# Criteria for regulating and managing radioactive material in South Africa compared to the criteria of the ISO 14001 Environmental Management System within the mining and minerals industries.

A mini-dissertation presented to the Potchefstroom University for Christian Higher Education.

Conforming partially to the requirements of the MASTERS PROGRAMME IN ENVIRONMENTAL MANAGEMENT AND - ANALYSIS

BY

**MRS A R DE CLERCQ**

**STUDENT NUMBER : 122654382**

**NOVEMBER 2002**

## OPSOMMING


Titel: **'n Vergelyking tussen die vereistes vir kwaliteitbeheerstelsels wat die reguleerders van radioaktiewe materiaal in Suid-Afrika stel vir die mynbou en mineraalverwerkingindustrieë, en die vereistes van die ISO 14001 omgewingsbestuurstelsel.**

Studieleier: **Prof A.B. de Villiers**

Student: **Me. A.R. de Clercq**

Graad: **Meestersprogram in Omgewingsbestuur**

Die Nasionale Kernreguleerderwet, Wet no 47 van 1999, en die Wet op Gevaarhoudende Stowwe: Groep IV Gevaarhoudende Stowwe (Wet No 15 van 1973) reguleer die gebruik van radioaktiewe materiaal in die mynbou en mineraalverwerkingindustrieë in Suid Afrika. Die twee wette word deur verskillende reguleerders beheer. Die meegaande regulasies van elke wet bevat vereistes wat betrekking het op kwaliteitbeheer. Die twee reguleerders stel egter nie dieselfde vereistes in terme van kwaliteitbeheer nie.

Hierdie studie ondersoek die ooreenkomste en verskille tussen die kwaliteitbeheervereistes wat gestel word deur die twee reguleerders van radioaktiewe materiaal, en die vereistes wat gestel word deur 'n internasionaal aanvaarbare omgewingsbestuurstelsel, soos die ISO 14001 bestuurstelsel.

Die metode van ondersoek berus op 'n vergelyking tussen die vereistes van die ISO 14001 stelsel en die vereistes gestel deur die verskillende reguleerders. Die navorser identifiseer algemene doelwitte vir die geïntegreerde ISO 14001 stelsel en ondersoek of die ander twee stelsels daaraan voldoen. Spesifieke doelwitte vir elke komponent van die ISO 14001 stelsel word ook geïdentifiseer. Die student bepaal of 'n soortgelyke vereiste deur die verskillende reguleerders daargestel word en of die doelwitte van die komponent dieselfde is.

Die resultate van die ondersoek toon aan dat die kwaliteitbeheerstelsel soos vereis deur die

Nasionale Kernreguleerder, al die bestuurskomponente van die ISO 14001 bevat en dat dit moontlik is om die twee stelsels te integreer. Die vereistes wat die Departement Gesondheid: Direktoraat Stralingsbeheer stel, voldoen slegs gedeeltelik aan die vereistes wat die ISO 14001 stelsel stel, omdat dit nie al die basiese komponente van 'n volledige bestuurstelsel bevat nie. Die Direktoraat vereis onder meer nie die formulering van 'n beleid nie. Verder is die vereistes rondom bestuursbetrokkenheid ook baie beperk.

Op grond van die resultate van die ondersoek word die volgende aanbevelings gemaak:-

- Reguleerders van radioaktiewe materiaal behoort uniforme vereistes te stel rondom die beheer van aktiwiteite wat met radioaktiewe materiaal uitgevoer word.
- Die implementering van 'n volledige, effektiewe bestuurstelsel om aktiwiteite wat met radioaktiewe materiaal uitgevoer word te bestuur, behoort 'n vereiste van beide reguleerders te wees. Die ISO 14001 omgewingsbestuurstelsel bevat al die vereistes van so 'n stelsel. 'n Bestuurstelsel, soos ISO 14001, sal die doeltreffendheid van organisasies verhoog om te voldoen aan regulatoriese vereistes.

## ABSTRACT

Title: **Criteria for regulating and managing radioactive material in South Africa compared to the criteria of the ISO 14001 Environmental Management System within the mining and minerals industries.**

Study leader: **Prof A.B. de Villiers**

Student: **Mrs A.R. de Clercq**

Degree: **Masters Programme in Environmental Management**

The National Nuclear Regulator Act (NNRA) (Act no 47 of 1999) and the Hazardous Substances Act (Act no. 15 of 1973): Group IV Hazardous Substances regulate the use of radioactive material in the mining and minerals processing industries in South Africa. Two different regulatory bodies enforce these Acts. Both sets of regulations promulgated in terms of these Acts contain quality management requirements. However, there are differences between the quality management requirements prescribed by the different regulators.

This study investigates in which areas the quality management requirements of the two regulators agree with the conditions of the internationally accepted ISO 14001 environmental management system (EMS). It also identifies the discrepancies between each requirement of the ISO 14001 EMS and the corresponding quality management requirement required by each regulator.

The method of investigation is a comparative analysis between the ISO 14001 EMS and each regulator's requirements. The benefits of implementing the integrated ISO 14001 EMS were identified. This research evaluated the quality management requirements of each regulator and determined whether it would result in the same benefits. Specific objectives for each component of the ISO 14001 EMS were also identified. For each regulator, the student determined if a similar management requirement existed and if that specific requirement had the same objective.

From the results of the comparative analyses the student concluded that the quality management system required by the National Nuclear Regulator, the regulator of the NNRA, contains all the core elements of the ISO 14001 EMS and could be integrated into the ISO 14001 EMS. The quality management requirements of the other regulator, the Directorate, only partially meet that of the ISO 14001 EMS. The reason for that is that the Directorate does not require all components of a complete management system such as a policy statement, management review process, etc.

The author concludes that it is recommended that the regulators of radioactive material in South Africa should follow a consistent approach in regulating activities carried out with radioactive material. Furthermore, both regulators should require the implementation of an effective management system, such as the ISO 14001 EMS. This will contribute to the effectiveness and efficiency of organisations to control activities carried out with radioactive material and to achieve compliance with regulations.

## ACKNOWLEDGEMENTS

I would like to acknowledge and thank the following people for their input, their hard work, patience and support, without which this thesis would never have been possible:

- to Prof. Braam de Villiers, the study leader;
- to Gerrit Kornelius of SASOL SSF who recommended the methodology to follow in this study;
- to Sietse van der Woude of the NNR who helped me with the interpretation of legislation and conclusions made in this study;
- to Ross Garcin for reviewing and providing advice on the content of this document; and
- to FOSKOR for allowing me to use their Audit Report.

Also to my husband, Adriaan de Clercq, for his tolerance, his understanding and support.

Above all, to my Maker who deserves all the credit.

## CONTENTS

## ABBREVIATIONS

| | |
|---|---|
| ALARA | As low as reasonably achievable |
| AEC | Atomic Energy Corporation of SA |
| CNS | Council for Nuclear Safety |
| CQE | Certified Quality Engineer |
| EMS | Environmental Management System |
| IAEA | International Atomic Energy Agency |
| ICRP | International Commission on Radiological Protection |
| IRCA | International Registered Certified Auditor |
| ISO | International Standards Organisation |
| LD | Licensing Document |
| NEA | Nuclear Energy Act (Act no 131 of 1993) |
| NECSA | South African Nuclear Energy Corporation |
| NNR | National Nuclear Regulator |
| NNRA | National Nuclear Regulatory Act |
| OEP | Occupationally exposed person |
| QMP | Quality Management Programme |
| QMS | Quality Management System |
| RPO | Radiation Protection Officer |
| RP Programme | Radiation Protection Programme |
| SAATCA | South African Auditor and Training Certification Association |

## DEFINITIONS/GLOSSARY

All the definitions used in this document were quoted from either the NEA, the ISO 9000:2000 or the ISO 14001:1996 standards.

| | |
|---|---|
| Activities: | In any manner use, possess, produce, store, enrich, process, reprocess, cause to be conveyed, dispose of or carry out any other activity involving radioactive material which is capable of causing nuclear damage. |
| Compliance: | The affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract, or regulation. |
| Certification: | Procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements. |
| Continual Improvement: | Process of enhancing the environmental management system, with the purpose of achieving improvements in overall environmental performance. It is a continuous effort to improve in line with the organisation's environmental policy. |
| Environment: | Surroundings in which an organisation operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelation. The environment in this context extends from within an organisation to the global system. |
| Environmental Aspects: | Elements of an organisation's activities, products, and services, which can interact with the environment. |
| Environmental Impact: | Any change to the environment, whether adverse or |

| | |
|---|---|
| | beneficial, wholly or partially resulting from an organisation's activities, products or services. |
| Environmental Management System: | Those parts of the overall management system that include organisational structure, planning activities, responsibilities, practices, procedures, processes and resource developing, implementing, achieving, reviewing and maintaining the environmental policy. |
| Environmental Policy: | Statement by the organisation of its intentions and principles in relation to its overall environmental performance which provides a framework for action and for the setting of its environmental objectives and targets. |
| Nuclear Damage: | Any injury to, or the death or any sickness or disease to a person; or other damage, including any damage to or any loss of use of property or damage to the environment, which arises out of, or results from, or is attributable to ionising radiation. |
| Quality Management System: | System to establish a quality policy with quality objectives, and to achieve those objectives. |
| Quality Objective: | Something sought, or aimed for, related to quality. |
| System: | Set of interrelated or interacting elements. |

# CHAPTER 1: INTRODUCTION

## 1.1 Background

It is known that exposure to radiation emitted from radioactive material can be hazardous to human health. It is therefore necessary to control activities carried out with radioactive material to protect users of this material and the public from unnecessary exposure.

This was already recognised in the early 20th century when experiments with X-rays and radioactive minerals indicated that exposure to high levels of radiation can cause clinical damage to the tissues of the human body. This resulted in the formation of the ICRP in 1928, a non-governmental scientific organisation. Its function was to establish basic principles and recommendations for radiation protection . The ICRP still plays a leading international role in the compilation of safety standards and recommendations in the control of radioactive material. Legislators also use these safety standards and recommendations.

In addition, long term epidemiological studies of populations exposed to radiation, especially the survivors of the atomic bombing of Hiroshima and Nagasaki in Japan in 1945, have demonstrated that exposure to radiation also has a potential for the delayed induction of malignancies.

Historically radiation protection focused on the protection of human health, and not on the environment. This is still seen in the manner in which the concept "detriment" is described by the ICRP. "Detriment" is seen as the probability of fatal cancer attributable to radiation exposure; the probability of incurring a non-fatal cancer; the probability of severe hereditary effects; and the length of time of life lost, if the harm occurs (ICRP, 1991). All of these are related to human health.

The application and use of radioactive material in South Africa is widespread. Radioactive material is used for medical, commercial and other purposes. Radioactive material can be encapsulated in a sealed source e.g. in measuring instruments such as density gauges, industrial radiography gauges, moisture gauges or radiotherapy instruments that are used for the treatment of cancer patients. It can also be used in chemical form such as radioactive tracers and then it is referred to as unsealed sources. Radiation can also be generated with electrical instruments such as X-ray machines and linear accelerators.

Radiation emitted from radioactive material also occurs naturally e.g. gamma rays and cosmic particles from outer space and in ore in the crust of the earth. In some ores the concentration of this material can be so high that it becomes a hazard to individuals living nearby, e.g. some granites. Individuals active in mining or living close to mines, where ore containing radioactive material exceeds specific concentrations, will also be at risk.

Two regulatory bodies in South Africa exist which control activities carried out with radioactive material. These two bodies are the Department of Health: Directorate Radiation Control (the Directorate) and the National Nuclear Regulator (NNR), who succeeded the Council for Nuclear Safety (CNS). These bodies are empowered by different Acts and apply two different sets of requirements to enforce these Acts.

Both sets of requirements contain quality management requirements. However, there are differences between the quality management requirements prescribed by the different regulators. Many users of radioactive material are also interested in implementing, or have implemented, the Environmental Management System (EMS) standard ISO 14000. The EMS ISO 14000 shares common management system principles with quality management system principles. It is therefore relevant to ask if, and how, the ISO 14000 series can be integrated into the existing management systems required by the regulators of radioactive material.

## 1.2 ISO 14001 Environmental Management System in South Africa

More and more regulations in South Africa, e.g. those promulgated by the Department of Environmental Affairs and Tourism, Department of Minerals and Energy, Department of Water Affairs and Forestry, are now requiring the use of EMS in regulatory programmes. The ISO 14001 standard is accepted widely as the base on which to establish such a programme.

Additional to this, many organisations in South Africa strive to obtain certification against the generally accepted international EMS, ISO 14001. This is, for instance, to demonstrate that the organisation implements good environmental management principles or to facilitate trade and remove trade barriers.

## 1.3 Legislation on radioactive material in South Africa

As already mentioned in section 1.1 of the Introduction, two regulatory bodies regulate organisations in South Africa carrying out activities with radioactive material. Three Acts regulate the use of radioactive material in South Africa. These Acts are the Hazardous Substances Act no 15 of 1973, the Nuclear Energy Act no 46 of 1999 and the National Nuclear Regulator Act no 47 of 1999. The Nuclear Energy Act no 46 of 1999 is not of relevance to this study. It is limited in its application in that it establishes the South African Nuclear Energy Corporation Limited (NECSA) and the regulation of activities applicable to that organisation.

The purpose of the Acts regulating radioactive materials is to safeguard persons, property and the environment against nuclear damage. However, control structures, dose limits and risks currently focus mainly on the protection of people and not the environment. This is due to the historical development of safety standards and recommendations on the control of radioactive material. The assumption that if people are adequately protected the environment will also be, was made. (Currently this assumption is under investigation by the ICRP to ensure that environmental matters are adequately addressed by ICRP recommendations.)

