# AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES

by

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# DECLARATION

I declare that **AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

_____ _____

**SIGNATURE** **DATE**

**(MKHULISENI NGUBANE (MR)**

# DEDICATION

I dedicate this study to **God** my Creator, the Lord and my Saviour **Jesus Christ**, and to

**My** late **Mother** who was such a loving, caring and hard working woman.

# ACKNOWLEDGEMENT

I want to thank the following persons for their respective contributions to this dissertation:

- My wife, **Ziningi Ngubane**, for her love, patience and support.
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# AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES


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## ABSTRACT


The purpose of this study was to evaluate the effectiveness of the database system used at the South African Radiation Control Authority and compare it with RAIS (Regulatory Authority Information System). A radiation regulatory authority requires an adequate and effective data management system in order to carry out its regulatory control program efficiently and effectively. RAIS is a comprehensive system that includes all of the main functionality required to support a regulatory framework.

A mixed methods approach, including a quantitative descriptive comparative evaluation research study was conducted to determine if the database system currently used by the South African Radiation Control Authority is effective as a data management tool for a regulatory body. Two analyses were conducted. Firstly, the specification records of the South African database system were compared with that of RAIS. Secondly, current database users were surveyed by means of a structured questionnaire.

Both analyses reveal that RAIS performs better than the Radiation Control database in the main areas of the regulatory framework. The study results also highlight some of the shortcomings and strengths of the Radiation Control database.



**KEY CONCEPTS**

Database; RAIS; Radiation sources; Radiation protection; Radiation regulatory framework; Radiation safety; Authorisation; Inspection; Enforcement; ERD.

**Table of contents**

## CHAPTER 1

## ORIENTATION TO THE STUDY

## CHAPTER 2

## LITERATURE REVIEW

# CHAPTER 3

## RESEARCH DESIGN AND METHOD

## CHAPTER 4

## ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

## CHAPTER 5

## CONCLUSIONS AND RECOMMENDATIONS

## LIST OF ABBREVIATIONS

| | |
|---|---|
| ALARA | As Low As Reasonably Achievable |
| A/RPO | Acting Radiation Protection Officer |
| BSS | International Basic Safety Standards |
| CPU | Central Processing Unit |
| DA | Democratic Alliance |
| DAIR | Department of Authorization, Inspection and Regulation |
| DAV | Data Authoring and Versioning |
| DBA | Database Administrator |
| DBMS | Data Base Management System |
| ERD | Entity Relationship Diagram |
| ERM | Entity Relationship Model |
| FAO | Food and Agriculture Organization |
| IAEA | International Atomic Energy Agency |
| IBM DB2 | International Business Machines (Corporation) Database 2 |
| IEC | International Electrotechnical Commission |
| ILO | International Labour Organization |
| INES | International Nuclear and Radiological Event Scale |
| ISO | International Organization for Standardization |
| ICSRS | International Catalogue of Sealed Radioactive Sources |
| JDBC | Java Database Connectivity |
| LAEC | Lebanese Atomic Energy Commission |
| MOU | Memorandum of Understanding |
| MSA | Microsoft Access |
| NEA | Nuclear Energy Agency |
| NECSA | National Energy Corporation of South Africa |
| NNRA | Nigerian Nuclear Regulatory Authority |
| NROD | National Register of Occupational Doses |
| ODBC | Open Database Connectivity |
| ODP | Oracle Data Provider |

| | |
|---|---|
| OECD | Organisation for Economic Co-operation and Development |
| OLE | Object Linking and Embeding |
| PAHO | Pan American Health Organization |
| PDA | Personal Digital Assistant |
| PL | Procedural Language |
| PPE | Personal Protective Equipment |
| QA | Quality Assurance |
| RAC | Real Application Clusters |
| RAIS | Regulatory Authority Information Sources |
| RDBMS | Relational Database Management System |
| RP | Responsible Person |
| RPO | Radiation Protection Officer |
| RPI | Radiation Protection Institute |
| RSA | Republic of South Africa |
| RSS | Radioactive Sealed Sources |
| SAEC | Sudanese Atomic Energy Commission |
| SRS | Sealed Radiation Source Registry System |
| SQL | Structured Query Language |
| TSAs | Thematic Safety Areas |
| WHO | World Health Organization |
| XML | Extensible Markup Language |

## LIST OF TABLES

## LIST OF FIGURES

## ANNEXURES

| | |
|---|---|
| Annexure A | Approval from the university |
| Annexure B | Letter seeking permission from the Department of Health: Directorate Radiation Control |
| Annexure C | Letter of approval – DoH: Directorate Radiation Control |
| Annexure D | Data collection tool 1 (Criteria Checklist) |
| Annexure E | Letter of consent |
| Annexure F | Data collection tool 2 (Questionnaire) |
| Annexure G | Entity Relationship Diagrams (RAIS & Radiation Control databases) |

# CHAPTER ONE – ORIENTATION TO THE STUDY

## 1.1 INTRODUCTION

For a radiation regulatory authority, adequate data management is essential to ensure effective management of its regulatory control programme. It is indeed needed to both keep the national register for radiation sources and to manage the large amount of data with which the regulatory authority is daily confronted, such as the data related to authorisation, inspection and enforcement processes (IAEA 2009c:2; Suman & Alhabbal 2008:327).

The South African Directorate Radiation Control (Radiation Control), through the Hazardous Substances Act, 1973 (Act 15 of 1973), is responsible for the regulatory control of radiation sources in South Africa. The database system used by Radiation Control to fulfil its mandate as a regulatory authority is divided into two databases. The 'x-rays' database is used for the management of information pertaining to x-rays (or Group III radiation sources). The 'isotopes' database is used for the management of radioactive sources (or Group IV radiation sources) information. The two databases are not linked and do not communicate with each other.

This study seeks to explore and evaluate the database system used by the Radiation Control as a data management tool suitable to fulfil the functions required of the regulatory authority.

## 1.2 BACKGROUD INFORMATION ABOUT THE RESEARCH PROBLEM

### 1.2.1 Radiation Control in South Africa

Radiation Control, as a radiation regulatory authority, is responsible for regulating the sale and use of radiation sources in South Africa. It falls under the National Department

of Health. It has its head office in Bellville, Cape Town and three regional offices also in Bellville, Pretoria and Durban (see figure 1.1 below).

Radiation Control's mission statement is: "The promotion and maintenance of health within the framework of the National Health Plan and specifically the protection against injury or disease caused by technological devices, including sources of radiation, by furthering the safe and legal use of such devices" (Directorate Radiation Control 2013).

Radiation Control's aim is: "To provide an appropriate standard of protection to all South African citizens against ionizing radiation without unduly limiting the beneficial practice giving rise to radiation exposure" (Directorate Radiation Control 2013).

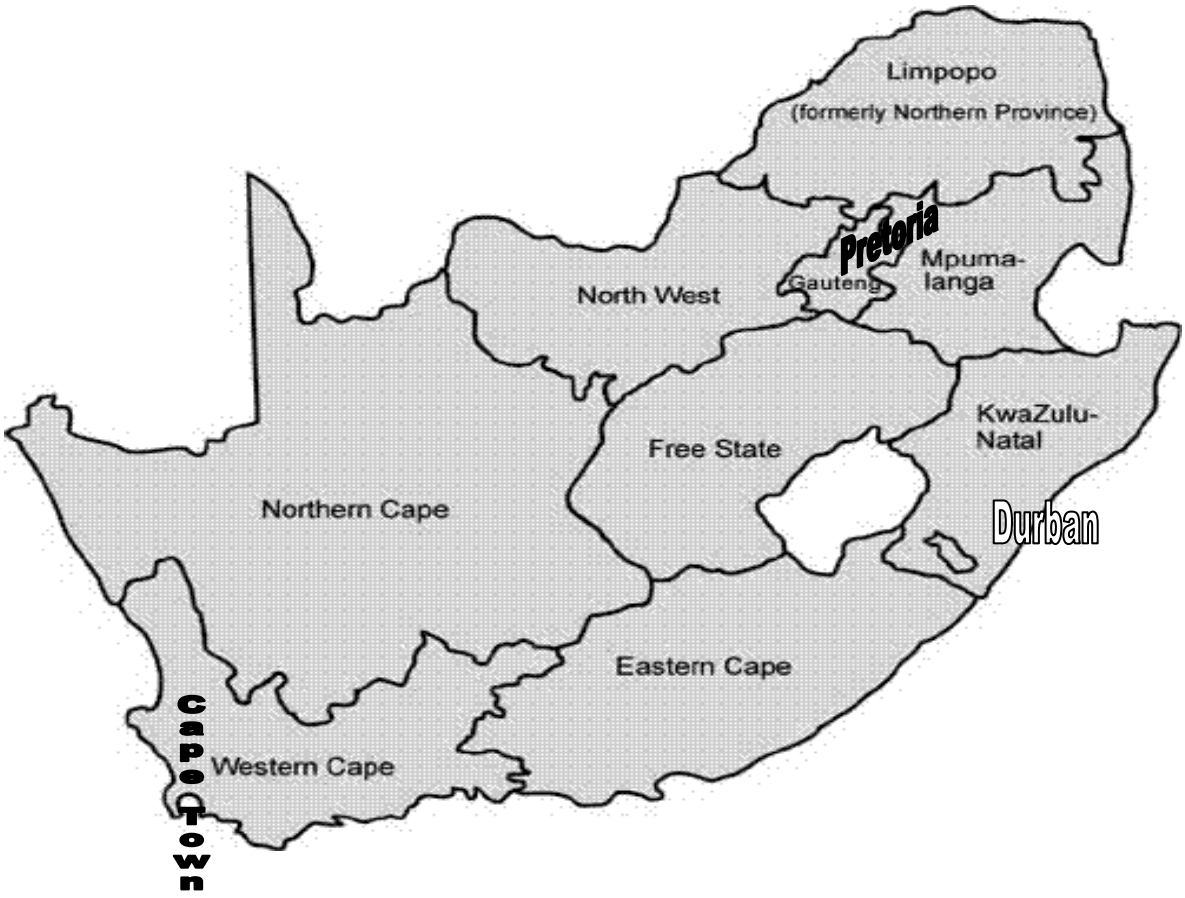



**Figure 1.1 Map of South Africa with the location of Radiation Control offices**

The regulatory framework of Radiation Control has established legislation in the form of the Hazardous Substances Act, 1973 (Act 15 of 1973) and the accompanying Regulations. Figure 1.2 below outlines the Radiation Control regulatory infrastructure in South Africa through an organisational chart.

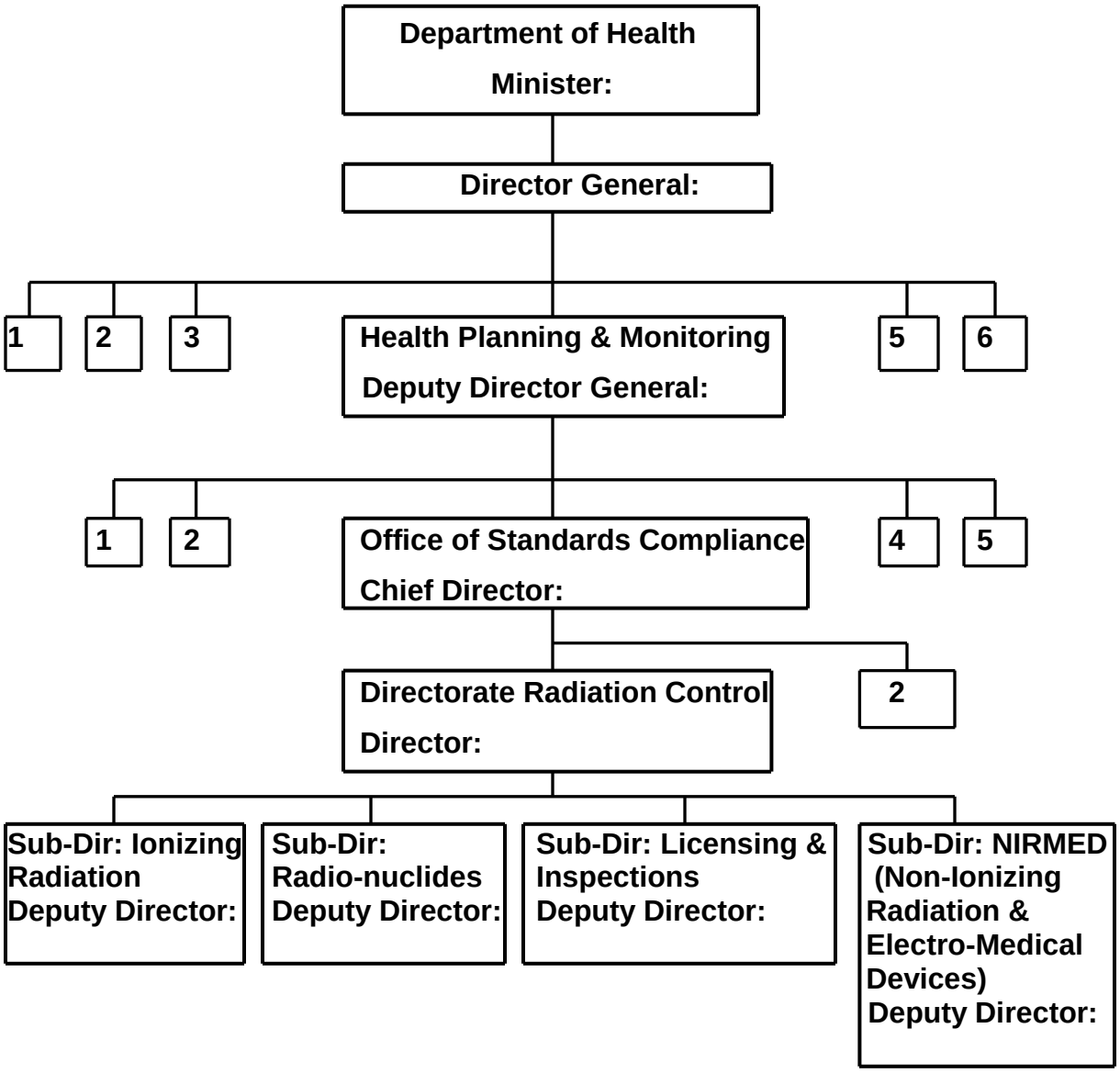



**Figure 1.2 Radiation Control Organogramme**

(Adapted from http://sites.google.com/site/radiationcontroldoh/

### 1.2.2 Current status of data management in Radiation Control

Data are currently managed both in paper and electronic format in Radiation Control. There are hard copy files for licensees at regional offices and head office. Each regional office keeps files for those licensees that are under its direct control. There are also duplicate files for each of the licensees at head office.

Information is entered in these files by inspectors when they conduct inspections or follow-ups. The administration officer/s may also enter or put a form or page/s in the file when they have answered a call or received data from the licensees by fax, e-mail or post. Some of the data, such advices with updated information after an inspection, are first sent by post to head office to be processed then returned to the relative regional office for filing.

The database is managed at head office by the designated official who works as the database administrator (DBA). There are other staff members also at head office who have rights to enter data into the database as and when it is received from regional offices or directly from licensees (see section 4.3.1).

### 1.2.3 The international Regulatory Authority Information System

The Regulatory Authority Information System (RAIS) is a software application developed by the IAEA in order to help member states' regulatory authorities in managing their regulatory activities in accordance with IAEA Safety Standards and guidance (RAIS 2012). See section 2.3.

RAIS has been developed by the International Atomic Energy Agency (IAEA) as part of a supporting set of actions designed to assist countries in managing their regulatory control programmes. RAIS can assist the regulatory authorities in managing information related to both the national radiation sources inventory and their routine regulatory activities. It also covers the national regulatory infrastructure information, facilities and

departments, radiation events and accidents, occupationally exposed workers and technical services (IAEA 2009c:2).

Since the IAEA introduced RAIS in 2004, more than sixty-four countries use RAIS on a regular basis. Whilst 26% of the countries use RAIS without modification, 74% have customized the system to varying degrees (IAEA 2009b:3; IAEA 2011:1).

#### 1.2.3.1 Current status of Radiation Control's data management

There has been little co-operation between the IAEA and South Africa's Radiation Control prior to 2010. As a result the data management tools used by Radiation Control are not compatible or related in any way to the RAIS program. The database systems used by Radiation Control do not, for instance, provide for an interface for connection to the International Catalogue of Sealed Radioactive Sources (ICSRS).

The national register for radiation sources, where it exists, is essential in assessing the level of radiation safety in the country and the effectiveness of the regulatory programme. There have been several reports concerning lost or stolen radiation sources in the country while Radiation Control is not even aware of the situation. Even after the situation is reported, lack of full information on the database limits the ability to trace the licensee or the lost radioactive source (IAEA 2009b:2).

Kahn (2011:3) reported that the Democratic Alliance (DA) had asked the IAEA to intervene and help track down more than 200 missing radioactive sources in this country. The same report indicated that Radiation Control has no idea where these radiation sources are, whether they are high or low risk, and whether there are additional sources that may exist. Reports also show that there is no reliable and accurate national register of radiation sources in South Africa.

The researcher has, through working with the Radiation Control database for the past seven years, been exposed to its limitations. This might influence the researcher's

objectivity in the conduct of the study. In order to avoid this, the study has been supplemented with both database systems' functional requirements and specifications. The functional requirements and specifications have been used to cross-validate the questionnaire responses against the analysis.

Within this context, it is relevant to investigate whether or not Radiation Control's database system is adequate and effective in supporting the required functions and performance of the regulatory programme.

## 1.3 RESEARCH PROBLEM

The research problem is to develop a methodological framework for the assessment and evaluation of a health software application using the South African Radiation Control Database as an example.

## 1.4 AIM OF THE STUDY

### 1.4.1 Research purpose

The purpose of the study is to evaluate the theoretical and actual effectiveness of the current database system used by the Radiation Control when compared with international best practice, as reflected in RAIS.

### 1.4.2 Research Objectives

The objectives of the study are to:

- Compare the functional and data storage capabilities of the current database system used by Radiation Control with RAIS.
- Evaluate implementation experiences of the South African database system against the structural and functional features of the system.

## 1.5 SIGNIFICANCE OF THE STUDY

Currently there is no consistent and common approach to the data management of the radiation regulatory control framework in South Africa. It is hoped that the results of the study will have implications on the way radiation regulatory control data is managed and thus contribute to radiation safety and security in the country, as well as the effectiveness of the regulatory programme.

The results of the study will hopefully also highlight the need for a properly maintained register for radiation sources, which will lead to increased public health and safety. The results will also provide baseline information that can be used to re-engineer mechanisms to improve the level of radiation safety and security and the regulatory programme in the country. Finally, the results of the study may be used as a basis for further research related to policy implementation (Carson, Schetnan, Hasan & Mohamed 2008:58).

## 1.6 DEFINITIONS OF TERMS

For the purpose of this study, the following terms were used as defined below:

### 1.6.1 Authorisation

According to the IAEA (2004a), authorisation means permission granted by a regulatory body to a natural or legal person (including a facility or department) who has submitted an application to manage a radioactive source.

### 1.6.2 Database system

A database system is an organisation of components that defines and regulates the collection, storage, management, and use of data in a database environment. The database system is made up of five major parts, namely, hardware, software, people, procedures, and data. A database is a shared, integrated computer structure that houses a collection of related data. It contains two types of data: end-user data (raw facts) and metadata (data characteristics and relationships) (Rob & Coronel 2007:18 & 639).

### 1.6.3 Management and radiation sources

Management in this study means all activities, administrative and operational, that are involved in the manufacture, supply, receipt, storage, use, transfer, import, export, transport, maintenance, recycling or disposal of radioactive sources (IAEA 2003:31).
A radiation source refers to a *radiation generator*: a device capable of generating radiation, such as x-rays, neutrons, electrons or other charged particles, which may be for scientific, industrial or medical purposes; and a *radioactive source*: is a radioactive material that is either permanently sealed in a capsule or closely bonded and in a solid form, including commercial radioisotopes in liquid form (IAEA 2003:31).

### 1.6.4 RAIS – Regulatory Authority Information System

RAIS is a software application developed by the IAEA to assist member states in managing their regulatory activities (IAEA 2004a:3).

### 1.6.5 The regulatory authority/body's regulatory control

Regulatory authority is described as an entity or organization or a system of entities or organizations designated by the government of a country or state as having legal authority for exercising regulatory control with respect to radioactive sources, including issuing authorizations, and thereby regulating one or more aspects of the safety or security of radioactive sources (IAEA 2004a:3).

Regulatory control means any form of control or regulation applied to facilities or activities by a regulatory body for reasons related to radiation protection or to the safety or security of radioactive sources (IAEA 2004a:3).

## 1.7 RESEARCH DESIGN AND METHOD

A research design is "a blueprint for the conduct of a study that maximises control over factors that could interfere with the internal validity of the findings" (Burns & Grove 2005:211). Research design and method comprise the overall plan for data collection and analysis (De Vos 1998:123; Polit & Beck 2008:694). The research design used in this investigation is a mixed method approach, including a quantitative research design using a non-experimental, descriptive and evaluation approach supported by a qualitative analysis of the database metadata description. The research design and methodology will be discussed in more depth in chapter 3.

### 1.7.1 Population

The population refers to all the elements (individuals, objects, or substances) that meet certain criteria to be included in a given universe (Burns & Grove 2005:40). The population also means the entire set of individuals having common characteristics in which a researcher is interested (Polit & Beck 2008:761).

The study population in this study included all the records of the specifications of the database system and RAIS, and the users of the database at Radiation Control. (Refer to chapter 3).

### 1.7.2 Sample and sampling

A sample means a subset of the population which is selected for a study. Its members are called subjects. Sampling refers to the process of selecting a group of people, events, behaviours, or other elements for the purposes of conducting a study (Burns & Grove 2005:40; Polit & Beck 2008:339).

All the employees of the Directorate Radiation Control, who use the database and consented to participate, were used in the study, largely because of the defined number of users of the system. The specifications applicable and relevant to the South African radiation regulatory framework were selected to be used as criteria to compare the database systems. (Refer to chapter 3).

### 1.7.3 Data collection

Data collection is the precise, systematic gathering of information relevant to the research purpose or specific objectives, questions, or hypotheses of a study. In quantitative studies it involves the generation of numerical data to address the research purpose or specific objectives and questions (Burns & Grove 2005:42; Stommel & Wills 2004:362).

Data were collected using the specifications records of the two database systems and a questionnaire that served as a structured interview guide. (Refer to chapter 3).

### 1.7.4 Data analysis

Data analysis refers to the systematic organisation and synthesis of research data which, in quantitative studies, is the testing of hypotheses using the same data. Data analysis is conducted to reduce, organise and give meaning to data (Burns & Grove 2005:733; Polit & Beck 2008:751).

Qualitative metadata was analysed by comparing the fields supported by the two databases and the theoretical degree of database integrity. Quantitative data was analysed using the applicable descriptive statistic. (Refer to chapter 3).

### 1.7.5 Validity and reliability

Validity, in measurement, describes the degree to which an instrument measures that which it is meant to measure. Reliability means the extent of consistency or dependability with which an instrument measures an attribute (Polit & Beck 2008:764 – 768). The measures to ensure internal and external validity and reliability in this study are described in chapter 3.

### 1.7.6 Ethical considerations

Ethics refers to the degree to which research and procedures adhere to professional, legal, and social obligations to the study participants (Polit & Beck 2008:753). Ethics is concerned with matters of right and wrong. Ethical considerations include the right to privacy and refusal to participate in the research; anonymity and confidentiality; full disclosure about the research, and not to be harmed in any manner.

In this study, the researcher submitted the research proposal to the Higher Degrees Committee of the Department of Health Studies of Unisa (University of South Africa) for

approval. The researcher also obtained permission to conduct the study, and respected respondents' rights. The respondents were asked to sign a written, signed consent before participating in the study. Their names, phone numbers, addresses and other details were not included in the questionnaire which ensured confidentiality (refer to annexure A and annexure E).

## 1.8 SCOPE OF THE STUDY

Limitations are restrictions or problems in a study that may decrease the generalisability of the findings and may be theoretical and methodological (Burns & Grove 2005:39). The sample size of the respondents used in the study is small due to a small number of users or employees of the regulatory body, Radiation Control. The researcher does not have previous experience of working with RAIS.

## 1.9 STRUCTURE OF THE DISSERTATION

Chapter 1 introduces the study and describes the problem, aim and significance of the study and the research design and methodology.

Chapter 2 covers the literature review.

Chapter 3 describes the research design and method.

Chapter 4 presents the analysis, presentation and description of the research findings.

Chapter 5 concludes the study and outlines some recommendations.

## 1.10 CONCLUSION

In this chapter, the reader has been introduced to an investigation of the database systems for the management of radiation sources. The chapter covered the background information about the research problem, research problem, aim and significance of the study, definition of terms, research design and method, and scope of the study.

Chapter 2 discusses the literature review.

# CHAPTER TWO – LITERATURE REVIEW

## 2.1 INTRODUCTION

The literature review focused on two main areas: database concepts and radiation sources.

The database concepts refer to a database system that involves the database data collection with the database management system (DBMS). It also includes database and metadata features, the Radiation Control database system and its features, RAIS, and database schemas.

Radiation sources refer to a radiation generator and a radioactive source. It includes radiation source applications, categorization of radioactive sources, ICSRS, lost or missing radiation sources, and the national register of radiation sources.

A summary of the literature reviewed is provided at the end of the chapter.

## 2.2 DATABASE CONCEPTS

### 2.2.1 The database and the DBMS

A database, in simple general terms, is an organised collection of data for one or more purposes, usually in digital form. The data are typically organised to model relevant aspects of reality, e.g. the list of licensees due for inspection, in a way that supports processes that require such information, e.g. finding a licensee with particular radiation source applications (Stair & Reynolds 2006:728).

Rob & Coronel (2007:6) explain that the term database is correctly applied to the data and its supporting structures, and not to the DBMS. The DBMS is a collection of

programs that manages the database structure and controls the access to the data stored in the database. The database data collection with the DBMS is called a database system (Rob & Coronel 2007:7; Stair & Reynolds 2006:728).

The DBMS is the system in which related data is stored consistently and according to a model that has been proven to have integrity and support data storage and reporting. A relational database management system (RDBMS) stores data according to a relational model that has been proven to support data storage and reporting when stored in a normalised format. The phrase ‘related data’ means that the data stored pertains to a particular schema design, in this case, the relational model. A dimensional database stores data according to a model that is optimised for data querying (Stair & Reynolds 2006:206; Rob & Coronel 2007:6 & 547).

The term ‘database system’, state (Rob & Coronel 2007:6–7), implies that the data are managed to some level of quality that is measured in terms of accuracy, availability, usability, resilience and integrity. This in turn often implies the use of a general-purpose DBMS. A general-purpose DBMS is typically a complex software system that meets many usage requirements and supports databases that are often large and also complex. The most common general-purpose DBMS is the RDBMS (Stair & Reynolds 2006:731).

The use of databases and DBMSs is now widespread such that most organisations and companies, from small to large, heavily depend on databases for their operations and the development their technology and products. Well known RDBMSs include *Oracle*, *IBM DB2*, *Microsoft SQL Server*, *PostgreSQL*, *MySQL* and *SQLite*. A database is not generally portable across different DBMS, but different DBMSs can inter-operate by using standards such as the Structured Query Language (*SQL*) and the Open Database Connectivity (*ODBC*) to support a single application (Rob & Coronel 2007:36; Stair & Reynolds 2006:735).

