max activity for radioactive sources, maximum kVp and mAs for X-ray Machines and maximum energies and intensity for other sources). Activity should be preferably quoted in GBq (1 Ci = 37 GBq).
- State the source form (e.g. sealed, open). For machines state whether automated, or manually controlled.
- State manufacture's name and full contact address that is presently valid. Abridged addresses will not be acceptable to NNRA. If possible provide the telephone, fax and e-mail addresses of the manufacturer. You can obtain this information from your supplier if different from the manufacturer.
- State the model name or model number of the source and preferably both.
- State the serial number of the source. This number must be traceable to the manufacturer.
- State the design standardization, giving the organization's name and number (e.g. SON yyyy…, ISO yyyy or IEC yyyy) . The NNRA may demand in some cases that you present the Standardization Certificate as part of authorization requirement. You should be able to obtain the above information from the supplier or manufacturer.
- State the use of each source. This may be the same as already shown in NNRA/AUT/-020. Note that though a user can have multiple sources, sources for different practices should have separate authorization.
- State whether source facility is fixed or mobile. Give the address where each permanent facility or source is used, irrespective of whether it is the same as that of the permanent business address already stated in form NNRA/AUT/-020. This must be street address; a post office box is not acceptable. A storage address must be an in-state storage address. If the device will be used at a permanent facility or facilities, give the specific address of each. If the source is mobile give the geographic locations that your operations cover (e.g. whole of Nigeria, Any State, Some LGA etc.) This information is necessary for the Authority to determine the transport and emergency facilities needed by the applicant.

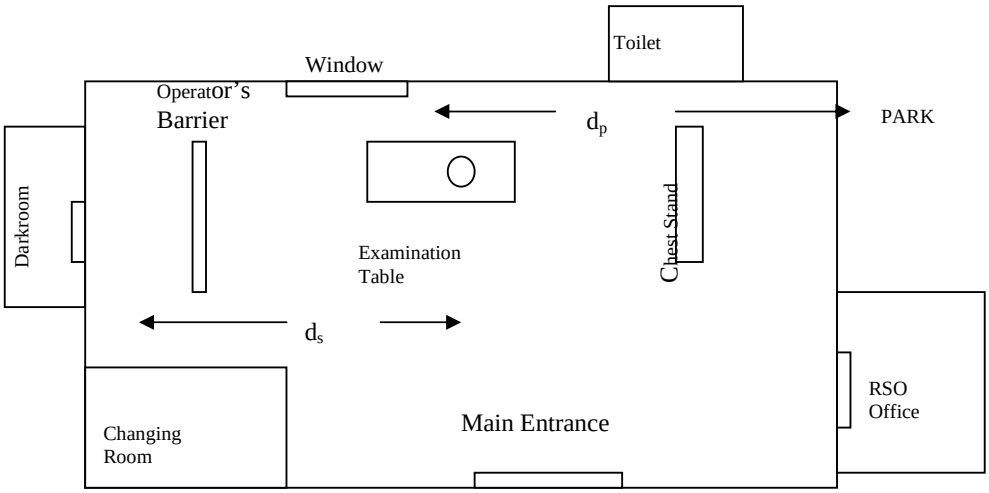
Signature of Applicant

The applicant must duly sign after the entries in the Table. Un-signed forms will not be processed. Where an applicant uses more than one form, all of them must be duly signed and numbered appropriately.

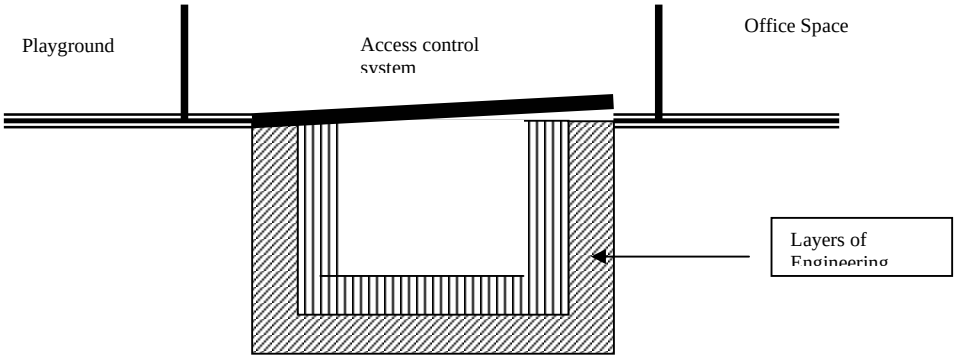
RADIATION SAFETY PROGRAMME

Facilities and Equipment

The sketch needed should be explicit, but as simple as possible. An example of a sketch for a medical diagnostic facility is shown below. The sketch should as much as possible be representative of the premises available in such a way that the occupancy and regularity of use of adjacent areas, rooms, houses and their distances from the source are properly indicated.



