

IsoStock (Cloud) General Features

This document outlines all the general features of the IsoStock (Cloud) software.

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Introduction

IsoStock (Cloud) is a cloud-based management system designed to simplify the management of radioactivity records. Additionally, it helps users of radionuclides meet the regulatory agency's requirements for radiation safety.

IsoStock (Cloud) features a fully configurable setup to accommodate the differences in regulations that apply across countries. These include the Environment Agency (EA), Natural Resources Wales (NRW), Scottish Environment Protection Agency (SEPA) and Northern Ireland Environment Agency (NIEA), but is also deployed internationally.

IsoStock is used in many industries, including Universities, Pharmaceuticals, Research institutions, healthcare, and manufacturing. It is configured individually for each customer using the software's built-in tools.

General features

- IsoStock (Cloud) maintains records with full traceability and an audit trail of all radioactivity arriving
 on a site, documenting everything that happens to it while on site, and when and how it finally leaves
 the site.
- Aids in meeting the regulatory requirements in your country, in the area concerning the recording of holdings, accumulations and disposals of radioactive substances.
- Warns visually when exceeding a user-selected percentage of holding, accumulation and disposal limits. Automatically updates decay, in any units, producing an accurate measurement to the minute at any time, but reports in the units applicable to your country, i.e. MBq or mCi
- Automatic calculation of decay across all options.

- Single nuclide and multi-nuclide sources with isotopic composition recorded as activity per nuclide, mass of each nuclide, percentage of activity per nuclide.
- Automatic generation of reference codes with user-defined formats for each area of the system.
- Enter requests users can enter requests, which can later be authorised.
- Enter orders system checks against limits to ensure they will not be exceeded when compounds are delivered.
- Standard requests for quickly duplicating requests and regular orders
- Receiving to holding stores for confirming receipt of a package, e.g. by a security department, without having to confirm the compound's details
- Records all transactions against compounds and builds a history on a 'page per compound' basis.
- Sub-sampling for usage, splitting, diluting, synthesis and generator elution.
- Flexible use of activity units on a per compound basis Bq, KBq, MBq, GBq, TBq, Ci, mCi, μCi.
- Flexible use of quantity units on a per compound basis μl, ml, l, μg, mg, g, capsules, vials, doses, boxes, kits, tips, vials, aliquots.
- Two-part request and dispense option for moving compounds between departments to minimise reordering compounds that other departments may no longer need.
- Preparation option for sub-sampling based on an activity required at a specific time in the future.
- Structured representation of the site, organised by departments, locations, and stores.
- Stock checks based on departments, users, or locations, complete with a record against each compound that the check was made.
- Comprehensive waste and decay store management accurate activity tracking of waste containers with a complete breakdown of contents.
- Consignments organise waste containers into a single consignment for disposal to a waste collection company with forward decay calculations.
- Quickly provides information retrospectively in the event of an investigation.
- Records certificates for holding, disposal, accumulation, acquisition and sealed sources.
- Manages sealed sources with leak tests and location checks.
- Barcode and labelling functions.
- Historical record of all data.
- Extensive search facilities for quickly finding data.
- All day-to-day screens feature a flexible report function showing details of highlighted items, or details in list form in selectable formats.

- Further reports provided with parameters for dates, departments, user, list order, etc.
- All reports are exportable in PDF and Excel format.
- Highlights compounds which have not been disposed of within specified time periods
- All entries are fully editable with an audit trail specifying user, time and reason, and the previous replaced data.
- Fully customisable security access with multiple levels and Azure SSO

Requests, orders and receiving compounds

- End users can enter requests for compounds to be available on specified dates.
- A department head can control the ordering process by authorising users' requests. Authorisation
 numbers can be optionally recorded, and a compound reference code can be allocated, ready for the
 compound's arrival.
- Users can see which of their requests have been authorised or declined.
- IsoStock (Cloud) checks holding limits to establish that they won't be exceeded when the compound arrives.
- Orders can be received in full or in part.
- On receipt, the compound's details can be updated with reference dates or any difference in quantity or activity.
- Compounds can be received as a closed package into a temporary holding area without updating details, leaving the user to update details when it arrives in the lab.
- Compounds can be entered as they arrive without using the requests or orders stage.
- Compounds can be received from the clipboard if the details have been sent by email by another site using IsoStock (Cloud).
- Standard Requests can be stored for regularly ordered compounds with any of the details defaulted.

Tracking and recording radioactivity in research

- IsoStock (Cloud) will fully track the use and movement of radioactivity through the processes in a typical research environment.
- A compound is shown on a single page with all the details and corresponding transactions, in a similar
 way to how they would in a paper system. All transactions are recorded in a list underneath the
 compound details.
- A user can take a subsample from a compound, creating a "Use" record against the original, and creating a new compound with its own reference code for the subsample.
- Reference codes can be allocated to new compounds and subsamples automatically, with a flexible format.

