

The Regulatory Authority Information System

RAIS 3.1 WEB

The Regulatory Model

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1 Introduction

1.1 Background

One of the statutory functions of the IAEA is to establish or adopt standards of safety for the protection of health, life and property in the development and application of nuclear energy for peaceful purposes, and to provide for the application of these standards. The *Safety Requirements* [1] establish the basic requirements for legal and governmental infrastructures for nuclear, radiation, radioactive waste and transport safety. Essential parts of the national infrastructure comprise legislation and regulations, a regulatory authority empowered to authorize and inspect regulated activities and to enforce the legislation and regulations.

Additionally, the *Code of Conduct on the Safety and Security of Radioactive Sources* [2] requires each State to “maintain a national register for radioactive sources... and to endeavor to harmonize the formats of their registers”. This recommendation is also to be developed for other radiation sources.

Maintaining the national register for radiation sources requires developing adequate data management tools to facilitate data storage, analysis and follow-up actions. Adequate data management is needed not only to keep a national register for radiation sources, but also to manage the large amount of data with which the regulatory authority is daily confronted while performing its regulatory functions. It is also essential for assessing the level of radiation safety and security in the country and the effectiveness of the regulatory programme.

A principal requirement for any regulatory data management tool is conformity with the underlying regulatory system in the country. It has to reflect, for example, the applicable classification of radiation sources, the system of notification and authorizations adopted, the regulatory requirements on responsibility distribution for radiation safety issues, the professional qualification requirements for occupationally exposed workers, etc. This principal requirement represents a challenge for the harmonization of data management in different countries with different regulatory systems.

The *Regulatory Authority Information System* (RAIS) has been developed by the IAEA as part of a supporting set of actions designed to assist countries in managing their regulatory control programme.

RAIS promotes a consistent and common approach to the regulatory control of radiation sources, whilst offering flexibility to respond to specific needs of the countries, with due account of their national legislative framework, administrative structure and institutional and regulatory framework.

The previous version, RAIS 3.0, has been issued in 2004 in MS Access environment. In 2006, it was extended for implementation on SQL Servers. As of the date of this document, this version is in use, to varying degrees, in more than 63 countries.

The current version, RAIS 3.1 Web, is the most recent product in RAIS evolution series. It provides a web interface for RAIS 3.0 and incorporates additional features and enhancements. Compatibility with RAIS 3.0 is maintained.

RAIS 3.1 Web is distributed with a full set of documentation. The installation package of RAIS 3.1 Web contains the following documents:

- 1 ***RAIS 3.1 Web Regulatory Model:*** This document describes the underlying regulatory model and emphasizes its ability to be ‘tailored’ according to the national regulatory systems. This document has a pure regulatory character with no technical details.
- 2 ***RAIS 3.1 Web Administrator’s Guide:*** This is a technical document consisting of two parts: Part I describes the RAIS 3.1 Web installation process and its customization to satisfy national needs. Part II describes the advanced customization mechanisms in RAIS 3.1 Web using its internal tools.
- 3 ***RAIS 3.1 Web User’s Guide:*** A technical and regulatory document explaining the day-to-day work with RAIS 3.1 Web. It also contains tips for good practice and for resolving some typical regulatory situations in form of *How to’s*.

1.2 Objectives

This document introduces the underlying regulatory model adopted by default in RAIS 3.1 Web. Furthermore, provides an overview on the customization possibilities of RAIS 3.1 Web to satisfy the needs of different national regulatory systems.

1.3 Scope

This document provides an overview on RAIS 3.1 Web and its features and describes the essential parts of the regulatory model adopted in RAIS 3.1 Web. It covers:

- The national administrative, legislative and regulatory infrastructure.
- The structure of the regulatory system including:
 - Classification of practices.
 - Facility status.
 - Classification and status of radiation sources and associated equipment.
 - The authorization system.
 - The inspection system.
 - Enforcement.
 - Regulatory control aspects related to occupationally exposed persons.
- Information related to radiation events
- Technical services available in the country

1.4 Structure

This document consists of three chapters. After the introductory chapter, a general overview on RAIS 3.1 Web and its features is provided in chapter two. Chapter three elaborates the regulatory model provided by default in RAIS 3.1 Web.

2 RAIS 3.1 Web – General Description

2.1 What is RAIS 3.1 Web?

RAIS 3.1 Web is the most recent product in the RAIS evolution series. It maintains the structure and functionalities provided by RAIS 3.0 and provides a web-based interface in addition to a collection of new and/or enhanced features.