Sketches of storage facilities should specify the access control system and the distances of occupancy from the sources. Also state the materials and the different levels of barriers.



Example of a sketch of pit type storage facility is shown above. For cabinet storage or walled building, sketch the housing facility appropriately.

The NNRA may require that that the certificate construction supervision or quality control be presented. Safety Analysis Report (SAR) would be demanded for some specific practices and these shall include the evaluation of geological parameters, must be done by competent geologists or geological firms. This and other requirements could be obtained from practice specific regulations issued by the NNRA.

Safety Systems

Details of shielding assessment, and access control design may be referred to an RSA. Design in depth and fire protection designs should be referred to an qualified and recognizable engineering expert.

Regarding control of access to the radiation sources, especially when the sources are to be located in a room that can be locked to prevent access by unauthorized persons, you need to state in your application in a manner that constitutes a positive commitment that proper management of the access control must be instituted. If the source will not be located in a room that can be locked, you should explain how the requirements of the practice specific regulations will be met to ensure that your sources will not be stolen or cause undue exposure of workers and the public. Authorized materials in an unrestricted area must be secured from unauthorized removal from the place of storage and if in a secured storage must be under the constant surveillance and immediate control.

Regarding fire protection, you should confirm that the room where the source and irradiator will be located will be equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) that is adequate to ensure the integrity of the source in a case of fire. Alternatively, you should describe the conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of fire-fighting personnel) that ensure a very low level of radiation risk attributable to fires.

Radiation Protection

To describe the management structure, an organogram may be used. However, radiation safety duties must be properly specified and responsibilities assigned if necessary with names. The list of radiation protection equipment can be given in form of a table containing all the items mentioned in the instruction for preparing radiation protection programme accompanying your application form.

Staff Training and Experience

Among the general requirements for issuance of specific authorizations is the requirement that your staff must be qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life and or environment. The information you present on this topic should show how you would satisfy this requirement.

State the name, training, and expertise of each person classified as radiation worker in your organization. The qualifications should be restricted to trainings in safety and radiation protection as well as ability to handle the source to be authorized and the training should include:

(a) The basics of the design and operation of the source

(b) The principles and practices of radiation protection.

(c) The biological effects of radiation.

(d) The written procedures for routine and emergency operations.

A person appointed as a radiation safety officer, or as a user should have adequate training and experience in radiation protection and safety. How the specific instruction was or will be obtained should be described. Acceptable training and

experience also may be obtained from on-the-job training or at a source manufacturer's course consisting of a combination of radiation safety lectures, classroom exercises, written tests, and hands-on work on self-shielded source and irradiators.

All individuals who work in or frequent controlled areas should be instructed in the health protection problems associated with exposure to radiation sources and recognition of signs and postings as well as general emergency procedures. In addition, persons who actually work with sources should receive training in the safe use of radioactive material. You should submit a general description of the training you will provide to all persons working in or frequenting your restricted areas and provide more specific information about the training of source and irradiator operators. Persons who will operate the sources under the supervision of a responsible individual do not need to be designated by name; however, the following should be submitted.

(a). An outline of the training programme for these persons, including the topics that will be covered. Topics expected to be included in the training programme are:

(i) the principles and fundamentals of radiation safety and good safety practices related to the use of radioactive materials,

(ii) the use of radiation detection instruments, and

(iii) the technique of operation of the source and irradiator.

This training usually is several hours long and may be covered in part by instructions provided to workers to meet the requirements of specific regulations

(b). A means of evaluating the understanding of the individuals who have completed the training programme.

(c). A discussion of the on-the-job training that will be given to trainees. The training should consist of a minimum of several complete irradiation procedures by the trainee under close supervision by a responsible individual.

(d). The name of the training instructor and his qualification if he or she is not the appointed adviser. The minimal qualifications for an instructor should be the same as those of the radiation safety adviser.

Radiation Protection Equipment

Personnel monitoring equipment is to be used by individuals entering controlled areas who are likely to receive a dose in excess of 10% of the dose specified in the NiBRRI. The specified annual dose to the whole body of adults is 20 mSv. The whole body includes the head, trunk (including male gonads), arms above the elbow, and legs above the knee. The specified annual dose limit to the skin or any extremity (shallow dose equivalent) is 500mSv. The specified occupational dose limit for the embryo/fetus of a declared pregnant woman is 1 mSv. Thus, you will need to monitor all gamma source users with a TLD or OSL or other device which can be evaluated by NNRA In determining the need for personnel monitoring equipment, you should consider both the doses related to the source and irradiator and the doses from other sources of radiation.