Some general-purpose DBMSs, like *Oracle*, *Microsoft SQL Server*, and *IBM DB2*, have been developed over a period of many years. General-purpose DBMSs aim to satisfy as many applications as possible. This means that DBMSs support a particular database schema, for example the relational database schema. Specialised databases are created by configuring a general-purpose DBMS to support specified data model and data storage.

An *active database* is a database that includes an event-driven architecture that can respond to inputs from both inside and outside the database. Possible uses include security monitoring, alerting, statistics gathering and authorization. Most modern relational databases include active database features in the form of database triggers, procedural code that is automatically executed in response to certain events on a particular table or view in a database (Rob & Coronel 2007:611).

A general objective of a database is to provide a single integrated store of information in the company (Rob & Coronel 2007:593).

### 2.2.2 Database features

Features commonly offered by DBMSs include query ability, backup and replication, rule enforcement, security, computation, change and access logging, and automated optimization.

*Querying* is the process of requesting attribute information from various perspectives and combinations of factors. A database query language and report writer allow users to interactively interrogate the database, analyze its data and update it according to the users' privileges on data. An example of this is: "How many sealed radioactive sources are in Gauteng?" (Rob & Coronel 2007:430; Smith 2006:S15 – S17).

In *backup and replication*, copies of data attributes need to be made regularly in case primary disks or other equipment fails. A periodic copy of data attributes may also be

created for a distant organization that cannot readily access the original. The DBMS usually provide utilities to facilitate the process of extracting and disseminating data attribute sets. When data are replicated between database servers, so that the information remains consistent throughout the database system and users cannot tell or even know which server in the DBMS they are using, the system is said to exhibit replication transparency (Rob & Coronel 2007:604; Wikipedia Database management system ... 2012).

*Rule enforcement* refers to the concept that data attributes are always expected to be stored in a way that maintains the data integrity and reliability and this is enforced by the database schema and other rules on the data. For example, there may be a rule that says each radiation source can have only one generator, identified by a serial number, associated with it. If somebody tries to associate a second generator with a given source, we want the DBMS to deny such a request and display an error message (Rob & Coronel 2007:602; Wikipedia Database management system ... 2012; Smith 2006:S16).

S*ecurity* is one of the main features of a database to protect against unauthorised access to private data. For security reasons, it is desirable to limit who can see or change specific attributes or groups of attributes. This may be managed directly on an individual basis or by the assignment of individuals' and groups' privileges. In the most elaborate models, role-based access is through the assigned to individuals and groups who are then granted entitlements (Rob & Coronel 2007:592; Wikipedia Database management system ... 2012).

A DBMS may support standard *computations* requested on data attributes, such as counting, summing, averaging, sorting, grouping, cross-referencing, etc. Rather than have each computer application implement these from scratch, they can rely on the DBMS to supply such calculations (Rob & Coronel 2007:426; Wikipedia Database management system ... 2012).

*Change and access logging* captures data concerning the person or roles that has accessed particular data attributes, as well as any changes, and when the changes were made. Logging services allow this by keeping a record of access occurrences and changes. In *automated optimization*, those frequently occurring usage patterns or requests may be optimised by a DBMS. In some cases the DBMS will merely provide tools to monitor performance, allowing a human expert to make the necessary adjustments after reviewing the statistics that are collected (Stair & Reynolds 2006:206; Wikipedia Database management system ... 2012).

### 2.2.3 The Radiation Control database system

The Directorate Radiation Control currently uses an Oracle Database 10g Std Edition. Cyran et al (2005) describes the Oracle database as “a collection of data treated as a unit”. The purpose of which is to store and retrieve related information. A database server is important in solving the problems of information management, and it also prevents unauthorised access and provides efficient solutions for failure recovery (Cyran et al. 2005).

A server, in general, manages a large amount of data in a multiuser environment so that many users can concurrently access the same data. This simultaneous access of the same data by many users is known as data concurrency (Cyran et al. 2005).

Cyran et al (2005) mention that Oracle includes software mechanisms which help it fulfil three main important requirements of an information management system:

#### *2.2.3.1 Data concurrency of a multiuser system must be maximized*

The main concern of a multiuser database management system is how to control concurrency, that is, the simultaneous access of the same data by many users. Without adequate concurrency controls, data could be updated or changed improperly, compromising data integrity (Cyran et al. 2005).

#### *2.2.3.2 Data must be read and modified in a consistent fashion*

Data access consistency means that the data that a user is viewing or changing are not changed, by other users, until the user is finished with the data. This is called read consistency, and as supported by Oracle, guarantees that the data set are consistent and do not change during statement execution. Read consistency also ensures that readers of database data do not wait for writers or other readers of the same data, and vice versa. It also ensures that writers only wait for other writers if they attempt to update identical rows in concurrent transactions (Cyran et al. 2005).

#### *2.2.3.3 High performance is required for maximum productivity from the many users of the database system*

This is achieved through firstly, locking mechanisms in which Oracle uses locks to control concurrent access to data. Secondly, quiesce database is when a database system is put into a quiesced state in which the database administrator can safely perform certain actions whose executions require isolation from concurrent non-DBA users. Thirdly, Real Application Clusters (RAC) combines the processing power of these multiple interconnected computers to provide system redundancy, near linear scalability, and high availability. Lastly, Oracle provides unique portability across all major platforms and ensures that applications run without modification after changing platforms (Cyran et al. 2005).

### 2.2.4 Radiation Control database features

Oracle (2004) states that the “Oracle Database Standard Edition is optimised for deployment in medium-sized business environments”. It is supported on either a single server supporting up to a maximum of 4 CPUs (central processing units), or on a clustered server environment, with a total maximum of 4 CPUs in the cluster. Oracle Database 10g Standard Edition is available on all Oracle’s supported operating systems, including Windows, Linux and UNIX (Oracle 2004).

Oracle Database Standard Edition is preconfigured for production usage, and comes with automated space, storage and memory management, automatic backup and recovery, and automatic optimizer statistics management. It has a built-in Enterprise Manager 10g Database Control console that provides a web-based interface that shows at a glance, the current status of the database and cluster environment, and allows database administration actions from any browser connected to a system (Oracle 2004).

Oracle Database 10g Standard Edition supports all standard relational data types, as well as native storage of *Extensible Mark-up Language* (XML), Text, Documents, Images, Audio, Video and Location data. Data are accessed through standard interfaces such as SQL, *Java Database Connectivity* (JDBC), SQLJ, DBC .Net, *Object Linking and Embeding* (OLE .Net) and *Oracle Data Provider* (ODP .Net), SQL/XML and XQuery, and *Distributed Authoring and Versioning* (WebDAV). Stored procedures deployed in the database can be written in both Java and Procedural Language (PL/SQL). Oracle Database 10g Standard Edition also provides built-in analytical, statistical and modeling capabilities that can be used in any SQL based Business Intelligence environment (Oracle 2004).

Oracle Database Standard Edition provides for robust support for database roles, auditing, and data encryption, which in turn provides strong access control and accountability to address your security and privacy needs (Oracle 2004).

## 2.3 REGULATORY AUTHORITY INFORMATION SYSTEM – RAIS

RAIS promotes a consistent and common approach to the regulatory control of radiation sources (RAIS 2012). RAIS offers flexibility and customizability which allow regulatory bodies to respond to specific needs of their countries with regard to the national legislative framework, administrative structure, and institutional and regulatory framework (IAEA 2009b: 2).

In order for a regulatory body to effectively maintain the national register for radiation sources, development of adequate data management tools is required to facilitate data storage, analysis and follow-up actions. Adequate data management is also essential for assessing the level of radiation safety and security in the country and the effectiveness of the regulatory programme (IAEA 2009b:2).

RAIS 3.0 was initially developed in a Microsoft (MS) Access environment, and then extended for implementation on SQL Server platforms. Then RAIS 3.1 Web which offers a web based environment with remote access, access by authorized representatives of facilities, enhanced data access through functional and data roles, multilingual capability, enhanced incident module and public communication was released (IAEA 2009b:2 – 4). As of February 2012, RAIS 3.2 Web which offers additional features that enhance the managerial aspects of RAIS and add more flexibility to the customization options was released (RAIS 2012).

RAIS is a comprehensive database system covering by default all main areas of the regulatory framework. These are: national regulatory infrastructure information; facilities and departments; radiation sources and associated equipment; authorisation, inspection; enforcement; workers; radiation events; and technical services (RAIS 2012).

### 2.3.1 Features and advantages of RAIS

RAIS offers a wide range of customization to respond to the specific needs of countries' national legislative and regulatory framework. For example: the scope such as data tables and data fields; interface controls such as menus and data filters; background functionalities such as data consistency checks and data protectors; and reporting and data analysis tools (RAIS 2012).

The main advantages of RAIS are:

- Compatibility with the IAEA Safety Standards,
- Extensive customizability which young regulatory bodies may use as a guide or model to establish their regulatory program, while mature ones may tailor the system according to their own national system,
- Data consistency checking to reduce human errors,
- Regulatory activities description as processes, providing a link to the regulatory body management system and processes such as authorisation, inspection and enforcement,
- Protection of vital data against unintentional modification or deletion,
- Access control to protect data against unauthorised access and to ensure data confidentiality – enhanced by functional roles and data roles in RAIS 3.1 Web and RAIS 3.2 Web,
- A means for information dissemination to the public which the regulatory body can customise according to its policy,
- Includes catalogues on manufacturers and models of sealed sources, radiation generators and associated equipment,
- A secure interface for connection to the ICSRS in RAIS 3.1 Web and RAIS 3.2 Web,
- Online submission of data by the facilities, subject to validation by the regulatory body in RAIS 3.1 Web and RAIS 3.2 Web, and
- Significant savings as a ready-made database, especially for developing nations.

The regulatory body has a huge responsibility requiring execution of a lot of tasks and dealing with loads of data and information. RAIS is a database created by the IAEA to help regulators track every parameter associated with their activities. RAIS combines the strengths of an extensive inventory and a detailed record of national expertise. It stores information on every radiation source and the facility in which it is used, plus records of licenses and registration. It also has a complete record of personnel and users qualifications and the radiation doses received by individuals in occupational or medical settings (Thematic Safety Areas 2012).

Suman (2011:3) says that recent consultations between the IAEA and its member states recommended including the National Register of Occupational Doses (NROD) within the default scope of the RAIS. Although the primary scope of RAIS is the control of radiation sources, its technical feasibility and wide use proves that it can serve as a platform for establishing an NROD and be a viable and effective option.

In the implementation of the NROD, the use of RAIS customisation tools and features proved to be efficient and effective in making the NROD interface easier to use and more user-friendly. RAIS customisation features also proved, for example, their efficacy in producing reports (Suman 2011:5 – 6).

### 2.3.2 Other countries' implementation and use of RAIS

As of December 2011, more than seventy countries are using RAIS on a regular basis. Of these 26% use RAIS without modification and 74% have customized the system to varying degrees (RAIS 2012).

Suman & Alhabbal (2008:328) report that Syria is one of the first countries which started using RAIS 3.0 as the MS Access version and, later on, the SQL Server version. This provided for RAIS' initial and continuous testing with bulk data in day-to-day work in Syria. Although it proved to be a powerful tool for managing regulatory activities, the daily application with massive data indicated a need for further improvement in its scope

and interface. Therefore numerous enhancements were made to RAIS in Syria, using the RAIS 3.0 Creator or the advanced customisability option and some ‘intrusion’ (modification) of the core system. This was done with careful consideration to keeping compatibility with the original RAIS 3.0.

In Egypt, the RAIS Personal Digital Assistant (PDA) was developed as part of a barcode-based system implementation to track radioactive sealed sources (RSS). The system allows users in the field to verify RSS data, gather RSS audit information, and upload that data to the RAIS database. The main purpose of the system is to protect human health and environment in Egypt from mismanaged RSS through comprehensive RSS management capabilities development. The program includes an automated cradle-to-grave tracking of RSS in use and in storage through implementation of the RAIS database (Carson et al 2008:1-2).

In the program: RAIS tracks authorization, licensing, import/export, use, and disposal of RSS; manages activities such as inspections and audits; Provides a template for RSS management that can be customised to meet individual national needs and regulatory requirements; and is available on the internet and/or web based. Carson et al (2008:2) further reports that in order to completely automate RSS tracking in Egypt: software had to be developed to allow two-way communication between the RAIS database and a PDA; and a barcode identification system to uniquely identify all RSS in the country was needed.

However the RAIS PDA Application does not provide mechanisms for adding a sealed source, in its current form. Therefore sealed sources must be added to the system by using the RAIS database software before and soon after data consolidation for synchronisation between RAIS PDA Application and RAIS, and to prevent data integrity problems (Carson et al 2008:2).

The Department of Authorization, Inspection and Regulation (DAIR) of the Lebanese Atomic Energy Commission (LAEC) is using RAIS 3.1 Web software to manage their regulatory programme (Regulatory Authority Information ... 2011).

The objective of using this software is: to keep registry/records of LAEC regulatory data such as facilities, radiation sources, workers and doses; to manage the regulatory information; to manage the regulatory activities such as authorizations, inspections and enforcement; and data analysis tools such as sources inventory and follow-up as well as practice profiles (RAIS 2012).

In Sudan, the Sudanese Atomic Energy Commission (SAEC) uses RAIS 3.0 which is designed primarily as a tool for the management of information related to the regulatory control of radiation sources. (Regulatory Authority Information ... 2008) also states that RAIS 3.0 can also be used as guidance for developing, assessing and improving the regulatory authority's quality assurance programme.

In Ghana, the Radiation Protection Institute (RPI) as national regulatory authority coordinates the activities of all relevant agencies concerned with radiation and radioactive sources utilisation. The RPI uses RAIS to track radioactive sources and wastes generated by collecting statistics on sources imported into and exported from Ghana. Radiation sources and radioactive waste inventory have also been established using RAIS and Sealed Radiation Sources Registry System (SRS) (Gbadago, Fletcher, Kyere, Adu, Schandorf, Glover, Anim-Sampong, Addo and Dagadu 2005:97-98; Adu, Gbadago and Glover 2003:1).

The Nigerian Nuclear Regulatory Authority (NNRA) uses RAIS for the purposes of the National Radioactive Source Tracking System. In this system a licensee reports on all information of manufacture, transfer, receipt, export or disposal of sources (Nigerian Safety and Security of Radioactive Sources Regulations, 2006, Paragraph 20(1)).

When Hua and Hao (2000:4-5) did a study on the radiation sources database establishment in China, they recommended RAIS as a good reference to use. They further said that most of the contents in the Chinese radiation sources database will be the same as the RAIS system. The study recommended that a joint research team study RAIS and consider the Chinese practice and domestic situation. Then a national database of radiation sources would be established with reference to the experiences of the IAEA's RAIS and other member countries of IAEA.

### 2.3.3 Database Schemas

A schema is a description of the entire database. In other words, schema is the structure of the database that defines the objects in the database (Stair & Reynolds 2006:207; Oracle 2005).

Rob & Coronel (2007:219) describe a schema as a group of database objects, like tables, indexes, views, and queries, which are related to each other. Schemas provide a logical grouping of database objects by function or owner and can enforce a first level of security by allowing the user to see only the objects (e.g. tables) that belong to him/her.

Therefore a database schema of a database system is its structure as described in a formal language supported by the DBMS. It refers to the organisation of data to create a blueprint of how a database will be constructed. The database administrator specifies, according to his/her applications' knowledge, the facts that can enter the database or those of interest to the possible end-users (Stair & Reynolds 2007:206; Oracle 2005).

Entities, attributes, relationship, and constraints are the basic building blocks of all data models. An entity is anything, e.g. a person, a thing, or an event, about which data are collected, stored, and maintained. An attribute refers to a characteristic of an entity. A relationship describes an association among entities. A constraint refers to a restriction placed on the data (Rob & Coronel 2007:30; Stair & Reynolds 2006:731).

An entity relationship model (ERM) is a data model that describes relationships among entities at the conceptual level using an entity relationship diagram (ERD). An ERD is a diagram that depicts an ERM's entities, attributes, and relations (Rob & Coronel 2007: 643). According to Stair & Reynolds (2006:730), an ERD refers to a data model that use basic graphical symbols to show data organisation and relationships.

Comparing the relational and ER diagrams of the two databases (South African Regulatory database and the RAIS) gives an indication as to their data storage capabilities (see Figure 2.1 to Figure 2.4 below).

#### *2.3.3.1 Radiation Control Database*

In an Oracle database system, a schema is associated with each database user and a schema object is a logical data storage structure. A schema comprises a collection of schema objects. Examples of schema objects include tables; views; sequences; synonyms; indexes; clusters; database links; snapshots; procedures; functions; packages. Non-schema objects may include users; roles; contexts; and directory objects (Oracle 2005; Rob & Coronel 2007:219).

Below are two examples of abridged ER diagrams of the Radiation Control database. For full ERDs refer to annexure G:

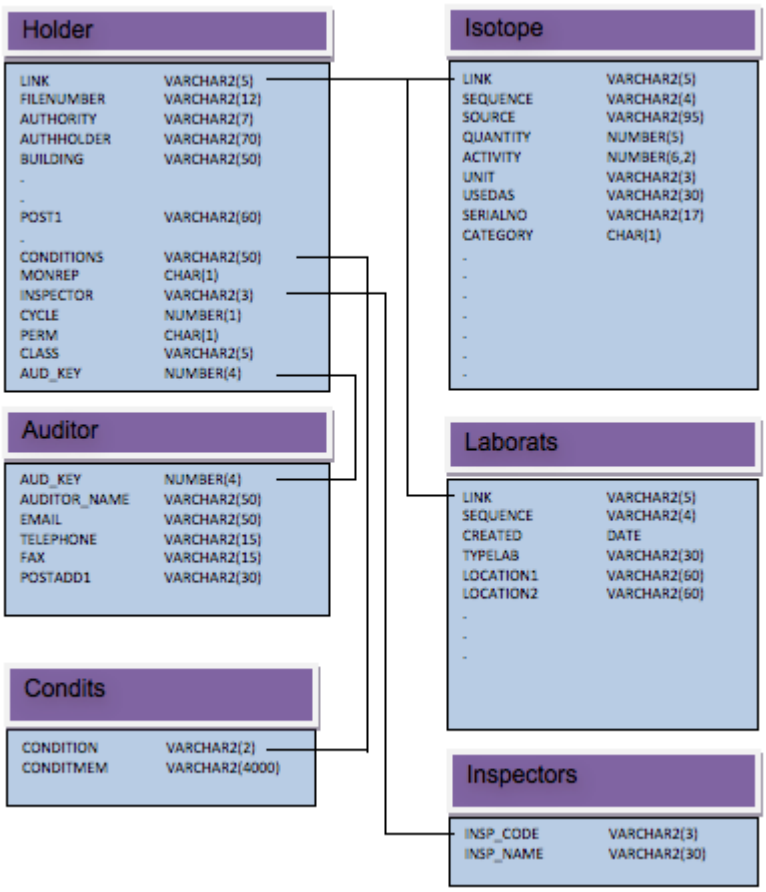
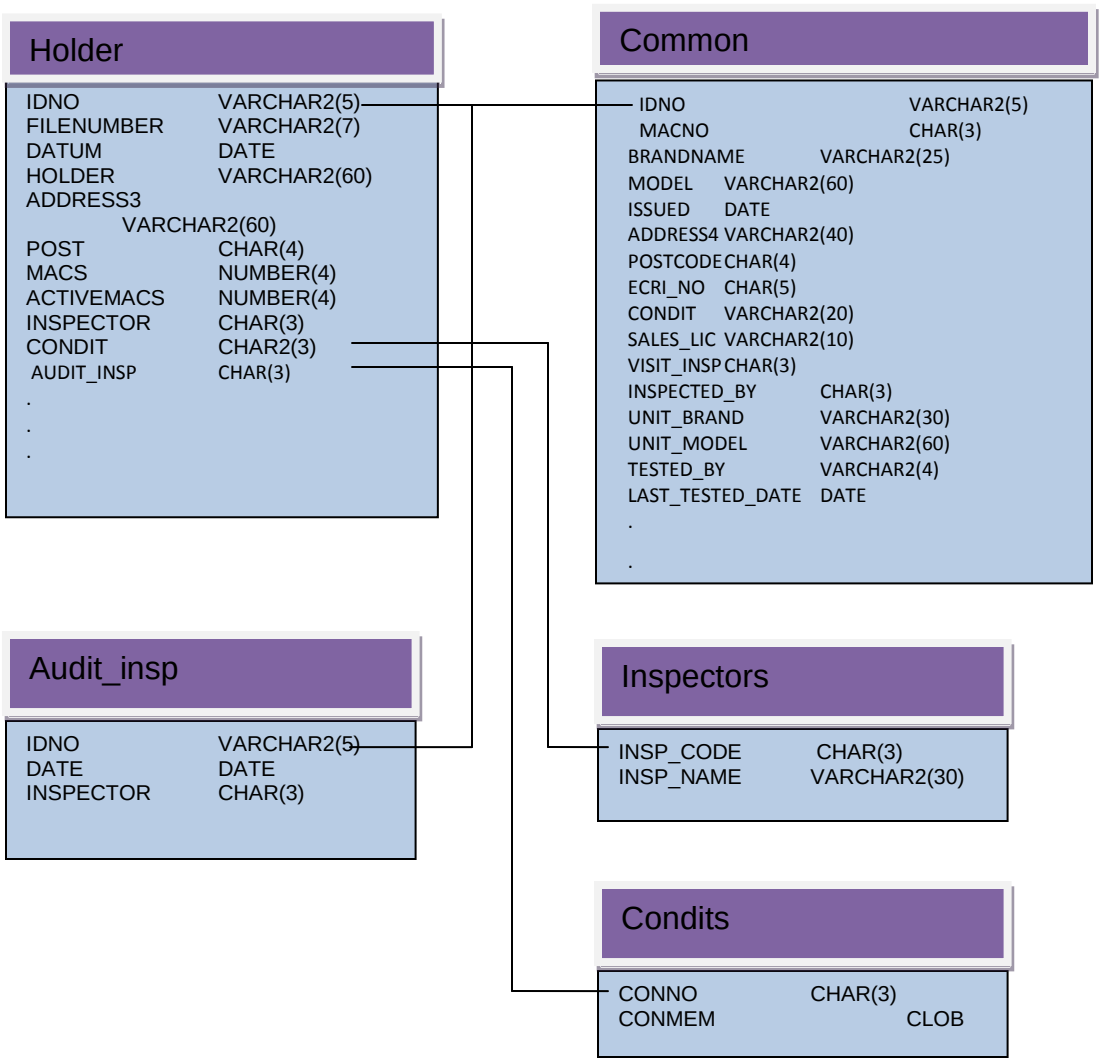



**Figure 2.1 Entity Relationships – Isotope Schema**

(Adapted from http://oracape3.health.gov.za:7778/portal/page?_pageid=33,1065&_dad=portal&_schema=PORTAL)




**Figures 2.2 Entity Relationships – X-Rays Schema**

(Adapted from http://oracape3.health.gov.za:7778/portal/page?_pageid=33,1065&_dad=portal&_schema=PORTAL)

Building of an ERD usually requires an understanding of the entities about which the organization needs to store information as well as the attributes of those entities and the relationships between them. It also involves identifying the business rules and the operational requirements (Rob & Coronel 2007:124–125). Business rules refer to brief,

precise, and unambiguous descriptions of policy, procedure, or principle in a certain organisation.

#### *2.3.3.2 RAIS*

RAIS is available in several versions: RAIS 3.0 with SQL Server Extensions (supports MS Access as well as SQL servers); RAIS 3.1 Web; & RAIS 3.2 Web. RAIS 3.2 Web was released in February 2012 and it features extended data access controls, enhanced implementation of the roles and responsibilities as assigned within the regulatory body, extended ability to produce reports and certificates, and an enhanced implementation of enforcement as a regulatory process. The new version also has some additional customisation features (RAIS 2012).

Below are two examples of ER diagrams of the RAIS database pertaining to similar structures contained in the SA regulatory Oracle database. For other RAIS ERDs refer to annexure G:

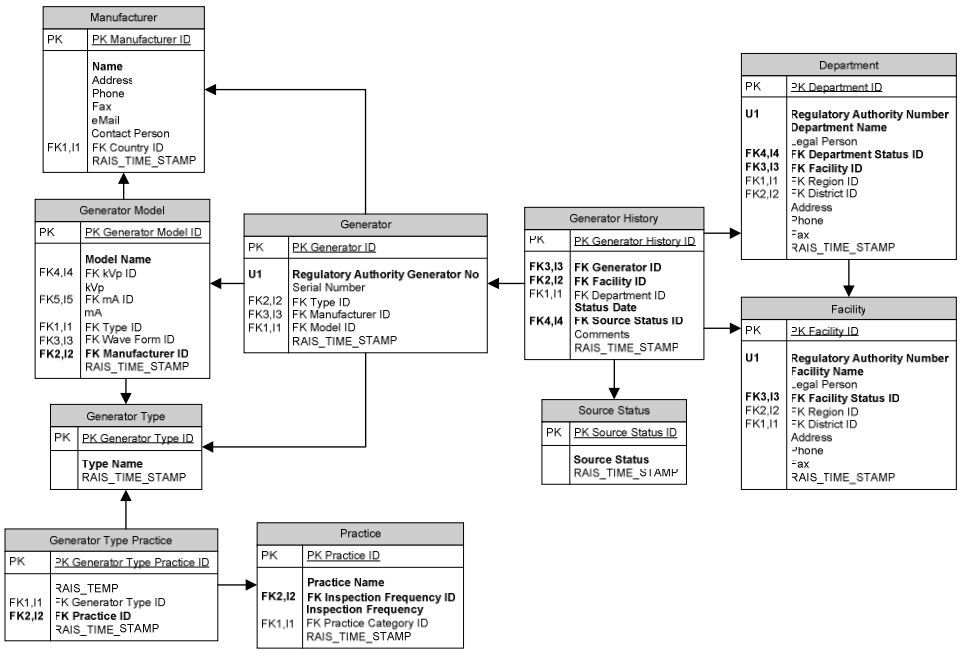



**Figure 2.3 Entity Relationship Diagram – Radiation Generators**

(Source: IAEA 2009c)

The ER diagrams of RAIS appear to be well designed and the database's extensive customisability feature means that the database can be adapted extensively. As a database that is supporting radiation regulatory bodies, RAIS ER diagrams demonstrate familiarity and relevance in terms of business rules, and data modeling features.

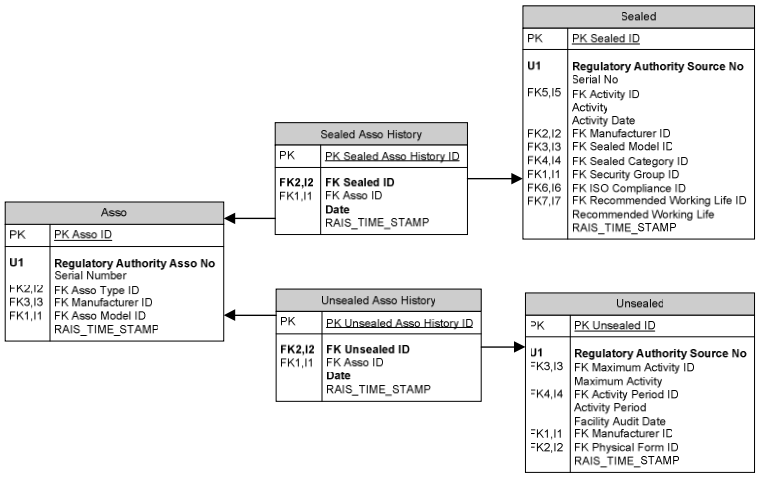



**Figure 2.4 Entity Relationship Diagram – Source–Equipment Association**

(Source: IAEA 2009c)

The entity names of all tables, entities and attributes appear to satisfy best practices in naming conventions. The entities represent a single subject and are in third normal form (3NF) level relationship to one another. The granularity of the entity instances is clearly defined. The primary key (PK) is clearly defined in all tables and supports the selected level of data granularity. There is a clear foreign key (FK) in each table as a reference to a related entity. Types of relationships, and connectivities and cardinalities are clearly indicated in the relevant entity relationships (IAEA 2009c:30–31; Rob & Coronel 2007:110–202).