All legislation on radioactive material are based on the basic principles of radiation protection, which are (IAEA SS115, 1996):

- ***Justification of the practice***: No practice should be adopted unless its introduction produces a net positive benefit. This principle seeks to balance technical, health, economic interests and social interests of society.
- ***Optimisation of the practice:*** All exposures should be kept *as low as reasonably achievable* (ALARA). In this decision, economic and social factors should also be taken into account. This principle seeks to find a balance between society's health and the cost of radiation protection.
- ***Individual dose limitation***: The dose equivalent received by individuals should not exceed the recommended limits. This principle demonstrates that there exists a level of dose above which the consequences for the individual and society would be widely regarded as unacceptable.

These principles were adopted from safety standards and recommendations published by the IAEA and ICRP.

### 1.3.1 Hazardous Substances Act no 15 of 1973

This Act is administered by the Department of National Health. Its primary purpose is to "provide for the control of substances which may cause injury or ill health to, or death of human beings by reason of their toxic, corrosive, irritant, strongly sensitising or flammable nature " (Glazewski, 2000: 690).

Four groups of hazardous substances are distinguished in this Act:

- Group I and II are substances which are dangerous due to their toxicity;
- Group III substances concern electronic products, e.g. X-ray machines and linear accelerators; and
- Group IV substances concern radioactive material used ***outside nuclear installations*** and which are ***not used in the nuclear fuel cycle***, e.g. uranium and its daughter products. This radioactive material must also

exceed stipulated activity levels or has been declared as requiring control by the Minister. These activity levels and material are described in Government Gazette No. 14596 dated 26 February 1993.

The Department of Health: Directorate Radiation Control (the Directorate) regulates Group III and IV Hazardous Substances. Regulations were compiled in terms of the Hazardous Substances Act and were also published in Government Gazette No. 14596 dated 26 February 1993.

These regulations also address QMS requirements, such as document control, employee training, auditing and reporting requirements.

### 1.3.2 National Nuclear Regulator Act 47 of 1999

The Nuclear Energy Act no 131 of 1993 is relevant to radioactive material used ***inside nuclear installations*** and which is ***used in the nuclear fuel cycle***, e.g. uranium and its daughter products, plutonium, etc. Two Acts repealed the Nuclear Energy Act no 131 of 1993. These are the Nuclear Energy Act no 46 of 1999 and the National Nuclear Regulator Act 47 of 1999 (Glazewski, 2000: 554).

The Nuclear Energy Act 46 of 1999 is of relevance to NECSA, which succeeds the Atomic Energy Corporation. The main functions of the Corporation are to:

- undertake and promote research in the development of nuclear energy and radiation sciences and technology;
- promote radioactive source material, special nuclear material and restricted material; and
- process and enrich source and nuclear material.

The South African Nuclear Energy Corporation Ltd. is therefore not empowered to be a regulatory body. The Nuclear Energy Act no 46 of 1999 and its implications are ***not applicable*** to this study and will therefore not be discussed in more detail.

The National Nuclear Regulator Act no 47 of 1999 (NNRA) establishes a juristic person known as the National Nuclear Regulator (NNR) (the Regulator). The functions of this regulator, which are applicable to this study, are described in Government Gazette No 20760 dated 23 December 1999, section 5. These are to:

5 (a) provide for the protection of persons, property and the environment against nuclear damage through the establishment of safety standards and regulatory practices;

5(b)(iii) exercise regulatory control related to safety through the granting of nuclear authorisations.

The purpose of passing two Acts to replace the Nuclear Energy Act no 131 of 1993 is to separate the functions of nuclear safety (addressed by the NNRA), from those of development and the application of nuclear technology (addressed by Nuclear Energy Act no 46 of 1999). It also provides for more transparent and accountable governance of the South African nuclear industry. The NNRA does not apply to:

- conditions where the radioactive content is below stipulated activity levels;
- Group IV Hazardous Substances as defined in the Hazardous Substances Act no 15 of 1973 (see 1.3.1);
- exposure to ionising radiation emitted from equipment, declared to be Group III hazardous substances in terms of the Hazardous Substances Act no 15 of 1973 (see 1.3.1).

For the purpose of this study the National Nuclear Regulator Act no 47 of 1999 is of relevance.

### 1.3.3 Interim Period

It has been mentioned that the NNRA replaces the Nuclear Energy Act (Act no 131 of 1993) (NEA). The National Nuclear Regulator is the legal successor to the Council for Nuclear Safety (CNS) since 2000.

Currently the Regulator is compiling standards and requirements to implement the NNRA. In the interim period the status quo remains and control over radioactive material is carried out according to the systems developed by the CNS while the NEA was still the accepted legislation.

The NEA requires that organisations carrying out activities with radioactive material implement a formalised quality management programme as part of the licensing process. The minimum requirements of such a programme are described in the Regulator's licensing document LD-1084 (see Appendix III).

## 1.4 Purpose and Problem Statement

*The purpose of this study will be to determine:*

1.4.1 to which extent current QMS required for the control of radioactive material in South Africa, agree with the conditions of the ISO14001 EMS (*see Chapters 4, 5 and 6*);

1.4.2 to identify the discrepancies between the QMS, or components of the QMS, required by the two regulators of radioactive material and the ISO 14001 EMS (*see Chapters 4, 5 and 6);*

1.4.3 if the ISO 14001 management systems requirements could be integrated into the QMS requirements required by the regulators of radioactive material (*see Chapter 6);*

1.4.4 if the ISO 14001 standard could be used as management system for control of radioactive material and its impacts on the environment (*see Chapter 6*).

## 1.5 Who will benefit from this study?

This study will provide useful information to:

- ***Regulators*** of radioactive material. This study will help them to establish to which extent their prescribed QMS requirements agree with the internationally accepted environmental management system ISO 14001. These results should also be useful to determine how management systems

for the control of radioactive material could be improved or modified. This information could be especially useful to the Regulator who is currently in a process of compiling standards and regulations in terms of the new NNRA.

- ***Organisations which are, or wishing to be ISO14001 certified***, but who are also regulated by the Act on radioactive material. This study will help them to determine which areas of their existing QMS need attention or improvement, or how their systems should be extended or integrated.
- ***ISO14001 certification auditors.*** This study will help them to plan to which extent organisations regulated by the regulators of radioactive material should be audited.

The Regulator agreed that Audit report CNS/42/97/10, discussed in section 5.3, could be used as supportive results to demonstrate that the quality management system (QMS) required can be fully integrated into the ISO 14001 EMS. This will serve as confirmation that conclusions and recommendations made in this study on the Regulator's requirements are valid.

## 1.6 Scope of Study

Both the NEA and regulations relating to the use of Group IV Hazardous Substances are relevant to a wide spectrum of users.

This study will focus only on the activities carried out with radioactive material in the mining and minerals processing industries. It is therefore not relevant to licenses issued to Koeberg Nuclear Power Station or NECSA, as already mentioned.

It is relevant to all mining and mineral processing organisations to whom a standard nuclear licence was issued (a standard Nuclear Licence is attached as Appendix I). Special licences with limited conditions in these industries will not be investigated.

It is also relevant to all users of radioactive material in the mining and minerals processing industries that fall under the jurisdiction of the Directorate. Those are

users of industrial gauges, density gauges, level gauges, belt mass meters, thickness gauges and other analytical units that contain radioactive sources. Authorisations issued by the Directorate to users in the Medical Industries and to users of Group III Hazardous Substances, e.g. equipment using radio frequencies and generating X-rays, will not be included in this study.

## CHAPTER 2: ISO 14000 STANDARDS

### 2.1 History of Development of ISO 14000 series

The ISO 14000 series emerged primarily as a result of the United Nations Conference on the Environment and Development held in Rio de Janeiro during 1992. This Summit generated a commitment to protection of the environment across the world (Von Zharen, 1996 : 8).

During the past decade the environmental field has seen a steady growth of global, national and regional standards. The British Standards Institution developed BS 7750, the Canadian Standards Association developed environmental management, auditing, eco-labelling and other standards, the European Union developed all of these plus the eco-management and audit regulations (EMAS) . Additional to this, organisations such as the ICRP, the IAEA and others, published recommendations regarding the regulating and management of radioactive material, which also are of relevance to the environment, e.g. the disposal of radioactive waste.

ISO assessed the need for international environmental management standards. They formed the Strategic Advisory Group on the Environment (SAGE) in 1991, to consider whether such standards could serve to:

- promote a common approach to environmental management similar to quality management;
- enhance an organisation's ability to attain and measure improvements in environmental performance; and
- facilitate trade and remove trade barriers.

In 1992 the ISO Technical Committee (TC) 207 was formed to develop such international environmental management standards. The committee and its sub-committees included representatives from industry, standards organisations,

government and environmental organisations from many countries. The new series of ISO14000 standards are designed to cover:

- environmental management systems
- environmental auditing
- environmental performance evaluation
- environmental labelling
- life-cycle assessment
- environmental aspects in product standards

The EMS ISO14001 shares common management system principles with the quality management system (QMS) ISO 9001 (Van Zharen, 1996 : 13). The core elements used in ISO14001 mirror those of ISO 9001, such as: a policy statement, top level management commitment, document control, employee training, corrective action, management review and continual improvement. However, the underlying philosophies of the ISO 14000 and ISO 9000 QMS are different. The ISO 14000 series emphasises the need to recognise the importance of environmental protection, while ISO 9000 is mainly focussed on customer satisfaction of a product, especially reproducibility and quality. Therefore the application and aims of the various elements of the management systems may differ due to different purposes and different interested parties.

## 2.2 To whom do the standards apply ?

Different reasons exist why organisations in South Africa implement an EMS. As has been mentioned earlier, certain regulators in South Africa require such an EMS. In South Africa regulators accept ISO 14001 as an EMS. Other reasons why organisations implement the ISO 14001 EMS are to stimulate exports; it could be demanded by a South African subsidiary company of an international organisation, or for publicity value. This is due to the increasing international demand that organisations demonstrate responsible behaviour in terms of the environment.

The ISO 14001 EMS is therefore not a legally required system, but is voluntarily accepted by an organisation as a management system. This management system consists of interrelated processes or core elements and enables organisations to meet objectives effectively and efficiently. Barnard (1999 : 64) describes it as follows: "the ISO 14001 system is considered to be a simple, basic and effective management system."

Another advantage of the ISO 14001 EMS is that it is also of relevance to all types and sizes of organisations and that it is designed to encompass diverse geographical, cultural and social conditions (Von Zharen, 1996 : 15).

The basic requirements of the ISO14000 series are a *commitment to continual improvement of environmental performance, prevention of pollution* and *compliance with applicable legislation and regulations.* It does not establish environmental performance requirements beyond what is articulated in the organisation's policy, objectives and targets, and the requirements of applicable legislation and regulations.

## 2.3 What do the standards apply to?

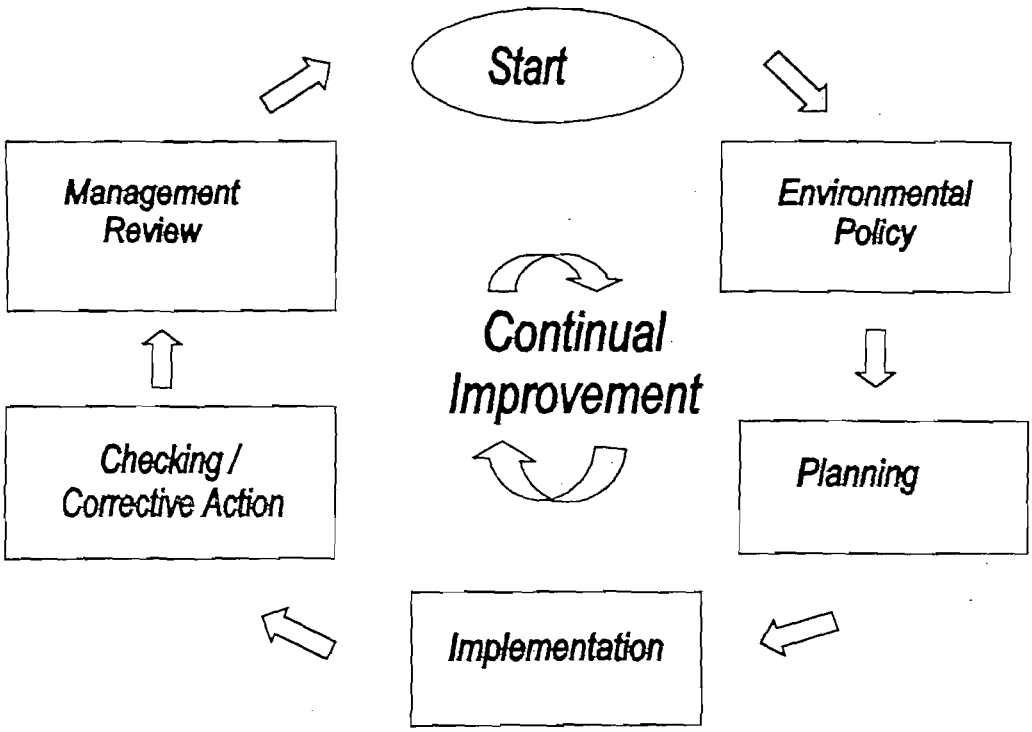
The ISO14001 EMS was designed as management system for managing environmental matters. However, each organisation may decide the extent of coverage of this management system, because there does not appear to be a limit to its coverage. It can be generalised to include the organisation's whole value chain, such as its products, services, activities, operations, facilities, transportation, liabilities, etc.