Radiation Survey Instruments

Some Regulations requires the performance of such surveys as are necessary to evaluate the extent of radiation hazards that may be present and to comply with regulatory requirements. In order to perform appropriate surveys, you need to have operable, calibrated instrumentation. State the type of survey or contamination monitors that will be available You do not need to name the manufacturer or the model number of the survey meter except it is specifically requested by NNRA or by specific practice regulations. The reasons for the survey meter are the need to determine normal radiation levels near the source and irradiator, in the room housing the source and irradiator and in adjacent unrestricted areas, and the need to detect radiation levels that may indicate safety interlock and shielding failure, sealed source displacement, or sealed source failure with a resultant spread of contamination.

In order to perform adequate surveys, instruments must be operable and calibrated with an appropriate radiation source. State that the instrument will (1) be calibrated so that the readings are within ±20% of the actual values over the range of the instrument and (2) be calibrated at least annually and after servicing (other than a simple battery exchange). Also state that calibration records will be kept for a minimum of 2 years after each calibration, and identify your selected means of calibration. There are three options for calibration:

(a) If the instrument will be returned to the manufacturer for calibration, so state,

(b) If a contractor will perform the calibration, state the name and address of the firm

(c) If the instrument will be calibrated in-house, provide the experience and training in instrument calibration of each named person who will perform the calibrations and the methodology to be used.

Personnel and Workplace Monitoring

As a authorized user, you must have a system of personnel and workplace monitoring. For example, tests to determine if there is any leakage from sources are necessary. This must be performed at intervals. Measurements in this regard must be quantitative measurement and equipment used must be sensitive to detect low activity.

The options for Monitoring measurements are:

(a) Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.

(b) Use a commercial kits. You take the sample and send the sample to the kit supplier, which reports the results to you.

(c) You perform the entire monitoring sequence, including taking the sample and measurement.

For option (a), specify the name, address, and authorization number of the consultant or commercial organization. For Option (b), specify the kit model number and the name, address, and authorization number of the kit supplier. State if the test samples will be taken by your RSA or RSO. Include in the application, a statement that any indication of possible source leakage shall be reported to the NNRA For Option (c), state whether the test sample will be taken and measured by your RSA or RSO. Procedures would be requested by NNRA. You should commit to use of an instrument capable of quantitatively measuring 185 Bq or less activity.

Local Rules, Quality Assurance and Records

Local rules are simple guidance and instructions that are made visible in working places and are expected to be followed by workers as first steps to implementing a policy of adhering to ALARA doses. It also includes simple actions to be taken in case dose levels are exceeded. Sometimes they act as enlightenment on risks. However, this is not meant to act as a clog in the wheel of smooth running of the system.

Quality assurance programmes are directed at perfecting the working of the whole system, reduction of unnecessary doses, waste of materials, resources and time. It leads to efficiency and precision. It should include active processes of management of resources, and maintenance of machineries and following of procedures. Proper quality assurance system must involve accurate record keeping and auditing of procedures and safety culture.

Operating and Emergency Procedures

You should provide your personnel with written operating and emergency procedures and you should state in your application that the written procedures will be provided to each person who uses the sources. The operating procedures should be maintained at the control station, and the emergency procedures should be conspicuously posted in the area. It is not necessary to submit the detailed operating and emergency procedures to NNRA. However, you should list the topics covered in your procedures, and you should state that these procedures include instructions in the following topics and will be available prior to use of the source or source and irradiator.

(a) Step-by-step procedures for operation of the source. (Information may be extracted from the source manufacturer's manual).

(b) Determination and recording of radiation doses to persons operating the source.

(c) The methods to ensure that only authorized persons will use the source.

(d) Inspections, test procedures, and maintenance to ensure that all safety interlocks, devices, and components associated with the source and irradiator are functioning properly.

Prohibited modifications (for example, changing the safety control system or removing the source) should be stated. Emergency situations, e.g., when a survey reveals abnormal radiation levels around the source, personnel should leave the source and irradiator room or area, lock the door or barricade the area, and contact the individual responsible for the emergency. Telephone numbers for the source manufacturer's representative should be included. In addition, your procedures should require that a survey be made with a radiation survey meter outside the source and irradiator area or room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 2 millisieverts per hour.

Plans for Installation and Certain Repairs

You should discuss your plans for source and irradiator installation, pre-operational check-out, and repairs or alterations involving removal of shielding or access to the authorized material. Normally these plans indicate that the tasks will be performed by the supplier or other persons, (through maintenance agreement) who are specifically authorized by the NNRA for such work. If your plans depart from the normal, you

should clearly explain how these tasks would be safely and adequately performed.

Transport of Radioactive Sources and Waste Management

Because of the nature of the authorized material contained in devices, your only option for disposal is to transfer the material to an authorized recipient. Authorized recipients are the original supplier of the device, a commercial firm which should be known to NNRA. Other authorized recipients may be named by NNRA in future. Apart from this arrangement and until NNRA approves recipients, no one else is authorized to receive and dispose of authorized material. Special arrangements may be made through NNRA to transfer sources to recipients who may likely need them for other suitable operations

Before transferring radioactive material, you must package and ship the material in accordance with the NNRA regulations governing the transport of radioactive materials. Applicants are required to seek advice of their Radiation Safety Advisers in these matters.