The time stamp attribute records the explicit order in which transactions are submitted to the DBMS. Time stamping is a technique used in scheduling concurrent transactions, in transaction management, that assigns a unique time stamp to each transaction and can also be used to implement an audit trail that is potentially an important feature of a database with legal application. A transaction refers to a sequence of database operations, i.e. one or more database requests, that accesses the database (Rob & Coronel 2007:653).

All RAIS database tables have the time stamp attribute (RAIS_TIME_STAMP) in them. Time stamps must have two properties of uniqueness, which ensures that no equal time stamp values can exist, and monotonicity, which ensures that time stamp values always increase. The functions of time stamps include stopping, rolling back, and re-scheduling conflicting transactions (Rob & Coronel 2007:415).

The disadvantage of time stamping approach is that each value stored in the database requires two additional time stamp fields. Time stamping also increases memory needs and the database's processing overhead. However the power and storage capabilities of modern computers ensure that these are not really significant limitations compared to the value of having a database that implements regulatory compliancy.

## 2.4 FUNCTIONAL REQUIREMENTS FOR A DATABASE APPLICATION

Functional requirements for a database application refer to a set of inputs, the behaviour, and outputs. Functional requirements define functions or specific behaviours such as calculations, technical details, data manipulation and processing and other specific functionality that specify what a system is supposed to accomplish (Rob & Coronel 2007:215 – 268; OFIN Functional requirements ... 2013).

The functional requirement document is also called functional specifications or functional requirement specifications and defines the capabilities and functions that a (database) system must be able to perform successfully (Rob & Coronel 2007:65 – 90; OFIN Functional requirements ... 2013; Tsiknakis, Grangeat, Binz, Potamias, Lisacek, Gerfault, Paulus, Manakanatas, Kritsotakis, Kondylakis, Perez, Plexousakis, Kaforou & Kafetzopoulos 2007:6065 – 6069).

The functional requirement specifications for a database system should include:

- Descriptions of data to be included into the system;
- Descriptions of operations performed by each screen;

- Descriptions of work-flows performed by the system;
- Descriptions of system reports or other outputs;
- Who can enter data into the system; and
- How the system meets applicable regulatory requirements.

The functional specifications and the system should be understood by the general users or readers without them needing any particular technical knowledge to do so.

As mentioned above, the functional requirements should include the functions that are performed by specific screens and the outlines of work-flows performed by the system. It should also cover other business, regulatory or compliance requirements that the system must meet. These include *interface*; *business*; *regulatory/compliance*; and *security* requirements (OFIN Functional requirements ... 2013; Stair & Reynolds 2006:555 – 652)).

### 2.4.1 Interface requirements

As many other systems, the database system needs to provide data for other systems or for users. The system may also require data from other systems. Identifying the interface requirements involves:

- Identify the sources of required data;
- Identify the data items and data structures required for the exchange;
- Consider alternatives or select methods of data exchange;
- Identify relevant protocols for the data exchange; and
- Document or reference the technical requirements for data exchange including: the source; data items; data structures; timing, method; and protocols.

Examples of interface requirements include: *field accepts numeric data entry*; *screen can print on-screen data to the printer*; and *field only accepts dates before the current date* (Rob & Coronel 2007:347 & 547; OFIN Functional requirements ... 2013).

### 2.4.2 Business requirements

Business requirements define what must be done to achieve value. Examples of business requirements include that: *data must be entered before a request can be approved*; *all personnel using the system will be trained accordingly*; and *clicking the Approval Button moves the request to Approval Workflow* (OFIN Functional requirements ... 2013).

Rob & Coronel (2007:31) define a business rule as a precise, unambiguous, and brief description of a policy, procedure, or principle within a specific organisation. Business rules describe the business polices that apply to the data stored on a company's databases. Some business rules are especially important to the database designer because they can be incorporated into the *logical schema* of the database. The database designers apply certain constraints to ensure that the database honours the company's business rules. The business rules constraints also help preserve data integrity. They are divided between two categories: *field constraints within tables*, and *relationship constraints between tables* (Relational Database Design 2013; Stair & Reynolds 2006:21 – 36).

### 2.4.3 Regulatory/Compliance requirements

Applicable legislation and regulations require organisations to safeguard data and prove compliance. The regulations mainly include requirements for ensuring privacy, integrity and confidentiality of data, and accountability for change, as well as implementation of audit and security controls to protect regulated data (Application Security Inc. Regulatory and Industry Compliance 2013).

Examples of regulatory/compliance requirements include that: *the database will have a functional audit trail*; *the system will limit access to authorised users*; and *the spreadsheet can secure data with electronic signature*. The primary controls are: *sensitive data access auditing*; *privileged user monitoring*; *development and*

*maintenance of secure Web applications* (OFIN Functional requirements ... 2013; Application Security Inc. Regulatory and Industry Compliance 2013).

### 2.4.4 Security requirements

Different categories of requirements are appropriate depending on the system being described. Database security requirements arise from the need to protect data: first, from accidental loss and corruption, and second, from deliberate unauthorised attempts to access or alter that data. Security means protecting the data against accidental or intentional use by unauthorised users (Rob & Coronel 2007:592; Oracle. Database Security Guide – Security Requirements, Threats and Concepts 2013).

Examples of database security requirements include that:

- *Members of the Data Entry group can enter requests but not approve or delete requests;*
- *Members of the Managers group can enter or approve a request, but not delete requests;* and
- *Members of the Administrators group cannot enter or approve requests, but can delete requests.*

The functional specifications describe what the system must do, and how the system does it is described in the design specifications (Rob & Coronel 426 – 484; OFIN Functional requirements ... 2013).

### 2.4.5 Overview of application architecture

There are two common ways to architect a database, namely client/server or multitier architecture. A distributed database management system (DDBMS) manages the storage and processing of logically related data over interconnected systems. Both data and processing, in these systems, are distributed among several sites (Oracle 2005; Rob & Coronel 2007: 456).

#### 2.4.5.1 Client/Server architecture

In multiple-site processing, single-site data (MPSD) approach, multiple processes run on different computers sharing a single data repository. Multiprocessing uses more than one processor for a set of related jobs. This distributed processing reduces the load on a single processor by allowing different processors to concentrate on a subset of related tasks. This in turn improves the performance and capabilities of the system as a whole (Rob & Coronel 2007:465; Oracle 2005).

The client, or front-end, database application is the one that initiates a request for an operation to the database server. The client requests, processes, and presents data which is managed by the server. The client workstation can be optimised to its job, runs on a different computer than the server, and many can simultaneously run against one server (Oracle 2005; Rob & Coronel 2007:466).

The server, or back-end, application typically has large memory and storage capacities, along with fast and efficient communications abilities. The server receives and processes request statements from client applications. The computer that manages the server can be optimised for its duties. Server systems consists of multiuser computers such as supercomputers, mainframes, and severs (Stair & Reynolds 2006:124; Oracle 2005).

#### 2.4.5.2 Multitier architecture

The multiple-site processing, multiple-site data (MPMD) scenario refers to a fully DDBMS with capabilities for multiple data processing and transaction processing at multiple sites. A multitier architecture has the following components:

- A client or initiator process that starts an operation;
- One or more application servers that perform parts of the operation;
- An end or database server that stores most of the data used in the operation;

The application server provides access to the data for the client and performs some of the query processing, which removes some of the load from the database server. The application server can also serve as an interface between clients and multiple database servers, and also provide additional security (Rob & Coronel 2007:466; Oracle 2005).

The multitier architecture enables the use of an application server to:

- Validate the credentials of a client, such as a Web browser;
- Connect to a database server; and
- Perform the requested operation on behalf of the client.

### 2.4.6 Functional model

Stair & Reynolds (2006:13) define a model as an abstraction or approximation that is used to represent reality. A functional model, in this case, refers to a structured representation of the functions, i.e. activities, actions, processes, operations, within a defined or modelled system or subject area. The purposes of the functional model involve: *to describe the functions and processes*; *help with information needs discovery*; *assist identify opportunities*; and *establish a basis for determining product and service costs* (Rob & Coronel 2007:312 – 351).

#### 2.4.6.1 Radiation Control database functional model

An Oracle database is a collection of data treated as a unit. The purpose of a database is to store and retrieve related information. A database server is the key to solving problems of information management (Oracle 2005).

A schema is a collection of database objects. Rob & Coronel (2007:219) describe a schema as a group of objects, such as tables and indexes, which are related to each other. Schema objects are logical structures that directly refer to the database's data. The most common schema objects include structures like tables, indexes, views, clusters, and synonyms (aliases). Indexes are optional structures associated with

tables. Views are customised presentations of data in one or more tables or other views (Oracle 2005; Rob & Coronel 2007:219 – 224).

*Tables* are a basic unit of data storage in an Oracle database, wherein data is stored in *columns* and *rows*. A table is defined with a table name, such as `licensees`, and a set of columns. Each column is given a column name, such as `licensee_id`, `last_name` and `authority_no`, a datatype, such as `VARCHAR2`, `DATE`, or `NUMBER`, and a width. Datatype refers to a certain meaningful representation of data inside the computer as a pattern of 1s and 0s. The width can be predetermined by the datatype, for example in `DATE`. Precision and scale instead of datatype are defined if a column is of `NUMBER` datatype. A row is a collection of column information corresponding to a single record (Oracle 2005; Patrick 2002:231).

The rules for each table column, called integrity constraint, are specified. For an example `NOT NULL` integrity constraint forces the column to contain a value in every row. SQL statements are used to insert rows of data after a table has been created. SQL is an ideal database language in that it allows one to create database and table structures, perform basic data management chores (add, delete, and modify), and perform complex queries that transform raw data into useful information. SQL can also used to query, delete, or update table data (Oracle 2005; Rob & Coronel 2007:215)

One of the most important parts of an Oracle database is its data dictionary, which is the central set of read-only reference tables and views of each Oracle database. Stair & Reynolds (2006:209) define a data dictionary as a detailed description of all the data used in the database. The data dictionary contains:

- The definitions of all schema objects (tables, views, sequences, procedures, functions, and so on) in the database;
- The name of the data item, aliases or other names that may be used to describe the item;
- The range of values that can be used, and default values for columns;

- The names of Oracle users, a notation of the person responsible for updating data item and the various users who can access it;
- Privileges and roles each user has been granted;
- Auditing information, such as who has accessed or updated various schema objects;
- A list of reports that use a particular data item; and
- Other general database information.

The data dictionary can also include a description of data flows, the way records are organised, and data processing requirements (Stair & Reynolds 2006:209; Oracle 2005).

2.4.6.2 RAIS functional model

RAIS can be used as a default system or it can be customised according to the national administrative, legal, and regulatory structure. The customisation may involve changes to the regulatory system settings without altering the table structure, queries, or interface. It may also include customisation of the tables, queries, or interface (Suman. 2012). (See section 2.3.3.2 above).

Access to RAIS is subject to an authentication process, user name and password, which provides for data confidentiality and operation tracking. Data confidentiality is ensured by restricting access to RAIS to users having specific permissions. The concept of assigning user permissions is based on data and functional roles (IAEA 2009e).

The data role filters data from the database. Any data that is not covered by the permissions of the data role is filtered out and thus not accessible to the user assigned to that data role. The functional role governs which masks the user can access and what operations (view, add, edit, and delete) can be performed by the user on each of the masks. Functional roles also specify the level of validation required for the data entered by the user (Suman 2012; IAEA 2009e).

2.4.6.2.1 User types

RAIS provides for five preconfigured combinations of data roles and functional roles in the form of user types:

- Administrator – users of this type have full access to RAIS including adding, modifying, deleting, and viewing all data, modifying regulatory system model, and modifying regulatory system data;
- Regulator – these users have full access to the input menu which allows them to view, modify, add, and delete all regulatory data;
- Restricted Access Regulator – these users have similar access permission as the Regulator but their access to the input menu is restricted to view only;
- Licensee – users of this type are authorised representatives of facilities, who have full permissions in the input menu masks. They are however only allowed to access data related to their facility; They are allowed to add, edit, and delete any data related to their own facility subject to the regulatory body's validation process; and
- Guest – this user type is only allowed to view global and public information.

RAIS administrators are also allowed to define users into the RAIS system and assign access permission. RAIS regulators have only view permissions to the Regulatory System menu, are not allowed to alter regulatory system data, and the administration menu is not accessible to them. Licensees have view access to the global and public information but no access to the administration menu and non-public regulatory system data (IAEA 2009e).

The public data, by default, are collected in the statistics menu and the two menu items, namely Co-operation and Co-ordination, and Regulatory Reference, of the submenu Regulatory System/Regulatory Reference. RAIS also provides for a generic user type, named 'Other', which is applicable to all users for whom different combination of data roles and functional roles is required (IAEA 2009e).

### 2.4.7 An ideal Radiation Control database system

Based on the researcher's experience at Radiation Control, the views of the fellow colleagues and the literature review, an ideal Radiation Control database should be as follows (see sections 2.2 to 2.4 above):

- The database should be tailor made for the radiation regulatory authority or it should be customisable to conform with the national legislative frameworks, administrative structures, and institutional and regulatory frameworks;
- The database should be a relational Web based and equipped with a translation mechanism so that it is multilingual;
- Its scope should be comprehensive to cover all the main areas of the regulatory framework (national regulatory infrastructure information, facilities and departments, radiation sources and associated equipment, authorisation, inspection, enforcement, workers, radiation events, and technical services);
- It should be compatible with relevant international standards such as the IAEA Safety Standards;
- The database should be equipped with data consistency checking to reduce human errors;
- It should also have strong data security measures (including access control) to protect data against accidental or intentional use by unauthorised users;
- It should also be able to protect vital data against unintentional modification or deletion;
- The database should provide a means for information dissemination to the public, with the public area customised according to the regulatory body's policy; and
- The database should have extensive support base in terms of updates, technical services (maintenance and training), installations, and customisation of the system.

## 2.5 RADIATION SOURCES

Radiation sources, including both radioactive materials and radiation generators, are used throughout the world for a wide variety of peaceful purposes including medicine, industry, agriculture, science, research and education. They are also used for various military purposes (IAEA 2003:1).

The International Basic Safety Standards (BSS) establish basic requirements for protection against the risks associated with exposure to ionizing radiation and for the safety of radiation sources that may deliver such exposure. BSS also provide an internationally harmonised basis for ensuring the safe and secure use of ionizing radiation sources (IAEA 2004b; IAEA 2003:1).

### 2.5.1 Categorisation of radioactive sources

Since there is a wide variety of uses and activities of radiation sources, a categorisation system is necessary so that controls applied to sources are commensurate with the radiological risks involved (see Table 2.1 below). The categorisation of sources seeks to provide a fundamental and internationally harmonised basis for risk-informed decision making and to assist in many activities related to the sources safety and security, such as:

- Developing and refining international and national safety standards;
- Developing and refining national regulatory infrastructures to meet national circumstances;
- Optimising decisions about priorities for regulation within resource constraints;
- Optimising security measures for radioactive sources, including potential malicious use;
- Emergency planning and response; and
- Developing national strategies for control over radioactive sources;

This categorisation applies mainly to radioactive sealed sources used in medicine, industry, agriculture, research and education. However it can be equally applied to some sources under military control and unsealed radioactive sources. The categorisation is not relevant to radiation generators such as x-ray machines, particle accelerators, nuclear materials, sources within military or defence programmes, disused radioactive sources waste management, radioactive material packages in transport, and applications where factors like specific activity, chemical properties and half-life are considered (IAEA 2003: 2; IAEA 2009:4-6).

There are five categories of sources and four security groupings have been identified for these source categorisations:

**Table 2.1 Source Categorization and Security Groups**

| Security Group | Source Category | Examples of Practice |
|---|---|---|
| A | 1 | • Irradiators<br>• Teletherapy<br>• Radioisotope thermoelectric generators (RTGs)<br>• Fixed multi-beam teletherapy (gamma knife) |
| B | 2 | • Industrial Radiography<br>• High/medium dose rate brachytherapy |
| | 3 | • Fixed gauges (e.g. Level, dredger, conveyer)<br>• Well logging gauges |
| C | 4 | • Low dose rate brachytherapy (except those in Security Group D)<br>• Fill / Thickness gauges<br>• Portable gauges (e.g. moisture / density)<br>• Bone densitometers<br>• Static eliminators |
| D | 5 | • Low dose rate brachytherapy eye plagues and permanent implant sources<br>• X-Ray fluorescent (XRF) devices<br>• Electron capture devices |

(Source: http://www.aelb.gov.my & http://ansn.aelb.gov.my)

### 2.5.2 Role of a Regulatory Programme

The regulatory control programme's role is an important one in providing adequate oversight of safety in the use of radiation sources for purposes such as medical, industrial, agriculture, research, and education practices. The primary purpose of a regulatory programme is to provide an appropriate standard of protection and safety for humans without unduly limiting the benefits of the practice giving rise to the exposure (IAEA 2004b).

Radiation sources with an activity that is above exemption levels that are set by the national and international standards must be accounted for from the moment they are acquired to the day they are retired, i.e. from manufacture to disposal or cradle-to-grave tracking system. At this point standards for radioactive waste disposal must be strictly followed (IAEA 2007:4).

The requirements for an adequate national radiation safety infrastructure, in compliance with international standards, comprise five thematic safety areas (TSAs):

#### *2.5.2.1 Regulatory Infrastructure*

The first step is to establish legislation that allows beneficial or justified uses of ionising radiation and provides for adequate protection of people and the environment. The legislation must provide a mechanism that achieves such an aim through the establishment of a regulatory body or authorities which must be provided with adequate human and financial resources. The legislation also provides principal requirements and enforcement instruments to address non-compliance. Regulations provide detailed requirements or further detail on the application of the laws. One of the most important tasks of the regulatory body is to have a system of notifications, authorisations, inspection and enforcement. This includes the creation and maintenance of an accurate national register of all radiation sources (IAEA 2007:6; IAEA 2004b).

*(a) Legislative Framework*

The legal framework will depend on individual national circumstances, namely:

- The overall legal system;
- The procedure for issuing regulations;
- The legislative body, e.g. governing the functioning of the regulatory authority;
- New or additional legislation, e.g. replacing old legislation; and
- Overlaps, conflicts or gaps in coverage of radiation protection and safety, e.g. in RSA where there is more than one regulatory authority – interagency co-ordination and co-operation.

The legislation, e.g. Hazardous Substances Act, 1973 (Act 15 of 1973), is established by the national legislative body. The legislation then establishes fundamental structures and concepts, the infrastructure of regulatory control, defines the structure of the legal framework for radiation protection, and sets out the scope of the legislation and the principal protection and safety requirements (IAEA 2004b; IAEA 2007:5-6).

The legislation should recognise that radiation uses introduce important benefits in medicine, industry and research. It should also recognise that exposure to radiation might cause harmful health effects to people and that people's health and safety must be protected while permitting beneficial uses of radiation. The legislation should also provide for exclusions and exemptions of which specific criteria and values must be defined in regulations (IAEA 2007).

Performance regulations give general requirements, and specify overall radiation safety requirements and basic operational parameters. Prescriptive regulations give detailed requirements, and state how to achieve radiation safety. Most regulations are both performance and descriptive oriented and they give precise parameters in areas such as notifications, authorisations, inspections, and enforcements (IAEA 2007).

A notification may refer to a document submitted to the regulatory authority by a legal person (of a facility or department) to notify it of an intention to acquire or use radiation sources. A notification is the basic mechanism which provides information to the regulatory authority about a proposed action. An application for authorisation may also serve as notification. Apparatus exempted by the regulatory authority require notification (conditional exemption) (IAEA 2007).

Categorisation of sources is used in the authorisation process so that controls to be applied should be commensurate with the radiological risks that the sources and materials present. Of particular concern are those radiation sources which have the potential for causing significant harm to persons or have the potential for widespread contamination. Categorization is also a tool that can be used in authorization and other relevant decision-making processes.

Inspections can satisfy the regulatory body that the licensee complies with the legislation, regulations and any imposed conditions; facilities, equipment and work performance comply with requirements; persons employed by the operator, including contractors, possess the necessary competence; and deficiencies and deviations are identified and corrected (or justified) without undue delay.

Enforcement is an action taken by the regulatory authority to require a registrant, licensee or other responsible party to correct matters of non-compliance with regulatory requirements. Where appropriate, the application of penalties (prosecution, suspension or cancellation of the authorization/license, confiscation of the radiation sources, etc.) may be used as enforcement (IAEA 2004b; IAEA 2007:5-6).

Exclusions mean that some sources are not amenable to regulatory control, e.g. $^{40}K$ in human body; cosmic radiation at the surface of the earth; and low concentrations of naturally occurring radionuclides in raw materials. Some practices and sources may be exempted from regulatory control requirements including those of notification and authorization. Some may be exempted from procedural requirements of regulations to

accommodate a specific situation, provided that the same level of protection and safety can be achieved by alternative methods (see Table 2.2 below). Exemptions shall not be granted to practices deemed not to be justified (IAEA 2004b; IAEA 2007:5-6).

**Table 2.2 Exemption**

| Nuclide | Activity Concentration Bq $g^{-1}$ | Activity Bq |
|---|---|---|
| $^{3}H$ | $1 \times 10^{6}$ | $1 \times 10^{9}$ |
| $^{7}Be$ | $1 \times 10^{3}$ | $1 \times 10^{7}$ |
| $^{14}C$ | $1 \times 10^{4}$ | $1 \times 10^{7}$ |
| $^{15}O$ | $1 \times 10^{2}$ | $1 \times 10^{9}$ |

(Source: http://www.aelb.gov.my & http://ansn.aelb.gov.my)

*(b) Regulations*

Regulations are more specific in terms of radiation protection and safety requirements. They are developed by the regulatory authority and issued by the legislative body, Ministry or regulatory authority, depending on the national legal system. They apply to practices and sources within practices.

The regulation, in its broadest sense, encompasses the introduction and conduct of any practice involving radiation sources. It is however a task that can only be fulfilled by defining precise parameters in different areas such as notification, authorisation, inspection and enforcement. These are four key processes the Regulatory Authority must oversee to fulfil its mandate to regulate the introduction and conduct of any practice involving radiation sources (IAEA 2004b; IAEA 2007:5-6; Thematic Safety Areas 2012).

*(c) Codes of Practice, Guidelines*

They are practice specific requirements or guidelines which are usually developed and issued by the regulatory authority. They give practice specific advice on how to achieve protection and safety defined in legislation or regulations. They may or may not be legally binding which means that there may be other procedures available that can be followed to achieve the same protection and safety goals (IAEA 2004b).

*2.5.2.2 Radiological Protection in Occupational Exposure*

There are millions of employees around the world who come into contact with or actively apply radiation sources. Employers and licensees hold full responsibility for employees' health and safety, including individual and workplace monitoring; health surveillance and occupational exposure records; general radiation protection information and workers' training; personal protective equipment (PPE) provision and following strict procedures for personal exposure monitoring (IAEA 2007:9).

The regulatory body must oversee regulations that cover both dose limits and the implementation of a systematic approach to optimising radiation protection. This includes ensuring that monitoring and measurement services are duly accredited and delivering reliable results. The regulatory authority also plays a vital role in protecting workers through its power to conduct inspections and suspend or revoke licenses where failure to comply with set standards exists (IAEA 2007:9).

The regulatory authority must seek, as its objective with regard to radiation occupational safety, to foster a safety culture that is encouraged by management and supported by staff, including the assessment of controlled and supervised areas, the provision and use of appropriate protective devices and the provision of personal radiation monitoring. The radiation protection measure must be adequate to the source (IAEA 2004b; Thematic Safety Areas ... 2012).

#### *2.5.2.3 Radiological Protection in Medical Exposure*

The regulatory body's objective here is to provide the knowledge and skills necessary to apply the basic principles of optimization and justification for diagnostic and interventional radiology procedures as related to patient doses (IAEA 2004b).

Medical procedures form the most common cause through which people are exposed to artificial radiation. Medical practitioners have the prime responsibility for ensuring radiological protection of patients. This involves justification and optimisation for the particular use of radiation. All medical radiology procedures must be justified by weighing the diagnostic benefits they produce against the radiation detriment they might cause, taking into account the benefits and risks of available alternative techniques that do not involve radiation exposure. Optimisation means that the objective of patient protection in diagnostic and interventional radiology must be to maximize the margin of benefit over the potential risk, taking into account social and economic circumstances (IAEA 2004b; IAEA 2007:9-10).

Calibrations are to be performed before the first use of a radiation source on patients, after maintenance and at intervals prescribed by the regulatory authority. Radiopharmaceuticals are calibrated in terms of the activity to be administered. Calibrations (measuring equipment and radiation sources) are to be traceable to a laboratory recognized by the regulatory authority (IAEA 2004b; IAEA 2007:11).

#### *2.5.2.4 Public and Environmental Radiological Protection*

Regulation of public and environmental exposure has the same aim as medical and occupational exposures, to protect people from the adverse effects of radiation. The only difference is the additional 'everywhere' and 'now and the future' dimensions that apply to the public and environmental radiological protection. People and the environment are constantly exposed to low levels of ionizing radiation, mostly from natural sources and some human activities.

Potential sources of public and environmental radiation exposure from human activity can be divided into two categories: radioactive effluents and radioactive waste. Radioactive effluents can be in gas or liquid form and are discharged into the atmosphere or water. Radioactive waste represents all disused material and equipment that contain some elements of radioactive substances.

Effective control of public and environmental radioactive hazards depends on the establishment of a regulatory infrastructure, which clearly defines policies for clearance from regulatory control, discharge control and waste management. Management of radioactive waste includes arrangements for the return of spent sealed sources to the manufacturer; and transferring the waste to local storage, disposal facility or a licensed waste management organization (IAEA 2004b; IAEA 2007:10-11).

#### *2.5.2.5 Emergency Preparedness and Response*

Minimising the impact of radiological emergencies requires fast action on the part of many individuals, from first responders like the police, fire-fighters, civil defence and medical personnel to the regulatory body and senior government officials. A vital aspect of the radiation protection infrastructure is the establishment of procedures and training personnel for emergencies.

Emergency preparedness means being ready to respond to a broad range of situations that can occur anytime, anywhere. Wide spread use of nuclear technologies in diverse applications such as industry, medicine, and agriculture, means that smaller amounts of radioactive material are found on more sites. It also means that there are more sites susceptible to external impacts such as flooding, fire, or accidents caused by human error (Thematic Safety Areas 2012).

The role of the regulatory authority should be specified in national emergency preparedness plans. The regulatory authority needs training programs; equipment; facilities; logistic support; and funding in order to be able to implement its role and

functions in emergency response. Licensees have the primary responsibility for emergency response. However, the regulatory authority, together with other appropriate organizations, should have plans to co-ordinate and implement support for protective actions. The regulatory authority may have a specific role in off-site emergency situations where a licensee is not directly involved (IAEA 2004b; Thematic Safety Areas 2012).