The advantage for an organisation to follow a co-ordinated approach by implementing a system like ISO14001 in all areas of management, is that a consistent management system will exist throughout the whole organisation. This will ensure an increase in effectiveness in achieving goals and targets and a better understanding of the system among employees.

## 2.4 ISO14001: Core Elements (This is summarised in Appendix II).

Figure 1 illustrates diagrammatically how the five key processes or elements of the ISO 14001 EMS interact and that it should form a dynamic cycle to ensure continual improvement.

**Figure 1: Key components of ISO 14001 system**



## 3.1 The National Nuclear Regulator Act (Act no 47 of 1999)/ The Nuclear Energy Act (Act no 131 of 1993)

The legislative structure consists of three levels. The first level is the basic law (NNRA or NEA) that establishes the regulatory body and defines its scope, functions, duties and powers. At the second level are the regulations and standards relating to this Act and the authorisations or licenses issued in terms of these regulations. The third level consists of the advisory documents such as the licensing documents, licensing guidelines and licence specific procedures compiled by the licence holder. (These documents become mandatory when included in a Nuclear Licence.)

According to the NEA no person shall, except under the authority of a nuclear licence granted to such a person carry out activities involving radioactive material, which is capable of causing nuclear damage. (It is foreseen that this Nuclear Licences will be replaced by Nuclear Authorisations under the NNRA.)

Organisations such as gold mines, minerals sands processors, etc., carrying out these activities with radioactive material must apply for a Nuclear Licence in accordance with the provisions of the NEA.

The conditions of licence are structured in a standard format addressing ten particular areas. Each area has its own requirements. These are described in licensing documents known as LD-documents, which form part of the licence and are therefore mandatory.

Licence guides (LG) are also issued to licensees but only serve as guidance documents. These documents provide additional information to licensees on how best to compile licence specific procedures.

Licensees are also required to compile procedures that describe how compliance to requirements will be achieved. These procedures become licence documents when approved by the Regulator. This approach to licensing allows organisations to address issues in a licence specific manner and provides for a degree of flexibility.

Paragraphs 3.1.1.1 to 3.1.1.10 give a brief summary of the standard licence conditions (see also Appendix I).

#### 3.1.1.1 Scope

All areas under direct control of the licensee on which activities with radioactive material are carried out must be identified.

#### 3.1.1.2 Quantitative hazard assessment

Licensees are required to conduct quantitative assessments of the radiation hazards associated with their operation to, as appropriate, the underground workforce, surface workers and to the public. These assessments become licence-binding documents and are incorporated into the organisation's nuclear licence.

Hazard assessment must subsequently be maintained and revised on a regular basis.

#### 3.1.1.3 Operational limitations

Two specific operational limitations are currently placed on licensees prior to the establishment of a radiation protection programme:

- demolition and disposal of contaminated plants e.g. uranium and acid plants
- major maintenance of such plants

#### 3.1.1.4 Operational radiation protection

On the basis of the hazard assessments, operational radiation protection programmes are established commensurate with the nature, extent and magnitude of

the hazard. These programmes must ensure compliance with the radiation dose limitation systems, which is embodied in LD-1074.

The radiation protection programme in respect of the workforce must comply with the requirements of LD-1085.

Control and monitoring of contaminants into the public domain, resulting in a dose to the members of the public and contamination of the environment must be established according to LD-1086. Environmental monitoring programmes must complement this to demonstrate their effectiveness.

#### 3.1.1.5 Radioactive Waste Management

The establishment of a waste management programme in accordance with LD-1087, which systematically identifies, characterises, processes and disposes of waste generated by the activity, is required.

This programme must not only address operational waste arising, but also the decommissioning and closure of sites.

#### 3.1.1.6 Transportation

A programme to demonstrate that waste products and components arising from the licensed site, which is potentially contaminated with radioactive material, are transported according to the IAEA Regulations for the Safe Transport of Radioactive Material is required.

#### 3.1.1.7 Physical Security

A physical security system must be in place to prevent unauthorised access to radiological controlled areas and to prevent the unauthorised removal of such material.

#### 3.1.1.8 Occurrences

A system to identify, categorise and report occurrences to the regulator and management must be compiled according to LD-1082 and LD-1089.

#### 3.1.1.9 Quality Management

Licensees are required to establish a formalised quality management system, in accordance with LD-1084, in order to provide an assurance of ongoing compliance with conditions on site. It is important to note that the Regulator requires organisations to follow a system approach to management. LD-1084 identifies the interrelated processes for the required management system.

(This condition is of specific relevance to this study in that it requires a formalised QMS to be implemented. The requirements contained in especially LD-1084 will therefore be investigated in more detail in Chapters 4, 5 and 6.)

#### 3.1.1.10 Scheduling

In view of the retrospective nature of the licensing process (facilities such as gold mines were in operation long before the NEA became applicable to the industry), licensees are required to establish schedules to demonstrate the time scales in which the required programmes will be developed and implemented.

### 3.1.2 LD-1084

***( Quality Management Requirements for Activities Involving Radioactive Material: Mining and Minerals Processing) - Core Elements***

Condition 3.1.1.9 of the nuclear licence requires that all activities carried out within the scope of a licence, shall be subject to the requirements of the QMP described in LD-1084 revision 3: Quality management requirements for activities involving radioactive material: Mining and Minerals Processing. Only the core elements of this document are listed (LD-1084 is attached as Appendix III).

- Responsibility
- Management Policy and Quality Management Programme
- Management Review
- Organisation
- Quality Management Document
- Document Control
- Design
- Process Control
- Inspection and Testing
- Corrective Action
- Records
- Audits and Surveillance

### 3.1.3 Compliance

*Inspections* are carried out on a regular basis. During the inspection facility operations are observed, workplace and environmental monitoring programmes are reviewed and corresponding records are inspected to determine compliance with regulatory requirements.

*Audits* are conducted at defined intervals or when deemed necessary when indications are found of management system problems. The purpose of auditing is to assess the effectiveness of the QMS and to identify possible breakdowns and deficiencies in operating practices and management system application.

Licensees are also requested to submit annual and quarterly reports to the Regulator as proof of compliance.

## 3.2 The Hazardous Substances Act (Act no 15 of 1973): Regulations relating to Group IV Hazardous Substances

The Directorate is responsible for administering the legislation contained in the Regulations relating to Group IV Hazardous Substances (Group IV HS) published in 1993. The Regulations contain detailed instructions to make the Hazardous Substances Act effective, and have the same legal force as the Act itself.

The legislative structure consists also of three levels, similar to that of the structure used by the Regulator. The first level is the law (e.g. Hazardous Substances Act, 1973), that establishes the regulatory body and defines its scope, functions, duties and powers. At the second level are the regulations relating to this Act and the authorisations issued in terms of these regulations. On the third level are the advisory documents such as the Codes of Practice, which are usually mandatory.

### 3.2.1 Licensing Process

It is the obligation of any person carrying out activities with Group IV HS, to apply for an authority to work with this material. The Regulations consist of a number of general application regulations. The Regulations also require that components of a QMS be implemented, such as administrative and reporting requirements. However, it does not require the implementation of a formalised QMS and therefore does not follow a system approach to quality management.

The Directorate also has the authority to compile any other condition with regard to a specific authority. These conditions are normally contained in a Code of Practice. These documents are usually issued with an authority and describe the minimum requirements necessary to ensure compliance to the regulations.

### 3.2.2 Components of QMS contained in Regulations and accompanying Codes of Practice

As stated earlier, the Directorate does not require in its regulations that an authority holder must implement a quality management system. However, components of quality management requirements are integrated in the Regulations and its accompanying Codes of Practice. These will be discussed in more detail in Chapter 4 and will be identified according to the Core Elements of ISO 14001 (see Appendix II).

### 3.2.3 Compliance

*Inspections* are carried out on a regular basis. During the inspection facility operations are observed, workplace and environmental monitoring programmes are reviewed and corresponding records are inspected to determine compliance with regulatory requirements.

Licensees are also requested to submit annual and quarterly reports to the Directorate as proof of compliance.

# CHAPTER 4 COMPARISON BETWEEN MANAGEMENT SYSTEMS REQUIRED BY ISO 14001, NEA NO 131 AND BY REGULATIONS RELATING TO GROUP IV HAZARDOUS SUBSTANCES

## 4.1 Method of Comparison

Benefits and Specific Objectives for each management system were identified and are listed in Tables 4.1, 4.2 and 4.3. Benefits are those outcomes that will be achieved by having the total management system in place. Specific Objectives are identified according to the Core Elements of the ISO 14001 system. The author determined these benefits and objectives by using various publications, including Internet documents (SASOL SYNTHETIC FUELS, 1999; EPA, 2000; Gonzales et al.:, 2000).

Benefits and objectives of the different management systems will be compared to identify areas of similarities and dissimilarities.

## 4.2 ISO 14001 EMS compared to LD-1084 and the regulations of Group IV Hazardous Substances

### 4.2.1 Benefits

| *No | ISO14001 | QMS REQUIREMENTS OF REGULATOR | REGULATIONS RELATED TO GROUP IV HS |
|---|---|---|---|
| 1 | Proof of organisation's commitment to *responsible care* of the environment. | The required policy describes organisation's commitment to comply with requirements. | Regulator does not require a formalised QMS. |
| 2 | The *efficient management* of all environmental obligations through a systematic approach to planning, controlling, measuring and improving all environmental matters. | The *efficient management* of all regulatory obligations through a systematic approach to planning, controlling, measuring and improving all radiation matters. | The *efficient management* of all regulatory obligations through a systematic approach to planning, controlling, measuring and improving all radiation matters. |
| 3 | To achieve compliance with all regulations. | To achieve compliance with all requirements pertaining to radiation. | To achieve compliance with all regulations pertaining to radiation. |
| 4 | A dynamic management tool to ensure *continual improvement.* | A dynamic management tool to ensure the ALARA principle could be achieved. | Regulator does not require a formalised QMS. Therefore a dynamic management tool will not be developed. |
| 5 | An *understandable and practical system* to ensure employee involvement and commitment. | Limited to employees exposed to ionising radiation. | Limited to employees exposed to ionising radiation. |
| 6 | To provide documented evidence of compliance to regulations and commitments. | To provide documented evidence of control over activities with radioactive material. | To provide documented evidence of control over activities with radioactive material. |
| 7 | Proof of organisation's commitment to prevent pollution. | Do not address prevention of pollution. Pollution allowed within limits determined by regulator. | Do not address prevention of pollution. Pollution allowed within limits determined by regulator. |

*The numbering used is that of the benefits identified by the author of this document.

## 4.2.2 Specific Objectives: A comparison between ISO 14001 EMS and the QMS of the Regulator

| *ISO 14001 EMS* | | | *Regulator's requirements* | | |
|---|---|---|---|---|---|
| ***No*** | ***Core Element*** | ***Objective of Core Element*** | *****Number*** | ***Core Element*** | ***Objective of Core Element*** |
| 1.1 | Environmental Policy | To ensure Management's commitment.<br>To *support the mission and goals* set by the organisation in the environmental sphere.<br>(*these goals include principles, objectives and targets) | Condition 3 of LD-1084 | Responsibility | Ensure Management's commitment to radiation protection. |
| | | | Condition 4 and 7 of LD-1084 | Management and QMP | Ensure implementation of QMP.<br>To ensure a safety and environmental protection policy, supported by a documented QMP exist, which are binding on all levels of management.<br>Quality objectives related to radiation protection are stated. |
| 1.2 | Planning | The *efficient management* of all environmental obligations through a systematic approach to planning, controlling, measuring and improving environmental matters.<br>Impacts will be controlled in a *cost-effective* manner. | Condition 1.2.1 of Nuclear Licence | Assessments | Assessments in respect of all operations and activities relating to radioactive material, which could give rise to a risk of nuclear damage, must be conducted. |
| | | | Condition 9 of LD-1084 | Design | That any change in equipment, item or activity having an affect on radiation protection is systematically evaluated according to approved procedures.<br>That competent personnel evaluate and execute these changes.<br>The impact on radiation protection due to changes in equipment configuration; operational procedures and |

| | | | | | |
|---|---|---|---|---|---|
| | | | Condition 10.2.2 | Process Control | schedules are evaluated.<br><br>Procedures describing the modus operandi and acceptance criteria must be compiled. This requirement requires analysis and planning of all operations. |
| 1.2.1 | Environmental Aspects | *All* environmental obligations will be identified and more *efficiently* met, and in so doing will save costs. | Condition 1.2.1 of Nuclear Licence | Assessments | See 1.2 |
| 1.2.2 | Legal/Other requirements | To comply with *all* regulations pertaining to the environment. | | | Requirements are limited to the NNRA. |
| 1.2.3 | Objectives and Targets | To *move beyond compliance.*<br>To improve environmental performance continuously. | Condition 1.1.2 of LD-1074<br><br>Condition 4.1 of LD-1084 | Dose limitation programme<br><br>Quality Management Programme | All doses received must be kept as low as reasonably achievable (ALARA) or optimised. A statement of intent is also acceptable.<br><br>Written policy with quality objectives must be compiled. |
| 1.2.4 | Environmental Programme | The design and implementation of *improvement programmes* e.g. pollution prevention programmes. | Condition 1.1.2 of LD-1074<br><br>Condition 4.1 of LD-1084 | | The design and implementation of *programmes* how the ALARA principle will be met is not required.<br><br>Written policy with quality objectives must be compiled. |
| 1.3 | Implementation and Operation | To ensure that *continual improvement* of environmental impacts are achieved, to *prevent* | Condition 10 | Process Control | To achieve compliance to requirements relating to radiation protection. |

