NATIONAL NUCLEAR REGULATOR

For the protection of persons, property and the environment against nuclear damage

REGULATORY GUIDE

National Dose Register

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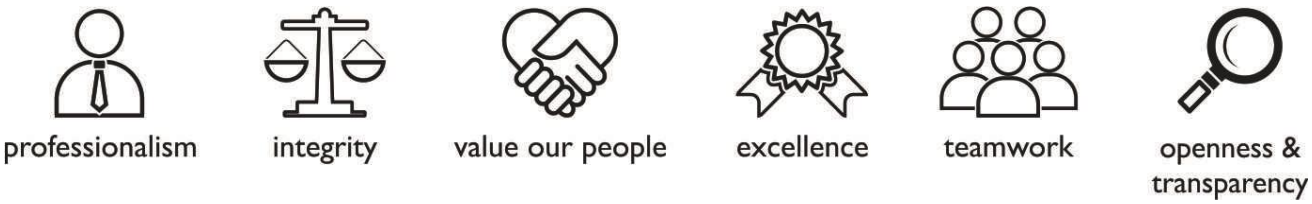

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1 INTRODUCTION

The National Nuclear Regulator (NNR) is primarily mandated to monitor and enforce regulatory safety standards for the achievement of safe operating conditions, prevention of nuclear accidents or mitigation of nuclear accident consequences, resulting in the protection of workers, the public, property and the environment against the potential harmful effects of ionising radiation or radioactive material.

The International Atomic Energy Agency's (IAEA) International Basic Safety Standards (BSS) requires that records of individual occupational doses of workers predominantly working in radiation controlled areas be kept and made available to the competent authorities and to the individuals.

International best practice for record keeping of internal and external national occupational radiation doses is through the utilisation of a central dose registry. In South Africa, the regulatory body has established a National Dose Register (NDR) which is a centralised system for recording occupational radiation exposures in the country. The NDR uses the Regulatory Authority Information System (RAIS), which is a software application developed by the IAEA, for recording occupational doses. The NDR data will be used for tracking a registered worker's cumulative dose based on data provided by the authorisation holder. It will assist in minimising the possibility of a worker receiving a dose greater than the dose limit while moving from one employer to another or from one site to another. Furthermore, it will ensure that dose records are maintained and remain retrievable in the long term regardless of whether a worker changes employment.

Legislation specifies that authorisation holders for any facility or activity that gives rise to radiation risks retains the prime responsibility for safety and is liable for any nuclear damage caused by their facility or activities. The Safety Standards and Regulatory Practices of NNR regulations also require that authorisation holders establish and maintain an organisational dose register of every occupationally exposed worker.

All workers with the potential of receiving an effective dose of more than 1 mSv/a are monitored by a recognised Dosimetry Service Provider for radiation exposure. The records of occupational exposure may be used to analyse dose distributions and exposure trends, to develop effective monitoring programmes and to demonstrate the effectiveness of ALARA implementation.

2 PURPOSE

This Regulatory Guide is intended to assist authorisation holders and prospective authorisation holders in maintaining records of occupational radiation exposure to workers in compliance with regulatory standards and to upload such records to the NDR in accordance with authorisation conditions.

3 SCOPE

This Regulatory Guide sets out the duties of authorisation holders to report records of occupational exposure to the NDR, as well as guidelines governing the reporting and is applicable to all authorisation holders.

The document does not replace the submittal of routine occupational exposure reports by authorisation holders to the NNR as required by the authorisations.

This document does not replace the requirement for authorisation holders to establish and maintain an organisational dose register for occupationally exposed workers.

4 TERMS, DEFINITIONS AND ABBREVIATIONS

4.1 Terms and Definitions

"Authorised Dosimetry Service Provider (ADSP)" means a Dosimetry Service Provider approved or authorised by the NNR. An ADSP may be an authorisation holder.

"Competent authority" means any national or international regulatory body or authority designated or otherwise recognised as such for any purpose in terms of these guidance.

"Data Upload Template" means an Excel spreadsheet consisting of different fields which is used to upload records of occupational exposure to the National Dose Register.

"Dosimetry Service Provider (DSP)" means a body or an individual having the competence for calibration, reading or interpretation of individual monitoring devices; or for measurement of radioactivity in the human body or in biological samples; or for assessment of doses, whose capacity to act in this respect is recognised by the competent authorities.