Similarly to its ancestor, RAIS 3.0, RAIS 3.1 Web is a management tool for information related to the regulatory control of radiation sources. It offers assistance to the regulatory authority in managing its routine regulatory activities such as keeping an inventory of radiation sources, authorization, inspection, etc. Its regulatory model can be used as a ‘template’ which can be utilized by young regulatory authorities in building their own regulatory systems. Furthermore, RAIS 3.1 Web is provided with many tools for analyzing programme data, which facilitate extracting performance indicators and assessing the overall performance of the regulatory programme. It can thus be used as guidance for developing, assessing and improving the regulatory authority’s quality assurance programme.

Example *With RAIS 3.1 Web it is possible to retrieve, nationwide, complete information about the inventory of radiation sources of any type in the country and how they are controlled. It is also possible to identify sources of any security group in import, transport, use, etc.*

RAIS 3.1 Web provides a web interface for RAIS 3.0, which could be used for example by inspectors in the field, regional offices of the regulatory body and by authorized representative of facilities to access their facility's data. RAIS 3.1 Web can also be used within the regulatory body’s intranet as a replacement for the MS Access RAIS front-end.

The web interface for RAIS provides for:

- Remote access of the regulatory authority staff members, such as inspectors in the field or regional offices of the regulatory authority. The web interface can also be used within the regulatory authority’s intranet as a replacement for the MS Access RAIS front-end
- Remote access by other relevant authorities such as the Health, Environmental, Transport or Customs authorities.
- Access by authorized representatives of facilities to their own facility’s data.
- A means for communication between facilities and the regulatory body.
- A means for electronic submission of inventory data, application of authorization and other issues, subject to validation by regulatory authority officers and legally acceptance in each of the using countries’ legislative system.
- A means for information dissemination to the public such as published laws, regulations, statistical and other information related to safety and public concern.

RAIS 3.1 Web incorporates also:

- Enhanced users' management, providing for more flexibility and security in assigning user privileges.
- Extended description of the regulatory system by incorporating references and links to regulatory documents such as laws, regulations, codes of practice, coordination and cooperation agreements and memoranda of understanding, conventions and other safety agreements to which the country is party.
- The possibility, through hyperlinks, to access external documents such as laws, regulations, sources technical sheets, authorization certificates, inspection reports, etc.
- Enhanced module for managing information related to radiation events.
- A secure interface to retrieve information from the "International Catalogue of Sealed Radioactive Sources" (ICSRS), facilitating data import on sealed sources and associated equipment¹.

2.2 Features of RAIS 3.1 Web

RAIS 3.1 Web demonstrates:

- Compatibility and consistency with the international standards and relevant IAEA documentation [1] - [6].
- Customizability: RAIS 3.1 Web is designed for easy adjustment and modification at any time to suit the needs of different regulatory systems without compromising consistency with internationally applicable standards.
- Rationality: RAIS 3.1 Web is designed to manage information in real situations even where parts of the information might be missing. Data are classified in three categories:
 1. *Mandatory*: a minimal subset of the data, which is 'vital' for the system and for the assurance of the usefulness of the information. No record can be saved if mandatory data are missing or left blank.
 2. *Recommended*: data which are important from the point of view of the regulatory authority, but might be missing or unknown at the time of data entry.
 3. *Non-mandatory*.
- Internal data consistency checking tools to facilitate cross-checking data, examining its consistency and detecting user mistakes. If a non-consistency is suspected, a warning will be issued and the RAIS user is responsible for making a decision to correct the data, reject it or accept it as is.
- Data confidentiality: Through data roles and functional roles, RAIS 3.1 Web provides a powerful mechanism for configuring users' permissions and controlling their access.
- Data protection: RAIS 3.1 Web includes a protection mechanism which enables the regulatory authority to protect parts of the data from being unintentionally modified or deleted.

¹ For data security reasons, connection to the ICSRS is only possible through a separate login process, provided that RAIS user has the necessary permission to access the catalogue.

- User friendliness: RAIS 3.1 Web includes many optical and informational guidance to assist its users in minimizing and detection of human error. Informative and warning messages are communicated in clear text to the user.

2.3 Scope of RAIS 3.1 Web

RAIS 3.1 Web covers:

1. Infrastructure information, i.e. the national administrative legislative and regulatory infrastructure.
2. Facilities
3. radiation sources and associated equipment
4. Authorization.
5. Inspection
6. Enforcement
7. Radiation events
8. Occupationally exposed persons.
9. Technical services.