| | | | | | |
|---|---|---|---|---|---|
| | | *pollution*, to *achieve compliance* with all relevant legislation. | | | To optimise radiation impacts by minimising doses to the public. |
| 1.3.1 | Structure and Responsibility | Ensure that each employee is aware of his *roles, responsibilities and position* in the organisational structure regarding environmental performance. | Condition 6 of LD-1084<br><br>Condition 1.2 of LD-1085 | Organisation<br><br>Organisation | To identify and document responsibilities, functional roles levels of authority, and lines of external and internal communication.<br><br>To ensure the RP function has sufficient authority and independence to stop unsafe operations.<br>To ensure that adequate competent, qualified and trained staff is available to execute the RP Function. |
| 1.3.2 | Training and Awareness | To ensure employee involvement by working in an environmentally conscious way.<br>To ensure employees are able to *react to, prevent and minimise* environmental aspects.<br>To ensure *employees support* the environmental policy. | Condition 7 of LD-1085 | Training of OEP's | OEP's must be trained in:<br>• nature of radiation hazards<br>• *principles of radiation protection*<br>• site specific procedures controlling radiation hazards<br>This is to ensure awareness and competency to manage radiological impacts. |
| 1.3.3 | Communications | Improve *public opinion* and awareness.<br>Improve employee awareness and commitment. | Condition 6 of LD-1084 | Organisation | To ensure lines of external and internal communication exist. |
| 1.3.4 | Environmental Documentation | To ensure that a documented, systematic, accessible and practical system is available. | Conditions 3, 8 and 10.2 of LD-1084 | Document Control | To ensure that all activities related to radiation protection are carried out through the proper use of procedures.<br>To establish a documented and authorised programme |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | designed and documented by competent and qualified personnel.<br>To ensure regular reviews of the documents take place. |
| 1.3.5 | Document Control | Provide evidence of environmental programme to managers, employees, regulators and public.<br>Ensure efficient, documented system of control over all environmental documents. | Condition 8 of LD-1084<br><br>Conditions 2.4 and 3.5 of LD-1086 | Document Control | To ensure the QMP includes administrative and functional controls.<br>To ensure the existence of an efficient, documented document control system applicable to all documents related to radiation protection.<br><br>To ensure adequate records are kept and submitted to regulator. |
| 1.3.6 | Operational Control | *All* aspects of normal operational conditions that could have an effect on the environment are identified and controlled by procedures. | Condition 9 and 10 of LD-1084 | Process Control | To ensure all areas of control over radioactive material are identified and planned.<br>To ensure documents contain the necessary information to make it effective.<br>To ensure compliance is achieved in all areas related to radiation protection through using authorised procedures and instructions. |
| 1.3.7 | Emergency Preparedness | All aspects of foreseen accidents and disasters can be controlled. | Condition 4.3.8 of Nuclear Licence | Occurrences | A system to identify, categorise and report non-conformities and occurrences to management and the regulator must be compiled |
| 1.4 | Checking and Corrective | A dynamic feedback system to ensure | Condition 12 of | Corrective Action | Measures must be established, documented and |

| | | | | | |
|---|---|---|---|---|---|
| | Action | *continual improvement, prevention of pollution and compliance with legal requirements and the policy.* | LD-1084 | | authorised to ensure that any matter adverse to quality are promptly identified, corrected and recorded. |
| 1.4.1 | Monitoring and Measurement | Ensure that all appropriate data is collected and interpreted.<br>To ensure all equipment is functioning according to specifications. | Condition 11 of LD-1084 and *condition 6 of* LD-1085 | Inspection and Testing | To ensure systems and equipment function according to specifications and to verify the operating status of these systems to prevent their inadvertent operation and use.<br>To ensure equipment are calibrated and adjusted according to nationally recognised standards. |
| | | | Condition 5 of LD-1085 | Radiation Surveillance Program | An approved, documented Radiation Surveillance Programme is required. |
| 1.4.2 | Non-conformance and Corrective / Preventative Action | To prevent the recurrence of incidents and accidents.<br>To verify that activities are carried out according to documented instructions and programmes. | Condition 11 of LD-1084 | Inspection and Testing | To verify that activities are carried out according to instructions and procedures.<br>To ensure deficiencies and non-conformities are promptly identified and evaluated and appropriately documented. |
| | | | Condition 12 of LD-1084 and LD-1082 | Corrective Action | Measures must be established, documented and authorised to ensure that any matter adverse to quality is promptly identified, corrected, reported and recorded. This also acts as preventative action to avoid non-conformities. |
| 1.4.3 | Records | Provide evidence of environmental programme to managers, employees, regulators and public. | Condition 13 of LD-1084 | Records | To ensure the existence of an effective documented administration system to manage records. |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | That records are created, stored and maintained.<br>That QM records are legible and traceable to the item, equipment or activity involved.<br>To demonstrate the effective operation of the quality system.<br>To demonstrate compliance to regulating requirements. |
| 1.4.4 | EMS Audits | A dynamic tool to determine the effectiveness of the EMS. | Condition 14 of LD-1084 | Audits and Surveillance | To ensure that the QMP is implemented and effective in all areas.<br>To determine status of compliance with the QMP.<br>To ensure audits and surveillance are performed regularly and systematically.<br>To ensure that audit results are regularly reviewed. |
| 1.5 | Management Review | To determine the suitability, adequacy and effectiveness of the EMS.<br>To ensure management's involvement.<br>To ensure management's awareness of current status of compliance.<br>To ensure improvement over control. | Condition 5 of LD-1084 | Management Review | To determine the suitability, adequacy and effectiveness of the EMS.<br>To ensure management's involvement.<br>To ensure management's awareness of current status of compliance.<br>To ensure improvement over control. |

* *The numbering used is the same as in Appendix II: Core Elements of ISO14001.*

** *The numbering used is the same as in LD-1084.*

| 4.2.3 Specific Objectives: A comparison between ISO 14001 EMS and the QMS requirements of the Directorate | | | | | |
|---|---|---|---|---|---|
| *ISO 14001 EMS* | | | *Department of Health: Directorate Radiation Control* | | |
| **No* | *Core Element* | *Objective of Core Element* | ***Number* | *Core Element* | *Objective of Core Element* |
| 1.1 | Environmental Policy | To ensure Management's commitment.<br>To *support the mission and goals* set by the organisation in the environmental sphere.<br>(*these goals include principles, objectives and targets) | Not required | Not required | A specific company Policy is not required in the Regulations. |
| 1.2 | Planning | The *efficient management* of all environmental obligations through a systematic approach to planning, controlling, measuring and improving environmental matters.<br>Impacts will be controlled in a *cost-effective* manner. | Condition 22 (1)<br><br>Condition 24 (1) | Estimation of potential doses<br><br>Assessments of hazards | All potential doses to which an employee or visitor to the site might be exposed, must be assessed.<br><br>The magnitude and nature of any radiation hazard to any person must be assessed before work with radioactive material is commenced. |
| 1.2.1 | Environmental Aspects | *All* environmental obligations will be identified and more *efficiently* met, and in so doing will save costs. | Condition 24 (1) | Assessments of hazards | See 1.2<br>The Directorate assists the authority holders by identifying the different components of the organisation's obligations that require planning e.g.:<br>♦ Emergency Procedures<br>♦ Equipment Safety specifications<br>♦ Transportation<br>♦ Storage Requirements<br>♦ Disposal and Transfer of Sources<br>Site specific requirements must be described in the company's Internal Rules. |
| 1.2.2 | Legal/Other requirements | To comply with *all* regulations pertaining to the environment. | | | Requirements are limited to the conditions of the Hazardous Substances Act. |
| 1.2.3 | Objectives and Targets | To *move beyond compliance*. | Condition 2.1 (b) of | | Organisations are not required to formulate additional |

| | | | | | |
|---|---|---|---|---|---|
| | | To improve environmental performance continuously. | Code of Practice: Ionising Radiation Dose Limits and annual limits of intake of radioactive material | | objectives and targets besides those contained in the Regulations and Codes.<br>Doses must be optimised according to the ALARA principle. Authority holders are not required to compile programmes to demonstrate how the ALARA objective will be met. |
| 1.2.4 | Environmental Programme | The design and implementation of *improvement programmes* e.g. pollution prevention programmes. | Not required | | The organisation is required to compile Internal Rules that is site specific. However, these rules focus on human health.<br>The design and implementation of *programmes* of how the ALARA principle will be met are not required. |
| 1.3 | Implementation and Operation | To ensure that *continual improvement* of environmental impacts are achieved, *to prevent pollution*, to *achieve compliance* with all relevant legislation. | | | To achieve compliance to requirements relating to radiation protection. |
| 1.3.1 | Structure and Responsibility | Ensure that each employee is aware of his roles, responsibilities and position in the organisational structure regarding environmental performance. | Condition 5<br><br>Condition 28 | Responsibilities<br><br>Advisors | Appointment of at least RPO and acting RPO. The authority holder can delegate all legal responsibilities to these individuals.<br>The Directorate might require that an authority holder appoint a radiation protection advisor in special circumstances. |
| 1.3.2 | Training and Awareness | To ensure employee involvement by working in an environmentally conscious way.<br>To ensure employees are able to *react to, prevent and minimise* environmental aspects.<br>To ensure *employees support* the environmental policy. | Condition 5 (iii) | Training employees who work with radiation | All persons who handle radioactive material must be informed of:<br>• health and safety measures of these substances;<br>• user guidelines applicable to the substance.<br>*(Exception: in the case of Industrial Radiography the Directorate specifies more extensive requirements.)* |

| | | | | | |
|---|---|---|---|---|---|
| 1.3.3 | Communications | Improve *public opinion* and awareness. Improve employee awareness and commitment. | Condition 5 (iii) | Employee training and awareness | All persons who handle radioactive material must be informed of:<br>• health and safety measures of these substances;<br>• user guidelines applicable to the substance.<br>No requirements are specified in terms of the public, except for visitors visiting the site. |
| 1.3.4 | Environmental Documentation | To ensure that a documented, systematic, accessible and practical system is available. | Condition 7 | Internal Rules | Site specific rules must be compiled, specific to circumstances on site. This must include safe systems of work that will restrict exposure. |
| 1.3.5 | Document Control | Provide evidence of environmental programme to managers, employees, regulators and public. Ensure efficient, documented system of control over all environmental documents. | Conditions 9 and 10 | Records and Safekeeping of records and registers | Only the following is specified:<br>• specified documents must be available on site;<br>• to ensure adequate records are kept and submitted to regulator;<br>• safekeeping of records for specified time;<br>• inspection purpose: employees or inspector.<br>A documented system of how documents will be controlled is not required. |
| 1.3.6 | Operational Control | *All* aspects of normal operational conditions that could have an effect on the environment are identified and controlled by procedures. | See 1.3.4 | See 1.3.4 | See 1.3.4. Internal Rules are enforceable as operational and occupational conditions. |
| 1.3.7 | Emergency Preparedness | All aspects of foreseen accidents and disasters can be controlled. | Applicable Code of Practice | Emergencies | The Directorate specifies the requirements. However, site specific issues must be addressed in the Internal Rules. |
| 1.4 | Checking and Corrective Action | A dynamic feedback system to ensure *continual improvement, prevention of pollution and compliance with legal requirements and the policy.* | Condition 26 (b) | Checking and Corrective Action | The holder of the authority has the ultimate legal responsibility. However, he can delegate responsibilities to the RPO. Condition 26 (b) states that the RPO must ensure that the provisions of the regulations and conditions in the authority are complied with. No further requirements are specified. |
| 1.4.1 | Monitoring and Measurement | Ensure that all appropriate data is collected and interpreted. | Condition 5 (b)ii | Technical surveys | Technical surveys must be conducted to ensure reliability and general technical excellence of equipment. |

| | | | | | |
|---|---|---|---|---|---|
| | | To ensure all equipment is functioning according to specifications. | Condition 11<br><br>Condition 22 | Monitoring<br><br>Dose Limits | Radiation levels and contamination must be measured. Monitoring equipment must be calibrated.<br><br>All registered workers must where a dosimeter. These dosimeters must be replaced and analysed on regular, prescribed intervals. |
| 1.4.2 | Non-conformance and Corrective / Preventative Action | To prevent the recurrence of incidents and accidents.<br>To verify that activities are carried out according to documented instructions and programmes. | Condition 25<br><br>Condition 26 (b), (c) | Investigation and notification of overexposure<br><br>RPO's responsibilities | Where employer suspects that person has probably been over-exposed, an investigation must be conducted. This must be reported to the Directorate.<br><br>RPO must ensure provisions of regulations and conditions are complied with. He must inform the authority holder of any radiation incident or over-exposure. |
| 1.4.3 | Records | Provide evidence of environmental programme to managers, employees, regulators and public. | Conditions 6(5), 9, 11(c), 14(1), 15, 22 (6) and 25(2). | Records and Registers | The Directorate specifies the different records that must be kept, e.g. appointment records, stock records, dose records, register of all radiation workers, medical records, etc. |
| 1.4.4 | EMS Audits | A dynamic tool to determine the effectiveness of the EMS. | See 1.4. | See 1.4. | See 1.4. |
| 1.5 | Management Review | To determine the suitability, adequacy and effectiveness of the EMS.<br>To ensure management's involvement.<br>To ensure management's awareness of current status of compliance.<br>To ensure improvement over control. | Condition 25 (1) | Investigations into overexposures | The employer is only responsible to conduct an investigation when a suspected overexposure has occurred. This must be notified and reported to the Directorate. |

* *The numbering used is the same as in Appendix II: Core Elements of ISO14001.*

** *The numbering used is the same as in the Regulations pertaining to the Hazardous Substances Act published in Government Gazette No 14596 dated 26 February 1993.*

In Chapter 4 Benefits and Specific Objectives for each management system were identified and listed in Tables 4.1, 4.2 and 4.3. Benefits are those outcomes that will be achieved by implementing all the components of the total management system. Specific Objectives are identified according to the Core Elements of the ISO 14001 system. The author determined these objectives by using various publications, including Internet documents (SASOL SYNTHETIC FUELS, 1999; EPA document, 1998; Gonzales et al., 2000).