"National Dose Register (NDR)" means a centralised radiation dose record system that contains the dose records of individuals who are monitored for occupational exposures to ionising radiation.

"Occupational exposure" means radiation exposure of workers incurred in the course of their work.

"Records of occupational exposure" means exposure records or dose records. For the NDR, occupational exposure records refer to the Total Effective Dose, the sum of doses from external exposure and committed doses.

"Third Party" means a prospective employer, a DSP, a Technical Support Organisation or a scientific organisation that might need access to records from the NDR, but excludes regulatory entities and the NDR itself.

4.2 Abbreviations

ADSP	Authorised Dosimetry Service Provider
ALARA	As Low As Reasonably Achievable
BSS	Basic Safety Standards
IAEA	International Atomic Energy Agency
IP	Internet Protocol
NDR	National Dose Register
NNR	National Nuclear Regulator
NNRA	National Nuclear Regulator Act, Act No. 47 of 1999
RAIS	Regulatory Authority Information System
RG	Regulatory Guide
SABS	South African Bureau of Standards

5 RESPONSIBILITIES

1) Authorisation holders should:
   a) Ensure maintenance of records of occupational exposure in compliance with NNR standards;
   b) Ensure that the records of occupational exposure and other information are submitted to the NDR in the manner prescribed by the NNR;
   c) Submit records of occupational exposure frequently to the NDR in accordance with authorisation conditions or authorisation holder standards.
   d) In the case of multi-regulated facilities, only upload the occupational exposure records relevant to the nuclear authorisation;
   e) Ensure the accuracy of occupational exposure records submitted to the NDR;
   f) Inform current workers of the existence of the NDR and information required to be reported to the NDR;
   g) Provide mechanisms to ensure valid consent is given by workers to make data available to a third party; and
   h) Identify, appoint and authorise relevant staff to upload occupational exposures; and to access data in the NDR, in accordance with authorisation holder quality policies and standards.
2) Dosimetry Service Providers which are not authorisation holders should:
   a) Where necessary and as required by the NNRA, apply for authorisation for the approval of such dosimetry services; and
   b) Provide measurement results of occupational exposures to authorisation holders.

6 USE OF DOSIMETRY SERVICES

1) All workers with the potential of receiving an effective dose of more than 1 mSv/a should be monitored for radiation exposure.

2) A Dosimetry Service Provider recognised by the Regulator should be used to measure the occupational exposures received by workers.

3) Authorisation holders, when deciding whether to use an ADSP to measure and monitor worker occupational exposures, should take relevant case-specific factors into account, including, but not limited to:

   a) Number of workers involved;

   b) Nature of work and the associated work processes;

   c) Types and inventory of radionuclides to be encountered;

   d) Potential magnitude, distribution and range of the anticipated doses;

   e) Traceability of the dosimetry methods to national standards;

   f) Sensitivities and practical limitations of dosimeters and dosimetric methods;

   g) Reliability and degree of accuracy in the assessment of dose; and

   h) Capacity and promptness of availability of measurement results both during normal and accident situations.

7 PROVISION OF RECORDS OF OCCUPATIONAL EXPOSURES

7.1 General

1) The authorisation holder should inform each worker of the results of the individual monitoring.

2) The authorisation holder should have electronic mechanisms and systems in place to keep and maintain records of occupational exposure.

3) The authorisation holder should inform each worker of the reporting of the worker's records of occupational exposures to the NDR.

4) The records of occupational exposure should be in a format that is compatible with the NDR.

5) Processes should be in place to ensure that the data fields to be provided and the updates thereof are included in the authorisation holder Management and Quality Systems.

6) Uploading records of occupational exposures to the NDR should not prevent authorisation holders from providing the NNR with reports of occupational exposures as stipulated in the authorisations or holder standards.

7.2 Data to be Reported to NDR

1) The authorisation holders should provide the information as indicated in Appendix 1 to the NDR.