For each of these areas, the scope of information to be included in RAIS 3.1 Web can be customized at any time. By default, RAIS 3.1 Web includes a predefined set of information, which conforms to international standards and would cover a regulatory authority's needs in many countries.

RAIS 3.1 Web does not cover nuclear activities or accounting of nuclear materials.

RAIS 3.1 Web is not designed to manage dosimetry data. However, it includes information on annual doses of occupationally exposed workers and accidental doses received during radiation events as these doses are relevant for assessing the overall level of radiation protection in the country and hence the effectiveness of the regulatory system.

Example *RAIS 3.1 Web may be used to manage the whole authorization process starting from application for authorization until the issuing of the certificate, and any other related actions afterwards such as amending, modifying or withdrawing.*

Example *RAIS 3.1 Web may be used to develop the regulatory inspection programme in a specified period of time.*

2.4 'Details' and 'Status' data

The relevant data to many of the items covered in RAIS 3.1 scope may be split into 'details' and 'Status'.

Details are specific to the item of concern itself. They are independent of the item's condition in its working environment and don't change in time. Examples of such data are the serial number of a source or the expiry date of an authorization.

Status includes all relevant data which are related to the item's conditions in its working environment such as the facility possessing the source. This data is usually time dependent. The sequence of the statuses builds the 'history' of the item.

Example *A sealed source has some specific characteristics such as its radionuclide(s), the radioactivity at some date, the serial number, shape, etc. This information is the details of a sealed source.*

Data on the facility controlling the source, the source use status (e.g. whether in use, in transport or in storage) and the associated equipment in which the source is installed are time dependent. They are part of the sealed source history.

Status information can be organized in different histories. For example, radiation generators have in RAIS 3.1 Web a history related to their use status, and another history related to their calibration status

Note

Technically, Details and Status data are stored in different data tables. Different history tables can be associated to a particular item.

2.5 Regulatory Authority Numbers (RAN)

Each data item needs a unique identifier, which is a unique string permanently assigned by the regulatory authority to the item regardless of any changes in its working conditions. In RAIS 3.1 Web, this unique identifier is called the Regulatory Authority Number (RAN).

In RAIS 3.1 Web, RAN is required for:

- Facilities
- Departments
- Radiation generators
- Sealed sources
- Unsealed sources
- Associated equipment
- Authorization process
- Authorization status
- Inspection
- Enforcement action
- Persons
- Radiation events
- Persons exposed in radiation events

In some cases, specific characteristic of a data item might be usable for unique identification of the item. However, care should be given to ensure the practicality and uniqueness of such characteristic as this is not the case in many situations.

Examples

1. A facility name, if used to identify facilities, can lead to ambiguities if two facilities have the same name. A unique combination of facility information, such as name, region, practice, etc. is a better candidate for identifying a facility.
2. The serial number of a sealed source can be thought as a proper unique identifier. However, in the real world, serial numbers might be missing in some cases, limiting their practicability as unique identifier in RAIS 3.1 Web.
3. For persons: The following characteristics are not recommended for use RAN: The person name because it is not unique; The personal id, driving license or passport numbers if they have timely limited validity.

The choice of RAN is basically a regulatory authority decision. The regulatory authority needs to establish a system for assigning RANs to the different items. However, regulatory authority may make use of some national assignment of unique identifiers, if applicable, as a RAN. This has the advantage of providing a shared identification of items with other governmental authorities.

Example Some countries have a unique registration number for economic entities, including radiation facilities. The regulatory authority may use this registration number as RAN for facilities.

Example Some countries assign a national number for their inhabitants, which is unique and permanently assigned to the person even after death. Such a national number could be a good candidate for RAN, but the regulatory authority should take into consideration persons working in the country's territory, who have other nationalities, if no national number is assigned to them.

When the regulatory authority establishes a system for RAN, RAIS 3.1 Web may be customized to automatically assign the RAN when new data items are entered. Details are given in *RAIS 3.1 Web Administrator Guide – Part II*.

2.6 Access privileges in RAIS 3.1 Web

The user access privileges in RAIS 3.1 Web are described in chapter 7 of *RAIS 3.1 Web Administrator's Guide – Part I*. For convenience, a brief summary is provided in this section.

RAIS 3.1 Web incorporates a powerful mechanism for configuring users' permissions and controlling their access. This mechanism provides RAIS administrators with a wide range of possibilities for granting or denying access privilege for every user to different menu items as well as different data sectors.