The comparisons made in tables 4.2.1 to 4.2.3 will be analysed and discussed in this chapter. The management system requirements of the Regulator will be compared to those contained in the ISO 14001 EMS. Separate from that, the management system requirements of the Directorate will be compared to those contained in the ISO 14001 EMS. Inter-comparisons of the Regulator's requirements and those of the Directorate will not be done.

## 5.1 Benefits: A discussion of the comparisons made in table 4.2.1

### *5.1.1 Benefit 1*

*(Proof of organisation's commitment to responsible care of the environment)*

***Regulator:***

The implementation of the Regulator's QMS will demonstrate that the organisation is committed to achieve compliance with the Regulator's requirements. This will be achieved by defining quality objectives and through the design and implementation of a quality management programme. It differs from ISO 14001 in that its scope is limited to radiological matters, with its focus on mainly human health. ISO 14001 requires that all aspects of the environment will be considered, with its focus on the quality of the environment and not human health. ISO 14001's scope and application are therefore different from that of the Regulator's QMS.

***Directorate:***

The Directorate does not require that a formalised QMS with all its components be implemented. It specifies components of a QMS that need to be implemented. Important components of a QMS, such as defining a policy and the management review of compliance with regulations, are not

required. One of the most important purposes of a policy statement is to define quality objectives for the organisation. These objectives demonstrate an organisation's, and especially management's, commitment to comply with regulations. It also requires a commitment from all levels inside the organisation. Therefore there is a significant difference between this benefit, the benefit of commitment, and that of the ISO 14001 system and the requirements of the Regulations on the Group IV Hazardous Substances.

### *5.1.2 Benefit 2*

*(The efficient management of all environmental obligations through a systematic approach to planning, controlling, measuring and improving environmental matters)*

***Regulator:***

By implementing the Regulator's QMS the organisation could also achieve a systematic approach to planning, controlling, measuring and improving radiation related matters. This will also result in the efficient management of radiation related obligations. This benefit is therefore similar for the two management systems.

***Directorate:***

The Directorate does not require a system approach to management. However, some components of a QMS are required. These components require a systematic approach to controlling radiological obligations. The Directorate therefore has less stringent requirements compared to the Regulator or ISO 14001 EMS. This is especially true in the areas of commitments made by management, controlling and improvement of radiation matters. This could result in less efficient control over radiological obligations. Therefore there is a significant difference between this benefit (the benefit of efficiency) of the ISO 14001 system and the requirements of the Regulations on the Group IV Hazardous Substances.

### *5.1.3 Benefit 3*

*(To achieve compliance with all regulations)*

***Regulator:***

The QMS of the Regulator has the same benefit as the ISO 14001 EMS.

***Directorate:***

The requirements of the Directorate have the same benefit as the ISO 14001 EMS.

### *5.1.4 Benefit 4*

*(A dynamic management tool to ensure continual improvement)*

***Regulator:***

The QMS of the Regulator will have the same benefit as the ISO 14001 EMS. This is to follow a system approach to management and, in doing so, to provide a dynamic management tool, to manage radiological obligations and to adhere to the ALARA principle. This benefit is also similar for both systems in terms of the optimisation of control.

***Directorate:***

The Directorate does not require a formalised and complete management system that will result in this benefit. This benefit will only be partially met, due to the fact that only components of a management system are required. Therefore there is a difference between this benefit of the ISO 14001 system and the requirements of the Regulations on the Group IV Hazardous Substances.

### *5.1.5 Benefit 5*

*( An understandable and practical system to ensure employee involvement and commitment)*

***Regulator:***

This benefit is similar for the two management systems. Employee involvement and commitment on all levels of the organisation are therefore required. However, the Regulator's QMS is restricted to employees exposed to radiation. It must be noted that the Regulator's mandate is only the regulation of activities carried out with radioactive material and it could

therefore be argued that the Regulator's responsibility should not extend further than those employees affected by these activities.

***Directorate:***

The Directorate does not require a complete management system to be implemented. The employee's understanding of the management system, employee involvement at all levels of the organisation and their commitment to radiological obligations are therefore not required. It is also possible to delegate the responsibilities in terms of radiological obligations to individuals, e.g. the RPO or acting RPO. Therefore there is a significant difference between this benefit of the ISO 14001 system and the requirements of the Regulations on the Group IV Hazardous Substances.

### 5.1.6 *Benefit 6*

*(To provide documented evidence of compliance to regulations and commitments)*

***Regulator:***

This benefit is similar for both systems.

***Directorate:***

This benefit is similar for both systems.

### 5.1.7 *Benefit 7*

*( Proof of organisation's commitment to prevent pollution)*

***Regulator:***

The Regulator allows pollution within specified limits on a licensed site. These limits are based on the requirement that the dose to the public (i.e. humans) is restricted. However, on a non-licensed site the Regulator requires that contamination is cleaned down to background levels. The two management systems differ in this benefit.

***Directorate:***

The Directorate does not address pollution prevention and allows pollution within specific limits, similar to that required by the Regulator. The two management systems differ on this benefit.

## 5.2 Specific objectives: A discussion of the comparisons made in tables 4.2.2 and 4.2.3.

### 5.2.1 Policy

***Regulator:***

The quality statements in the Policy required by both systems have different objectives and minimum requirements. The ISO14001 EMS requires as a minimum a commitment to *compliance with all relevant environmental laws and regulations*, *prevention of pollution* and to *continual improvement* in environmental impacts.

The only requirement of the Regulator is that the Policy statement contains quality objectives that will be met during all phases of operation, which include demolition and end of life-cycle events. It corresponds in that it requires compliance to laws and regulations, but differs in that the objective of pollution prevention and continual improvement are not required. However the ALARA principle required by the Regulator contains the concept of optimisation, which requires improvement and development. "Continual improvement" and optimisation do not imply that the same outcome will be reached.

The objective of pollution prevention mentioned in ISO14001 could be adopted by the QMS requirements of the Regulator.

***Directorate:***

A Policy stating the organisation's commitments to radiological protection is not required. This could lead to a lack of management's commitment to radiological protection. The Regulations make it possible that Management can delegate all responsibilities to the RPO or acting RPO.

This can result in a lack of participation from Management, inadequate provision of resources, or lack of support in control through all levels of the organisation. In the ISO14001 the responsibility of management is dispersed throughout the whole organisation. This results in better interaction between different levels in the organisation, which results in more creativity, initiative and support in resolving problems and achieving compliance. The lack of a policy statement is therefore a significant difference from the ISO 14001 system requirements.

### 5.2.2 Planning

***Regulator:***

Both systems require assessments and the planning of hazards during all phases of operation, shutdown and decommissioning. Quality objectives are also required in terms of the organisation's policy statement.

***Directorate:***

The Codes of Practice published by the Directorate provides comprehensive information on the specific requirements laid down in its regulations. These documents provide detailed instructions on what the different regulations require and how it must be implemented. It serves as minimum requirements of the Directorate in order for an organisation to achieve compliance.

Due to the comprehensive information provided by the Directorate in the Codes of Practice, limited additional planning of radiation protection matters by organisations is required, except on how to make these requirements site specific. However, due to the omission of requiring a quality policy, quality objectives that will improve the safety culture in an organisation, might not be identified.

#### 5.2.2.1 Environmental Aspects

***Regulator:***

The ISO14001 requires that all environmental aspects must be identified by the organisation. The Regulator requires that any potential radiation hazards to persons; the public and property are identified, with emphasis on human health. These objectives are compatible if the ISO14001 EMS is generalised to include workers health and safety and the Regulator puts more emphasis on the protection of the environment.

***Directorate:***

The ISO14001 requires that all environmental aspects must be identified by the organisation. The Directorate requires that all potential doses to employees or visitors to the site must be assessed, before work with radioactive material commences. The emphasis is also on human health, similar to that of the Regulator. These objectives are compatible if the ISO14001 EMS is generalised to include workers health and safety, and the Directorate puts more emphasis on protection of the environment.

#### 5.2.2.2 Legal and Other Requirements

***Regulator:***

The ISO14001 requires that all regulations and laws relevant to the environment are identified and complied with. The Regulator limits itself to the laws and regulations on radioactive material. It must be noted that the mandate of the Regulator is to control activities carried out with radioactive material. Compliance to all other regulations and laws are therefore not the Regulator's concern.

***Directorate:***

The ISO14001 requires that all regulations and laws relevant to the environment are identified and complied with. The Directorate limits itself to the laws and regulations on radioactive material. It must be noted that the mandate of the Directorate is to control activities carried out with radioactive material. Compliance to all other regulations and laws are therefore not the Directorate 's concern.

#### 5.2.2.3 Objectives and Targets

***Regulator:***

As mentioned before, the objectives and targets of the ISO14001 is aimed at "moving beyond compliance" towards "continual improvement". The organisation is required to define specific objectives and targets in this regard. These objectives and targets must be specific enough to form the basis for definite action and support objective evidence of improvements.

The principles specified by the Regulator are that all practices must be justified, doses to individuals must be kept within specified dose limits and that a licensee must strive to keep doses ALARA (optimisation). Objectives and targets could be formulated in a general manner. Specific programmes and procedures to ensure that the ALARA principle is met are not required. There is therefore a difference between the objectives of the different systems in this area.

***Directorate:***

No specific objectives or targets in respect of control are required, except compliance to all regulations. A general objective is to keep doses as low as reasonably achievable (ALARA) and that all practices are justified. A programme providing detail on how this objective will be met is not required. This area contains differences between the objectives of the different systems.

#### 5.2.2.4 Environmental Management Programmes

***Regulator:***

The ISO14001 EMS requires environmental programmes describing how improvement in environmental impacts will be achieved, even if compliance to all laws and regulations had been reached. This could be seen as an optimisation process. The Regulator requires that the ALARA principle will be implemented. Specific programmes that describe how this will be

met are not required. The requirement of "continual improvement" and the ALARA principle is therefore similar in that both contain elements of development and improvement. However, these two principles will not necessarily result in the same outcome.

***Directorate:***

The ISO14001 EMS requires environmental programmes describing how improvement in environmental impacts will be achieved, even if compliance to all laws and regulations had been reached. Although the Directorate requires that the ALARA principle will be implemented, no formalised programmes on how this will be achieved are required. The requirement of "continual improvement" and the ALARA principle is therefore similar in that both contain elements of development and improvement. However, these two principles will not necessarily result in the same outcome.

### 5.2.3 Implementation and Operation

***Regulator:***

This component of the ISO14001 is aimed at ensuring that the principles *continual improvement, prevention of pollution and achieving compliance* to laws and regulations are achieved.

The requirement of "continual improvement" and the ALARA principle are similar in that both contain elements of development and improvement. However, these two principles will not necessarily result in the same outcome. The justification principle of radiation protection, however, allows for pollution within specified limits, but does not address all the aspects of pollution prevention. Furthermore, the justification of a practice is not always based on pure radiological concerns and the regulator is often restricted by other concerned parties in its decision making process. The final judgement is often made by the government and not by the regulator, although the regulator has an important say in the matter. For instance, the government can decide that a practice can continue for economical reasons or social

reasons, such as job creation, although the radiological consequences are not justified. This area contains differences between the objectives of the different systems

*The objective of compliance to laws and regulations are similar.*

***Directorate:***

The explanation given for the Regulator is also applicable to the Directorate.

#### 5.2.3.1 Structure and Responsibility

***Regulator:***

The ISO14001 requires that the organisational structure and responsibilities in terms of environmental performance must be identified. Each employee has a responsibility towards environmental matters.

The Regulator's QMS also requires the documented description of the organisational structure, but is limited to the management and workers affected by radiation hazards. Additional to this, the Regulator requires adequate competent, qualified and trained staff, who has sufficient authority and independence to stop unsafe operations. The independence of such a function is not a requirement of the ISO14001 EMS.

It should be mentioned that the additional requirements of the Regulator on the organisational structure are not specified in the quality management document LD-1084, but in LD-1085 (Requirements for the control of radiation hazards: Mining and Minerals processing).

The objective in terms of organisational structure specified by the two systems is therefore compatible.

***Directorate:***

The regulations allow that all responsibilities can be delegated to specific individuals. Such a

person is in control of all activities related to radiation. This corresponds to a command and control approach, where organisations only ensure that the minimum requirements set by the Directorate, are met. In the ISO14001 the responsibilities of management are dispersed throughout the whole organisation. This results in more inter-action between different levels in the organisation, which result in more creativity and initiative in resolving problems and achieving compliance. Responsibilities are so dispersed throughout the organisation. There are differences between the objectives of the different systems in this area.

#### 5.2.3.2 Training, Awareness and Competence of personnel

*Regulator:*

Both systems require training and awareness programmes. The main differences is that ISO14001 is limited to environmental matters whereas the Regulator's QMS is limited to workers and the public's health and safety in respect of radiation matters. Training and awareness programmes are also limited to workers whose work involves work with radioactive sources by the Regulator.

However, the use of radiation warning signs is mandatory and can be regarded as part of an awareness programme to all workers. The obligation is on the worker to inquire about the meaning and implication of the radiation warning sign. This can result in a lack of knowledge among the workers that are not directly working with radioactive material, on the safety and health consequences of exposure to radiation. There are differences between the objectives of the different systems in this area.