2) The authorisation holders should:

   a) Include the NDR responsible person name and contact details;

   b) Provide the company name, subcompany names, and the companies for which radiation monitoring services are provided;

c) Provide the minimal set of information required to define a company such as its name and one identifier;

d) Provide the data of all the workers that are monitored;

e) Provide the minimal set of required information for workers such as initials, last name, ID number, and additional identifiers;

f) Specify the nationality of each worker;

g) Specify for worker status the minimal set of required information including the person identification number, the employer identification, the status date and the actual status;

h) Specify each change of employment status for a given worker;

i) Provide the work activities or the predefined sector that the worker is active where available;

j) Provide as a minimum the effective doses at the required upload frequency;

k) Provide additional dose information, where required to do so according to authorisation conditions;

l) Provide as a minimum the worker identification, the beginning and end dates of the dose record's measuring period, the dose value and its unit. The beginning and end dates may be the same in certain cases e.g. when a measurement does not necessarily represent a fixed monitoring period but rather a measurement at a specific point in time as in the case of internal dosimetry;

m) Provide optional fields (such as dose measure, radiation type, etc.) where possible or as required by the authorisation; and

n) Use sufficient identifiers for each data input.

7.3 Access to NDR

1) The authorisation holders should:

a) Formally request access to the NDR after upload of the test environment has been completed and verified by the NNR;

b) Provide to the NNR an IP address which will ensure restricted access to the NDR;

c) Provide the name of the lead representative responsible for the upload of occupational exposure records to the NNR;

d) Select and appoint alternate representatives for upload of records in case the lead representative is not available to fulfil this role; and

e) Ensure that security and confidentiality of NDR credentials, software and records are ensured amongst NDR nominated users.

7.4 Upload of Occupational Exposure Records to NDR

1) The authorisation holders should:

a) In the case of multi-regulated facilities, only upload the occupational exposure records relevant to the nuclear authorisation;

b) Upload records to the NDR after uploads on the test environment have been completed and verified by the NNR;

c) Upload occupational exposure records to the NDR in accordance with this guideline and frequencies specified in the authorisations or authorisation standards;

d) Ensure that the records are uploaded without delay, and no later than within one month of completing the measurement period or as agreed with the Regulator on a case-by-case basis; and

e) Upload all historical occupational exposure records to the NDR within the timeframe agreed with the NNR.

7.5 Accuracy and Validation of Data

1) Authorisation holders should:

   a) Ensure that the data reported to the NDR is accurate and current;

   b) Before the next required upload, verify that the previously uploaded records are correctly reflected in the NDR; and

   c) Where relevant make corrections to any previously submitted dose records.

8 CONSENT FROM WORKERS

1) Consent from workers to provide occupational records to third parties should be obtained in writing.

2) The authorisation holder should obtain consent from a prospective employee to access their previous occupational dose records.

3) The proof of consent should be filed in the medical file of the worker.

4) When extracting information and providing such information to third parties, the proof of consent obtained from a worker should be registered in the NDR.

5) Consent should also be registered for prospective employees that were not appointed afterwards. Where a worker chooses not to provide consent to a third party, the authorisation holder should register this in the NDR.

9 REPORTS

1) The authorisation holder should obtain reports relating to its workers' occupational exposures from the NDR for information and comparison purposes.

2) Reports generated from the NDR should be handled with the necessary provisions of the authorisation holder's management system.

10 QUALITY ASSURANCE

1) The authorisation holders should ensure that aspects related to data integrity, accuracy, validation, security and confidentiality of occupational exposure records are included in its management system.

11 REFERENCES

[1] Act No. 47 of 1999, National Nuclear Regulator Act (proposed Amendments)

[2] GSR Part 3 (Interim) Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA, 2011

[3] NNR National Dose Register, Draft Data Provider Manual, 2015

[4] Safety Standard and Regulatory Practices (SSRP) No. 388

[5] Radiation Protection 160, Guidance for Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation in the European Commission, 2009

[6] STUK, Radiation Protection and Exposure Monitoring of Nuclear Facility Workers in Finland, 2014

[7] STUK, The Dose Register and Data reporting, 2014

APPENDIX 1: TEMPLATE FOR UPLOADING DOSE RECORDS TO THE NDR

The occupational dose records should be uploaded to the NDR using a predefined template (Excel) which contains elements listed and described below.