OTHER MATTERS

Authorization Fees

The applicant should refer to the prevailing NNRA Authorization Fee Schedule to determine the appropriate licensing fee. No action will be taken on applications filed without the proper fee.

Certification

If you are an individual applicant acting in a private capacity, you must sign the completed application form. Otherwise, the application should be dated and signed by a representative of organization or legal entity that has authority to make binding commitments and sign off on official documents. The signing official must certify that the application contains information that is true and correct to the best of his/her knowledge and belief. The NNRA will not process an unsigned application, and it will be returned for proper signature.

Amendments to an Authorization

After you are issued an authorization, you must conduct your programme in accordance with (1) the statements, representations, and procedures contained in your application and other correspondence with the NNRA (2) the terms and conditions of the authorization, and (3) the NNRA regulations.

It is your obligation to keep your authorization current. If any of the information provided in your application is to be modified or changed, submit an application for an authorization amendment. You must comply with the terms and conditions of your authorization until it is actually amended. NNRA regulations do not allow you to implement changes solely on the submission of an amendment request.

An application for an authorization amendment may be prepared either on the application form, or in a letter. It is advisable to make and keep at least a copy of your complete applications and letters to NNRA

Your application should specify your authorization number and clearly describe the nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific. Identify the pertinent

information by date, page, and paragraph. For example, if you wish to change the RSO, your application for an authorization amendment should specify the proposed RSO's name, training, and experience. The qualifications of the proposed RSO should be equivalent to those specified in this guide or an appropriate regulation

You need to include the appropriate fee with an amendment request. The NNRA will not issue the amendment prior to receipt of the proper fee as specified in the Fee Schedule.

Renewal of a License

Licenses are issued for a specified period. Send an application for renewal, in duplicates, to NNRA. Retain one copy, the authorization requires that you possess and use authorized material in accordance with the statements and representations in your renewal request and in any supplements to it. It is important that the appropriate fee, accompany your application for authorization renewal. The NNRA will not issue the authorization renewal prior to receipt of the fee.

You may submit an entirely new application for renewal as if it were for a new authorization without referring to previously submitted information. The NNRA prefers this method for renewals, especially for those applicants who reference a large number of documents and/or old documents. Submitting an entirely new application allows you to reevaluate your programme periodically and consolidate the description of your programme into one or two current documents. A new application ensures that your programme contains all needed information as requested in current regulations. As an alternative to a new application, you may review your current authorization to determine whether the information about sources accurately represents your current and anticipated programme. Identify any necessary additions, deletions or changes and then prepare information as appropriate for the change(s).

Review the documents submitted to NNRA in the past to determine whether the information is up to date and accurately represents your facilities, equipment, personnel, radiation safety procedures, locations of use, etc. The documents considered to represent your current programme must be identified by date. Also identify any out-of-date and superseded documents and indicate the changes that are necessary. Documents referenced in your authorization should not be older than 5 years unless all the information in the document accurately represents your current programme. If you need to update information in documents 5 years old or older, you should submit a new application.

Review current NNRA regulations to ensure that any changes in the regulations are appropriately covered in your programme description. After you have completed your review, submit a letter to the NNRA, with the proper application fee for an authorization renewal. Include the name and telephone number of the person to be contacted about your renewal application and include a current mailing address if it is not indicated correctly on your authorization.

If you file an application for an authorization renewal at least 30 days before the expiration date of your present authorization and include the appropriate application fee, your current authorization will automatically remain in effect until the NNRA takes final action on your renewal application.

If you do not wish to renew your authorization, dispose of all authorized radioactive material possessed in an authorized manner. Request for authorization to terminate radioactive materials license" and send it to the NNRA before your authorization

expires. Also you must let NNRA know before decommissioning any practice or source.

If you cannot dispose of all the authorized radioactive material in your possession before the expiration date, you must request an authorization renewal for "storage only" of the radioactive material. The renewal is necessary to avoid violating the NNRA regulations that do not allow possession of authorized material without a valid authorization.

Termination of a License

You may request termination of your authorization at any time. This notification should include a request to terminate the authorization and must include a completed authorization form and accurate information on sources or procedures to be terminated.

Importation of Radiation Source(s) and Radiation Equipment

Separate Licence is issued for importation of radiation sources and or radiation equipment for holders of current Authorizations (Licence to Use and Registration of Premises). The licensee should submit an application with information on the Activity for radiation sources and maximum KVp and mAs for X-ray and similar equipment, Serial number(s) of the source and or equipment and a signed agreement/undertaking from the manufacturer or supplier of the readiness to accept back the source and or equipment at the end of its useful time.