- Subsamples are fully traceable and shown against the parent compound as a transaction. There are
 options to move between the parent and child compounds.
- Sub-sampling/dispensing can be made in units of activity, quantity, or percentage. It is always decay-corrected to the given date and time, and the other figures are automatically calculated.
- Using the dilute/synthesise option, a subsample can be taken and given a different name and units of quantity. The activity is fully traceable from the parent compound.
- A subsample is treated like any other compound, so all transactions can be made to any compound/subsample regardless of how many times they are split.
- All compounds and subsamples have reference code, name, batch/lot numbers, quantity and activity, concentration, specific activity, reference date/time, received/created date, storage location, supplier, catalogue code, nuclide, cost
- Units can be selected for each individual compound. Activity can be in kBq, MBq, GBq, TBq, μCi, mCi, Ci. Quantity can be expressed in standard units, such as mg, g, μl, or ml. As transactions can be recorded in quantity, there are also units such as capsules, doses, kits, vials, boxes, aliquots, and tips, where the volume/mass is less relevant.
- Disposals can be recorded against the compound. Multiple routes can be selected simultaneously, and proportions can be allocated by quantity, activity, or percentage.
- New containers can be created at the time of disposal and allocated unique reference codes automatically
- Subsamples can be moved between locations, departments or users.
- Free text notes can be recorded against any compound.
- Generate/elute option for recording e.g. Tc99m from a Mo99 generator.
- Combine compounds, taking all or part of two or more compounds to create a new compound.
- Transfer compounds off-site, creating a consignment with the details. The consignment is placed on the clipboard in text format along with coded data that can be emailed to another site that uses IsoStock (Cloud).
- Two-part request and dispense option for transferring compounds between users in different departments. Both parties must complete their respective parts of the transaction.
- Treatment preparation option for creating a subsample that needs to be of a given activity at a given date/time. Useful for short-lived nuclides.
- Option to adjust the quantity of a compound to account for over-dispensing that was not known at the time of receipt.
- Generic beta, alpha and activation product nuclides for complex compounds, or where the makeup is unknown.
- Break apart option for sub-sampling generic beta and alpha compounds into known nuclides.

- A free text transaction for recording anything that cannot be categorised into one of the other options.
- Attach documents of any type to any compound.
- View the decay table of any compound with selectable units. The table shows the activity of both the whole compound and at different proportions. For example, a 250µl sample will be shown, with the decay from 5µl to 250µl at 5µl intervals.
- View decay graph of any compound.
- Compounds can be copied to the clipboard, with the format and layout defined in the setup.
- Compound labels can be printed with barcodes, with the format and layout defined in the setup.
- Automatically calculates the quantity, activity, percentage, etc., based on entered figures combined with the concentration, date, time and half-life. The user-entered fields are always highlighted.
- Compounds can be shown in list form. Columns can be sorted, resized and ordered to the users' requirements.
- Options for listing compounds belonging to selected departments and users in a given location. Free text search on compound name, catalogue codes, project numbers, batch numbers, and lab book numbers.
- Quick find option to select a compound by reference code. A historical list to instantly jump to a recently accessed compound. The list is personal to the user.
- All historical records can be searched for and displayed.
- All transactions are recorded with the date, time and the user.

Safeguards and ONR (currently in development)

- IsoStock (Cloud) will fully track the use and movement of radioactivity in nuclear material to aid with Safeguards and ONR compliance.
- Sources can be described with their common nuclide name for easy identification, and the isotopic composition.
- Options for sources and subsamples show both total activity and composition (mass and activity) at each stage
- Each source and subsample has options for Material Form, Container and State.
- Reporting grouped per parent materials with weights and changes of each nuclide.
- All the previous research options are available on these sources.

Tracking and recording radioactivity in nuclear medicine

• IsoStock (Cloud) will fully track the use and movement of radioactivity through the processes in a typical nuclear medicine environment.

- Records requests for radiopharmaceuticals based on ARSAC investigations, on a specified day.
 Requests can be individual items (with or without patient information) or multi-dose.
- Records receipt of activity by logging new items against the requests.
- Labels can be printed with reference numbers, nominal dose activity and patient information (user-defined formats).
- At the time of dosing, the administrator can quickly locate the material by stock number, patient name, or radiopharmaceutical.
- For patient-specific doses, this information is presented to the administrator as a check. In the absence of patient information being provided to the radiopharmacy, it can be entered at this stage.
- IsoStock (Cloud) will provide a guide volume to withdraw based on the activity required. The administrator then checks the actual activity from a calibrator and records it into IsoStock (Cloud). There is also a guick "ALL" button that records administering the entire dose.
- IsoStock (Cloud) provides a report showing the decay of the dose administered for patients leaving the site.
- Disposal records can be quickly recorded based on the investigation type and IPEM Excretion Factors. These will proportion the activity between e.g. drain, patient, etc., as well as handling residual activity in sharps, etc.
- The remaining dose/container can either be moved to the decay store or can be quickly disposed of using a "discard" button.
- IsoStock (Cloud) can provide historical reports for ARSAC information to aid clinical audit.