1. File Information

Field Name	Type	Purpose	Mandatory?	Notes
Template Version	Text	This is a predefined version number and should NOT be changed	Yes	
NDR Number	Text	This is an identification number that the NNR has communicated to holders. It will be predefined and should NOT be changed	Yes	
Name	Text	This is the company name. It will be predefined and should NOT be changed	Yes	
NDR Token	Text	This is a unique token that the NNR has communicated to you. It will be predefined and should NOT be changed	Yes	**It is strictly confidential and should not be shared with anybody outside the holder organisation!**
Responsible Person Name	Text	Name of the person in the holder organisation responsible for the NDR data transfer	No	
Responsible Person Email	Text	Email address of the responsible person	No	
Responsible Person Phone Number	Text	Phone number of the responsible person	No	

2. Companies

Field Name	Type	Purpose	Mandatory?	Notes
Name	Text	Company's full name	Yes	
Short Name	Text	Company's short name (e.g. the official abbreviation)	No	
Practice Code	Choice List	SABS practice code applicable to the company	Yes	Refer to the worksheet "ReferenceList" to see the list of codes and their description
Address	Text	Company address	No	
Country	Choice List	ISO code of the company's country of operation	No	Refer to the worksheet "ReferenceList" to see the list of countries. If is left blank, country is assumed to be South Africa

ID1_Type	Choice List	Type of the primary identification number of the company	Yes	
ID1_Value	Text	Value of the primary identification number of the company	Yes	
ID2_Type	Choice List	Type of a second identification number of the company	No	
ID2_Value	Text	Value of the second identification number of the company	No (yes if ID2_Type specified)	
ID3_Type	Choice List	Type of a third identification number of the company	No	
ID3_Value	Text	Value of the third identification number of the company	No (yes if ID3_Type specified)	

3. Workers

Field Name	**Type**	**Purpose**	**Mandatory?**	**Notes**
FirstName	Text	Person's first name	No	
MiddleName	Text	Person's middle name	No	
LastName	Text	Person's last name (surname)	Yes	
Initials	Text	Person's initials	Yes	
BirthDate	Date	Person's birth date	No	Format "yyyy-mm-dd"
Gender	ChoiceList	Person's gender	Yes	"M", "F" or UNKNOWN"
Nationality	ChoiceList	ISO code of person's country of nationality	Yes	Refer to the worksheet "Reference List" to see the list of countries.
ID1_Type	ChoiceList	Type of the primary identification number of the person	Yes	For a South African worker, this MUST be "National ID"
ID1_Value	Text	Value of the primary identification number of the person	Yes	For a South African worker, this must be the "number" of the National ID
ID1_ValidFrom	Date	Start date of validity of ID1	No	Format "yyyy-mm-dd"
ID1_ValidUntil	Date	End date of validity of ID1	No	Format "yyyy-mm-dd"
ID2_Type	ChoiceList	Type of a second identification number of the person	No	
ID2_Value	Text	Value of the second identification number of the person	No (yes if ID2_Type specified)	
ID2_ValidFrom	Date	Start date of validity of ID2	No	Format "yyyy-mm-dd"
ID2_ValidUntil	Date	End date of validity of ID2	No	Format "yyyy-mm-dd"

ID3_Type	ChoiceList	Type of a third identification number of the person	No	
ID3_Value	Text	Value of the third identification number of the person	No (yes if ID3_Type specified)	
ID3_ValidFrom	Date	Start date of validity of ID3	No	Format “yyyy-mm-dd”
ID3_ValidUntil	Date	End date of validity of ID3	No	Format “dd/mm/yyyy”
ID4_Type	ChoiceList	Type of a fourth identification number of the person	No	
ID4_Value	Text	Value of the fourth identification number of the person	No (yes if ID4_Type specified)	
ID4_ValidFrom	Date	Start date of validity of ID4	No	Format “yyyy-mm-dd”
ID4_ValidUntil	Date	End date of validity of ID4	No	Format “yyyy-mm-dd”
ID5_Type	ChoiceList	Type of a fifth identification number of the person	No	
ID5_Value	Text	Value of the fifth identification number of the person	No (yes if ID5_Type specified)	
ID5_ValidFrom	Date	Start date of validity of ID5	No	Format “yyyy-mm-dd”
ID5_ValidUntil	Date	End date of validity of ID5	No	Format “yyyy-mm-dd”

4. Worker Status

Field Name	**Type**	**Purpose**	**Mandatory?**	**Notes**
PersonIDType	ChoiceList	IDType used to identify person	Yes	Use one of the ID types used on the Workers tab for this worker
PersonIDValue	Text	Associated IDValue used to identify this person	Yes	Use the associated ID value according to the specified person ID type
CompanyIDType	ChoiceList	IDType used to identify the employer company	Yes	Use one of the ID types used on the Companies tab for this company
CompanyIDValue	Text	Associated IDValue used to identify the employer company	Yes	Use the associated ID value according to the specified company ID type
StatusDate	Date	The date that the mentioned status has taken effect	Yes	Format “yyyy-mm-dd”
WorkStatus	ChoiceList	The actual status	Yes	
WorkActivities	Text	Specify the workactivities for this worker	No	Multiple workactivities for the same worker may be specified by delimiting them with a

				semicolon (e.g. “Mining; Radiography”)