### 2.5.3 National register of radiation sources

Establishing and maintaining an inventory of radiation sources can be challenging and time consuming (see Table 2.3). One of the roles of the regulatory authority is to actively seek out sources already in use or conduct a thorough search for disused sources as well as ‘orphan’ sources. Radiation sources already in use may or may not be registered and orphan sources are those that have been improperly disposed of or for which it is impossible to identify the owner (Thematic Safety Areas 2012).

According to the IAEA, the number of sealed radioactive sources worldwide is in the millions. However the existing registries show a much smaller number. There is a significant discrepancy between the estimated number of radioactive sources worldwide and the number of those actually registered. The reasons for this discrepancy include missing records of sources manufactured and distributed a long time (decades) ago; lack of comparison between records and physical inventories, i.e. verification of data; and lack of continuity of regulatory control, e.g. in the case of transferring sources to another user or illegal disposal of disused sources (IAEA International Conference 2003:278-279).

The radioactive source that is no longer needed or has become unfit for the intended use is classified as a spent or disused source. However the activity of a disused source may still be of the order of GBq or TBq (giga- or tera- Becquerel). Incidents and accidents with a wide range of consequences, including widespread contaminations and deterministic health effects, however have occurred as a result of spent radioactive

sources that have not been kept under regulatory control and technically sound management (IAEA International Conference 2003:278).

Deterministic radiation effect is the effect of ionising radiation leading to a functional loss of irradiated organ or tissue. This occurs if sufficient cells are killed or prevented from reproducing or functioning due to radiation. The seriousness of the loss of organ function is directly proportional to the number of cells affected, a threshold dose for deterministic effect exists, which must be exceeded for an effect to occur. The degree of pathological severity increases rapidly with the radiation dose. The deterministic radiation effects include skin reddening, eye lens opacity and permanent sterility (European Nuclear Society. Deterministic radiation effect. 2012).

The number of sources excluded from regulatory control does not depend on the countries' industrial development. However, the reasons for not having or losing control over sources are different between developing and developed countries. In developing countries, the problem often originates from the fact that the sources were imported before proper national legislation and regulatory control were introduced and the country's technical infrastructure and expertise were still limited. Although both the regulatory and technical infrastructure is in place, in developed countries, there is such a large number of sources that even if a small percentage of them is lost or unaccounted for, it can amount to a significant number (IAEA International Conference 2003:278-279).

**Table 2.3 National Register of Radiation Sources**

| Radioactive Sources | Category of radioactive sources | | | | | | X-Ray generators and Accelerators |
|---|---|---|---|---|---|---|---|
| Sealed (S) | 1 | 2 | 3 | 4 | 5 | Other (unknown activity) | In medicine and Industrial radiography practices |
| | | | | | | | |
| Unsealed (U) | | | | | | | |

(Source: IAEA 2009d:9)

It is necessary to analyse the whole life-cycle of the sources in order to identify when the sources are most vulnerable. The main phases of the life-cycle of sources are:

- Manufacturing (e.g. production of radionuclide, encapsulation, equipment manufacturing);
- Distribution to users (e.g. transportation, storage);
- Application period (e.g. medical, therapy, industry, etc);
- Transition period(s); and
- Disused/spent sources.

Manufacturers, distributors and users are not likely to lose the source, especially while it is still in their care. Therefore these phases are not so critical from the source control view point. The weak points of the life-cycle are when the sources are in the transition phase and when they become disused.

In South Africa there are all classes of radiation sources as shown in Tables 2.1 and 2.3. There is however no reliable or accurate register of radiation sources. The number

of missing radiation sources and their details, such as source type and activity are also unknown.

#### *2.5.3.1 Sources in transition*

Sources are in transition when they are transported, temporarily out of use, waiting for another application/user, or taken out of service but not declared as waste. The transportation of radioactive material/sources is usually under proper regulatory control. It is also in the carrier's interest that the consignment reaches its destination. If a source is temporarily out of use but the user intends to use it again for the original purpose, proper control is usually ensured. However the level of control may decrease when the source is not intended to be used for the original purpose anymore, but is stored with the aim of another application use or transferring it to another user. The same applies when the source is taken out of service but is not declared as waste but just stored for an indefinite period (IAEA 2009d:280).

#### *2.5.3.2 Disused/spent sources*

The main causes for sources becoming disused are radioactive decay, leaking or damage, obsolete equipment, alternate technology, or changes in priority.

The source not being used for the original purpose due to radioactive decay is usually the most common case. It is important however that the user maintains the same level of control for such a source until it is removed from the facility as its activity may still be in the order of GBq or TBq. The same applies in cases when the equipment containing the source is removed from the source or the whole application becomes obsolete and/or changed. Immediate action must be taken to isolate the area and to remove the damaged or leaking equipment or source from the user's facility by a qualified and authorised organisation (IAEA 2009d:280-281).

#### *2.5.3.3 Orphan sources*

An orphan source is a radioactive source which is not under regulatory control, either because it has never been under regulatory control, or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorization (IAEA 2009d:59).

Radioactive sources, as already mentioned, become orphaned if regulatory and physical control is lost over them. An example is when a source is placed in storage without notifying the regulatory authority, and then it is moved to another store with less physical control. Knowledge about the source degrades in time and eventually it lands in scrap storage and leaves the facility as scrap metal. Once it is mixed with scrap metal of another origin, it is almost impossible to track its origin. IAEA (2009d:281) says that typical problems with orphan sources include:

- Appearance at an unexpected location and time (usually in a public area and the environment);
- Unknown owner (need for an organisation to render the source safe);
- No technical documentation (need for technical capability to identify, transport, further manage); and
- Lack of financial resources (for collection and further management).

## 2.6 REGULATORY FRAMEWORK

The primary purpose of a regulatory program is to provide an appropriate standard of protection and safety for humans without unduly limiting the benefits of the practice giving rise to the exposure (IAEA 2004b; IAEA 2003:1).

Relevant international organisations that play a major role in the field of radiation protection include the International Commission on Radiological Protection (ICRP) and

the IAEA. These organisations have established fundamental radiation protection principles, recommendations and standards.

The International *Basic Safety Standards* for Protection against Ionising Radiation and for the Safety of Radiation Sources (BSS) are jointly formulated and sponsored by the Food and Agriculture Organization of the United Nations (FAO); IAEA; International Labour Organization (ILO); Nuclear Energy Agency of the OECD (Organisation for Economic Co-operation and Development NEA); Pan American Health Organization (PAHO); and World Health Organization (WHO).

The type of a regulatory system adopted in a country depends on its size, the complexity and safety implications of the regulated practices and sources, and the regulatory traditions in the country.

The main areas of the regulatory framework include the national regulatory infrastructure information, facilities and departments, radiation sources and associated equipment, authorisation, inspection, enforcement, workers, radiation events, and technical services.

### 2.6.1 National Regulatory Infrastructure

The implementation of the standards requires that a regulatory authority be established by the government to regulate the introduction and conduct of any practice involving sources of radiation. The regulatory authority should implement a national regulatory programme for the control of radiation sources.

The national regulatory infrastructure for radiation protection should be based on a safety culture, a safety-based attitude, and recommendations from international organisations along with the requirements of the national regulatory authorities. The infrastructure is comprised of legislation, regulations, a regulatory authority, and general provisions or services (see Figure 2.7 below).

The Hazardous Substances Act, 1973 (Act 15 of 1973) and the Regulations are used for the regulatory control of radiation sources and associated equipment by the Directorate Radiation Control of South Africa.

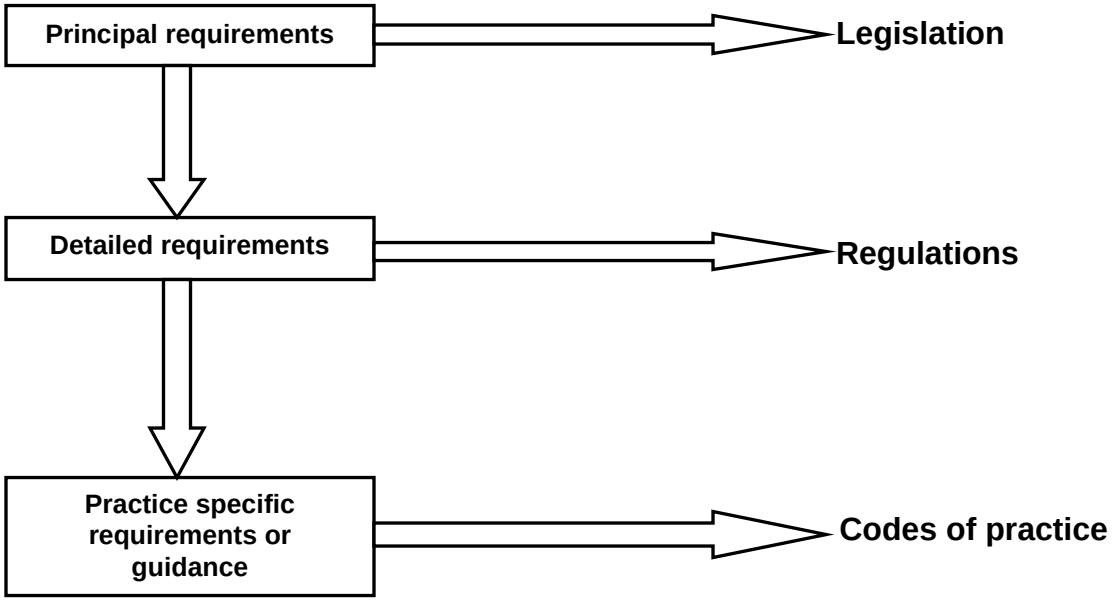



**Figure 2.5 Structure of the Legal Framework**
(Source: IAEA: 2004)

### 2.6.2 Facilities and Departments

There are many radiation facilities and departments of different applications operating worldwide. Radiation protection at all facilities consists of several basic elements: facility design; worker training, procedures, and supervision; and regulatory oversight (US EPA. Facility Safety and Environmental Impact 2012).

For all facilities, stationary and mobile, shielding of the radiation source is a key aspect of radiation protection. The amount of shielding necessary depends on the strength of the radiation source. Facility designs must also include multiple safeguards to protect worker health and the community should a natural disaster like an earthquake, fire, or tornado occur.

Facility regulation depends on the type of radiation source used. All radiation facilities must meet the requirements of the regulatory authority, such as the Directorate Radiation Control in case of South Africa. The main licensing requirements facilities must meet include: a design that incorporates multiple fail-safe measures; extensive and well documented safety procedures; and extensive worker training.

### 2.6.3 Workers and Radiation events

Licensees and/or employers are responsible for ensuring that all workers engaged in activities that involve or could involve occupational exposure to radiation are protected and monitored (see Table 2.4). Radiation exposure benefits or costs must be balanced with detriments through justification, optimization and limitation.

The justification of a practice implies doing more good than harm. The use of recognised dose limits implies an adequate standard of protection even for the most highly exposed individuals. The optimization of protection implies maximising the margin of good over harm (ALARA – As Low As Reasonably Achievable).

Workers must also be provided with suitable and adequate facilities, equipment and services for protection. They must also be provided with and properly trained in the use of appropriate protective devices and monitoring equipment. Appropriate training as well as periodic retraining and updating must also be provided to workers.

The main causes of radiation accidents include an inadequate regulatory framework in respect of authorisations, inspection and enforcements; and poor user safety culture in areas such as management, quality control and training and qualifications of personnel.

**Table 2.4 Occupational Dose Limits**

| Effective Dose Limits | |
|---|---|
| 20 mSv per year | |
| 50 mSv in any 12 month period | |
| Equivalent Dose Limits | |
| Lens of the eye | 150 mSv per year |
| Skin | 500 mSv per year |

(Source: IAEA 2003:1)

### 2.6.4 Technical Services

The technical services that are needed within or accessible to the regulatory infrastructure for an effective regulatory programme implementation must be clearly identified and their details available on the database. These include dosimetry services, analytical services, calibration services, radioactive waste management services, training services, and accreditation for services.

Essential technical services should be available to the authorised radiation users and to the regulatory authority locally (within the country) or through arrangements from outside the country (IAEA 2004b; IAEA 2003:1).

#### *2.6.4.1 Dosimetry Services*

For the assessment of external and internal doses, the accuracy and reliability of dosimetry service providers should be verified by the regulatory authority or by an acceptable third party organisation, i.e. an accredited third party service provider. Only those dosimetry service providers recognised by the regulatory authority should be authorised to provide services in the country.

The purpose of monitoring is to exercise control over individual dose; identify abnormally high doses; identify changes in working conditions; identify poor working practices; provide legal evidence; and provide security and confidence in safety procedures.

Employers must make adequate arrangements with a recognised dosimetry service provider to ensure that workers in controlled areas (radiation workers) are individually monitored.

*2.6.4.2 Analytical Services*

Analytical services should be able to provide a qualitative and quantitative analysis capability for radiation measurements that are commensurate with the radiation safety needs of the country; and recognised by the regulatory authority (possibly with external accreditation).

These include leak testing; identification of radionuclides; assessment of activity/activity concentration; and products/sources testing against national and international standards.

*2.6.4.3 Calibration Services*

Calibration services should use standards traceable to recognised national and international standards (ISO, IAEA, IEC). The services should also be recognised by the regulatory authority, possibly with external accreditation. Calibration service providers should use the same criteria and similar protocols.

Radiation surveys and/or measurements are performed to verify safe working conditions; confirm that sources are appropriately shielded; check that area classifications are satisfactory; maintain control of contamination; and satisfy regulatory requirements. Radiation monitors must be calibrated regularly.

#### *2.6.4.4 Waste Management Services*

Radioactive waste management facilities including long term storage and/or disposal must be available locally or through arrangements outside of the country.

#### *2.6.4.5 Training Services*

Training services for radiation users must satisfy the needs described in the users' radiation protection programme. They may also need to be recognised by the regulatory authority, possibly with external accreditation.

Training services need to provide different levels of training, for example: users and technicians; Radiation Protection/Control Officers; qualified experts; and line managers and employers. Formal qualifications may be required. Expert assistance may be required to support investigations by regulatory authority staff, and to advise radiation users.

## 2.7 SUMMARY

A review was performed of the relevant literature on the topic of regulatory databases for radiation and nuclear sources.

The following keywords and combinations of keywords were used: *radiation sources database*, *radiation regulatory framework*, *radiation safety and protection, authorisation; inspection and enforcement, RAIS*, etc.

Literature reviews were conducted in a number of physical and online databases, including the following: EBSCO Host, Lippincott Williams & Wilkins, PubMed, Health Physics, McGraw Hill, Sabinet, etc. Relevant South African and international legislation, regulations, statutes, policies and procedures were also searched.

The researcher also searched the UNISA library and enlisted the help of the librarians. Several searches were conducted on the internet, specifically for definitions of certain terms (Wikipedia) and technical information.

## 2.8 CONCLUSION

This chapter discussed the literature review conducted on database systems, RAIS and radiation sources to provide an insight into what is known about the use of database systems as a data management tool of radiation sources by regulatory authorities. The literature review revealed that a database is an important part of data and information management in a radiation regulatory control setup. It also showed that RAIS, as a database specifically tailor-made for regulatory bodies by the IAEA, is the most commonly used and might be more self-developed and consistent than other database systems used for this purpose.

Chapter 3 describes the research design and method used in this study.

# CHAPTER THREE – RESEARCH DESIGN AND METHOD

## 3.1 INTRODUCTION

This study was undertaken with the view of providing guidelines that may be used to improve data and information management at the South African radiation regulatory body, Radiation Control, in order to improve radiation safety, security and protection for the public and the environment. A mixed-methods approach, including quantitative and qualitative methods was used to guide the research process.

This chapter describes the research design and method, sampling, population, data collection and analysis, ethical considerations, and validity and reliability.

## 3.2 RESEARCH DESIGN

Polit and Beck (2008:66) describe a research design as an overall plan for obtaining answers to the research questions that have been posed and an explanation of how the researcher intends to cope with the difficulties that will occur during the research process. A research design is “a blueprint for the conduct of a study that maximises control over factors that could interfere with the validity of the findings” (Burns & Grove 2005:211; Polit & Beck 2008:765).

The type of design directs the selection of a population, sampling procedure, methods of measurement, and a plan for data collection and analysis (Burns & Grove 2005:40). According to Stommel and Wills (2004:32-33), a research design is “a plan according to which the research will be carried out. It specifies what observations to make or which variables to focus on, how to make them or which measurement procedures to adopt, and when to make them”. The research design outlines a plan or blueprint as to how the researcher will conduct the research (Polit & Beck 2008:66).

A non-experimental descriptive comparative design was used to generate data for this study. The design provided the researcher with an opportunity to gain a holistic view of the phenomenon and to identify the factors affecting the effectiveness of the database systems for a radiation regulatory body. The data obtained from the respondents were analysed using applicable statistical procedures.

The respondents' responses were also cross-validated against the actual structure and functional differences between the two database applications.

### 3.2.1 Non-experimental

The main purpose of non-experimental research is to describe phenomena and explore relationship between variables. In non-experimental studies, the researcher only makes observations and collects data, and does not attempt to intervene in any way to alter the phenomena of interest (Stommel & Wills 2004:144). Non-experimental designs are often used in certain studies because some human characteristics cannot be subjected to experimental manipulation due to ethical implications (Polit & Beck 2008:271 – 272).

In this study, a non-experimental research design was used since the researcher wanted to observe, describe and document factors affecting the effectiveness of database systems as data and information management tool of a radiation regulatory authority.

### 3.2.2 Descriptive

According to Polit & Beck (2008:274), the purpose of descriptive studies is to observe, collect, and document aspects of a situation as it naturally occurs. A descriptive study involves the identification of a phenomenon of interest and the variables that contribute to the phenomenon. It also provides a method for developing conceptual and operational definitions of the variables and for describing the variables themselves (Burns & Grove 2005:232; Polit & Beck 2008:274). Descriptive studies entail the

collection, analysis and interpretation of data. They also provide baseline information and are used to gain more information about characteristics within a particular field of study. The distinctive feature of this approach is that its primary concern is with description rather than with the testing of hypotheses or proving causality (Burns & Grove 2005:232).

The descriptive approach allowed the respondents to express their experience and situations while also assisting the researcher to describe and identify the factors affecting data and information management by the regulatory body using the database system. The researcher also systematically selected and reviewed literature that provided conceptual and operational definitions, and examined and described the phenomenon that is being studied (Burns & Grove 2005:232 – 241; Polit & Beck 2008:274 – 276).

### 3.2.3 Comparative

Comparative research, simply put, is the act of comparing two or more things with a view to discovering something about one or all of the things being compared. According to Polit & Beck (2008:204), in most studies, especially quantitative ones, researchers incorporate comparisons into their designs to provide a context for interpreting results. Researchers can structure their studies so as to examine different types of comparisons.

In this study, the researcher used a between-subjects comparison design to provide for a context to understand the findings. This was done by comparing the current Radiation Control database with RAIS using the specification records of the two database systems. The researcher also developed functional requirements for the database system needed in Radiation Control based on own and colleagues' experiences. The comparative study of the database systems was used to provide the context within which to understand and interpret the user acceptance study.

## 3.3 RESEARCH METHOD

The research method includes the population, sampling, data collection and data analysis.

### 3.3.1 Population

Polit & Beck (2008:67 & 337) describes the population as all the individuals or objects with common, defining characteristics, that is, the entire aggregation of cases in which the researcher is interested. The population is also all the elements (individuals, objects, or substances) that meet certain criteria for inclusion in a given universe (Kaplan [1964]; Kerlinger & Lee [2000] in Burns & Grove 2005:40). It is the population from which the study sample is drawn or selected. The study population includes the entire group of persons, objects or events which meet the criteria that are of interest to the researcher (Babbie 2007:190; Polit & Beck 2008:339).

All the employees of the Directorate Radiation Control who use the database and agreed to take part in the study were included as the study population. Of the thirty-three database users approached to participate in the study and agreed to do so, one did not return the questionnaire. The other user pulled out of the study due to being new and inexperienced with the Radiation Control database.

#### 3.3.1.1 Sampling

Sampling refers to the process for selecting a group of people, events, behaviours, or other elements with which to conduct a study in order to obtain information on the phenomenon of interest (Brink et al 2006:124; Burns & Grove 2005:341; Polit & Beck 2008:339).

In order for each person in the target or accessible population to have an equal opportunity to be selected for the sample, they have to be identified and listed. This

listing of members of the population is referred to as the sampling frame. The sampling frame is a comprehensive list of the sampling elements in the target population from which the sample is drawn (Brink et al 2006:124; Burns & Grove 2005:346).

In this study, the sampling frame was derived from all the registered employees of the Directorate Radiation Control who are users of the database. All registered employees of Radiation Control who use the database were targeted for the study. The total population was therefore sampled by selecting all those database users that consented to participate in the study.

#### 3.3.1.2 Sample

The sample size for this study was thirty-one Radiation Control employees who are all the users of the database system, except for the two, mentioned above, who declined to participate.

### 3.3.2 Data collection

Data refer to pieces of information that are collected during a study (Burns & Grove 2005:733). Data collection is the precise, systematic gathering of information relevant to the research purpose or specific objectives, questions, or hypotheses of a study. Quantitative research involves the generation of numerical data to address the research purpose or specific objectives and questions (Burns & Grove 2005:42; Stommel & Wills 2004:362).

The data necessary to meet the objectives of this study were obtained in two phases. Firstly the researcher used specification records of both database systems, Radiation Control's and RAIS, to complete a criteria-checklist. The checklist includes the database features which are applicable to a radiation regulatory authority and are used to compare the two database systems.

In completing the checklist, the researcher enlisted the services of two colleagues from the Ethiopian Radiation Protection Authority (ERPA) and the Namibia Atomic Energy Board (NAEB) as well as an official of the IAEA who works as a RAIS database administrator (DBA). The two regulators use RAIS as their database and one is an inspector and database administrator while the other an inspector and scientist, respectively. The researcher also used literature review to help complete the checklist.

Secondly a structured questionnaire was administered to the database users who work at the Directorate Radiation Control. The researcher handed each respondent the questionnaire and the written, signed informed consent letter. The researcher explained to the respondents that they should answer all questions as honestly as possible and that they could ask the researcher for anything unclear about the questions. The consent letter also explains about this and the objective of the study. The respondents' names and other details were not written in the questionnaire for ethical reasons.

The completed questionnaires were collected from the respondents by the researcher on the same day and some after one up to three days, to improve the response rate and minimise data loss and bias.

#### 3.3.2.1 Data collection instruments

Polit & Beck (2008:417) describe a checklist as a two-dimensional arrangement with a series of questions listed along one dimension, usually vertically, and response alternatives listed on the other. Checklists include several questions with the same response format. They are relatively efficient and easy to understand but usually used in self-administered questionnaires (SAQs) rather than interviews.

A structured interview guide is formalised so that all the respondents are presented with the same questions in the same order and manner (Brink et al 2006:151). The structured questionnaire helped the researcher to collect data within the scope of the study and similar types of information from all the respondents. This helped minimise

the researcher's role and influence of the data collection process and to enable a more objective comparison of results. The instrument was tested using similar population which was not included in the study.

Both data collection instruments used in this study were constructed using questions to address the objectives of the study. The researcher had done a literature review to gain some knowledge of the phenomenon of interest in the research.

The checklist was developed by the researcher using the functional requirements of an ideal radiation regulatory body's database and literature review. The checklist also covers the main areas of the radiation regulatory framework as indicated by the IAEA.

#### 3.3.2.2 Characteristics of the data collection instrument

The following are the characteristics of a structured data collection instrument (Babbie 2007:264-265; Brink et al 2006:151; Polit & Beck 2008:414):

- The wording used is pre-determined and standardised and the same instrument or method is used for all respondents.
- The researcher develops the data collection instrument beforehand.
- Respondents are asked to answer the same questions in the same order and with the same set of response options.
- The questions are asked orally in a face-to-face interview.
- The interviewer can clarify matters that the respondents do not understand clearly thereby obtaining relevant responses.
- It is most appropriate when straightforward, factual information is desired.
- The interviewer's presence decreases the number of "Don't knows" and "No answers".
- It achieves a higher completion rate.
- The researcher is required to have some knowledge of the expected behaviour.

In this study, the same interview guide was administered with all the respondents.

#### 3.3.2.3 Ethical considerations related to data collection

Research ethics is doing what is right and good during research; the application of general ethical principles to the realm of research. Ethics is a system of moral values that is concerned with the degree to which research procedures adhere to professional, legal and social obligations to the study respondents. Ethical considerations include the right to privacy including refusal to participate in the research, the right to anonymity and confidentiality, the right to full disclosure about the research and the right not to be harmed in any manner (Burns & Grove 2005:245; Polit & Beck 2008:753).

The researcher submitted his research proposal to the Higher Degrees Committee of the Department of Health Studies of Unisa (University of South Africa) for approval. A letter requesting permission to conduct a study was sent to the director of the Directorate Radiation Control and permission was obtained.

The letter of authorisation to conduct the study was shown to the respondents and they were assured that the study will not interfere with their daily routine at their work. Respondents were also informed that their participation was voluntary and that they were free to withdraw anytime without any punishment. They were also informed that the researcher intends to publish the results of the study and that every attempt will be made so that the data obtained will not reveal individual characteristics. The respondents were also issued with a written, signed informed consent which they signed when agreeing to participate in the study (see Annexure E).

No personal or institutional details were presented in the results of the study. The researcher maintained confidentiality and anonymity throughout data collection, analysis and reporting of the findings.

Each questionnaire was accompanied by a written, signed informed consent letter requesting consent for participation in the study (see Annexure E). The letter included the purpose of the study, the estimated time required to complete the questionnaire, and measures to ensure confidentiality and anonymity. The instrument does not contain names of the institution or the respondents. Respondents were not required to write any personal or institutional details on the questionnaire.

The study maintained a high level of ethical principles which include:

- **Beneficence principle** (doing good and refraining from doing harm). The study kept this principle by not posing any physical or emotional harm to the respondents. There were no wilful questions to the respondents. The questionnaire is structured to consist of both open- and close-ended questions.
- **Justice principle** (fair selection and treatment, privacy, anonymity, confidentiality, exploitation). This principle emphasises that the source of data must be protected by keeping informants nameless and this is exactly what happens in this study. Cameras and recorders were not used to collect data to further ensure confidentiality. The researcher always switched off cell phones during questionnaire administration to ensure confidentiality and avoid disturbances.
- **Respect for human being principle** (autonomy, informed consent, dignity, transparency, self determination). This principle requires that the researcher accord due respect to study respondents by granting them informed consent before the commencement of the study. The respondents were told that they have the right to terminate the session or request clarification of any aspect that they do not understand. The researcher also explained to the respondents their rights of voluntary participation and maintained high standard of informed consent in this study.

The researcher declared that he has no competing interests and will respect all the respondents' rights, including confidentiality of the responses.

### 3.3.3 Data analysis

Data analysis is the systematic organisation and synthesis of research data and the testing of hypothesis through that data. It is conducted to reduce, organise and give meaning to data (Burns & Grove 2005:733; Polit & Beck 2008:7510).

Data collected were analysed by a statistician using the Statistical Package for Social Studies (SPSS) version 20 in line with the objectives of the study.

## 3.4 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

Validity refers to the extent to which an instrument measures what it is supposed to measure. It is also the degree to which inferences made in a study are accurate and well-founded (Polit & Beck 2008:768). Burns & Grove (2005:42) define validity of an instrument as the extent to which the instrument actually reflects the abstract construct being examined.