*Directorate:*

The explanation given for the Regulator is also applicable to the Directorate.

#### 5.2.3.3 Communication

*Regulator:*

The objective of the requirement on "Communications" of the ISO14001 EMS is different from that of the current QMS required by the Regulator. The ISO14001 EMS has clearer statements about communication. Its most important objective is to bring about transparency, improved public opinion and involve the view of interested parties. The Regulator's emphasis in communication, however, is the communication between the regulator and the regulated organisation.

It must be noted that the Regulator's emphasis on the requirement to improve public opinion has changed. It is foreseen that new requirements and conditions applicable to organisations carrying out activities with radioactive material must provide for public participation, transparency and accountability under the new NNRA. The ISO14001 EMS is therefore in line with the requirements of the new NNRA.

***Directorate:***

The objective of the requirement on "Communications" of the ISO14001 EMS is different from that of the requirements of the Directorate. The Directorate 's emphasis in communication however is the communication between the Directorate and the regulated organisation. The ISO14001 EMS has clearer statements about communication. Its most important objective is to bring about transparency, improved public opinion and involve the view of interested parties. This is not an objective of the Directorate. In this area significant differences between the objectives of the requirements exist.

#### 5.2.3.4 EMS Documentation

***Regulator:***

This objective is similar for both systems.

***Directorate:***

The ISO 14001 EMS objective is to provide a documented, systematic and accessible

system, which is practical to implement. No detail on the content of these documents is prescribed. The only requirement is that through implementing these documents compliance to laws and regulations will be achieved and pollution prevention and continual improvement will be achieved.

The Directorate provides comprehensive information on its requirements in its Codes of Practice. Little additional information is required, except on how to make these requirements site-specific. This site-specific information is addressed in the Internal Rules of the organisation. It should provide information in the following areas of control:

- Emergency Planning
- procedure to be followed in the case of a loss or theft of the source
- safe storage of the source
- safe handling of the source
- the procedure to be followed when an employee is pregnant
- safe transport of a source
- identification of all regulations applicable to the authority
- sell or disposal of a source
- description of all the RPO's responsibilities and duties
- Source Leak Tests
- Rdiation Warning Signs
- Stock Records (frequency of taking, requirements of content)

The Directorate does not require organisations to submit these documents for approval, but they must be available during inspections or when requested by the Directorate.

The ISO 14001 EMS requires that an organisation takes responsibility for the manner in which it will ensure compliance, while the Directorate has a more prescriptive approach on

how compliance should be achieved. Although the Directorate and the ISO 14001 EMS have the same objectives (that is compliance and improvement), the approach followed to achieve this differs.

#### 5.2.3.5 Document Control

*Regulator:*

The purpose of the two systems for implementing a document control system is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems for the control of documents are similar.

*Directorate:*

The Directorate 's requirements for a document control system are not as stringent as those of the ISO 14001 EMS. The most important objective is to ensure that records are available to provide evidence of compliance. The objective of internal control and distribution of documents within the organisation is not emphasised. There is a significant difference between the objectives for this requirement in the two systems.

#### 5.2.3.6 Operational Control

*Regulator:*

The purpose of the two systems by implementing an operational control process is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve operational control are similar.

*Directorate:*

The Directorate 's requirement for Internal Rules addresses this objective partially. However,

the Directorate does not emphasise that the organisation must ensure compliance through using authorised procedures and instructions. There is a difference between the objectives for this requirement in the two systems.

#### 5.2.3.7 Emergency Preparedness and Response

***Regulator:***

Both ISO14001 and the QMP of the Regulator require that emergency preparedness programmes must be addressed and formalised in documented programmes. This objective is similar for both systems.

***Directorate:***

Both the ISO14001 EMS and the Directorate require that emergency preparedness programmes must be addressed and formalised in documented programmes. This objective is similar for both systems.

### 5.2.4 Checking and Corrective Actions

***Regulator:***

The purpose of the two systems for implementing a checking and corrective action system is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve an effective system for checking and corrective actions are similar.

***Directorate:***

The Directorate allows that the organisation's management delegates its responsibility for checking and corrective actions to the RPO or acting RPO. A documented, comprehensive process is not required. The objective that a dynamic feedback system exists through all levels of the organisation is therefore not necessarily met.

External communications to the Directorate and public services, police and fire departments, are limited to emergencies or accidents. However, when contingency arrangements are planned it is the responsibility of the organisation to inform public services on how it plans to act and what the responsibility of the public service will be in such a situation.

Internal communications are limited to workers involved with radioactive sources. Other workers and the general public do not have to be informed. The objectives of these two systems are therefore not the same in this area.

#### 5.2.4.1 Monitoring and Measurement

*Regulator:*

This objective for both systems is similar.

*Directorate*

This objective for both systems is similar.

#### 5.2.4.2 Non-conformance and Corrective and Preventative Action

*Regulator:*

The purpose of the two systems for implementing such a system is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve an effective system for non-conformance, checking and preventative actions are similar.

*Directorate:*

Checking and Corrective Action programmes are the responsibility of only the RPO. Minimum

requirements are investigations into accidents; incidents and suspected overexposures are conducted. No formalised programmes on how Checking and Corrective Action programmes will be conducted are required (see also 5.2.4.). The objectives of these two systems are not the same in this area.

### 5.2.4.3 Records

***Regulator:***

The purpose of the two systems for implementing a record keeping system is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve an effective record keeping system to ensure the maintenance, storage and update of all required records, are similar.

***Directorate:***

The purpose of the two systems for implementing a record keeping system is not exactly the same. ISO14001 focuses on environmental issues, while the Directorate's requirements focus on the protection of human health. However, the structures and principles required by both systems to achieve an effective record keeping system to ensure the maintenance, storage and update of all required records, are similar.

### 5.2.4.4 EMS audit

***Regulator:***

The purpose of the two systems for implementing audits is not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve an effective auditing system to monitor compliance and provide feedback are the same.

***Directorate:***

Audits and Surveillance programmes are not required, except for users of Industrial Radiography sources. However, the RPO and acting RPO are responsible to ensure that compliance to regulations is achieved. It is important to note that one of the most important objectives of management system audits is to determine the status of compliance to programmes and procedures and to report this to management. The objective of the ISO 14001 EMS will therefore only be partially met, in that management's involvement could be very limited. There exist a significant difference between the objective of these two systems in this area.

### 5.2.5 Management Review

***Regulator:***

The purpose of the two systems for implementing a management review process, are not exactly the same. ISO14001 focuses on environmental issues, while the Regulator's requirements focus on the protection of human health, as indicated in section 1.1 of the Introduction. However, the structures and principles required by both systems to achieve an effective management review process to ensure management's involvement are the same.

***Directorate:***

Management review is only required during the review of reports on accidents, incidents and suspected overexposures. Management is not required to take a leading role in implementing, administering and improving radiation related matters. The Regulations allow that this could be delegated to the RPO. This approach can result in a lack of commitment from management in that regular review of the status of compliance will not necessarily take place. This will affect the effectiveness of the organisation in achieving continual improvement and to take preventative and corrective action.

The ISO 14001 EMS objective will therefore not be met. There is a significant difference

between the objectives of this requirement in this area.

## 5.3 FOSKOR Audit Report

The CNS conducted a systems and implementation audit on FOSKOR's QMP on 29 and 30 July 1997. The Regulator granted permission that the results of Audit Report CNS/42/97/10 can be used to support the conclusions made by the author.

At that stage FOSKOR was already certified as an ISO 9002 company and was in the process of achieving ISO14001 certification.

The lead auditor, responsible for the design of the CNS QMS, concluded in the Summary of Audit Report CNS/42/97/10 (Council for Nuclear Safety, 1997: 4):
"The existing management programme as described in the FOSKOR Quality Management System is structured according to and currently meets the requirements of ISO9002." and,
"The processes developed and implemented to execute the radiation protection programme meet the requirements of LD-1084 within the ISO system. It was noted by the Audit Team that the RP Programme, although still new in application, is being tailored to fit into the existing quality management system without any visible signs of difficulty."

From the above quotations it can be concluded that the CNS recognised that the QMS as required in LD-1084 shares common management system principles with the ISO 9000 series and can therefore be fully integrated into an existing ISO9002 programme. (It must be noted that the lead auditor is an experienced auditor serving on ISO technical committees ISO TC 176 and 207, he is a CQE at the American Society for Quality and is a registered member at SAATCA and IRCA.)

The ISO14001 standard describes the relationship between ISO 9000 series and ISO 14001

(Von Zharen, 1996 : 13):

"*This standard shares common management system principles with the ISO 9000 series of quality system standards.* " and

"*It should be understood, however, that the application of various elements of the management system might differ due to different purposes and different interested parties*".

From the foregoing it can be concluded that it will also be possible to integrate the QMS requirements of LD-1084 into that of the ISO 14001 EMS. The reason for this is the common management system principles that are shared by LD-1084, ISO 9000 and ISO 14001.

# CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

## 6.1 Conclusions

Currently two sets of requirements, enforced by different regulators, exist to control activities carried out with radioactive material in the mining and minerals processing industries. The management system required by the Regulator is more extensive than that required by the Directorate. The management system required by the Regulator is compatible with the ISO 14001 EMS and the ISO 14001 EMS can be integrated into the management system required by the Regulator. The ISO 14001 EMS and the management system required by the Directorate is not compatible and these two systems can only be partially integrated.

The scope of this study is limited to the control of activities carried out with radioactive material in the mining and minerals processing industries. It must be remembered that the sources regulated by the Directorate in these industries are usually encapsulated. The risk of sealed sources to cause nuclear damage is much smaller than the naturally occurring radioactive material, U238, U235 and Th232 with their daughters, regulated by the Regulator, which is not contained. Nuclear damage only becomes a reasonable risk during an accident or when a source is lost and opened by an uninformed person. It could therefore be argued that the requirements to control these sources should not be as extensive as those required by the Regulator. However, the IAEA and ICRP see quality assurance as an important element of creating a safety culture to achieve adequate radiation protection. In section 2.29 of the IAEA Safety Series SS115 (IAEA SS115, 1996) the following is recommended:

"Quality assurance programmes shall be established that provide, as appropriate:

(a) Adequate assurance that the specified requirements relating to protection and safety are satisfied; and

(b) Quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures."

It is known that when an organisation implements a management system such as ISO 14001 to manage its responsibilities, it will improve its control over its activities and its compliance to regulations.

A possible explanation why the Regulator has more extensive requirements on quality management is that the Regulator based its requirements for regulating the mining and minerals processing industries, on those required for regulating the nuclear industries, e.g. Koeberg Nuclear Power Station. In the development of the regulatory requirements for the nuclear industry quality management played an important role.

The current international trend in government regulating is to follow a co-regulatory approach where responsibilities are shared between regulators and organisations. This is to ensure that mutual responsibility is taken to ensure that compliance to regulations is achieved. In the past a command and control approach was followed. Regulators took all the responsibility for the enforcement of regulations. The command and control approach was not successful in creating an effective safety culture in industry. An effective management system, such as the EMS ISO 14001, can contribute in creating an effective safety culture in industry, by providing a management tool to implement requirements and achieve control over its activities. Von Zharen (1996 : 41) identified the key core principles of an effective management system. These are:

- *commitment* to complying to all rules and regulations and environmental management, permeating *through all levels* of the organisation;
- *identification* of legislative and regulatory requirements and environmental aspects associated with the organisation's activities, products and services;
- *development of a management process* for achieving objectives and targets;
- *providing* appropriate financial and human *resources* to achieve objectives and targets;
- assignment of clear *procedures* for accountability and responsibility;

- establishment of a *management review* and *audit process* to identify areas of improvement; and
- development and maintenance of *communication with internal and external interested parties.*

## 6.2 NNR QMS requirements

In Chapters 4 and 5 it was demonstrated that the formalised QMS required by the Regulator, described in LD-1084, contains all the principles listed above. This approach followed by the Regulator is also in line with international practice and recommendations to require that organisations have a formalised management system as part of a regulatory programme.

The management systems required in ISO 14001 EMS and LD-1084 are compatible and can be integrated. Both systems contain all the fundamental components of an effective management system. Those are policy development, management review, document control, process control, training and educational systems, inspection and testing (process and equipment), preventative and corrective action and audits and surveillances. Section 4.2.2 and Chapter 5, section 5.2, demonstrated this. The conclusions made in the CNS Audit Report CNS/42/97/10 (Council for Nuclear Safety, 1997) discussed in section 5.3, also support this conclusion.

However, although the fundamental components of these two management systems are compatible and could be integrated, the benefit and objectives of each system are not necessarily the same.

The purpose of the QMS requirements specified by the Regulator is to help organisations to achieve compliance with all laws and regulations on radioactive material. It is restricted to the NEA and NNRA, which are the Regulator's only mandate. Its purpose is also to ensure that organisations control the process of implementing requirements and in so doing prevent any nuclear damage. Furthermore, the emphasis of the Regulator's regulations is on the

protection of human health.

The purpose of the ISO14001 EMS is to ensure that all aspects of an organisation impacting on the environment, including nuclear damage to the environment, are managed in an environmentally sound way. The ISO14001 EMS focuses on environmental matters and does not necessarily include worker health and safety. Although the ISO 14001 EMS could be generalised to any area of an organisation's activities, there is therefore a difference in focus between the two systems. These differences result in different objectives for the fundamental components of each system.