By default, RAIS 3.1 Web provides five preconfigured access privileges in form of built-in user types:

Administrator: This user type has full access in RAIS 3.1 Web, including adding, modifying, deleting and viewing all data, modifying regulatory system model and modifying regulatory

system data. Additionally, administrators are allowed to define users into the RAIS 3.1 Web system and assign access permission.

Regulator: This user type is allowed to view, modify, add and delete regulatory data, and only to view regulatory system data. They are not allowed to alter regulatory system data.

Restricted Access Regulator: This user type is allowed to view regulatory data, but they are not allowed to add, modify or delete any regulatory data or regulatory system data.

Licensee: Users of this type are authorized representatives of facilities. In addition to the global and public information, this user type is allowed to access only regulatory data about their own facility. However, adding, editing and deleting any data related to their facility is subject to validation process by the regulatory body.

Guest: This user type is only allowed to view global and public information, such as statistical data. Guests are not allowed to add, modify or delete any regulatory data or regulatory system data.

3 RAIS 3.1 Web Regulatory Model

This chapter describes the default regulatory model adopted in RAIS 3.1 Web. This model is compatible with international standards and guidance, including the Code of Conduct on the safety and security of radioactive sources, and takes into account experience and good practice in designing and implementation of regulatory programme.

Note

RAIS 3.1 Web incorporates extensive customizability features which allow the using countries to modify the default regulatory model according to their national regulatory system. Details of customization capabilities are provided in RAIS 3.1 Web Administrator's Guide

Note

Although, in many cases, this regulatory model may be used either as is or after minimal customization through the adjustment of regulatory system data, it is expected, that countries make use of the extensive customization features of RAIS 3.1 Web for adjusting or extending this model to satisfy national needs in any area, in which the national regulatory system deviates from the adopted one in RAIS 3.1 Web.

3.1 Infrastructure information

3.1.1 Country administrative infrastructure

Different countries differ considerably in their size as well as in geographical, political and economic situations. They also differ in the extent of use of radiation sources and the available know-how for their safe use.

From the country's administrative system point of view, two levels of administrative units are included which are called, in the default terminology, *regions* and *districts*². A country might consist of regions and these in turn might consist of districts. As part of RAIS 3.1 Web flexibility, the use of regions and districts is not mandatory.

Example *Consider the following three countries: Country A consists of several provinces. Country B is small and has no administrative subdivision. Country C is rather big. It consists of 'states', each of which consists of several regions. RAIS 3.1 Web is able to deal with all these situations.*

3.1.2 The regulatory body and other authorities and organizations

As the structure of the regulatory authority differs from one country to another, RAIS 3.1 Web includes the possibility of defining different authorities. For each authority, it is possible to define the officers and their tasks, such as authorization assessment, inspection, legal affairs.

² Country specific names can be defined at any time after the installation of RAIS 3.1 Web

Example RAIS 3.1 Web is able to deal with all of the following three situations:

- *Country A has a centralized system. There is a single regulatory authority responsible for the control of radiation sources in all practices, all types of exposure, emergency response, environmental protection, etc.*
- *Country B has a decentralized system. The responsibilities of the regulatory authority are distributed among several governmental bodies.*
- *Country C has a federal system. Each federal State has its own set of authorities.*

In addition to the regulatory body, any other national or international authority or organization involved in the regulatory control of radiation sources might be entered into RAIS 3.1 Web such as the ministry of health, the customs authority, environmental protection agency, etc.

3.1.3 Coordination and Cooperation

Information on formal coordination and cooperation of the regulatory body with other authorities and organization can be entered into RAIS 3.1 Web. Such coordination and cooperation is defined by the agreements name, reference number and date in addition to the institutions involved. The full text of the agreement might be included in RAIS 3.1 Web through a hyper link.

It is possible to cover bilateral as well as multilateral agreements.

3.1.4 Regulatory References

Laws, regulations, codes of practice and any other regulatory reference documents can be introduced in RAIS 3.1 Web. The full text might be included through appropriate hyper links. The types and possible status of such documents is customizable according to the national system.

Being accessible by the public, this part can be considered a means for information dissemination.

3.1.5 Classification of Practices

The scope of the regulatory system must cover all sources within practices which are not exempted nor excluded. The legislation or regulations in each country should define excluded and exempted exposures. RAIS 3.1 Web includes a list of common practices requiring regulatory control as in Table 1. This list needs to be customized according to the national regulatory system.