In this study, the internal validity of the research design was confirmed by pre-testing the research instrument. The results of this study should be a true reflection of the respondents' knowledge and perceptions of the database system as the regulatory body's information management tool, and not attributable to extraneous factors. In addition, the researcher's supervisor reviewed the structured interview schedule to check for logical flow of the questions.

Brink et al (2006:119) says that external validity refers to the extent to which the findings of a study can be generalised to similar settings. According to Burns & Grove (2005:736), external validity is concerned with the extent to which study findings can be generalised beyond the sample that is used in a study. External validity may be influenced, for instance by the Hawthorne effect. The Hawthorne effect occurs when the respondents, because they are aware that they are involved in a study, behave in a

certain way or give responses they believe to be socially acceptable but which are not their true experiences (Brink et al 2006:101).

In order to minimise the Hawthorne effect and thus improve external validity in this study, the researcher explained the study to the respondents and assured them of confidentiality and protection of their identities as their names were not required on the instrument. The respondents were requested to give honest responses and were informed that their responses would not affect them in any way as they were given anonymously (Brink et al 2006:101).

In most of the questions in the questionnaire, the respondents were requested to explain their response.

## 3.5 CONCLUSION

This chapter covers the research design and methodology, including the population, sampling, data collection and analysis, ethical considerations, and internal and external validity of the study.

Chapter 4 discusses the analysis, presentation and description of research findings.

# CHAPTER FOUR – ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

## 4.1 INTRODUCTION

Chapter 3 discussed the research methodology. This chapter discusses the data analysis and the presentation and description of the research findings. The researcher used a non-experimental, quantitative, comparative and descriptive research design to systematically gather information from the literature and users of the Radiation Control and RAIS database systems.

The purpose of the study was to evaluate the effectiveness of the current database system used by the Radiation Control.

The objectives of the study were to:

- Compare the capabilities of the current database system used by Radiation Control with RAIS.

The checklist (refer to annexure D) was used for this purpose. The researcher answered the checklist with the assistance of the literature review and the expert views. The Radiation Control database's database administrator (DBA) answered the checklist questions on behalf of the Radiation Control database. The RAIS part of the checklist questions was answered by two regulators from Namibia and Ethiopia, who have the working experience with RAIS. The Ethiopian colleague is also a RAIS DBA at the Ethiopian Radiation Protection Authority. The respondents (Radiation Control employees) did not participate in answering the checklist as they do not have the experience of working with RAIS. A RAIS DBA from the IAEA was also consulted by the researcher to help answer the checklist part of RAIS.

Since this checklist was only completed once (see sections 3.3.2 & 3.3.2.1), no statistical analysis of the data are presented. The responses are tabulated below (see table 4.1).

**Table 4.1 Checklist Results**

| Criteria | Sub-criteria | RC Database | RAIS |
|---|---|---|---|
| 1. National regulatory infrastructure information | Regulatory infrastructure information: | | |
| | Legislation information | No | Yes |
| | Regulations information | No | Yes |
| | Codes of Practice & Guidelines | No | Yes |
| | Regulator's responsibilities & functions | No | Yes |
| | Authority, power & resources provisions | No | Yes |
| | Division of responsibilities information: | | |
| | Authority's liaison & working procedures | No | Yes |
| | MoU | No | Yes |
| | International co-operation information | No | Yes |
| 2. Facilities & departments | Licensee information | Yes | Yes |
| | Radiation users' information | Yes | Yes |
| | RP / A/RPO information | Yes | Yes |
| | User & Legal Person | No | Yes |
| 3. Radiation sources and associated equipment | Radiation sources details & information | Yes | Yes |
| | National inventory register | Yes | Yes |
| | ICSRS link | No | Yes |
| 4. Authorisation | Authorisation information | No | Yes |
| | Licensing information | No | Yes |
| | Exemption & exclusions | No | Yes |
| 5. Inspection | Role & implementation procedure | No | Yes |
| | Inspectors' powers | No | Yes |
| | Inspector-legal person relation information | No | Yes |
| | Inspection regulatory requirements information | No | Yes |
| 6. Enforcement | Graded enforcement action information | No | Yes |
| | Enforcement action implications information | No | Yes |
| | Enforcement action interaction | No | Yes |
| 7. Remote Access | Online submission of applications | No | Yes |
| | Inspectors' database remote access | No | Yes |
| | Licensees' database remote access | No | Yes |
| | Public access for information distribution | No | Yes |
| 8. Customisation | Customisable to regulator's specific needs | Yes | Yes |

| | | | |
|---|---|---|---|
| (mechanisms) | Multilingual | No | Yes |
| | Upward compatibility | Yes | Yes |
| 9. Radiation incidences | Emergency response plan | No | Yes |
| | Dose limits information | No | Yes |
| | Dosimetry service | No | Yes |
| | Relevant bodies' link | No | Yes |
| 10. Technical services | QA information | Yes | Yes |
| | Technical services link | No | Yes |
| | Inspection Bodies information | Yes | No |
| | Leak tests procedures | Yes | Yes |
| | Services & repairs information | No | Yes |
| 11. Workers | Workers qualifications & responsibilities | No | Yes |
| | Workers' rights & limitations | No | Yes |
| | Verification & validation | No | Yes |
| | Fundamental requirements information | No | Yes |
| 12. Data integrity | Data validation | Yes | Yes |
| | Consistency & validation check | Yes | Yes |
| 13. Database model | Relational model | Yes | Yes |
| 14. Security | Access control | Yes | Yes |
| | Individual & group privileges | Yes | Yes |
| 15. Automated optimization | Frequent usage improved speed | Yes | Yes |
| | Performance monitoring tools | Yes | Yes |
| **Total items marked "yes"** | | **17** | **51** |
| **Total (Percentage)** | | **33%** | **98%** |

The total number of "yes" responses between the two database systems was compared descriptively. Radiation Control database received 33% (17) "yes" responses while RAIS received 98% (51), indicating that the RAIS database supports more of the required functions than the Radiation Control database.

It is possible that the sub-criteria: "Inspection Bodies information" is available under "QA information" in RAIS.

- Evaluate implementation experiences of the South African database system against the structural and functional features of the system.

For this objective, questionnaire (refer to annexure F) data were used. Responses to individual questions were analysed by a statistician. The researcher also cross-validated the responses against the systems' functional structure and model.

## 4.2 DATA MANAGEMENT AND ANALYSIS

Data were collected in two phases using a criteria checklist and a questionnaire. Firstly, the researcher answered the criteria checklist which compares the two database systems using information obtained from the literature review and four expert views. Secondly, the questionnaire was administered to thirty-five (35) users of the Radiation Control database. Thirty-one (31) respondents returned completed questionnaires.

A statistician analysed the data using the IBM SPSS version 20.0 computer program. Descriptive analysis was used since both objectives were purely descriptive. The categorical data were analysed, interpreted, and presented using frequency tables, percentages, and bar or pie charts as appropriate.

The researcher also cross-validated the respondents' answers with the actual structure and function differences between the Radiation Control and RAIS databases.

## 4.3 RESEARCH RESULTS

### 4.3.1 Sample characteristics

The respondents of this study were employees and users of the Department of Health: Directorate Radiation Control's database system. All the respondents have at least matriculation as their basic educational level.

- **Administration officer:** The number of administration officers that participated in the study was 8. Of these, 2 officers have read-only access to view and request some information from the database. The other 6 users have the same but also are able to enter data into the database.

- **Inspector:** The database is central to the inspectors' course of doing their work. They use it, among other things, to mainly plan their inspections, perform follow-ups, respond to queries from licensees, and monitor the progress made in their work. The inspectors however are only allowed access to view data retrieved from the database. The inspector database users mainly consist of officers of radiography background. There is one inspector who is of a scientist background with a B. Sc degree in nuclear physics.

- **Scientist:** The scientist users of the database have full access to the input menu which allows them to view, modify, add, and delete all regulatory data but only for the isotopes sub-directorate. These users are mainly of a medical physicist background.

- **Manager:** The management users of the database are composed of a director, four deputy directors, and two assistant directors. They have full access to the input menu which allows them to view, modify, add, and delete all regulatory data. The director has full access to the database. Among this user group is a deputy director who joined Radiation Control in 2010, is of medical physicist background, an IAEA liaison officer, and an admirer of RAIS.

- **Information management officer:** This user has full access to the database including adding, modifying, deleting, and viewing all data, modifying regulatory system model, and modifying regulatory system data. The user works as a database administrator but is employed by the department as an administration officer.

#### 4.3.1.1 Respondents' Position at Radiation Control

All the respondents (100%; N = 31) answered this question item. See figure 4.1 below.

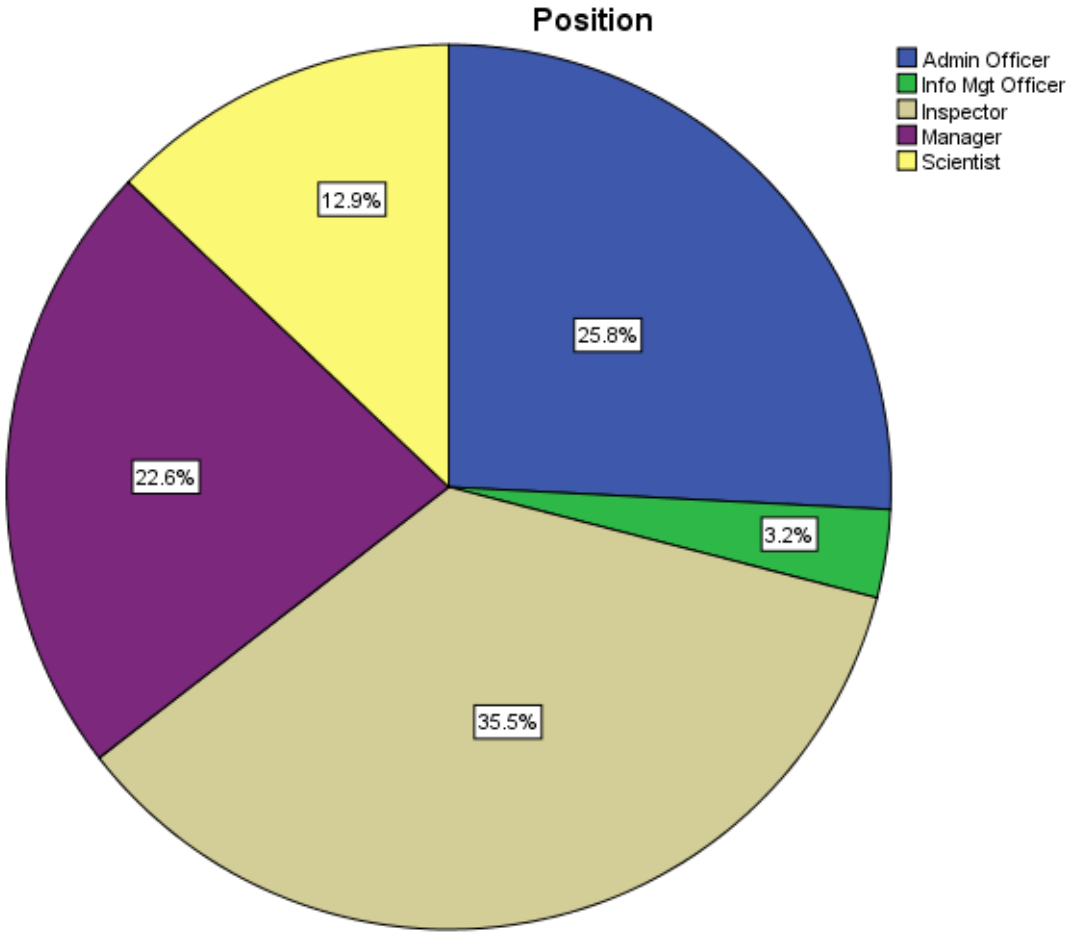



**Figure 4.1 Respondents' Position at Radiation Control**

The result showed that most of the database users at Radiation Control are inspectors, administration officers, or managers. See section 4.3.1 above regarding the details of the users' access/use of the database.

#### 4.3.1.2 Use of database per week

The respondents were asked to indicate the number of times each used the database in a week. See figure 4.2 below.

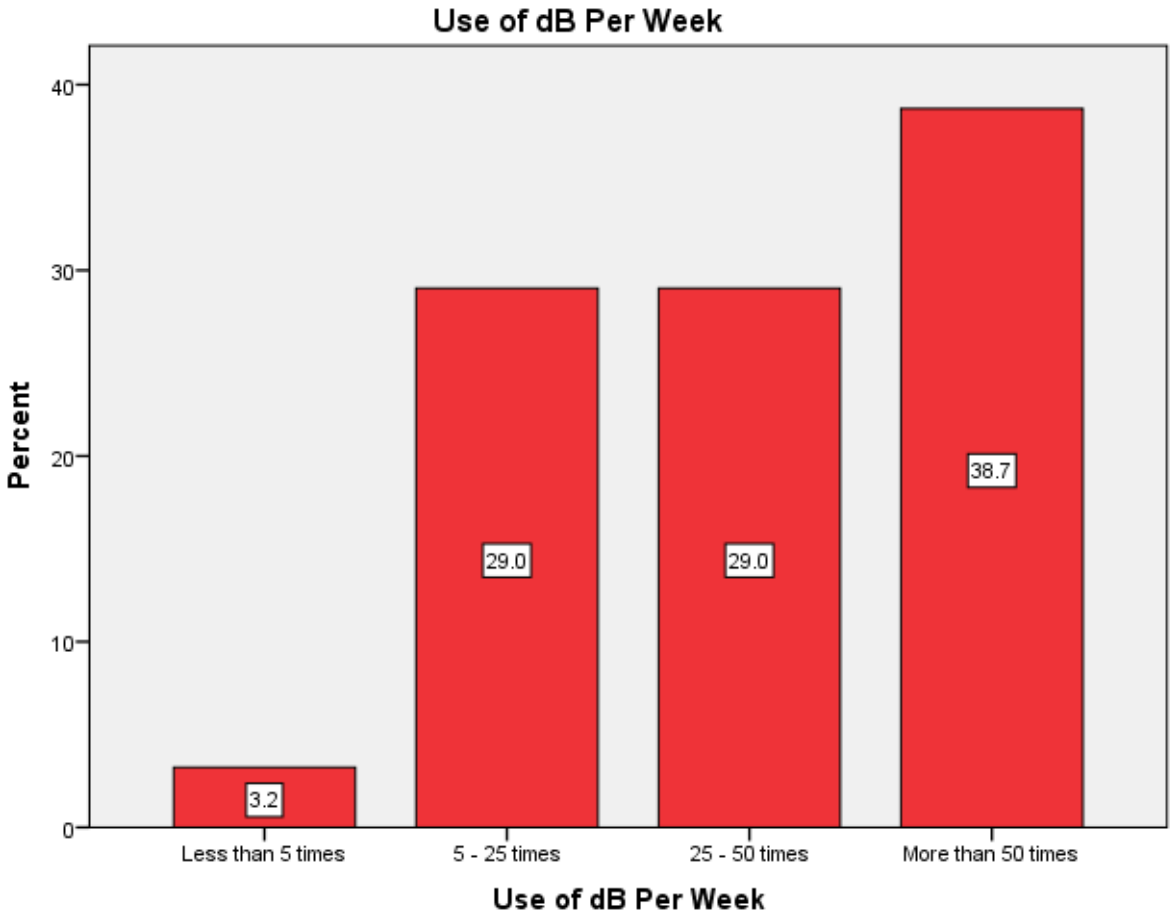



**Figure 4.2 Respondents' use of database per week**

The findings indicated that most of the respondents use the database more than 50 times in a week. The findings also revealed that the majority (68%) of the respondents use the database for 25 times or more per week.

#### 4.3.1.3 Remote Access Importance

For this item respondents were asked whether they thought it was important for the database to be remotely accessible. Of the respondents, 71% (n = 22) thought it was important while 29% (n = 9) did not think so.

The majority of the respondents expressed their wish for the database to be remotely accessible, especially for inspectors while they are out on duty performing inspections. If the database was remotely accessible, most respondents felt that inspectors would be able to obtain information updates and issue reports while on site. Others said it would help officers in regional offices to meet deadlines, issue reports in time and with online applications submission.

#### 4.3.1.4 Missing Data

The respondents were asked if they miss any data in the database that they would like to see added. There were 38.7% (n = 12) respondents that said they miss data in the database, and 61.3% (n = 19) said they did not miss any data.

Although the majority of respondents are satisfied with the data in the database, about 40% of the respondents believe that additional data would be helpful and were able to describe these data elements, mainly being descriptive data of licensees and radiation sources. Users' data needs also depend on their user profile and the type of information they require from the database.

This result shows that while most users may be able to get all the information they need from the database, there are those that require more but are unable to get it. It is to be expected that users such as inspectors, whose use of the database is more extensive and central to their work, may need more data which they're unable to get. It is this group of users too that collects more data to be entered into the database to either update, correct, or create new information.

#### 4.3.1.5 Inconsistent/ambiguous data

Respondents were asked if they ever encountered inconsistent / ambiguous data after sending queries to the database. Of the respondents, 71% (n = 22) said they did and 29% (n = 9) said that they did not encounter inconsistent data from the database.

The respondents explained their “yes” response by either citing human error as the cause for inconsistent data, or listing examples of such data like incorrect serial numbers and premises addresses. Others mentioned non-updated data and ‘inaccuracies due to collapse & poor management over many years’.

It is worth mentioning that these errors may be due to human error in entering and maintaining data, not as a result of the database structural problems.

#### 4.3.1.6 Features that could be added to the database

The respondents were asked whether there are features that they would like to see added to the database. There were 41.9% (n = 13) respondents that said there are features, and 58.1% (n = 18) that said there are no features they would like to see added to the database.

Most respondents that answered “yes” listed remote/online access, more alert features, and security details.

#### 4.3.1.7 Should the database be customisable?

The question was whether it is important for the database to be customisable to users’ specific needs? Of the respondents, 80.6% (n = 25) believed it is important, and 19.4% (n = 6) felt it is not important that the database be customisable.

A customisable database enables a regulatory body to match it with national needs which may include language, national legislative frameworks, administrative structures, and institutional and regulatory frameworks.

### 4.3.2 Database resources

The second section of the questionnaire focused on the database resources and its importance.

#### 4.3.2.1 Database human resources

The respondents were asked about the available human resources devoted to the database matters at Radiation Control. See table 4.2 below.

**Table 4.2 Human resources devoted to database matters**

| Database Human Resources | | |
|---|---|---|
| **Respondents responses** | **Count** | **Column N %** |
| Database Administrator | 28 | 90.3% |
| Information Resource Manager / Data Administrator | 2 | 6.5% |
| Other, Sen. Admin Officer, Assist. Dir. & Dep. Dir. currently used on database. | 1 | 3.2% |
| Total | 31 | 100.0% |

The respondents who answered with ‘Other’ to this question, explained that Radiation Control currently has an Administration Officer, Assistant Director and a Deputy Director working with the database. The three officials are not trained to administrate / work with the database.

It is important to note that the designated DBA is employed as an administration officer but has been working over the years as an ‘in-house information technology (IT) expert’, which includes working as the DBA. That means that there is no qualified database administrator or any other IT official manning the Radiation Control database.

#### 4.3.2.2 Importance of the database’s link with other relevant information Resources

This item sought the respondents’ opinion on the database’s linkage with other relevant authorities’ information resources, such as the IAEA, ICSRS, NNR, NECSA, etc. Of the respondents, 58.1% (n = 18) thought it is important, and 41.9% (n = 13) thought it is not important for the database to be linked to other authorities’ information resources.

The respondents listed different reasons and features that would be useful were the database to be linked to other relevant authorities’ information resources (see Table 4.3).

**Table 4.3 Reasons why respondents felt it was important for the database to be linked to other relevant information resources**

| Respondents' views | Count | Column N % |
|---|---|---|
| N/A | 18 | 58.1% |
| e.g. Customs - Imports/Exports | 1 | 3.2% |
| e.g. IAEA | 1 | 3.2% |
| e.g. NNR (NORM Material, Mining), Industrial Radiography, NECSA. | 1 | 3.2% |
| Esp. NNR for incidences reporting | 1 | 3.2% |
| For regulatory bodies' co-operation without relying on verbal communication. | 1 | 3.2% |
| guidance & rules on some source issues | 1 | 3.2% |
| Health & Safety | 1 | 3.2% |
| HPCSA, Med Aid Scheme, etc | 1 | 3.2% |
| Professional registration confirmation | 1 | 3.2% |
| Read only options should be available to an individual licensee/supplier | 1 | 3.2% |
| SARS, Customs, SAPS, SABS / Dosimetry | 1 | 3.2% |
| They should be able to check for licence/authority info when queries arise. | 1 | 3.2% |
| To combat fraud | 1 | 3.2% |
| Total | 31 | 100.0% |

It is important to note that it is managers, inspectors, and scientist user groups that usually attend seminars, workshops and training conferences which may involve interacting with other authorities' colleagues. The other 42% users that this result shows may be influenced by this fact and their user profile in their thinking.

#### 4.3.2.3 Consolidated data

The respondents were asked whether the database is able to give them consolidated data such as the national inventory of radiation sources. Those who answered with a 'No' were asked to explain their answer. Of the respondents, 54.8% (n = 17) said the database is not able, and 45.2% (n = 14) said it is able to give consolidated data.

The respondents, including those that answered ‘Yes’, mentioned that the data, e.g. the number of radiation sources in South Africa, issued by the database is inaccurate. As it is a fact that there is no reliable national sources inventory register in South Africa, the 45% respondents either did not understand the question or consider consolidated data to be something else other than, for example, the sources inventory. It may be that according to what those users need from the database whenever they use it, they do obtain all the data (consolidated data) from it.

The administration and manager user groups constitute about 48% and the inspector, scientist, and DBA user groups constitute about 52% of the respondents. The reason for almost even views of opinion on this question may lie in this information.

#### 4.3.2.4 Regulatory authority’s organisational structure

The question to the respondents was whether the organisational structure of the South African regulatory infrastructure is clearly outlined in the database. See figure 4.3 below.

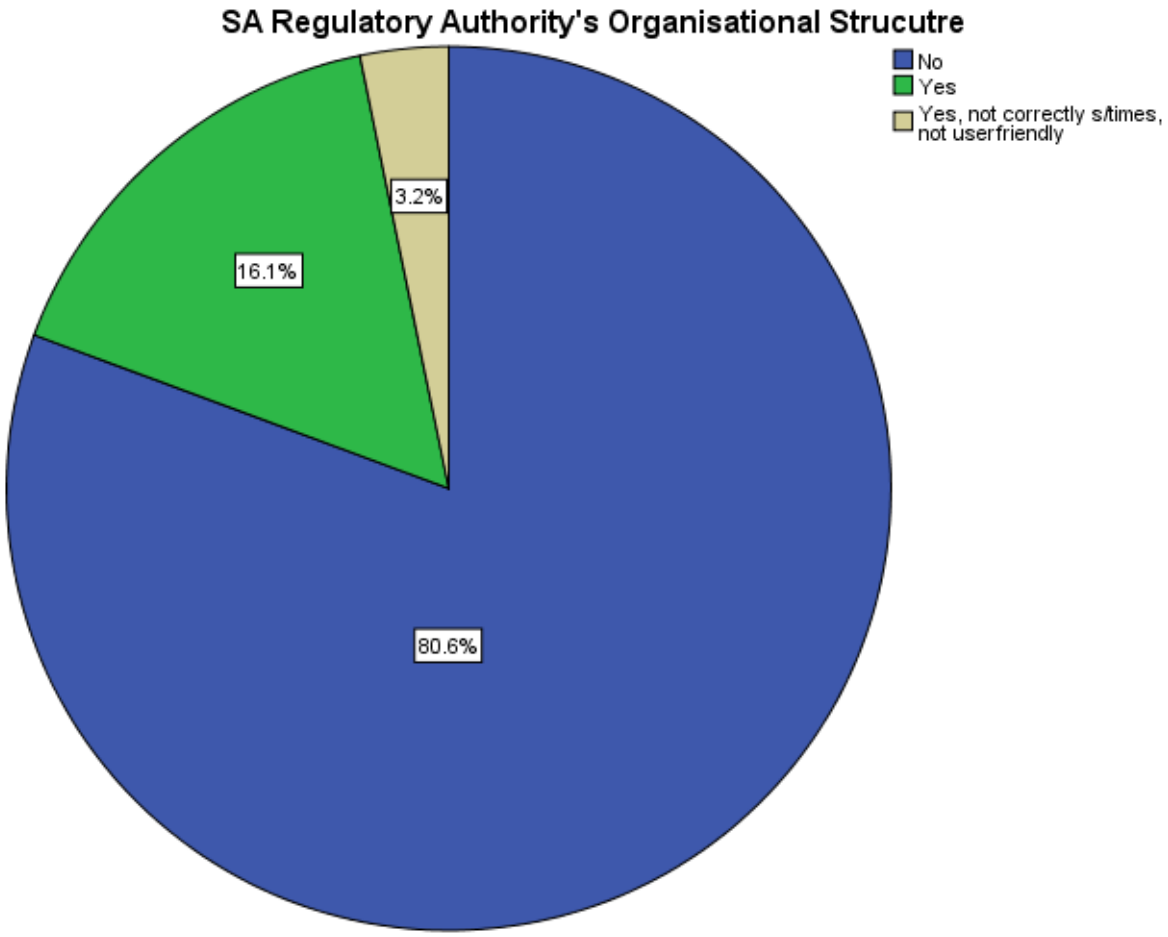



**Figure 4.3 The SA regulatory authority's organisational structure outline in the Database**

Most of the respondents who answered 'No' stated that the information is either not clearly defined or available on the organisational structure. Some felt that information on the organisational structure belongs to the website and not the database.

The result shows that the regulatory body's organisational structure needs to be improved whether on the database or the website. The regulator's website used to be lined to that of the National Department of Health but since about three years ago, this is no longer the case. As a result there is now a standalone website (https://sites.google.com/site/radiationcontroldoh/) which employees and the licensees

alike constantly complain that it's difficult to access. The main department's website (http://www.doh.gov.za/), revamped in 2011, also has some old Radiation Control documents and forms which are never updated.

#### 4.3.2.5 National and international bi- or multilateral agreements and MoU Information

The respondents were asked to indicate whether the database has information about memoranda of understanding and bilateral or multilateral agreements with other national or international bodies. Of the respondents, 80.6% (n = 25) said the database has no such information; 6.5% (n = 2) said it does; and 12.9% (n = 4) said that they 'don't know' whether or not the database has such information.

The respondents who answered "Yes" could have misunderstood the question or did not know what is meant by the memorandum of understanding or bilateral/multinational agreements.

For the record, the Radiation Control database and the website do not contain any details of the MoUs or agreements with other national or international bodies.

#### 4.3.2.6 Facilities and departments information to facilitate sources' tracking

The respondents were asked whether the database contains enough information about licensees to facilitate tracking of lost or stolen radiation sources. Of the respondents, 41.9% n = 13) agreed that it does; and 58.1% (n = 18) said that it does not have enough information.

Among the data the respondents mentioned as missing in the database for this purpose were premises addresses, contact details, and serial numbers. This information sometimes would be available but outdated or inaccurate.

The above-mentioned details depend on the data entered into the database and how often the database is updated to be accurate and complete. Therefore the database cannot be blamed for this as it is down to human error. It would help the situation if the database allowed controlled access to the licensees and inspectors, for instance, according to their user information needs. The annual reports issuing of the database also needs to be improved.