ISO14001 requires for instance clear statements on environmental objectives and targets, pollution prevention strategies, external communication and how continual improvement will take place. It also serves as a tool for an organisation to remain aware of the interactions that its products and activities have with the environment and to achieve and continuously improve the desired level of environmental performance (Fredericks I, McCallim D, 1995). This is not emphasised by the Regulator's QMS.

Another difference between the ISO 14001 EMS and the Regulator's QMS is that between the principles "*continual improvement*" mentioned in ISO 14001 and ALARA mentioned in the NNRA. One of the minimum requirements of the EMS ISO 14001 is that organisations shall ensure that "*continual improvement*" of environmental performance will take place. It could be argued that the objective of "continual improvement" contains elements of an optimisation process in that it requires development and improvement.

The objective of continual improvement is not mentioned in the NEA or NNRA. However, the principle of ALARA is mentioned, which is aimed at optimising all practices. This means that the best available protection and safety measures under the prevailing circumstances must be used to ensure that the magnitude and likelihood of exposures, and the number of

individuals exposed be ALARA. This principle seeks to ensure that the dose delivered and the risks entailed are constrained. This optimisation process should take into account (IAEA Safety Series 115,1996):

- individual and collective exposures,
- radiological and non-radiological risks; and
- the financial and social costs, the benefits and the financial liability for the remedial actions.

Although both regulators of radioactive material require the ALARA principle to be met, a principle such as ALARA can be interpreted in a subjective manner. Its interpretation can depend on the decision-makers discretion regarding what is considered as "reasonably achievable". Regulators often rely on cost-benefit analysis to establish a reasonable limit. Often the parameters used in a cost benefit analysis depend on the outcome that is wished to be achieved, and does not include the concerns of all stakeholders. The limit to an optimisation process can therefore be justified, whereas "continual improvement" implies no limit to improvement. It can be concluded that the outcome of the principles "continual improvement" and optimisation will not necessarily be the same.

### 6.3 Regulations on Group IV Hazardous Substances QMS requirements

The Directorate does not require a formalised management system in its regulatory programme. It requires some of the fundamental components required by a management system i.e. operational control and process control through the Internal Rules, inspection and testing, training programmes and records. However, these processes do not form a complete and integrated system. The benefits of having a formalised management system to control radiological obligations will therefore only be partially met.

The following important elements of a management system are not incorporated into its requirements, such as:

- policy development;
- Audits and Surveillances of procedures (required only for Industrial Radiography);
- Management Review during normal operations (excluding accidents and incidents);
- External Communications to the public.

These fundamental elements, such as the requirement of a policy statement and management review, will assist the organisation in achieving compliance effectively and efficiently. Involvement of management by sharing responsibilities and the involvement of employees on all levels of the organisation are also an outcome of these processes. In the current situation it is possible that a company moves its responsibilities onto the appointed RPO. This can result in a lack of management's involvement. Especially the advantages of a policy statement and management review process are very important in creating a safety culture inside an organisation.

Another very important process in the ISO 14001 EMS is audits and surveillance and the management review of the outcome of this process. This is necessary to evaluate the adequacy and effectiveness of the organisation in achieving compliance to regulatory requirements and to identify areas of improvement. This can help management to identify any non-compliance and non-conformances promptly and avoid unnecessary occurrences, penalties or fines.

It can therefore be concluded that the ISO14001 EMS is only partially compatible with the QMS requirements in the Regulations on the Group IV Hazardous Substances. Therefore, these two systems cannot be fully integrated. However, when an organisation implements the ISO14001 EMS and generalises it to worker health and safety, it will also meet all the QMS requirements of the Directorate.

## 6.4 Conclusions in terms of the Purpose of the Study

The purpose of this study was identified in section 1.4. The following conclusions are relevant

to section 1.4:-

6.4.1 The Regulator's QMS can be fully integrated into the ISO 14001 EMS in that both contain the same fundamental components of a management system. However, the objectives and targets of each component will differ in the different management systems. The fundamental reason for this is that the Regulator's mandate is restricted to the NEA and the NNRA and its QMS currently focus mainly on human health and safety, while the ISO 14001 EMS focus on the environment with all its applicable laws and regulations. These differences were discussed in more detail in Chapter 5.

The QMS requirements of the Directorate do not include all the principles and processes of a complete management system. It will therefore only partially meet the requirements of the ISO 14001 EMS.

6.4.2 The discrepancies between the QMS, or components of the QMS, required by the two regulators of radioactive material and the ISO 14001 EMS were identified in Chapter 5. See Chapter 5 for more detail.

6.4.3 The ISO 14001 management system requirements could be integrated into the management system requirements required by the regulators of radioactive material. The reason for this is that it contains all the fundamental components of an effective management system. This was one of the conclusions made in section 5.3. However, it should be generalised to human health and safety.

6.4.4 It will be possible to use the ISO 14001 EMS as management system to control radioactive material and its impacts. However, its focus should be generalised to include the health and safety of workers, and not only the environment.

## 6.5 Recommendations

Legislators and regulators realise that the fragmentation of control due to the existence of a variety of enforcement agencies detracts from effective management of obligations by legislators and organisations implementing legislation. Ineffective management usually results in the duplication of functions and procedures, omissions regarding safety requirements and inconsistency in the exercise of functions. This eventually results in non-compliance and occurrences by the regulated industries.

It can therefore be concluded that in organisations, that have to comply with both sets of requirements, confusion and ineffective management could result due to an uncoordinated and unsystematically structured management approach. Due to this, regulators must seek to be consistent in their requirements. The new NNRA recognises this by requiring that co-operative governance take place in that all organs of state must co-operate with one another.

Fredericks and McCallum (1995) mentioned that it is very important for any organisation to integrate the environmental management system with the organisation's other activities to be effective and efficient. The management system used by organisations should therefore contain all the core elements of an effective management system so that it could be generalised to all areas of work. ISO14001 EMS is such a management system.

The author is of the opinion that the Directorate should also require the implementation of a management system by organisations regulated by the Directorate. This will contribute to an organisation's ability to effectively and efficiently meet regulatory requirements.

This study indicated that both regulators could accept the ISO14001 EMS as a basis on which to establish an adequate management system. All additional requirements, specific to radiation protection, could be included in LD's or Codes of Practice.

## REFERENCES


**ACTS** see SOUTH AFRICA.

**BARNARD, D. 1999.** Environmental Law for All. Pretoria : Impact Books CC. 384 p.

**COUNCIL FOR NUCLEAR SAFETY. 1996.** Annual Report 1995/1996. Centurion. 76 p.

**COUNCIL FOR NUCLEAR SAFETY. 1997.** Audit Report CNS/42/97/10: FOSKOR Audit Report. Centurion . 9 p.

**CORNISH, S. 1998.** ISO14000 June 1998: Meeting Information: Frequently asked questions, ANSI 1997 - 1999. [Web:] http://www.iso.ch/html [Date of access: 11 February 2000].

**EPA DOCUMENT. 1998.** Environmental Management Systems. [Web: ] http://www.epa.gov./region 08/p2/ems/ems.html [Date of access: 20 February 2000].

**FREDERICKS I, McCALLLUM D.** (mgmt@mgmt14k.com) 2000. Article on International Standards for Environmental Management Systems: ISO14000. [E-mail to:] De Clercq, A.R. (adriaan.declercq@mweb.co.za) Febr. 2000.

**GLAZEWSKI, J. 2000.** Environmental Law in South Africa. Durban : Butterworths. 902 p.

**GONZALEZ E, GONZALEZ S, MONTESINOS D.** ISO 14000 Environmental Standards. [Web: ] http://www.iso.ch/presse [Date of access: 17 February 2000].

**IAEA SAFETY SERIES 115 (SSF 115). 1996.** International Basic Safety Series for protection against ionising radiation and for the safety of radiation sources. Vienna : International Atomic Energy Agency.

**ICRP. 1991.** 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Oxford : Pergamon Press.

**LAWS** see SOUTH AFRICA.

**LÖTTER, C. 1995.** Radiation Protection in South Africa: Some Legal and Constitutional Issues. (Paper delivered as part of the International Conference on Radiation Protection and Waste Management in the Mining and Minerals Processing Industries at Johannesburg on 20 – 24 February 1995. Centurion. 15 p.)

**METCALF, P.E. 1995.** South African Legislation, Standards and Licensing Process. (Paper delivered as part of the International Conference on Radiation Protection and Waste Management in the Mining and Minerals Processing Industries at Johannesburg on 20 – 24 February 1995. Centurion. 5 p.)

**SABS ISO 14001: 1996. 1996.** Environmental management systems: Specification with guidance for use. Pretoria : SABS.

**SABS ISO 9000: 2000. 2000.** Quality Management Systems - Fundamentals and Vocabulary. Pretoria: SABS.

**SASOL SYNTHETIC FUELS (SSF). 1999.** Environmental Awareness / Training, Employee Handbook, Revision 1. Rosebank : SASOL

**SOUTH AFRICA. 1993.** Hazardous Substances Act, 1973 (act no 15 of 1973): Regulations related to Group IV Hazardous Substances. *Government Gazette*, 14596: 25, February 26.

**SOUTH AFRICA. 1993.** Nuclear Energy Act, No. 131 of 1993. Pretoria: Government Printer.

**SOUTH AFRICA. 1996.** Organisational requirements for authority holders and their appointed radiation protection officers in respect of Group IV Hazardous Substances. Bellville : Department of National Health and Population Development. 9p.

**SOUTH AFRICA. 1999.** National Nuclear Regulator Act, No. 47 of 1999. Pretoria: Government Printer.

**VON ZHAREN, M. 1996.** ISO14001 Understanding the Environmental Standards. Rockville, Maryland: Government Institutes, Inc. 213 p.

# APPENDIX I: STANDARD NUCLEAR LICENCE

# LICENCE NO. NL-xx

Licence No. NL-xx, is hereby granted by the Council for Nuclear Safety (hereinafter referred to as the CNS) in terms of section 51 (1) of the above Act

to

xxxxx

Registration number:

Registered address :

(hereinafter referred to as the licensee)

subject to the terms and conditions set out herein.

# PART 1

LICENCE CONDITIONS

## 1.1 SCOPE

1.1.1 The licensee is authorised to carry out activities associated with radioactive material as set out, and on the site as identified, in section 2.1 of this licence.

## 1.2 HAZARD ASSESSMENT

1.2.1 Assessments, approved by the CNS, shall be conducted by the licensee in respect of all the operations and activities involving radioactive material as set out in section 2.1 of this licence and which could give rise to a risk of nuclear damage. The assessments must identify and quantify all potential radiation hazards:

1.2.1.1 to persons employed at or visiting the site

and

1.2.1.2 to members of the public.

1.2.2 Details of any proposed modification to existing facilities or amendment of any procedure or construction of any facility, which may have an effect on the risk of nuclear damage and which has not been addressed by the hazard assessments identified in section 2.2 of this licence, together with a quantitative assessment of its impact on the risk of nuclear damage, shall be submitted to the CNS by the licensee. Such proposals shall be approved by the CNS before being implemented.

## 1.3 OPERATIONAL LIMITATIONS

1.3.1 The limitations pertaining to normal operations and listed in section 2.3 of this licence shall be adhered to.

1.3.2 No activities involving the demolition or disposal of any plant used for the processing of radioactive material shall be undertaken prior to approval by the CNS of the radiation hazard assessment and the radiation protection programme for such activities.

1.3.3 No maintenance activities on any plant used for the processing of radioactive material, which may give rise to significant occupational exposure of personnel involved, shall be undertaken prior to the approval by the CNS of the radiation hazard assessment and the radiation protection programme for such activity.

## 1.4 OPERATIONAL RADIATION PROTECTION

### 1.4.1 WORKFORCE

1.4.1.1 Based on the results of the assessments referred to in clause 1.2.1, programmes embodying all aspects as required by CNS documents LD-1085: "Requirements for the Control of Radiation Hazards: Mining and Minerals Processing", and LD-1083: "Requirements for Medical Surveillance and Control of Persons Occupationally Exposed to Radiation: Mining and Minerals Processing", in the revisions specified in section 2.4.1, must be established and be submitted to the CNS for approval. These programmes must ensure and demonstrate that radiation doses to persons employed at the site and to visitors to the site are in compliance with the radiation dose limitation system set down in the CNS document LD-1074: "Requirements for Radiation Dose Limitation: Mining and Minerals Processing", in the revision specified in section 2.4.1 of this licence. The programmes, as approved by the CNS, shall be implemented by the licensee.

1.4.1.2 The provisions contained in the revision of documents listed in section 2.4.1 of this licence and submitted in terms of condition 1.4.1.1 of this licence, shall be adhered to.

### 1.4.2 PUBLIC

1.4.2.1 Based on the results of the assessments referred to in clause 1.2.1, programmes embodying all aspects as required by CNS document LD-1086: "Requirements for Control over Radioactive Effluent Discharges and Environmental Surveillance: Mining and Minerals Processing", in the revision specified in section 2.4.2 of this licence, must be established and be submitted to the CNS for approval. These must ensure and demonstrate that radiation doses to members of the public are in compliance with the radiation dose limitation system set down in the CNS document LD-1074: "Requirements for Radiation Dose Limitation: Mining and Minerals Processing", in the revision specified in section 2.4.1 of this licence. The programmes, as approved by the CNS, shall be implemented by the licensee.

1.4.2.2 The provisions contained in the revision of documents listed in section 2.4.2 of this licence and submitted in terms of condition 1.4.2.1 of this licence, shall be adhered to.

## 1.5 RADIOACTIVE WASTE

1.5.1 A radioactive waste management programme embodying all the requirements contained in the CNS document LD-1087: "Requirements for Radioactive Waste Management: Mining and Minerals Processing", in the revision specified in section 2.5 of this licence, shall be established and submitted to the CNS for approval.