Table 1 *The non-comprehensive list of practices requiring regulatory control in RAIS 3.1 Web. For information on inspection frequency, refer to section 3.5.*

Practice	Inspection Frequency (years)
Medical Practices	
Dental X-ray	5
Diagnostic and interventional radiology	2
Radiotherapy	1
Nuclear medicine	1
Non-medical Practices	
Industrial radiography	1
Industrial irradiation	1
Well logging	2
Analytical techniques involving ionizing radiation	5
Portable gauging	2
Fixed gauging, detection or analytical techniques	5
Non-medical use of unsealed sources	1
Production of radioactive sources	1
Radioactive waste management	1
Manufacture of radiation generators and associated equipment	1
Dealers /distributors	0

3.2 Facilities

3.2.1 Facilities and Departments

RAIS 3.1 Web is able to manage information about facilities with different organizational structures, e.g. small facilities with no departments and big facilities with departments.

Departments could be either in the same location or at different locations. They could have their own organizational structure such as their own director and radiation protection officer(s).

Facilities and departments could act in one or more practices. They could have their own set of radiation sources and could be authorized and inspected separately according to the specific regulatory system in the country.

3.2.2 Responsibilities and Organization

An important aspect of the control of radiation sources is a clear and adequate allocation of responsibilities. Thus, each facility or department is requested to define the responsible person and the radiation protection officer(s). Other key personnel and occupationally exposed workers can also be identified in RAIS 3.1 Web together with their qualifications, experience and tasks. See section 3.8 for additional details.

While recognizing their importance, RAIS 3.1 Web does not make these data mandatory as they might be unknown at the time of data entry in real situations.

3.3 Radiation Sources and Associated Equipment

It is important to distinguish between the radiation sources themselves and the equipment in which they are used. In RAIS 3.1 Web terminology, the latter is called *associated equipment*. Radiation sources may be radiation generators, sealed sources or unsealed sources.

RAIS 3.1 Web provides by default examples of classification of radiation sources and associated equipment based on the practices in which they are used. The reader is advised to refer to [4] for additional information

Note

While the use of most radiation sources and associated equipment is practice specific, there are some types of radiation sources which are not practice specific, e.g. static eliminating devices or smoke detectors.

Note

Some types of sources or associated equipment can be involved in several practices.

The relevant data on radiation sources and associated equipment are not only their specifications, but also the data of their use or handling. Thus each of these items has a *history* which records the relevant information of the source in the working place.

Examples

1. *In gamma industrial radiography, the associated equipment is the gamma projector. The radiation source is used in association with it. ¹⁹²Ir sources are frequently exchanged in normal radiography operations within the same associated equipment. RAIS 3.1 Web clearly distinguishes between the radiation source and the gamma projector in which it is used and keeps track of exchanging sources and the associated equipment.*
2. *^{99m}Tc generators are unsealed sources. The container itself could be considered as associated equipment.*
3. *Linear accelerators are considered as radiation generators.*
4. *Radiation survey meters may be considered as equipment associated with their calibration sources.*

3.3.1 Radiation Generators

Radiation generators are classified according to type. Most generators are used in specific practice(s). RAIS 3.1 Web provides by default a sample classification of radiation generators. This default classification is to be customized according to each country's system after the installation of RAIS 3.1 Web. Extract of the sample classification is presented in Table 2.

Table 2 *Examples of classification of radiation generators*

Practice	Type of radiation generator
Dental X-ray	Conventional dental X-ray device Panoramic dental X-ray device Scephalometric dental X-ray device
Diagnostic and interventional radiology	Portable X-ray device Conventional X-ray device Fluoroscopic X-ray device Mammography devices CT scanner C-arm X-ray device Angiography device Bone densitometer Veterinarian X-ray generator
Radiotherapy	Deep X-ray treatment device Simulator Linear accelerator Electron beam therapy device
Industrial radiography	Portable X-ray radiography device Fixed X-ray radiography device Industrial X-ray fluoroscopy device
Irradiation	Electron accelerators X-ray Calibration device
Fixed gauging, detection or analytical techniques	X-ray thickness gauge XRF device XRD device

Besides the history information of a radiation generator, RAIS includes a calibration history to record the dates of the generator calibration.

3.3.2 Sealed Sources

The categorization of sealed sources is based primarily on risk to human health. In [3][5], a five-category classification scheme is suggested:

- Category 1
- Category 2
- Category 3
- Category 4
- Category 5

Sealed sources are also to be classified on the basis of security considerations. A four-class scheme was introduced in [6]

- Security class A
- Security class B
- Security class C
- Security class D

Risk categorization and security classification of sealed sources is related not only to the source's physical properties but also to the condition of the source in its environment. This classification is part of the source history.