5. Effective Doses

Field Name	Type	Purpose	Mandatory?	Notes
PersonIDType	ChoiceList	IDType used to identify person	Yes	Use one of the ID types used on the Workers tab for this worker
PersonIDValue	Text	Associated IDValue used to identify this person	Yes	Use the associated ID value according to the specified person ID type
CompanyIDType	ChoiceList	IDType used to identify the employer company	Yes	Use one of the ID types used on the Companies tab for this company
CompanyIDValue	Text	Associated IDValue used to identify the employer company	Yes	Use the associated ID value according to the specified company ID type
BeginDate	Date	The begin date of the period of the doserecord	Yes	Format “yyyy-mm-dd”. Begin date is assumed to start at 00:00 on the specified day
EndDate	Date	The end date of the period of the doserecord	Yes	Format “yyyy-mm-dd”. End date is assumed to end at 23:59 on the specified day
ExposureType	ChoiceList	The type of exposure (internal, external or total)	Yes	
DoseValue	Decimal number	The actual dose value	Yes	
DoseUnit	ChoiceList	The unit of the dose value	Yes	
DataProvider Reference	Text	Specify internal reference of this dose (e.g. database record id)	No	This can be used to identify a submitted dose that needs to be corrected. It is the preferred method of correcting a dose
IsCorrection	ChoiceList	Used to correct a previously submitted dose record	No	If set to “Yes”, the record will overwrite any previously submitted dose records. Either the “DataProviderReference” field or the “OldValueToCorrect” field must be specified in this case
OldValueToCorrect	Decimal Number	The previously submitted value in case of a correction	No	If a correction is needed, and “DataProviderReference” was not provided for the original dose, the system will try to find the dose to correct according to

				this value and by looking up the same worker, company, period and exposure type
Comment	Text	Used to specify any comments about this dose record	No	

6. Additional Dose Information

Field Name	Type	Purpose	Mandatory?	Notes
PersonIDType	ChoiceList	IDType used to identify person	Yes	Use one of the ID types used on the Workers tab for this worker
PersonIDValue	Text	Associated IDValue used to identify this person	Yes	Use the associated ID value according to the specified person ID type
CompanyIDType	ChoiceList	IDType used to identify the employer company	Yes	Use one of the ID types used on the Companies tab for this company
CompanyIDValue	Text	Associated IDValue used to identify the employer company	Yes	Use the associated ID value according to the specified company ID type
BeginDate	Date	The begin date of the period of the doserecord	Yes	Format “yyyy-mm-dd”. Begin date is assumed to start at 00:00 on the specified day
EndDate	Date	The end date of the period of the doserecord	Yes	Format “yyyy-mm-dd”. End date is assumed to end at 23:59 on the specified day
DoseMeasure	ChoiceList	The appropriate dose measure	No	
RadiationType	ChoiceList	The appropriate radiation type	No	
DoseEquivalent	ChoiceList	The appropriate dose equivalent	No	
ExposedBodyPart	ChoiceList	The appropriate exposed body part	No	
DoseValue	Decimal number	The actual dose value	Yes	
DoseUnit	ChoiceList	The unit of the dose value	Yes	
DosimeterType	ChoiceList	The appropriate dosimeter type used	No	
DosimeterNumber	Text	The appropriate dosimeter number used	No	
DataProvider Reference	Text	Specify internal reference of this dose (e.g. database record id)	No	This can be used to identify a submitted dose that needs to be corrected. It is the preferred method of correcting a dose
IsCorrection	ChoiceList	Used to correct a previously	No	If set to “Yes”, the record will overwrite any previously submitted dose records. Either

		submitted dose record		the “DataProviderReference” field or the “OldValueToCorrect” field must be specified in this case
OldValueToCorrect	Decimal Number	The previously submitted value in case of a correction	No	If a correction is needed, and “DataProviderReference” was not provided for the original dose, the system will try to find the dose to correct according to this value and by looking up the same worker, company, period and exposure type
Comment	Text	Used to specify any comments about this dose record	No	