1.5.2 The provisions contained in the revision of documents listed in section 2.5 of this licence and submitted in terms of condition 1.5.1 of this licence, shall be adhered to.

## 1.6 TRANSPORTATION

1.6.1 Transporting off the site of radioactive material and any equipment or objects contaminated by radioactive material shall be subject to the relevant provisions of the International Atomic Energy Agency "Regulations for the Safe Transport of Radioactive Material", Safety Series No. 6, 1985 Edition (as amended 1990).

For the purposes of compliance with this condition the Council for Nuclear Safety is the National Competent Authority.

1.6.2 An annual report shall be submitted to the CNS detailing the number of consignments made during the preceding year, the radioactive content per consignment, the nature of the packaging and the names of the consignees.

1.6.3 The provisions contained in the revision of documents listed in section 2.6 of this licence and submitted with regard to condition 1.6.1 of this licence, shall be adhered to.

## 1.7 PHYSICAL SECURITY

1.7.1 A physical security system, approved by the CNS, which will prevent unauthorized access to areas containing radioactive material and will prevent the unauthorized removal of such material, shall be in place.

1.7.2 The provisions contained in the revision of documents listed in section 2.7 of this licence and submitted in terms of condition 1.7.1 of this licence, shall be adhered to.

## 1.8 OCCURRENCES

1.8.1 An occurrence reporting mechanism, approved by the CNS shall be established which will ensure that occurrences, as identified in the CNS document LD-1082: "Notification Requirements for Occurrences: Mining and Minerals Processing", in the revision specified in section 2.8 of this licence, are reported to the CNS by the licensee in accordance with the provisions of that document and as specified by CNS document LD-1089: "Verbal Emergency Communication with the Council for Nuclear Safety: Mining and Minerals Processing", in the revision specified in section 2.8 of this licence.

1.8.2 An emergency plan, approved by the CNS, shall be established to make provision for any occurrence involving radioactive material which gives rise to, or has the potential to give rise to, an unplanned exposure to radiation in excess of the respective annual effective dose limits for persons employed on the site, visitors to the site, and members of the public. This plan shall comply with the requirements contained in CNS document LD-1088: "Requirements for Emergency Preparedness: Mining and Minerals Processing", in the revision specified in section 2.8 of this licence.

1.8.3 The provisions contained in the revision of documents listed in section 2.8 of this licence and submitted in terms of condition 1.8.1 and 1.8.2, shall be adhered to.

## 1.9 QUALITY MANAGEMENT

1.9.1 All activities carried out within the scope of this licence shall be subject to the requirements contained in the CNS document LD-1084: "Quality Management Requirements for Activities Involving Radioactive Material: Mining and Minerals Processing", in the revision specified in section 2.9 of this licence.

1.9.2 The provisions contained in the revision of documents listed in section 2.9 of this licence and submitted in terms of condition 1.9.1 of this licence, shall be adhered to.

## 1.10 SCHEDULE

1.10.1 A programme scheduling the assessment of radiation hazards referred to in clause 1.2.1, the establishment of programmes and submission of documents as set out in clauses 1.4.1.1, 1.4.2.1, 1.5.1, 1.6.1, 1.7.1, 1.8.1, 1.8.2, and 1.9.1 respectively, and shall be submitted within two months of the date of this licence.

This licence is effective from the date of issue.

Issued at Centurion on the day of 19XX.

B C WINKLER

EXECUTIVE OFFICER

# PART 2

CONTENTS

# APPENDIX II: ISO 14001: SUMMARY OF CORE ELEMENTS

## 1.1 Policy

An organisation must state its commitment as to how environmental management will be organised, developed and maintained. This policy forms the framework for planning and action.

Minimum requirements are continual improvement of environmental impacts, prevention of pollution and compliance to all applicable legislation and regulations.

## 1.2 Planning

An organisation must formulate a plan to fulfil its environmental policy and to demonstrate how objectives and targets will be met.

### 1.2.1 Environmental Aspects

All environmental aspects of products, activities and services must be identified. Those that could have the most harmful impacts on the environment must be prioritised.

### 1.2.2 Legal and Other Requirements

The organisation must ensure that relevant laws and regulations are identified and ensure that it has access to these (this includes all requirements - local and national - to which the organisation must adhere in terms of the environment). Global enterprises must also take into account international laws and regulations.

### 1.2.3 Objectives and Targets

Environmental goals, in line with the policy, environmental impacts, views of interested parties and other factors, must be established. These goals must be specific. General concepts such as "reducing pollution" are not enough. Specific objectives and targets such as "reducing the release of $CO_2$ by 10 % per annum of current levels" are required.

### 1.2.4 Environmental Management Programmes

Actions to achieve objectives and targets must be planned and documented.

## 1.3 Implementation and Operation

### 1.3.1 Structure and Responsibility

Roles and responsibilities must be established and the resources provided.

### 1.3.2 Training, Awareness and Competence of personnel

The personnel must be trained and capable of carrying out their environmental responsibilities.

### 1.3.3 Communication

Documented procedures must describe the internal and external communication processes with all interested parties, on environmental management issues.

### 1.3.4 EMS Documentation

Information on the EMS and related documents must be maintained.

### 1.3.5 Document Control

The organisation must ensure procedures and other system documents are effectively managed.

### 1.3.6 Operational Control

Operations and activities must be identified, planned and managed in line with its policy, objectives and targets.

### 1.3.7 Emergency Preparedness and Response

Potential emergencies must be identified and procedures must be developed in order to mitigate or prevent them from occurring and how to respond to them if they do.

## 1.4 Checking and Corrective Actions

The Environmental Management System requires planned, comprehensive periodic audits to ensure that it is effective in operation and maintained.

### 1.4.1 Monitoring and Measurement

The procedure must include information how all key elements of operations and activities are monitored and performances are tracked.

### 1.4.2 Non-conformance and Corrective and Preventative Action

Procedures must be available for the management and control of any non-conformances and the prevention of possible recurrences.

### 1.4.3 Records

Adequate records of EMS performance must be kept.

### 1.4.4 EMS audit

Periodic audits must be scheduled and conducted to verify that the EMS is operating as intended.

## 1.5 Management Review

The EMS must be reviewed at defined intervals by managers for suitability, adequacy, effectiveness and to ensure continual improvement.

# APPENDIX III: LD-1084

LD-1084 REV 3

# QUALITY MANAGEMENT REQUIREMENTS FOR ACTIVITIES INVOLVING RADIOACTIVE MATERIAL: MINING AND MINERALS PROCESSING



APPROVED:

EXECUTIVE OFFICER

## 1. PURPOSE

1.1 This document details the CNS requirements for quality management that are of direct significance in assuring the radiation protection of licensee's personnel and the public.

## 2. SCOPE

2.1 This document applies to all organisational functions which could, radiologically, influence or affect the quality of the environment or of items, equipment, activities and services related to radiation protection. The requirements of this document support the principles related to radiation protection already detailed in the appropriate Nuclear Licence.

## 3. RESPONSIBILITY

3.1 The licensee has overall responsibility for the establishment and implementation of an appropriate quality management programme consistent with the requirements of this document.

## 4. MANAGEMENT

4.1 A written policy shall be prepared and issued by the licensee stating the quality objectives to be met during all phases of operation, shutdown and decommissioning. The policy shall be supported by a quality management programme which shall be implemented to enable these objectives to be achieved and verified. It shall be binding on all levels of management and shall establish and provide authority for the quality management programme and the discharge of the programme responsibilities.

## 5. MANAGEMENT REVIEW

5.1 The Quality Management Programme shall be reviewed at defined intervals by Executive Management to assess the status and adequacy of the programme. During this review, audit and surveillance findings, system deficiencies, document discrepancies, non-conformance reports, corrective action requests and any other performance related reporting mechanism shall be evaluated to determine the extent and consequences of the deviations and their effect on the programme.

5.2 The review process shall assess the effectiveness of the inspection, verification and audit functions in monitoring the achievement of the programme objectives.

## 6. ORGANIZATION

6.1 The organizational structure, functional responsibilities, levels of authority, lines of internal and external communication for management and the execution of activities related to radiation protection shall be clearly documented by the licensee.

6.2 The Executive Management shall identify, in the organizational structure, the persons responsible for the performance of inspections, verifications, auditing and reviewing the quality

management programme.

## 7. QUALITY MANAGEMENT DOCUMENT

7.1 The quality management programme shall be detailed in a written, authorised document approved by the CNS.

## 8. DOCUMENT CONTROL

8.1 The quality management programme shall include administrative and functional controls which shall be carried out in accordance with written, authorised procedures. Activities related to radiation protection shall be accomplished by written, authorised procedures, instructions, specifications or drawings, as appropriate.

8.2 Documents related to radiation protection shall be prepared, reviewed and verified for feasibility by technically competent personnel. Preparation shall be performed by designated personnel, and reviews and verifications shall be carried out by personnel independent of any direct responsibility for the original document preparation. Documents related to radiation protection shall be authorised for implementation by designated individuals.

8.3 Where procedures and instructions relating to radiation protection are not pertinent or available, temporary procedures and instructions may be utilised. The compilation and authorisation of these temporary documents shall be in accordance with written, authorised procedures.

8.4 All procedures and instructions relating to radiation protection shall be periodically reviewed. Revisions and changes to procedures, instructions and drawings shall be processed in the same manner as the original.

8.5 An approved document control system, for ensuring the correct utilisation of document revision, shall be established, documented, authorised, and implemented.

8.6 Procedures, where relevant, shall include appropriate quantitative or qualitative acceptance criteria for determining that important radiation protection activities have been satisfactorily accomplished.

## 9. DESIGN

9.1 Design and design changes for all equipment, items and activities impacting on radiation protection shall be controlled by written, authorised procedures. Designs and design changes related to radiation protection shall be executed by adequately trained, competent, authorised personnel.

9.2 Adequacy of designs impacting on radiation protection shall be verified by design review, alternative calculations or by testing of the designated item. Verification of designs related to radiation protection shall be undertaken by personnel who are independent of any direct responsibility for the original design process and who are at least as

competent as the designer.

9.3 The impact on radiation protection due to changes in equipment configuration, modifications and operational procedures, including their schedules, shall be assessed in terms of acceptable risk to a degree and in a manner commensurate with the requirements of the CNS.

## 10. PROCESS CONTROL

10.1 The provisions set out in 10.2 below apply, inter alia, to the following functions and areas of activity:

Operational Radiation Protection, Effluent Control, Environmental Surveillance, Radioactive Waste Management, Training and Qualification of Staff, Normal and Abnormal Operation, Routine and Special Maintenance, Fire Protection, Housekeeping, Physical Security, Emergency Planning.

In addition to the above, other areas of activity related to radiation protection may be identified and shall also be subject to the provisions in 10.2.

10.2 The following shall be addressed by those personnel designated by Management as responsible:

10.2.1 A broad description of the purpose, objectives, functions, responsibilities and procedure(s) defining the modus operandi, acceptance criteria and applicable quality standards for the associated tasks in each area of activity, shall be set down in writing.

This is Management's responsibility and must meet the requirements of the CNS.

10.2.2 The means by which radiation protection requirements are to be met shall be ascertained from written, authorised procedures and work instructions.

## 11. INSPECTION AND TESTING

11.1 To verify conformance with the documented instructions, procedures and drawings, a programme for inspection of items, services and activities shall be established, authorised and implemented.

11.2 A surveillance testing and periodic inspection programme shall be implemented to ensure that systems and equipment related to radiation protection will continue to operate, parameters being kept within prescribed limits, or will act to ensure safe conditions if these prescribed limits are exceeded.

11.3 Provision shall be made within the operating schedule to permit the performance of such surveillance, testing and periodic inspection in a timely manner. Deficiencies shall be promptly and appropriately

documented and evaluated for their effect on conformance to requirements.

11.4 Measures shall be established to identify the inspection and test status of individual items and for indicating the operating status of systems and components to prevent their inadvertent operation and use.

11.5 All inspection, measuring and test equipment in use shall be calibrated and adjusted against certificated equipment having traceability to nationally recognised standards.

## 12. CORRECTIVE ACTION

12.1 Measures shall be established, documented and authorised to ensure that conditions adverse to quality, which have caused or may cause a problem, such as failures, malfunctions, deficiencies, deviations, defective equipment, together with procedural and system non-conformances, are promptly identified, corrected and recorded. The root cause of the problem shall be determined and appropriate corrective action implemented to prevent repetition.

## 13. RECORDS

13.1 Procedures shall be established and authorised for identifying, collecting, indexing, filing, storing, maintaining and dispositioning of quality management records.

13.2 Quality management records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system in accordance with the requirements of the CNS.

13.3 All quality management records shall be legible and traceable to the item, equipment or activity involved. Quality management records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimise deterioration or damage and to prevent loss. Retention times of quality records shall be established in writing.

## 14. AUDITS AND SURVEILLANCE

14.1 Measures shall be undertaken to monitor the implementation and effectiveness of, and compliance with, the Quality Management Programme. Scheduled periodic audits and surveillance shall be performed in accordance with written authorised procedures. Audits and surveillance shall be performed by qualified personnel having direct access to that level of management necessary to ensure that, if necessary, appropriate corrective actions are identified. Personnel performing audit and surveillance functions shall be independent of any direct responsibility for the activities which they perform. Results of audits and surveillance shall be documented by the auditors/surveyors and reviewed by those organizations having responsibility in the area monitored.

Corrective action shall be taken by the responsible organization and the organization's management shall verify that deficiencies noted have been corrected.