#### 4.3.2.7 Radiation Sources details to facilitate tracking

This item asked the respondents whether the database has enough radiation sources details to facilitate tracking of lost or missing sources. Of the respondents, 35.5% (n=11) believed that it does; while 65.4% (n = 20) said it does not contain enough information.

The information that is useful in tracking a radiation source include the source details such as the serial numbers (container and source), make/type, activity of the source, date of calibration, etc. It is important that this information be complete and accurate in the database. This result and the one above (4.3.2.7) show that the database's data consistency checking to reduce human errors needs to be improved.

#### 4.3.2.8 Authorisation, inspection, and enforcement processes details

The respondents were asked whether authorisation, inspection, and enforcement processes were clearly outlined and explained in the database. Of the respondents, 19.4% (n = 6) responded "Yes"; while 80.6% (n = 25) responded "No".

Some of the respondents felt that these are not supposed to be on or functions of the database. However some also felt that it would be helpful and informative if these were available and explained in the database provided the database was accessible to the licensees. The responses for 19% of the respondents that answered "Yes" may be explained to misunderstanding the question, as there is no information on these processes in the database.

#### 4.3.2.9 Online submissions and monitoring of applications

The respondents were asked whether the database allowed online submission and monitoring of authorisation applications. See figure 4.4 below.

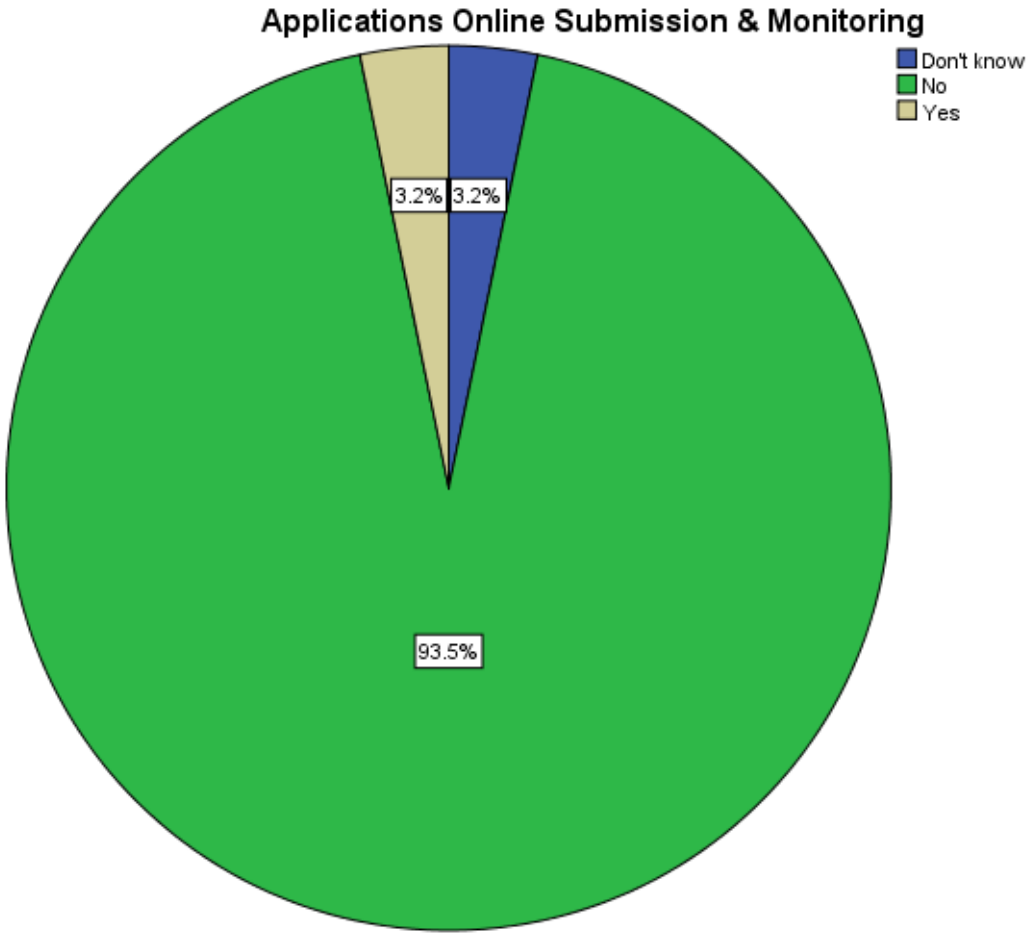



**Figure 4.4 Online submissions and monitoring of applications**

Online submission of applications and subsequent monitoring of its progress would help facilitate the smooth and prompt authorisation process. It would also provide for the basis of an accurate and complete data in the application forms and thus the database.

#### 4.3.2.10 Graded enforcement action process

The respondents were asked whether the process of graded enforcement action for non-compliance is explained in the database. See figure 4.5 below.

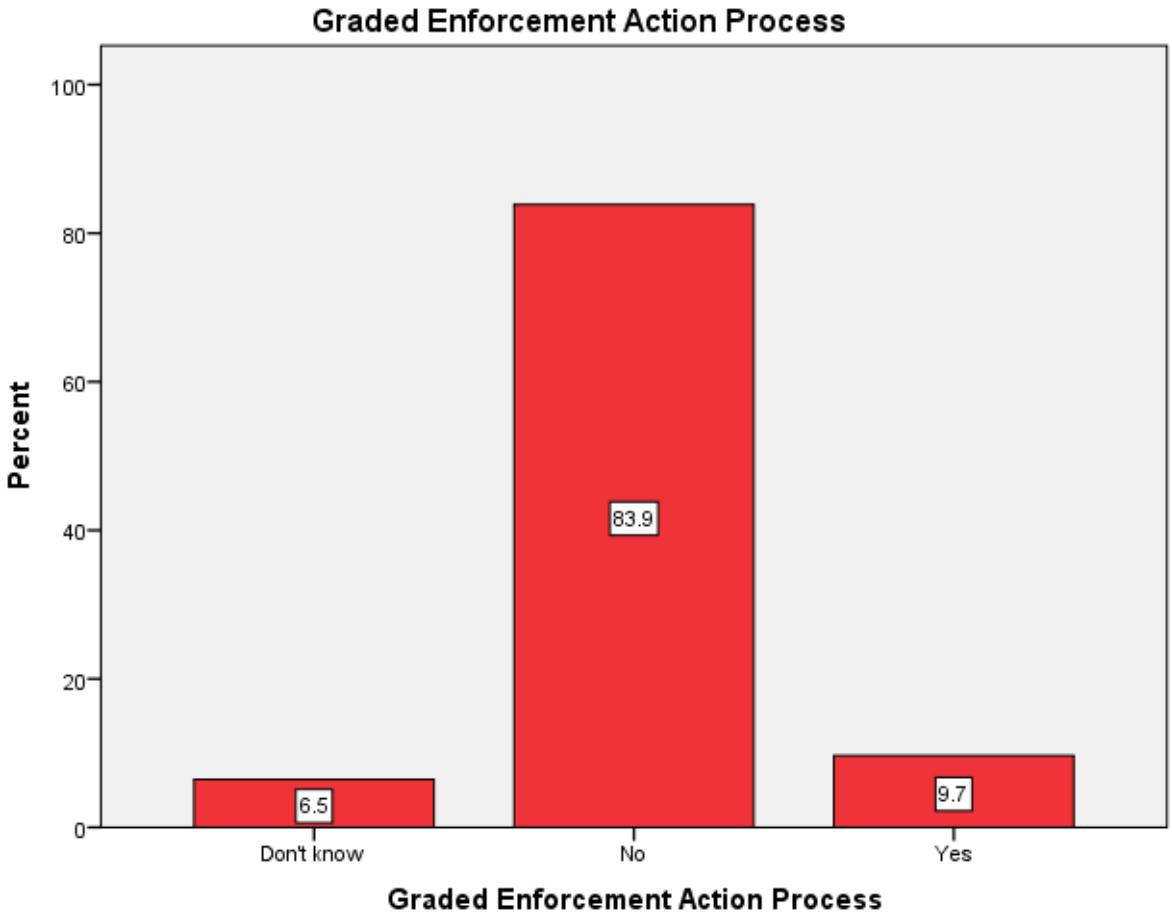



**Figure 4.5 Graded enforcement action process in the database**

Graded enforcement refers to corrective action or sanction according to the level of no-compliance. It is important that this process' information be clearly outlined and available to the licensees.

There are codes of practice documents available to the licensees on this process but they are found on the website.

### 4.3.3 Database Scope

This section discusses the findings and perceptions of the respondents with regard to the scope of the database.

#### 4.3.3.1 Regulatory processes and the database integration

The respondents were asked whether they thought the database was integrated within the regulatory processes such as the licensing, inspection and follow-up. Of the respondents, 41.9% (n = 13) thought that the database is integrated within the regulatory processes, while 58.1% (n = 18) thought it was not integrated.

The database which is integrated within the regulatory process, ideally, would be a comprehensive system which covers all the main areas of the regulatory framework (authorisation, inspection, enforcement, and so on); be remotely accessible; and provides a means for information dissemination. The current Radiation Control database does not offer any these services. This result however shows that about 42% of the respondents think that it is integrated. This may be down to their interpretation of the situation or what their work requires of the database.

#### 4.3.3.2 Importance of data consistency checking

The respondents were asked about their views on the importance of the database providing data consistency checking to reduce human errors. See figure 4.6 below.

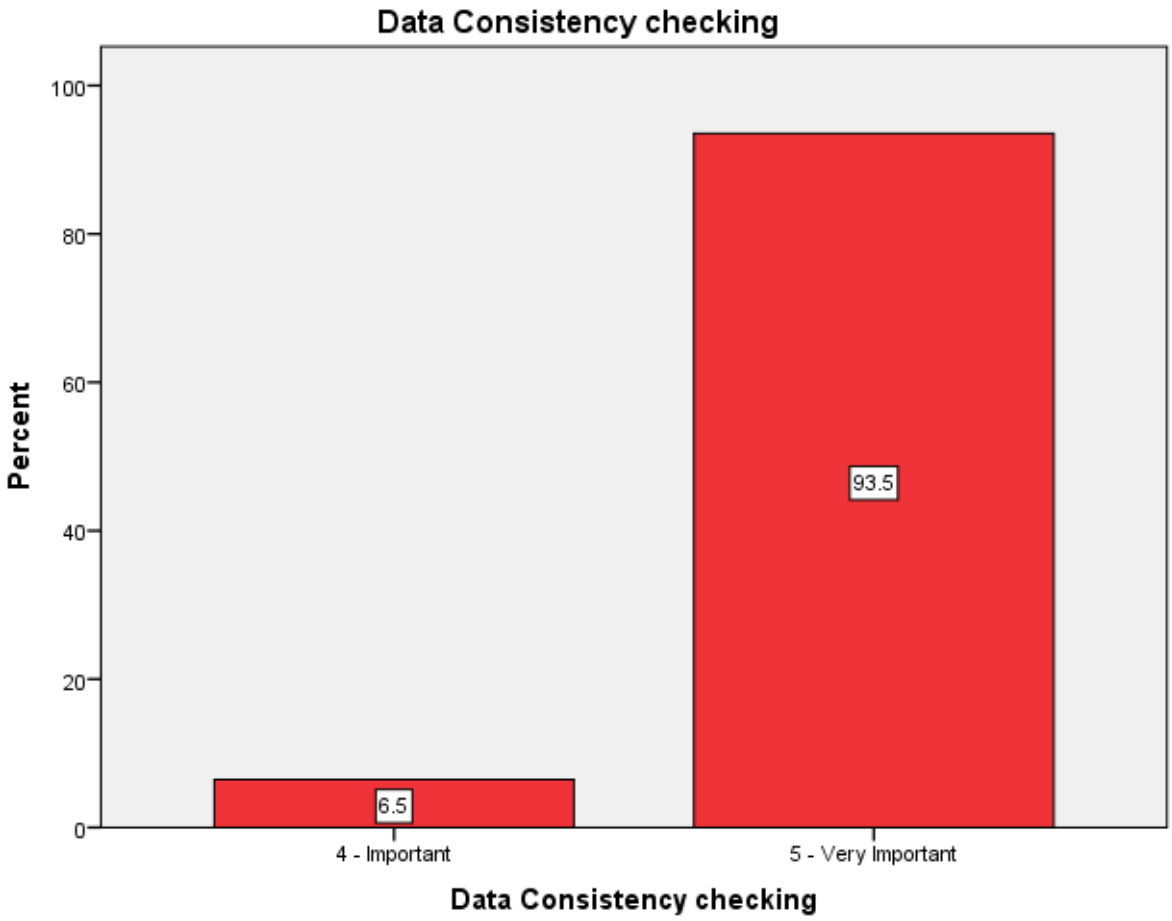



**Figure 4.6 Importance of data consistency checking**

Although the database has the data consistency checks feature, it is not clear whether it is efficiently set up to be used. Data consistency ensures, for instance, that each user observes a consistent data view that is validated, accurate and usable. This includes visible changes made by the user's own transactions (Oracle 2005; Rob & Coronel 2007:222 – 229).

#### 4.3.3.3 Protection of vital data

The respondents were asked about the importance of the database's ability to protect vital data against unintentional modification or deletion. See figure 4.7 below.

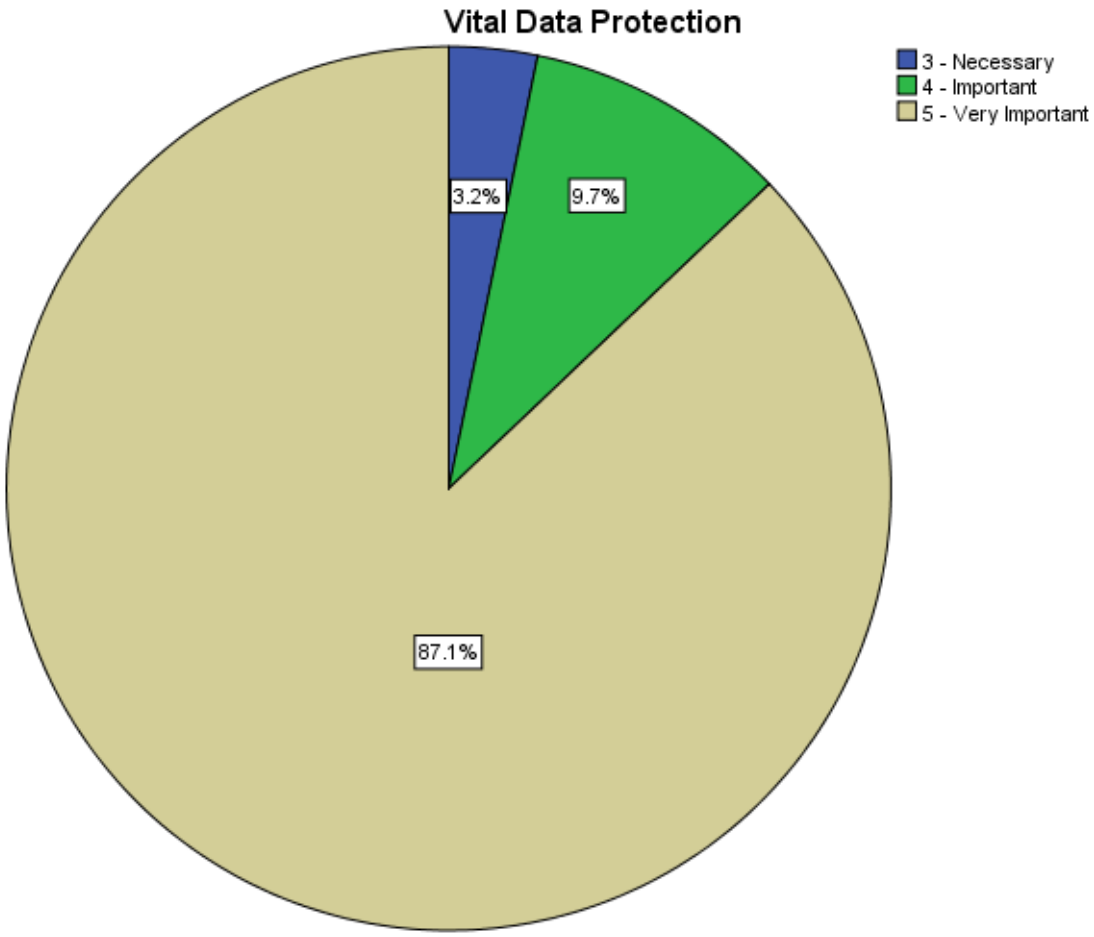



**Figure 4.7 Protection of vital data**

This is one of the very important specifications of a database and the respondents' response to this question (and other questions in section 4.3.3) is indicative of their understanding of the database's functional requirements.

#### 4.3.3.4 Database access control

The respondents were asked how important it is for the database to have access control to protect data against unauthorised access and to ensure confidentiality. Of the respondents, 90.3% (n = 28) thought that access control is very important; 3.2% (n = 1) thought that it is important; and 6.5% (n = 2) thought that it is necessary.

#### 4.3.3.5 Database as means for information dissemination

The respondents were asked if they thought it is important for the database to be available for use as means for information dissemination to the public, customised according to the regulatory body's policy. See figure 4.8 below.

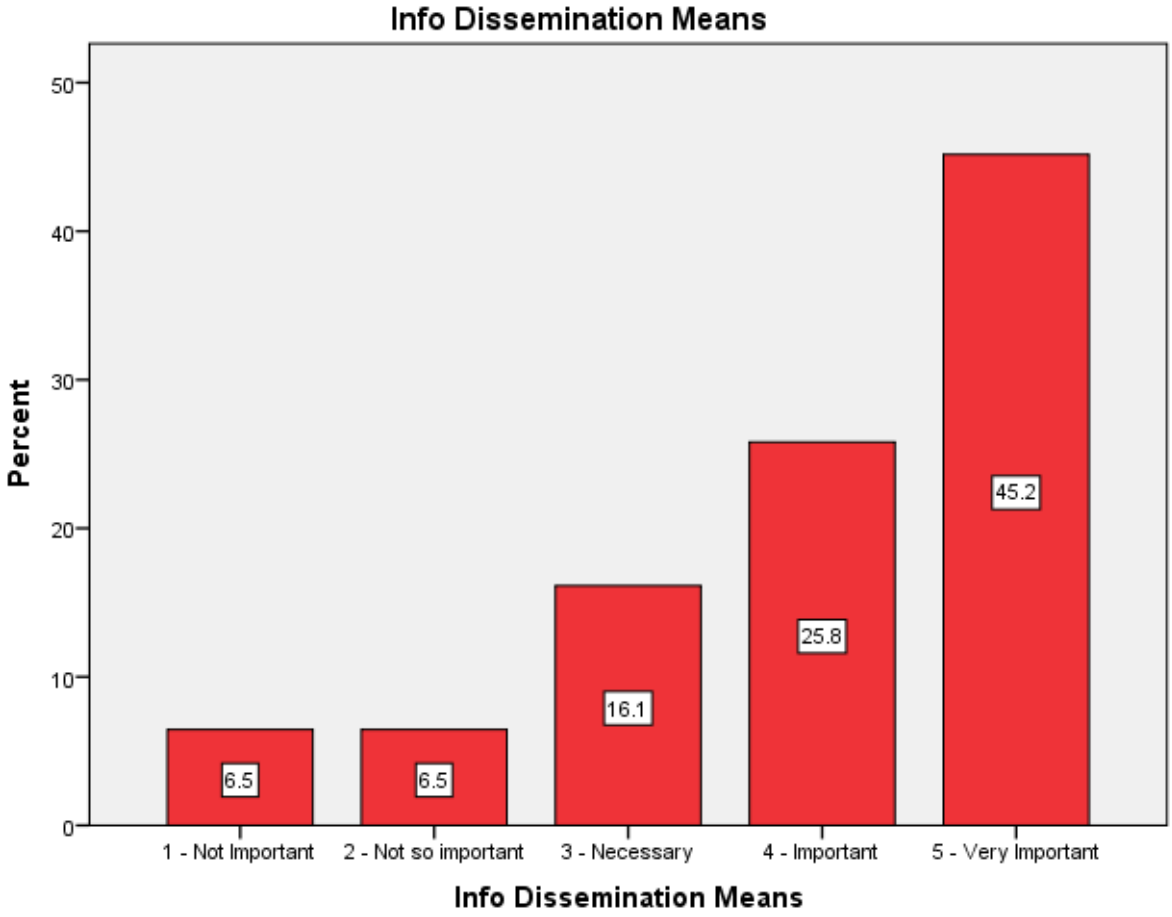



**Figure 4.8 Database as means for information dissemination**

#### 4.3.3.6 Interface for catalogues on sources and equipment manufacturers and models

The respondents were asked for their views on how important it is for the database to provide for an interface for catalogues on manufacturers and models of sealed sources, radiation generators and associated equipment. See figure 4.9 below.

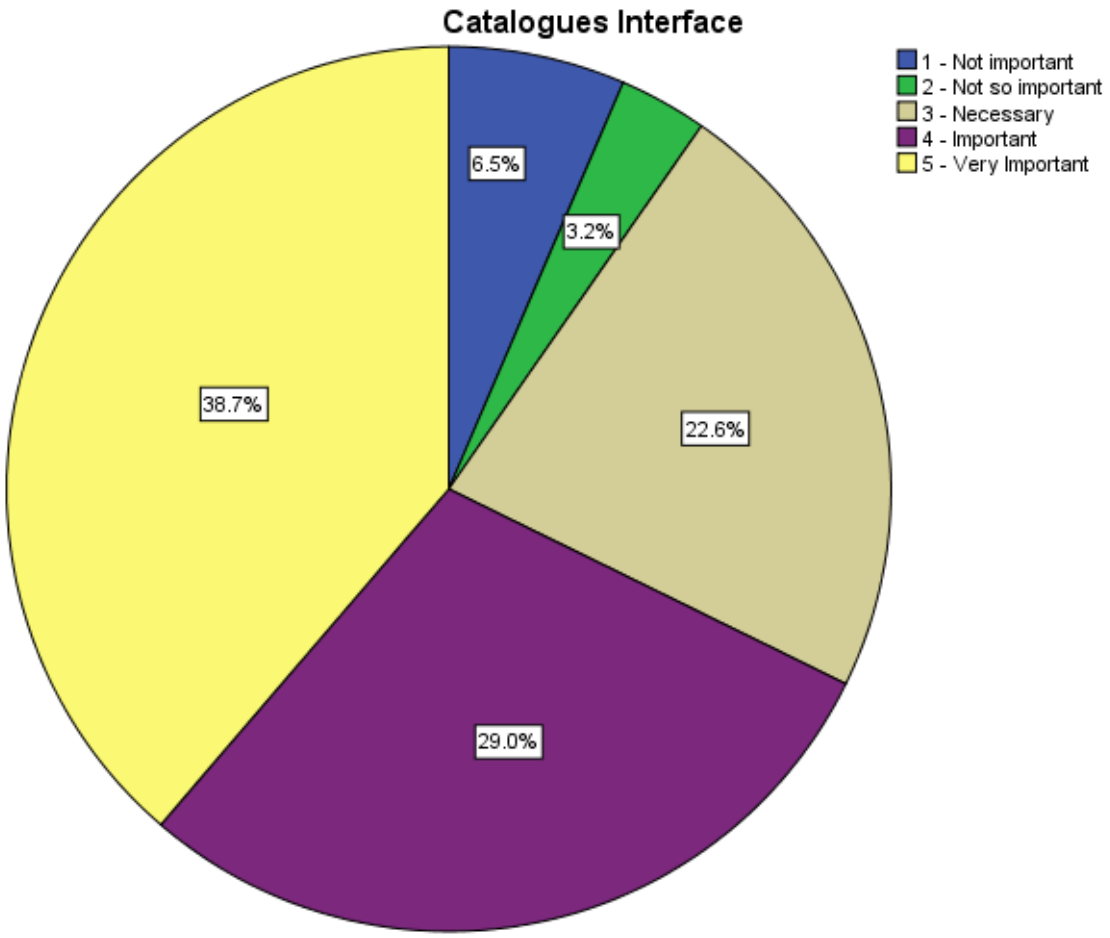



**Figure 4.9 Interface for catalogues on sources and equipment manufacturers and models**

This result might be reflective of the different views held by respondents from different sub-directorates according to their use of the database. The NIRMED and Ionising Radiation sub-directorates use catalogues a lot, especially in med-sales and

imports/exports sections. On the other hand, the Licensing & Inspections and Isotopes sub-directorates do not use this part as often.

#### 4.3.3.7 Online submission of data by facilities

The respondents were asked if they thought online submission of data by the facilities (applicant licensees), subject to validation by the regulatory body, was important. See figure 4.10 below.

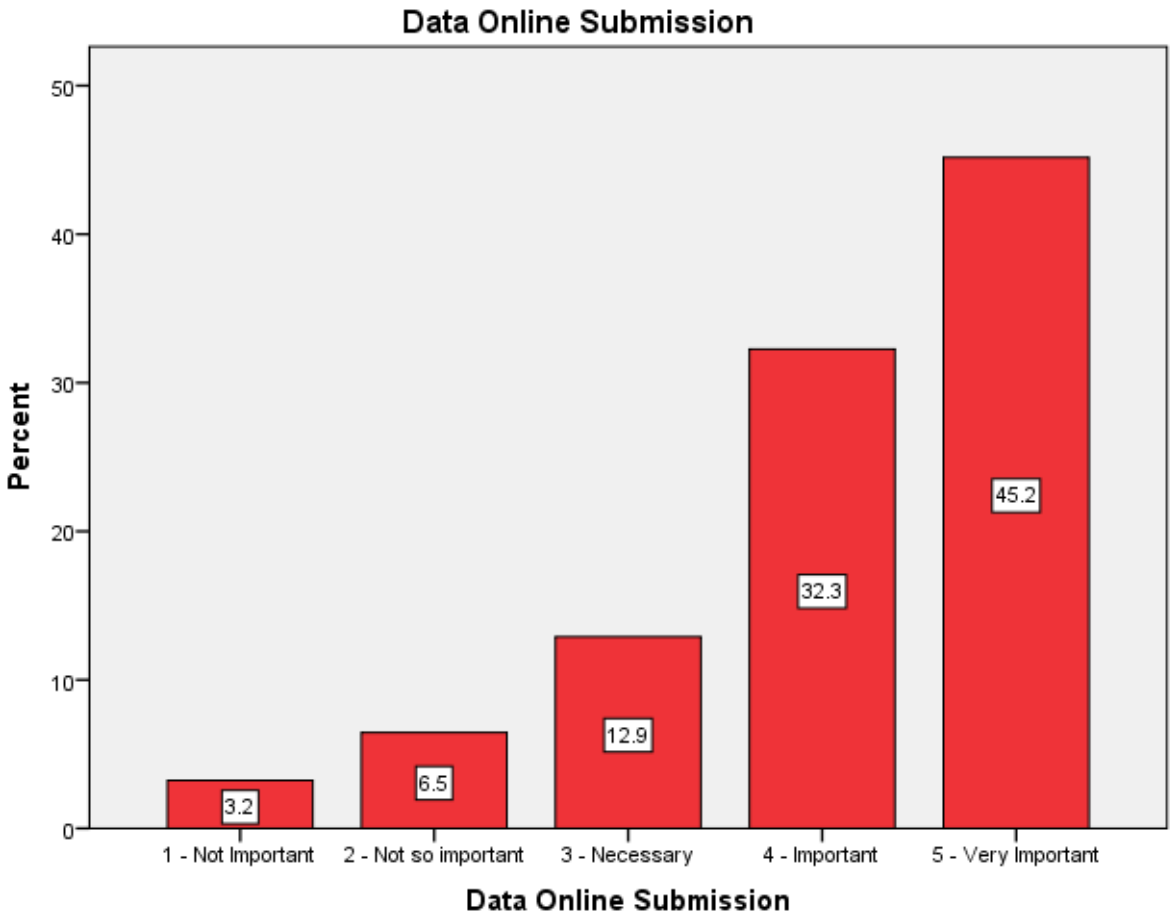



**Figure 4.10 Online submissions of data by facilities**

The Radiation Control database does not have the feature to allow any online submissions. The database is not remotely accessible to either the workers of the regulatory body or the public.