Security requires the presence of adequate physical barriers, which can be defined in RAIS in the sealed source history. A security plan should also be prepared if applicable, e.g. for import or transport of the source, and is simply a *yes/no* field indicating the existence of a security plan.

The history of a sealed source includes a 'facility audit date', i.e. the date of the inventory check to be performed by the facility periodically if the regulatory authority requires such an inventory audit.

The associated equipment with which the sealed source is to be used are identified separately as *sealed-associated* equipment history.

3.3.3 Unsealed Sources

Unsealed sources have no particular classification. Their specifications are defined by the maximum permitted activity in a given period. A regulatory authority defined source number is advised in order to uniquely identify the unsealed source.

The history of unsealed sources includes information about them in the working place. *Unsealed-associated* equipment history records the associated equipment with which the source is to be used.

3.3.4 Associated Equipment

Classification of associated equipment is based primarily on the type of use. Extract of the sample classification provided by default in RAIS 3.1 Web is given in Table 3. It is up to the country to modify this classification or introduce its own.

The history of associated equipment is recorded separately to keep track of the associated equipment in the working place. Associated equipment may be involved in *sealed-associated* equipment history or *unsealed-associated* equipment history as applicable.

Table 3 *Examples of classification of associated equipment*

Practice	Type of associated equipment
Radiotherapy	Teletherapy machine
	Brachytherapy machine
	Gamma knife
	Neutron beam therapy device
Nuclear medicine	SPECT camera
	PET camera
	Thyroid scanners
Industrial radiography	Pilot for crawler radiography device
	Portable industrial gamma projector
	Fixed industrial gamma projector
Irradiation	Mobile irradiation device
	Fixed irradiation device
	Calibration device
Portable gauging, detection or analytical techniques	Moisture meter device
	Moisture and density meter
Fixed gauging, detection or analytical techniques	Density meter
	Level gauge
	Thickness gauge
	Fluoroscopy device (radioisotopes)
	Chromatography device
	Selective gamma absorption device

3.4 Authorization System

The system of authorization differs considerably from one country to another. RAIS 3.1 Web is designed to cover the wide variation in authorization systems effectively.

3.4.1 Licensees and Registrants (Authorization Holders)

In some countries, the facility itself is to be authorized for all practices in which the facility is active regardless of its internal organization. In other countries, the departments within the facility may have the legal status to be separately authorized.

RAIS is able to manage both situations. Facility identification for the authorization is mandatory, but additional department identification is possible. This indicates an authorization which is issued for the department itself.

Example *In two countries, A and B, the ministry of health operates several hospitals. The regulatory system in country A considers the ministry a big 'radiation user' and issues the authorization*

for those hospitals in the ministry's name. On the other hand, the regulatory system in country B considers each individual hospital the registrant or licensee.

3.4.2 Scope of Authorization

Depending on the regulatory system in the country, authorizations may cover all sources in the facility or particular sources. Authorizations may also be issued without specification of source, but just for the practice itself or for maximum permitted radioactivity in a specific period of time.

All these situations are manageable with RAIS 3.1 Web.

Example *Facility A has two departments: D_1 is active in practice P_1 and is responsible for some sources, and D_2 is active in practice P_2 and is responsible for some other sources. Depending on the regulatory system, facility A may be authorized to operate in practices P_1 and P_2 in one authorization certificate, or in two separate certificates. The sources might be specified in the authorization certificate. It is also possible to authorize the departments D_1 and D_2 . If some of the sources in department D_1 are not safely and securely managed, D_1 might not be authorized to use these particular sources.*

3.4.3 Authorization Process

In RAIS 3.1 Web, authorization is considered to be a process starting with an application. It consists of many steps. By default, RAIS 3.1 Web uses following steps:

1. Application
2. Review for documentation completeness
3. Assessment
4. Approval or rejection
5. Issuance of authorization certificate
6. Subsequent action: e.g. the authorization can later be modified, amended, suspended or withdrawn.

These steps can be customized in accordance with the national authorization system. The authorization process defines the history of the authorization. Each step is a status, defined by date, responsible officer and separate status number if applicable. The process itself is identified by a RAN, the *authorization process number*, which remains unchanged throughout the process.