### 4.3.4 General database information

#### 4.3.4.1 Uncaptured relevant information

The question to the respondents was whether there is any relevant information that is not captured by the database. See table 4.4 below.

**Table 4.4 Database uncaptured relevant data**

| Uncaptured Relevant Info | | |
|---|---|---|
| **Respondents' answers** | **Count** | **Column N %** |
| No | 16 | 51.6% |
| Yes | 6 | 19.4% |
| Yes, certain info from application form | 1 | 3.2% |
| Yes, creation of new holder | 1 | 3.2% |
| Yes, inspector's test info & results | 1 | 3.2% |
| Yes, not related to database. | 1 | 3.2% |
| Yes, previous non-compliance; previous holders | 1 | 3.2% |
| Yes, QA results; outstanding inspection requirements | 1 | 3.2% |
| Yes, refer to previous questions | 1 | 3.2% |
| Yes, reports, follow-up findings, court cases, etc | 1 | 3.2% |
| Yes, some info not captured for a long time | 1 | 3.2% |
| Total | 31 | 100.0% |

The respondents were supposed to explain their answer if it was a 'yes', that there is uncaptured relevant data in the database. However some, 19.4% (n = 6), of them did not explain but just answered with a 'yes' response. Some respondents, 29% (n = 9), gave some form of explanation or examples of the relevant data they were missing in the database, as seen in the above table 4.3. All the examples of uncaptured data as provided by the respondents are listed on the above table.

#### 4.3.4.2 Limited database access for inspectors

What this question sought to find from the respondents was whether they thought inspectors should be allowed limited access to make changes or updates to the database. Of the respondents, 51.6% (n = 16) thought that inspectors should be allowed limited access to the database to make changes; and 45.2% (n = 14) thought that they should not be allowed limited editing access.

Although the question did not require any explanation of the respondents, one who answered with a ‘yes’ said that this should be subject to approval.

The inspectors currently do not have any rights to enter or update any data in the database. They have to submit handwritten information/data to the person(s) who then enter it to the database.

#### 4.3.4.3 Specific database access for licensees

The respondents were asked whether they thought the licensees or their official representatives should be allowed access to their facilities or departments’ information. Of the respondents, 54.8% (n = 17) thought that this should be allowed; and 38.7% (n = 12) thought that it should not be allowed.

Of the respondents that answered that specific access should be allowed to licensees, two more said that it must be limited and read-only access, respectively.

Currently there is no role-based update access to the database at Radiation Control. The DBA, the director, the deputy directors, the scientists, and six administration officers currently have some sort of controlled access to the database (see section 4.3.1 above).

#### 4.3.4.4 Division of Radiation Control database

Of the respondents, 77.4% (n = 24) indicated that they have no problem with the division of the database into x-rays and isotopes databases; and 22.6% (n = 7) indicated that they have a problem with this.

One of the respondents who answered ‘yes’ to the division of the database, commented that since there are different regulations and conditions for x-rays and isotopes, there should also be different databases.

The x-rays and isotopes databases are not linked to each other. There are licensees, for instance, who have both x-rays and isotopes radiation sources. With the two separate databases that do not even ‘talk’ to each other, it sometimes interferes with their regulatory control and the regulatory processes such as authorisation, inspection and enforcement.

There are also other small databases at head office (other than the x-rays and isotopes) such as the Industrial Radiography Med-Sales databases. While these database systems are mainly used at head office, there are occasions when other officers at regional offices need to access it for their work purposes.

This result therefore shows that while it might be necessary to split the database, there should be one overall main database for the regulatory body which allows controlled access to the officials according to their work needs.

#### 4.3.4.5 Other information resources database access

The respondents were asked if there are other national or international radiation information resources accessible through the database. Of the respondents, 6.5% (n = 2) said that there are other database accessible information resources; 77.4% (n = 24) said that there none; 16.1% (n = 5) said that they don’t know.

One of the respondents who said that there are no information resources accessible through the database added that there should be such resources.

There are currently no other radiation information resources accessible through the database. The internet is the only tool officers can use to access these resources.

#### 4.3.4.6 Access to other needed information resources

This item asked the respondents to indicate if they have access to other information resources they may need at their work. Of the respondents, 58.1% (n = 18) agreed that they do have access to other information resources they need; and 41.9% (n = 13) said that they do not have access.

In the course of doing their work, Radiation Control workers may need information which is not available on the database or the website. This relevant information includes Customs, radiation waste management services, International Nuclear & Radiological Event Scale (INES), environmental health services, and so on. It is important that they be able to access this information. They can currently only access this information through the internet.

#### 4.3.4.7 Source categorisation information

The respondents were asked whether the database has enough information about the categorisation and their associated risk. Of the respondents, 19.4% (n = 4) said that the database has enough information on source categorisation; 64.5% (n = 20) said that it does not; and 16.1% (n = 5) said that they do not know if it has such information. There is no information on radiation sources categorisation on the database.

#### 4.3.4.8 Database essential technical services information

The item required the respondents to indicate which of the listed essential technical services, if there were any, their information was available on the database. See figure 4.11.

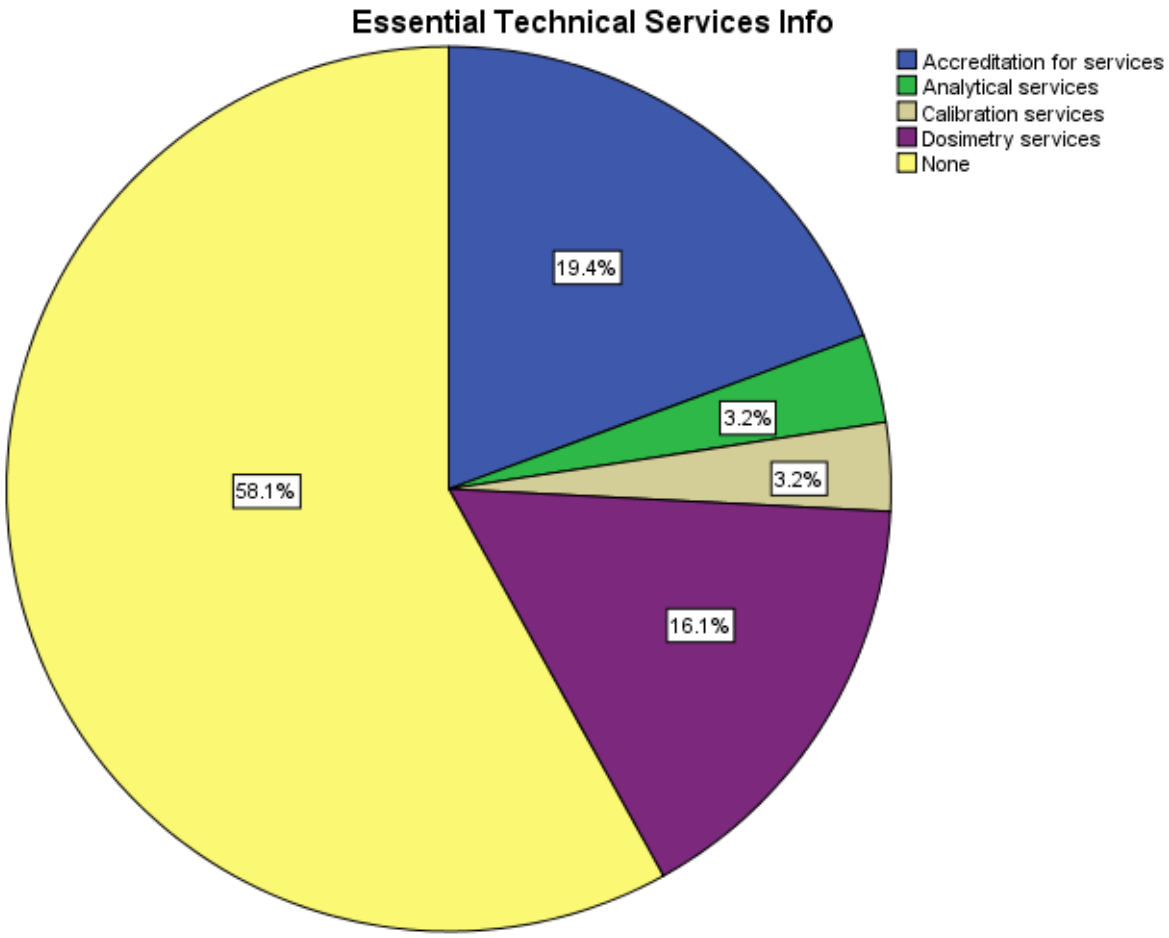



**Figure 4.11 Database essential technical services information**

The result shows that most respondents said that there is no information on the database about the essential technical services. However there are those that said that they can find information for some of the services. This may be as a result of the respondents confusing the licensees such as SABS, NECSA, Process Automation, and others. While these institutions do offer the essential technical services listed in the

question, they are on the database purely as licensees. One has to know that SABS, for example, offers dosimetry services but there is nothing on the database to this effect.

The current state of the data management at Radiation Control leads to a situation of uncertainty and missing information in the regulatory control programme. There is no consistent and common approach towards, for instance, the ways in which the databases' systems are updated with data. This leads to data inconsistency and poor data integration in both systems.

When information regarding facilities or licensees is received either by inspectors in the field or telephonically, it is handed over in writing to the databases administration personnel. However discrepancies between the information in the databases and that applicable to the licensees/facilities details arise regularly. There are always inaccuracies and anomalies with regards to data such as serial numbers or contact details, in the database.

The databases are web based but they do not allow remote access to the regulatory authority staff, such as inspectors in the field. The databases also do not provide for electronic submission of information such as applications or annual returns from licensees.

## 4.4 OVERVIEW OF RESEARCH FINDINGS

The research findings have shown how the two database systems (Radiation Control database and RAIS) compare with each other. It has also highlighted the strengths and the shortcomings of the Radiation Control database.

The comparative functionality checklist and results of four experienced experts revealed that RAIS supports more functions than the Radiation control database in terms of the main areas of the radiation regulatory framework. The Radiation Control database

scored 33% (17) “Yes” responses to RAIS’ 98% (51) “Yes” responses to questions of the supported functionality in the checklist. These results showed that RAIS is likely to be a more suitable database system for a radiation regulatory authority (see section 4.1 & Table 4.1).

It was however noted the sub-criteria: “Inspection Body information” might be covered under “QA information” in RAIS.

In the second phase of the study results analysis, the strengths and shortcomings of the Radiation Control database were highlighted. The functional requirements and models of both database systems including the ideal Radiation Control database system (see sections 2.2 to 2.4.7) were used to cross-validate the respondents’ answers. It was also noted that the Radiation Control database has some data type problems, such as having primary keys as VARCHARs, which can be a major contributor to data error.

In figure 2.1 (page 28 above), for instance, ‘Holder.Condits’ is of type VARCHAR250) and is related to ‘Condits.Condition’ which is of type VARCHAR2(2). This appears to be a type definition error with a potential to create database consistency checking error. In figure 2.2 (page 29 above), for an example, ‘Holder.AUDIT_INSP’ is shown to be related to ‘Condits.Conno’ and ‘Holder.Condit’ to ‘Inspectors.Insp_Code’. This may explain the corruption of data in the database.

The results showed that the users would prefer that the database offer remote accessibility. The results also revealed that most of the data or information available in the database is sufficient for most of the users to perform their duties. However the users also complained about the inaccuracies and lack of regular updates of the database. This could be as a result of the lack of qualified personnel devoted to supporting and maintaining the database as well as problems with data input.

The study results also showed that there are many improvements that could be done to the Radiation Control database and its contents. The database is not able to produce

reliable and consolidated information such as the national register of radiation sources. The improvements also include customisation to match national needs, consistency data checking, and issuing of reports. The database already has these capabilities but is not optimally used. The respondents thought that it would be beneficial if the database was able to link up with other authorities' information resources such as the NNR, NECSA, IAEA, or ICSRS.

The results indicated that some database users do not have confidence in the quality and type of information in the database such as the details of the radiation sources and facilities and departments. The results also showed that this depends on the user profile, accessibility status, and the level of knowledge each user possess. Since radiation control is the primary function of the Directorate Radiation Control, it is a concern that the database seem not to have enough good information to aid tracking of radiation sources. The processes of authorisation/licensing, inspection and enforcement are also not available, clearly outlined and explained in the database.

The respondents view the database as not integrated within the regulatory process which is very critical as this should be the main function of the database. The radiation regulatory authority's database ideally should comprehensively cover all the main areas of the regulatory framework (authorisation, inspection, enforcement, and so on.

The administration and manager user groups constitute about 48% and the inspector, scientist, and DBA user groups constitute about 52% of the respondents. This could have led to the almost even split between those respondents who said they can get consolidated data and those who answered that the database does not give them consolidated information. The organisational structure of the Radiation Control is not clearly outlined in the database, according to the results. Some respondents thought that while this is important, it should be in the website as opposed to the database.

The results also showed that the respondents support the splitting of the database. However the one main database for the regulatory body which has controlled access is

necessary for all the officials to do their work. The study results showed that there is no essential technical services information on the database. However some respondents mistook the licensee details such as those of SABS and NECSA on the database as meaning that the database has information on these and others as technical services.

## 4.5 CONCLUSION

This chapter has discussed the data analysis, presentation and interpretation of the research findings. The results were presented in tables, graphs, and figures.

Chapter 5 concludes the study, briefly discusses its limitations, and makes recommendations for practice and further research.

# CHAPTER FIVE – CONCLUSIONS AND RECOMMENDATIONS

## 5.1 INTRODUCTION

In this chapter, the following aspects are discussed: research design and method; summary and interpretation of the research findings; and conclusions. The recommendations; contributions and limitations of the study; and concluding remarks are also presented and discussed.

## 5.2 RESEARCH DESIGN AND METHOD

A quantitative research design was used in this study since it is appropriate to explore the database system and examine its effectiveness as a data management tool of the radiation regulatory body. A criteria checklist and questionnaires were used to collect data in order to analyse and compare the database systems with the view of highlighting the strengths or shortcomings of the Radiation Control database.

The study population consisted of all the employees of Radiation Control who use the database in their course of work. The researcher administered the questionnaire and was available to clear up any queries. This helped with the response rate as the sample size (31) was small. The respondents however answered the questionnaire on their own.

Data were collected using the checklist and the questionnaire. The researcher answered the checklist using the literature review and the expert views of three colleagues with working experience of RAIS and the Radiation Control database. The database administrator at Radiation Control answered for the Radiation Control database. On the RAIS side, a colleague from Namibia and Ethiopia, both RAIS with working experience, answered the checklist. The researcher also approached the RAIS DBA at the IAEA to assist in this regard. This was done to minimise bias. The

questionnaires were administered to complete the second phase of data collection (see chapter 3). The researcher developed the functional requirements and model of the database systems to be used to cross-validate the respondents' answers from the questionnaire.

A pre-test of the questionnaire was done at NNR with the users of the database who work there. This was done to ensure the validity and reliability of the instrument (questionnaire). It was as a result of this exercise that a "None" option was added to question 4.8 of the questionnaire (see annexure F).

The researcher adhered to a strict ethical code of conduct by obtaining a written permission from the Radiation Control Director to conduct the study there. The researcher also sought each respondent's consent through a written signed informed consent letter which accompanied each questionnaire (see annexure C and annexure E).

Confidentiality was maintained in the study from the construction of the questionnaire to the data collection process itself. The respondents were not required to write their names in the questionnaire and no recording was done during the questionnaire completion process. The researcher always respected the respondents' privacy and rights.

## 5.3 SUMMARY AND INTERPRETATION OF THE RESEARCH FINDINGS

The study results have shown that RAIS is likely to be more effective than the Radiation Control database as a radiation regulatory authority's data management tool. RAIS performed better than the Radiation Control database when the two systems were compared about the main areas of the regulatory framework (refer to table 4.1). RAIS promotes a consistent and common approach to the regulatory control of radiation sources; is flexible to respond to specific national needs; and pays due account to

legislative framework, administrative structure, and institutional and regulatory framework (RAIS 2012).

The study findings also highlighted the users' needs for a database with high quality accurate and reliable consolidated information that can be accessed from multiple points without compromising security and confidentiality. The results showed that the database is unable to produce consolidated data such as the national inventory of radiation sources. A well designed database facilitates data management and generates accurate and valuable information (Rob & Coronel 2007:9).

The respondents indicated in the study results that the South African radiation regulatory authority structure is not clearly outlined in the database. The database also lacks information capability to aid tracking of lost or missing radiation sources due to its poor information and details of licensees and sources. The results also showed that, while human error might plays a role, there are some structural problems with the Radiation Control database. A poorly designed database is likely to become a breeding ground for difficult-to-trace errors that may lead to bad decision making. Bad decision making can lead to the downfall of an organisation (Rob & Coronel 2007:9).

The Radiation Control database appears not to be integrated within the regulatory processes of licensing, inspection and enforcement, according to the study results. It is also not remotely accessible by the regulatory body officials or the licensees. Therefore it cannot be used as a means for information dissemination to the public. RAIS provides a means for information dissemination to the public which (the public area) the regulatory body can customise to its policy (RAIS 2012). This also means that the database cannot be accessed by inspectors on the field when they need it. A good database is the one that meets all user requirements (Rob & Coronel 2007: 131).

The study results indicate that the users would like a dynamic database that is remotely accessible, customisable and has upward compatibility features. The results of this study showed that the Radiation Control database does not allow remote accessibility

and does not have enough information about essential technical services. RAIS provides, through it customisation feature, for expanding of its scope to cover other areas (beside the regulatory framework main areas), if of interest to the regulatory authority (RAIS 2012).

The study findings distinguish between issues related to inherent database structural / functional problems and those that could be related to data quality. The findings also revealed that with better staff training and complement; and database maintenance, the Radiation Control database would be effective for the regulatory authority's information management needs.

### 5.3.1 Objective 1: To compare the capabilities of the current database system used by Radiation Control with RAIS.

The findings of this study revealed that RAIS performs better than the Radiation Control database in the main areas of the regulatory framework. The Radiation Control database received 17 yes responses (33%) while RAIS received 51 yes responses (98%) during the first phase of data collection. Based on these findings, the researcher concludes that RAIS is more suitable as a radiation regulatory authority database system than the Radiation Control database. Therefore the first objective of this study has been achieved (refer to section 4.1 and Table 4.1).

- ### 5.3.2 Objective 2: To evaluate implementation experiences of the South African database system against the structural and functional features of the system.

The study respondents revealed that they would like a relational database that is remotely accessible, gives them high quality of reliable and accurate consolidated information, and customisable. The study results revealed that the database currently used at Radiation Control is not remotely accessible and while it has most of the data

needed by the users, the quality and reliability of such data are in question to the respondents (see sections 4.3.1.3 to 4.3.1.7).

The findings also revealed that the database is unable to give users comprehensive consolidated information such as the national register of radiation sources. The database also does not have the capabilities to be multilingual. The scope of the database is not comprehensive enough to cover all the main areas of the regulatory framework. The database is not compatible with relevant international standards such as the IAEA Safety Standards. These findings indicate a database that is poorly resourced with features that makes it unable to give the users what they require.

The study results also highlighted that the database is not integrated within the regulatory process of the Radiation Control in South Africa. This however might be as a result of the way the database is being utilised. It was also revealed that the database is not linked to important relevant information resources such as the ICSRS. The results also showed that access control and data consistency check mechanisms of the database need to be improved.

The study results also showed that if the Radiation Control database was properly used by the adequately trained staff and maintained by enough and qualified personnel, most of the problems experienced with it would be eliminated.

**The study conclusions are that:**

- Based on the findings of this study, the researcher concludes that the Radiation Control database is not utilised effectively as a radiation regulatory body database system.
- The Radiation Control database needs to be restructured if its use is to be continued.
- Based on the findings, that the Radiation Control database is poorly managed and does not have enough and properly qualified personnel to maintain and use it.

- It is also concluded that with better staff training and enough qualified personnel dedicated to database matters, the Radiation Control database would be effective as a data management tool.
- Based on the findings of this study, the researcher concludes that RAIS would be more suitable than the Radiation Control database in the radiation control regulatory framework or programme.

"The IAEA supports states in the implementation of RAIS through regional and national workshops, and by providing the necessary equipment and expertise for installation and customization of the system" (Regulatory Authority Information ... 2011).

Based on the findings, the researcher has achieved all the objectives of the study.

## 5.4 CONCLUSIONS

The findings revealed that RAIS might be more suitable and effective as Radiation Control's database than the currently used one. When the two database systems were compared to each other, RAIS compared better than the Radiation Control database. Improvements to the database have been recommended by the respondents through highlighting its strengths and shortcomings as they completed the questionnaire. These include accessibility control and data consistency check mechanisms.

The researcher also developed the database functional requirements and model to cross-validate the respondents' answers against it. This was done in order to separate out issues that could be related to data quality from those that are inherent database structural / functional problems.

Regardless of whether Radiation Control decides to improve on the currently used database or move to change and replace it with RAIS, the study results have

highlighted several shortcomings and strengths of the database. Therefore all the objectives of this study have been achieved.

## 5.5 RECOMMENDATIONS

Recommendations to improve the functioning and use of the database were suggested by the respondents. These include a remotely accessible database which is integrated within the regulatory processes of authorisation/licensing, inspection, enforcement and follow-up. The study recommends that on-the-field workers such as the inspectors be allowed limited access to make changes and updates to the database, specifically on the licensee/radiation sources' details that they are working with at the time. The changes made by the inspectors must be subject to regulation by the database administrator/s.

Furthermore the directorate must employ more qualified personnel to deal specifically with the database matters. Based on the findings of this study, more people should be trained on how to use and manage the database to minimise and eliminate data anomalies and redundancies currently seen. This will also help improve the data consistency check during and data entry management.

The researcher recommends a switch to the RAIS database system. RAIS is a comprehensive system covering by default all the main areas of the regulatory framework. RAIS also provides for expanding of its scope to cover other areas of interest to the regulatory authority, through its customisation mechanisms. Through RAIS, as a database tailor made for the radiation regulatory body, most of the challenges currently faced would be resolved.

If the regulatory body was to change to using RAIS, the existing database would remain operational until the new one is completely operational, fully functional and the staff well trained to use it. As already mentioned above (see section 5.3.2), the IAEA would assist

with technical skills and human capital to ensure a smooth change-over to the new database. The data that is valid and accurate from the existing database would be used in the new one and inspectors would collect correct new missing data to be fed into RAIS.

It is further recommended that all Radiation Control staff who uses the database receive training on the use of the database.

**The summary of the recommendations includes:**

- The researcher recommends that Radiation Control should migrate to RAIS as its database system. A hybrid approach in which the Radiation Control database is modified according to the RAIS database scheme could also be considered as another option in this regard.
- The study recommends that improvements must be made to the Radiation Control database's resources and scope. The database should be made remotely accessible and more qualified personnel should be employed to focus on database matters.
- It further recommends that the database should be integrated within the regulatory processes of licensing / authorisation, inspection, enforcement and follow-up.
- The Directorate Radiation Control should utilise the findings of this study to improve the database in areas such as the details of the licensees and radiation sources information; data consistency check; and consolidated data like the national inventory of radiation sources.
- It is also recommended that the database should be used as a means for information dissemination to the public, and should include information on important factors like the categorisation of sources and their associated risk and the essential technical services.
- The researcher also recommends that role-based access be implemented to the database in order to restrict access of user groups to specific parts of the database

while defining those rights to read, write and/or update rights, according to each user's specific needs.

- The researcher also recommends that attention must be paid to data quality and to appointment of qualified staff to maintain the database.

## 5.6 CONTRIBUTIONS OF THE STUDY

This study has contributed by highlighting the poor state of the radiation control regulatory programme in South Africa. The study has also highlighted the shortcomings and strengths of the Radiation Control database. The findings of this study will, hopefully, go a long way in guiding the Department of Health: Directorate Radiation Control policy makers in making policies that will help reduce the number of lost, missing, or stolen radiation sources in South Africa. This will in turn contribute to the improvement of the public health system and radiation safety and protection in the country.

1. The study will create awareness to the health and safety policy makers about the needs to improve radiation safety and protection thereby improving public health in South Africa.
2. Based on the findings and recommendations of this study, the policy makers can make policies that help tighten the laws so that less or no radiation sources go missing and endanger the citizens of this country.
3. The results of this study have shown that there is a great need to improve radiation regulatory control in South Africa. This can be done by both employing more qualified people and training Radiation Control staff.
4. Further studies should be carried out to develop a multi-functional database system that will best meet the needs of a South African radiation regulatory framework.
5. Other studies may look into why the Directorate Radiation Control prefers this current database; what it would cost to migrate to RAIS; and how effective RAIS would be as an information management tool of Radiation Control.

## 5.7 LIMITATIONS OF THE STUDY

Quantitative research design was used in this study which has its strengths and weaknesses. The sample size was small due to a small number of the study population (database user employees of Radiation Control). There are a limited number of people with experience both of the Radiation Control database and of RAIS for the purposes of the comparative study.

There are three radiation regulatory bodies in South Africa (including NECSA and NNR). The study was conducted on Radiation Control only employees whose background, education level, knowledge of the database, etc may differ from those of other regulatory bodies.

There is a primary concern that the researcher is biased against the Radiation Control database due to the experience of working with it over the years.

Despite these limitations, the study provides valuable information that could help in improving the state of radiation regulatory programme and contribute positively to the radiation safety and protection, as well as the public health in South Africa.

## 5.8 CONCLUDING REMARKS

The poorly managed and utilised database, poor access control and data consistency check mechanisms, and the shortage of qualified database personnel are contributing to the less than effective radiation regulatory programme in South Africa. The Radiation Control database appears to be at the centre of the challenges facing Radiation Control such as a high number of missing sources and lack of good quality information to trace them. See section **4.3.2.1**, par. **3** on page 84 above.

The regulatory body efforts to exercise effective radiation control will continue to be frustrated until the poor state of its data and information management tool and systems is addressed and corrected. It is also very important that more people are trained and employed to contribute to the improvement of the radiation regulatory programme in South Africa.

“A well-designed database facilitates data management and generates accurate and valuable information” (Rob & Coronel 2007:9).

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# ANNEXURE A

# UNISA CLEARANCE CERTIFICATE

UNISA university of south africa

**UNIVERSITY OF SOUTH AFRICA**
**Health Studies Higher Degrees Committee**
**College of Human Sciences**
**ETHICAL CLEARANCE CERTIFICATE**

**HSHDC/76/2012**

Date of meeting: 7 August 2012 Student No: 3353-811-5

Project Title: An investigation of the dadabase systems for the management of radiation sources.