Example *In country A, the authorization process has only an 'authorization number' and is processed by a single officer starting from the application submission until the final decision. The authorization certificate is signed by the head of the regulatory authority and identified by the same authorization number.*

Example *In country B, the application for authorization is identified by an application number, and is sent to officer 1, who is responsible for the paper work. If the submitted documents are complete, the application is transferred to officer 2, who evaluates the application, conducts an inspection if necessary and recommends approval or rejection of the authorization. If the application is approved, officer 3 prepares the certificate which takes a separate authorization certificate number and is finally signed by the head of the regulatory authority.*

3.4.4 Authorization Types

RAIS 3.1 Web includes by default a set of authorization types which would be common for the majority of facilities and activities. For each authorization type, a predefined set of information is included. This set can be customized in the installation phase. Also, RAIS 3.1 Web offers the possibility of introducing new types of authorization if necessary.

The following authorization types are predefined in RAIS 3.1 Web:

1. Import authorization
2. Export authorization
3. Transfer authorization
4. Authorization to use/operate
5. Storage authorization
6. Authorization to release radioactive substances into the environment
7. Transport authorization
8. Authorization to produce radioisotopes
9. Authorization to manufacture devices, e.g. radiation generators or associated equipment.

Multistage authorizations are not provided by default, but RAIS is so flexible as to allow countries to introduce these types if necessary.

Example *In country A, a design authorization is required for radiotherapy centres prior to commencing construction work. The RAIS administrator in the country has to add this authorization type during the installation phase of RAIS.*

3.4.5 Authorization Information

All authorization types share a base set of information such as the authorization holder (licensee or registrant), date, expiry date. This base information is defined by default in RAIS 3.1 Web and includes:

1. Authorization holder, e.g. facility or department.
2. Sources authorized.
3. Persons involved, e.g. responsible person, radiation protection officer, workers.
4. Full record of the authorization process
5. Officers responsible for each step of the authorization process.

Besides this base information, RAIS 3.1 Web includes other information, which might be authorization type specific as described below.

3.4.5.1 Specific Information for Import/Export Authorization

Several scenarios are possible for importing radiation sources, for example:

- All sources covered in the import authorization are imported in a single action.

- Multiple import actions are carried out under one single import authorization. In each import action, only a part of the authorized sources is imported.
- The authorized facility does not import the authorized sources, fully or partially.
- There might be a significant time difference between issuing the import authorization and the import actions.
- Sources can be imported by the user facilities themselves or through a third party, e.g. dealers.

Similar possibilities apply to export authorization.

RAIS 3.1 Web offers the possibility of entering data on several import actions for a single import authorization, and also the possibility of identifying the actually imported subset among the sources which are authorized for import. For each import action, the relevant data set includes the date, the bill of lading number and the customs clearance number.

Additionally, for import of sealed radioactive sources of particular security groups, a security plan for the import/export period might be requested, depending on the applicable regulatory system.

Example *Dealers may import sources for a user facility. In this case, the dealer is the authorized legal person for import. Either the user facility should be identified in the import authorization or a separate transfer authorization should be issued. In any case, the user facility should have the authorization to use/operate the source.*

3.4.5.2 Specific Information for Transfer Authorization

A transfer authorization has to specify, in addition to the base information, information about the recipient facility and the type of transfer, namely:

- recipient facility or department
- recipient authorization, which allows it to receive the source
- date of transfer
- type of transfer, i.e. permanent or temporary. In the latter case, information is to be submitted about the return of the source to the origin.

3.4.5.3 Specific Information for Transport Authorization

In some cases, a specific authorization is required for the transport of radioactive material. In RAIS 3.1 Web, the transport authorization includes information about:

- Package type
- Package category
- Transport index (TI)
- Transport mode(s), including multimode transport
- Consignor
- Consignee
- Carrier

- Consignee authorization, which allows it to receive the source
- Place of origin
- Destination
- Date of shipment
- Date of receipt
- Exclusive use (y/n)
- Special arrangement (y/n)
- Existence of a security plan for transport of sealed sources of specific security classes.

3.5 Inspection System

Similarly to the authorization process, inspection is considered in RAIS 3.1 Web to be a process consisting of:

- Carrying out inspection
- Preparing the report
- Report verification
- Approval of the report
- Sending the report to the inspected facility.

These steps build the history of the inspection. In each step, the responsible officers can be identified. In this way, information about joint inspection carried out by officers from different authorities can be managed by RAIS 3.1 Web.

Example *It is possible for a nuclear medicine department to be inspected by a single inspector or by a team consisting of several inspectors. Inspectors could be all from the regulatory authority, or also from other authorities such as the ministry of health. To control discharges into the environment, inspectors from the authority responsible for environmental protection could join the inspection team.*

In RAIS 3.1 Web it is possible to identify if the facility as a whole is being inspected or only one of its departments. It is also possible to identify the inspected sources among the existing set in the inspected facility or department.