Researcher: Mkhuliseni Ngubane

Degree: Masters in Public Health (MPH) Code: DIS4953

Supervisor: Dr C Seebregts
Qualification: PhD
Joint Supervisor: -

**DECISION OF COMMITTEE**

**Approved** [√] **Conditionally Approved** [ ]

**Prof D van der Wal**
**CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE**

pp **Dr MM Moleki**
**ACTING ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES**

**PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES**

# ANNEXURE B

# STUDY SITE APPLICATION

Directorate: Radiation Control
P O Box 977
PRETORIA
0001

**Department of Health**
☎: 012-3959119
Fax: 012-3959125
Cell: 082 3199184
E-mail: NgubaM@health.gov.za
Web: http://www.doh/department/radiation/01.html

Enquiries : M Ngubane
Reference : 33538115
Date : 28 Nov 2011

ATT: **Mr JHI Olivier**

Director: Radiation Control

**Re: Request for Permission to Conduct a Study**

I request your permission to conduct a research study titled: AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES.

The study is part of my master of public health (MPH) degree studies that I'm doing at Unisa. Radiation Control staff will be requested to participate in the study by answering questions administered through a questionnaire.

I hope my request is met with your approval.

Thank you

M NGUBANE
RADIATION CONTROL OFFICER

# ANNEXURE C

# PERMISSION FROM DIRECTORATE: RADIATION CONTROL

DEPARTMENT OF HEALTH

Verw.
Ref.

AAN/TO

**Mr M Ngubane**

VAN/FROM J H I Olivier

**DIRECTORATE: RADIATION CONTROL**

Telefoon
Telephone **021-9486162**

U verw.
Your ref.

Navrae
Enquiries **JHI OLIVIER**

Gedateer
Dated

Datum
Date 2012-02-23

INSAKE
RE **YOUR REQUEST TO CONDUCT A STUDY REGARDING THE USE OF THE RADIO-NUCLIDE DATABASE**

I refer to your request regarding the above and the subsequent communication regarding this matter.

I herewith confirm my previous oral and written approval to proceed with your planned study project.

Please ensure that you liaise with Ms Nel in so far it will have an effect on staff of the Inspectorate. All interactions with head office staff should be through myself.

.

I wish you the very best for this project.

**DIRECTOR: RADIATION CONTROL**
**DATE: 2012-02 -23**

# ANNEXURE D

# DATA COLLECTION TOOL 1 (CHECKLIST)

Criteria Checklist

A – Radiation Control Database — Yes (Y) / No (N)
B – RAIS — Yes (Y) / No (N)

| | | A | B |
|---|---|---|---|
| **Criteria** | **Sub-criteria** | **RC Database** | **RAIS** |
| 1. National regulatory infrastructure information | ○ Regulatory infrastructure information:<br>➢ Does the database have the legislation information?<br>➢ Does it have the regulations information?<br>➢ Does it have the codes of practice & guidelines?<br>➢ Are the regulatory authority's responsibilities and functions available?<br>➢ Are the provisions for authority, power and resources available?<br>○ Division of responsibilities information: | | |

| | | | |
|---|---|---|---|
| | ➢ Are relevant regulatory authority's liaison & working procedures available on the database?<br>➢ What about Memoranda of Understanding (MoU) with other relevant bodies and organisations?<br>o Is international co-operation information (Bilateral & Multilateral agreements) available? | | |
| 2. Facilities and departments | o Does the database provide for full and comprehensive licensee (license/authority holder) information? | | |
| | o Does it provide for different applications of radiation users information? | | |
| | o Does it have the Responsible Person's / Acting/Radiation Protection Officer's full information and details (incl. qualifications and responsibilities)? | | |
| | o Does it make a clear difference between the user/s and/or legal person (licensee) information? | | |

| | | | |
|---|---|---|---|
| 3. Radiation sources and associated equipment | ○ Are all sources (x-rays & isotopes) information and details fully captured by the database? | | |
| | ○ Can a National Inventory / Register for radiation sources be retrieved from the database? | | |
| | ○ Does the database have a link to the International Catalogue of Sealed Radioactive Sources (ICSRS)? | | |
| 4. Authorization | ○ Is the authorization process & procedure information available? | | |
| | ○ Is the Notification/Registration or Licensing process (incl. and according to safety requirements) clearly outlined an available? | | |
| | ○ Are the Exemption and Exclusion procedures and requirements available? | | |
| 5. Inspection | ○ Is the role & implementation procedure made available on the database? | | |
| | ○ Are inspectors' powers & responsibilities clearly outlined and available? | | |
| | ○ Are inspectors – legal person relations made | | |

| | | | |
|---|---|---|---|
| | available?<br>○ Are all regulatory requirements of the relevant inspection available? | | |
| 6. Enforcement | ○ Is enforcement action that is graded according to non-compliance information on the database? | | |
| | ○ Are safety, instructions, sanctions, fines & suspensions implication outlined? | | |
| | ○ Is enforcement action interaction (regulatory authority & other national bodies) information available? | | |
| 7. Remote access | ○ Does the database allow online submission of licence applications or update? | | |
| | ○ Can the database be accessed by inspectors while on the field? | | |
| | ○ Can licensees' authorised personnel access it? | | |
| | ○ Can the public access it for information distribution by the authority? | | |
| 8. Customization (mechanisms) | ○ Is the database customisable to regulator's | | |

| | | | |
|---|---|---|---|
| | specific needs?<br>○ Is it multilingual?<br>○ Does it have upward compatibility features? | | |
| 9. Radiation incidences | ○ Is the emergency response plan information available on the database?<br>○ Does it provide dose limits information (incl. response procedure classification according to incidence type)?<br>○ Does the database provide the dosimetry service option / information?<br>○ Does it communicate and co-operate with other relevant organizations (e.g. IAEA) databases in case of incidences? | | |
| 10. Technical services | ○ Is QA (Quality Assurance) information available on the database?<br>○ Does it provide a link with other relevant technical services organisations / information?<br>○ Does it give Inspection bodies (accreditation/scope) | | |

| | | | |
|---|---|---|---|
| | information?<br>○ Does it provide information about leak tests procedures and relevant organisations?<br>○ Does it provide equipment, sources and instruments maintenance (services & repairs) information? | | |
| | | | |
| 11. Workers | ○ Does the database cater for workers' (authority and licensees) qualifications & responsibilities information? | | |
| | ○ Does it outline their Rights & Limitations / information? | | |
| | ○ Does it give details about workers' verification and validation procedure / information? | | |
| | ○ Are fundamental requirements of workers (esp. authority's or inspectors) available? | | |
| 12. Data integrity | ○ Does the database do proper data validation? | | |
| | ○ Does it have consistency and validation checks? | | |
| 13. Database model | ○ Is it a relational model? | | |
| 14. Security | ○ Does the database have security access control? | | |
| | ○ Does it have individual & group privileges? | | |

| | | | |
|---|---|---|---|
| 15. Automated Optimization | ○ Does the database have frequent usage improved speed?<br>○ Does it have performance monitoring tools? | | |

# ANNEXURE E

# LETTER OF CONSENT

**AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES**

Dear colleague / respondent

I am a registered student at Unisa busy with the master of public health degree studies. I am conducting a research study titled: AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES.

The purpose of my research is to examine and analyse the database systems in order to explore the effectiveness of the database system used by Radiation Control.

I would appreciate your participation by answering questions on the questionnaire as genuinely as possible.

Please note that your participation in the study is voluntary and you may withdraw from the study or interview at anytime you so wish. All data collected in the study will remain anonymous and will be kept confidential.

If you have any questions regarding the study please contact me on 031-3072111 or 0823199184 or 0822130347. If you prefer to e-mail me you may use NgubaM@health.gov.za or Mkhuliseni@yahoo.com or Mkhuliswa@gmail.com.

It will take approximately 45 minutes to 1 hour to complete the interview.

Thank you for consenting to participate in the study.

Mkhuliseni Ngubane
RCO, Student

……
Signed By: ……
Date: ……..

# ANNEXURE F

# DATA COLLECTION 2 (QUESTIONNAIRE)

# STRUCTURED INTERVIEW GUIDE

Please answer the questions as honestly as you can. No individual names are required since the information you give is strictly confidential. Remember you can decide to terminate the session without any penalty.

Respondent no: .....
Date: .....

## 1. The Database and Users

1.1 Which of these roles best describes your position within Radiation Control?

- Administration officer
- Inspector
- Scientist
- Manager
- Information management officer

1.2 How many times do you use the database in a week?

- Less than 5 times
- 5 – 25 times
- 25 – 50 times
- More than 50 times

1.3 Is it important that that the database be remotely accessible?

- Yes
- No
- If YES, please explain: .....

1.4 Do you miss any data in the database that you would like to see added?

- Yes
- No
- If YES, please explain: .....

1.5 Do you ever encounter inconsistent/ambiguous data while making queries from the database?

- Yes
- No
- If YES, please explain: .....

1.6 Are there any features which you would like to see added to the database?

- Yes
- No
- If YES, please explain: .....

1.7 Do you think it is important for the database to be customisable to the users' specific needs?

- Yes
- No

## 2. Resources

2.1 What are the available human resources devoted to the database matters?

- Information Resource Manager / Data Administrator
- Database Administrator (DBA)
- Alternate Database Administrator
- Other (*please explain*)

2.2 Do you think it is important for the database to be linked to other relevant authorities' information resources?

- Yes
- No
- If YES, please explain: .....

2.3 Is the database able to give you consolidated data such as the national inventory of radiation sources?

- Yes
- No
- If NO, please explain: .....

2.4 Is the organisational structure of the regulatory authority in South Africa clearly outlined in the database?

- Yes
- No
- If NO, please explain: .....

2.5 Does the database have information about memoranda of understanding and bilateral or multilateral agreements with other national and international bodies?

- Yes
- No
- Don’t know

2.6 Does the database contain enough information about the facilities and departments (licence holders) to facilitate tracking of lost or stolen radiation sources?

- Yes
- No

2.7 Does the database have enough details of the radiation sources to facilitate tracking of lost, stolen or missing sources?

- Yes
- No

2.8 Are processes of authorisation/licensing, inspection and enforcement clearly outlined and explained in the database?

- Yes
- No
- If NO, please explain: .....

2.9 Are licensees able to submit and monitor their application for authorisation on the database?

- Yes
- No

2.10 Is the process of graded enforcement action for non-compliance explained in the database?

- Yes
- No
- Don’t know

## 3. Scope

3.1 Do you think that the database is integrated within the regulatory processes such as the licensing, inspection and follow-up?

- Yes
- No

3.2 How important do you think it is for the database to provide for the following? *(5 = Very important; 4 = Important; 3 = Necessary; 2 = Not so important; 1 = Not important)*

i. Data consistency checking to reduce human errors:

- 5
- 4
- 3
- 2
- 1

ii. Protection of vital data against unintentional modification or deletion:

- 5
- 4
- 3
- 2
- 1

iii. Access control to protect data against unauthorised access and to ensure confidentiality:

- 5
- 4
- 3
- 2
- 1

iv. Means for information dissemination to the public, customised according to the regulatory body's policy:

- 5
- 4
- 3
- 2

- 1

v. Interface for catalogues on manufacturers and models of sealed sources, radiation generators and associated equipment:
- 5
- 4
- 3
- 2
- 1

vi. Online submission of data by the facilities (applicant licensees), subject to validation by the regulatory body:
- 5
- 4
- 3
- 2
- 1

**4. General**

4.1 Is there any relevant information in your work that is not being captured for the database?
- Yes
- No
- If YES, please explain:

4.2 Do you think the database should allow limited access to inspectors to make certain updates/changes?
- Yes
- No

4.3 Do you think the database should allow access to authorised representatives of licensees, such as A/RPO (Acting/Radiation Protection Officer) or Responsible Person, to their particular information?
- Yes
- No

4.4 Are you happy with the database being divided into the x-rays and isotopes

databases?

- Yes
- No

4.5 Are there other national or international radiation information resources accessible through the database?

- Yes
- No
- Don’t know

4.6 Do you have access to other information resources that you may need in your work?

- Yes
- No

4.7 Is there enough information on the database about the categorisation of radiation sources and their associated risk?

- Yes
- No
- Don’t know

4.8 Which of these essential technical services their information is available on the database?

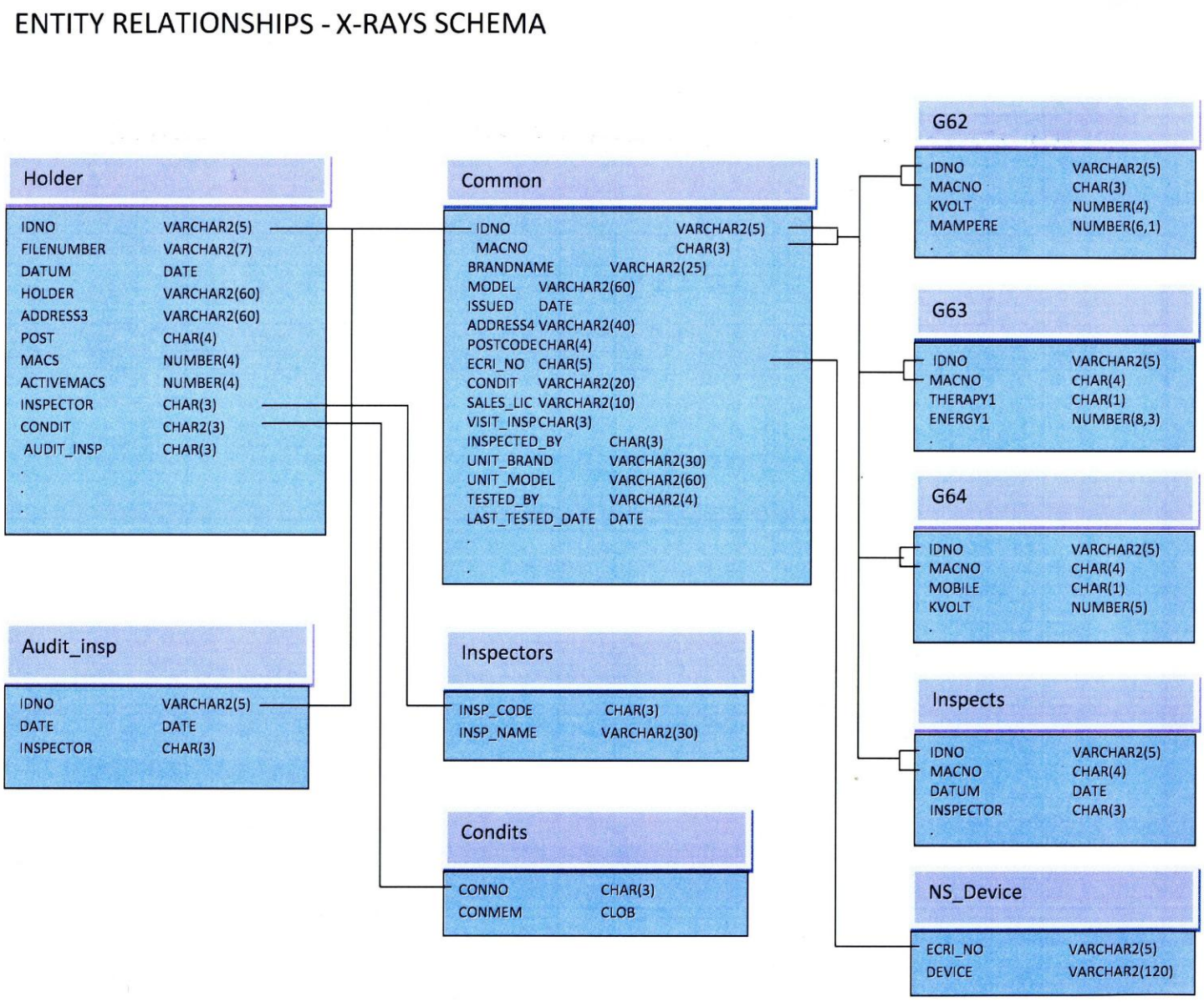
- Dosimetry services
- Analytical services
- Calibration services
- Radioactive waste management services
- Training services
- Accreditation for services
- None

# THANK YOU FOR TAKING TIME TO BE PART OF THIS STUDY

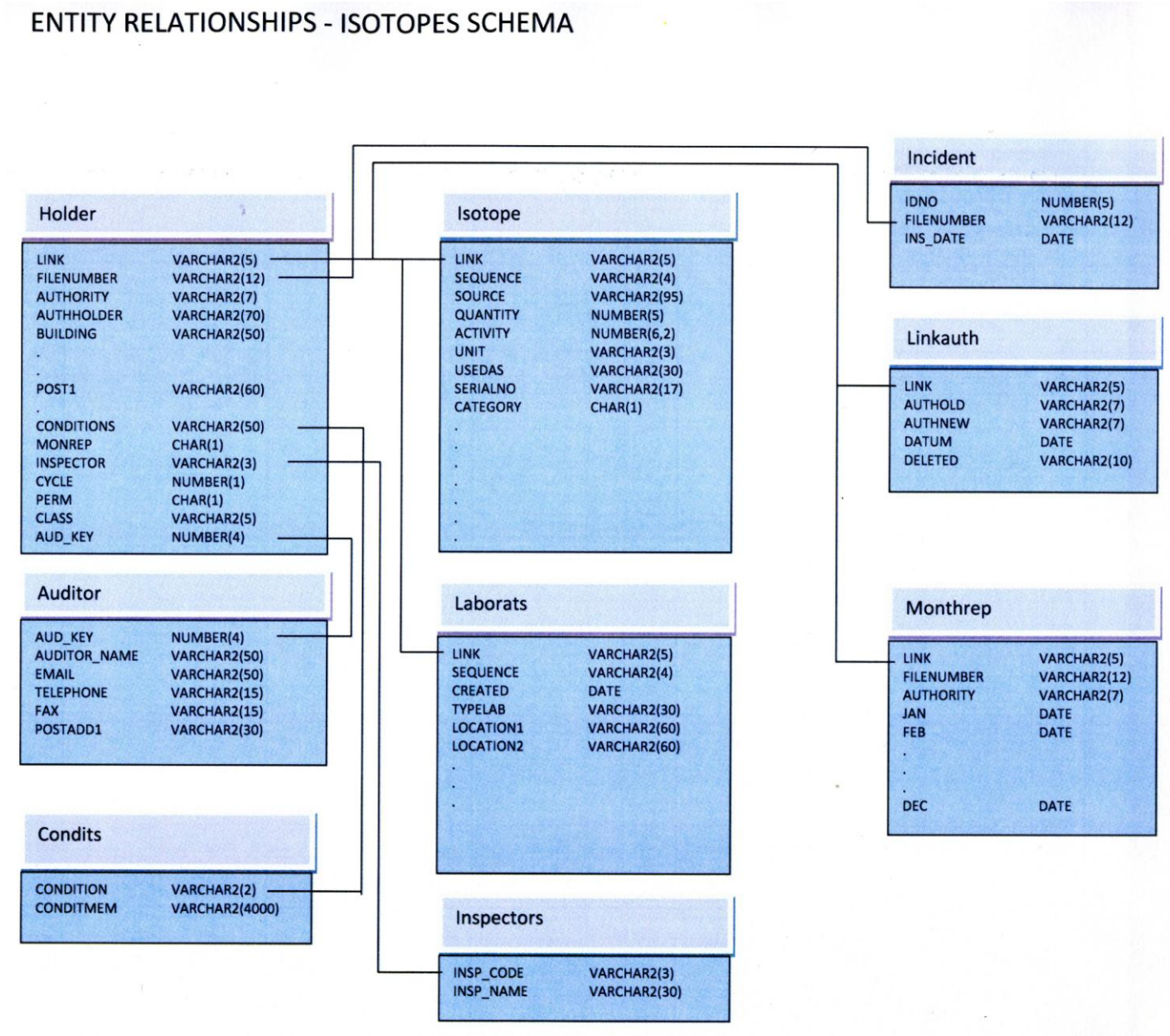
# ANNEXURE G: 1

# ENTITY RELATIONSHIP DIAGRAMS (RC DATABASE)

# ENTITY RELATIONSHIPS – X-RAYS SCHEMA



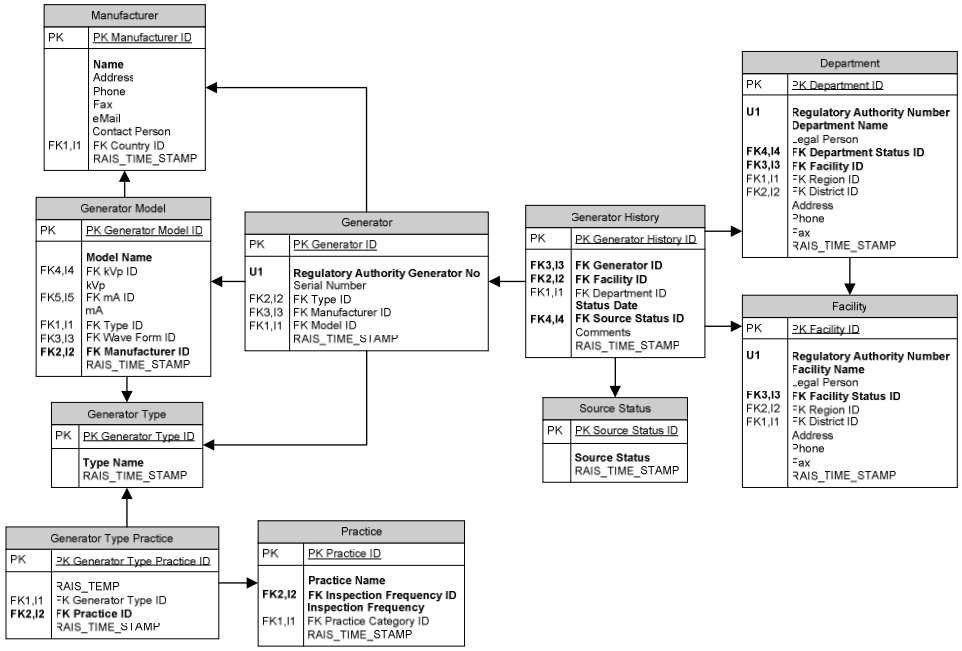
# ENTITY RELATIONSHIPS – ISOTOPES SCHEMA



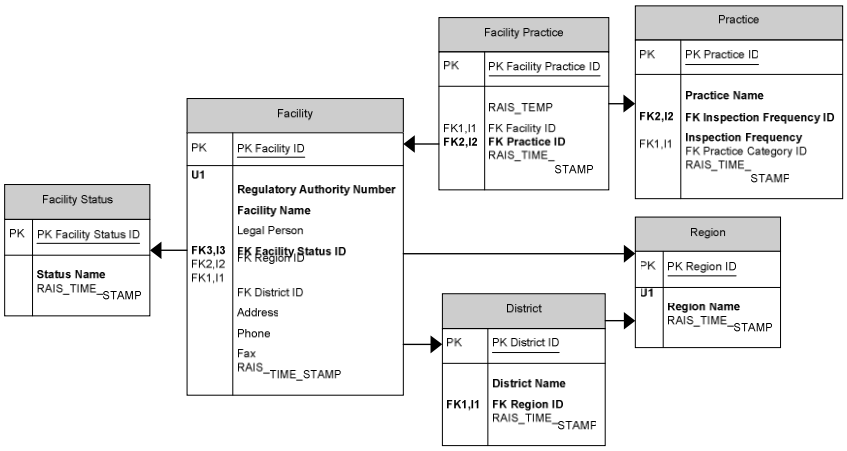
# ANNEXURE G: 2

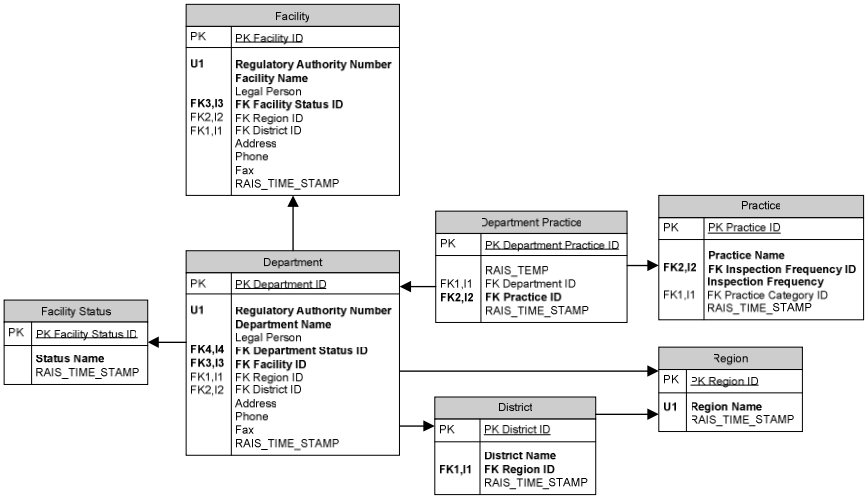
# ENTITY RELATIONSHIP DIAGRAMS (RAIS)

# SOURCES – RADIATION GENERATORS

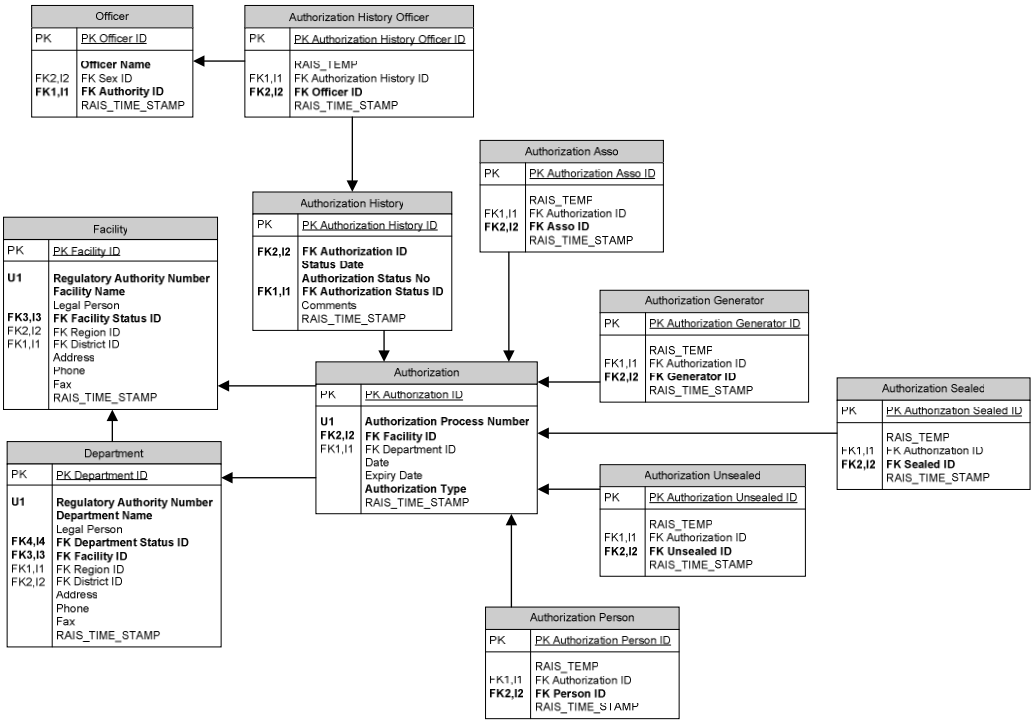


# FACILITIES AND DEPARTMENTS



# AUTHORISATIONS



# DECLARATION

Student number: 3353-811-5

# DECLARATION

I declare that **AN INVESTIGATION OF THE DATABASE SYSTEMS FOR THE MANAGEMENT OF RADIATION SOURCES** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

**SIGNATURE**
**(MKHULISENI NGUBANE (MR)**

22. 11. 2012
**DATE**