RAIS 3.1 Web provides for defining the inspection type through three attributes: *regular vs. non-regular*, *announced vs. non-announced* and *comprehensive vs. partial*.

The frequency of regular inspection is practice specific. The default values are given in Table 1. The regulatory authority is advised to define its own inspection frequencies in the Setup phase. RAIS 3.1 Web uses this information to assist the regulatory authority in building its inspection programme for any period.

Non-compliances detected during inspection can also be managed. RAIS 3.1 Web includes a predefined set of non-compliances categorized according to [7]. It is up to the regulatory authority to modify the list according to its own system.

3.6 Enforcement

In a case of non-compliance, the regulatory authority may decide to apply some enforcement actions according to its enforcement policy. RAIS 3.1 Web includes a list of possible enforcement actions. See Table 4. This list can be adjusted by the regulatory authority during the installation phase.

The information on enforcement actions includes, as applicable:

- set of non-compliances leading to enforcement action
- inspection on the basis of which enforcement action was decided
- officer(s) responsible for enforcement action
- due date
- response of facility/department
- follow-up inspection.

Table 4 *Default list of enforcement actions in RAIS 3.1 Web*

Warning letter
Suspension of authorization
Withdrawal of authorization
Financial penalty
Administrative penalty
Court prosecution
Request for compliance

3.7 Radiation Events

The regulatory authority might be involved, to varying degrees, in the preparedness and response to radiation events depending on the national system. RAIS 3.1 Web includes data on radiation events, which is useful from the regulatory authority's point of view:

- Date and location of the event. The location can be specified as an address or geographical coordinates (e.g. for events occurring in remote areas)
- Extent of the event and the emergency response level. RAIS 3.1 Web provides default lists for classification of the emergency response levels and event extents.
- The facility involved, if any
- The sources involved.
- Causes and radiation consequences of the event. RAIS 3.1 Web provides default lists of possible causes and possible consequences.
- Remedial actions taken and lessons learnt.
- The persons exposed to radiation due to an event. Persons can be members of the public, workers and, if the event is related to medical exposure, patients. Exposed workers need to be identified individually. For patients and members of the public, RAIS 3.1 Web provide for their identification either as individuals or as group of people.
- The doses received by the exposed individuals or groups and the health consequences thereof. RAIS 3.1 Web provides a default list of possible health consequences.
- IAEA notification and assistance provided.
- The reporting chain about that event, including data on the reporting organizations or facilities and to whom the report was sent.
- IAEA notification on the event and the support received from the IAEA, if applicable.

3.8 Occupationally Exposed Persons

In RAIS 3.1 Web, it is possible to identify the persons working in facilities or departments. The information includes:

- Personal data, such as name, age, gender
- Academic and professional qualifications
- Training courses in radiation protection attended (See section 3.9)
- Person tasks in the facility
- Experience (in years) in the current job
- Personal dosimetry status
- Annual occupational doses received
- Accidental doses.

With this information, RAIS 3.1 Web is able to:

1. Identify responsibilities in facility/department
2. Identify persons working concurrently in several facilities
3. Identify persons to be mentioned in authorization if required by country's regulatory system
4. Analyse annual dose distribution and development trends in each practice.

3.9 Technical Services

RAIS 3.1 Web also offers the possibility of managing information on technical service providers. They are considered as facilities which are active in the practice *service provider*. Thus, service providers can be authorized to use radiation sources and inspected just as any other facility. However, they have a special type of authorization, *accreditation*.

By default, information about accreditation includes only the certificate number, accreditation date, and the expiry date as applicable. Other information might be added during the installation phase.

For training service providers, additional information is included in RAIS 3.1 Web, namely the training events they are providing. This information is used to identify the training courses attended by workers as described in section 3.8.

4 References

- [1] INTERNATIONAL ATOMIC ENERGY AGENCY, Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety, Safety Standards Series No. GS-R-1, IAEA, Vienna, 2000.
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- [3] INTERNATIONAL ATOMIC ENERGY AGENCY, Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna, 1996.
- [4] INTERNATIONAL ATOMIC ENERGY AGENCY, Recommendations for the Safe Use and Regulation of Radiation Sources in Industry, Medicine, Research and Teaching, IAEA-Safety Series No. 102, IAEA, Vienna, 1990.
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- [7] INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Assessment plans for Authorization and Inspection of Radiation Sources, IAEA-TECDOC-1113, IAEA, Vienna, 2001.