Tracking and recording radioactivity in a radiopharmacy

- IsoStock (Cloud) will fully track the use and movement of radioactivity through the processes in a typical radiopharmacy.
- Records requests for radiopharmaceuticals to be prepared according to ARSAC, on a specified day.
 Requests can be individual items (with or without patient information) or multi-dose and can be for internal or external hospitals.
- Planning of larger intermediate batches from which to dispense multiple items. IsoStock (Cloud) will
 automatically group similar requests and calculate the overall activity required, applying decay
 calculation for the different intended dose times.
- Records generators and elutions and can provide guide activities for yield based on historical and planned elutions.
- Records all non-radiolabelled items, along with batch numbers, suppliers, dates, etc, used in the production, e.g. saline, pharmaceuticals, etc.
- During production, IsoStock (Cloud) ties together the original request, all non-radiolabelled compounds used, and the eluate.

- IsoStock (Cloud) handles all decay calculations between the date of the transaction, the intended
 dosing time, the reference time of the eluate, and concentrations, and provides details of the
 quantities required based on the target activity.
- Labels can be printed at the planning stage with reference numbers, nominal dose activity and patient information (user-defined formats).
- Labels can be printed at dispensing time with the above information, as well as actual activities, quantities, and other relevant details, for packaging. (user-defined formats).
- IsoStock (Cloud) keeps track of expiry dates for materials, as well as minimum and maximum activity in the supplier's specifications. These can all be set in default lists. It is possible to add special instructions that will be included on labels and the Nuclear Medicine dosing screen.
- Disposal records can be quickly recorded by selecting pre-agreed treatment types. These will
 proportion the activity between e.g. drain, patient, etc., as well as handling residual activity in sharps,
 etc.
- The remaining dose/container can either be moved back to the Radiopharmacy or can be quickly disposed of using a "discard" button.

Waste management and disposal

- Will account for both direct routes, such as aqueous waste to the drain, and accumulated waste in containers and held in a decay store.
- All direct waste streams can be defined as required, e.g. Drain waste can be split into individual sinks or labs, and labels given as they are named on your site.
- Waste containers can be named to describe the physical containers you use, e.g. 10-litre yellow bins. When making disposal, the user selects the waste stream, and if it is a container type, the reference code for that container. Only containers of the selected type will be displayed.
- Calculations for waste within a container are full decay corrected according to the material, date, time, and activity placed in them.
- Containers can be allocated to departments, locations, or shared.
- Containers can be used for single or multiple nuclides. Each nuclide is decay-corrected individually for an accurate record.
- The type of waste can be recorded for a container type, e.g. Solid, Organics, etc.
- A container type can be created to cover multiple waste items. The number of items to which the container applies is specified by the user.
- A container can be sealed to prevent further disposals. The date and time, along with the user, are recorded.
- The contents of a container can be viewed, showing each disposal that makes up the waste. This is fully decay-corrected.
- Containers can be placed inside other containers.

- The activity within a container can be manually entered to allow for sharps bins, etc., where the user may only make estimations of what went into them from their compounds.
- Count rate (with background) can be recorded, with calculated activity based on monitor and sensitivity.
- A department or user can request that a container be collected and can specify where it is to be collected from if this differs from the container's original location.
- A collection screen and report show all the containers that require collection. Age limits can be placed on container types so that any container over this age is also shown.
- Multiple waste containers can be selected and transferred to the Decay Store once collected.
- Accumulated waste in the decay store can be displayed, including container types, decay-corrected activity, nuclides, and age.
- The decay store can be split into any number of locations.
- Multiple waste containers can be selected and placed on a disposal consignment. This can be in preparation for a future collection which will take place.
- Disposal consignments can be decay corrected to a date in the future, i.e. when they are to be collected.
- Disposal consignment details can be copied to the clipboard for emailing to the collection contractor. This also contains data readable by another IsoStock (Cloud) system.
- Waste can be analysed to establish activity on a specific date in the future, or the date at which it (or the concentration) will have decayed to a given level.
- The waste screens show items that are close to and exceeding any limits.
- A consignment can be recorded as disposed of when it finally leaves the site.
- The consignment screen shows all outstanding consignments awaiting disposal, or historical disposals
 these are fully searchable by consignment reference, or by container reference.
- A decay graph of a container or consignment can be displayed.
- A decay table of a container or consignment can be displayed.
- Labels can be printed in a layout and format defined in the Setup.
- Waste details can be copied to the clipboard in a layout and format defined in the Setup.

Sealed Sources

- IsoStock (Cloud) will manage all your sealed or closed sources.
- Source details include name, manufacturer, serial numbers and model numbers of both the source
 and any surrounding housing or equipment. Also recorded are the date received, reference date,
 nuclide, activity, weight, owner, location, licence/registration details, and the frequency of leak tests,
 location checks and calibration.

- The sources are shown in list form, with all the transactions corresponding to the highlighted source.
- Sources can be moved between departments, locations or owners.
- Sources can be moved in and out of equipment.
- Leak tests can be recorded with the outcome and report numbers.
- Calibrations can be recorded with the outcome and certificate number.
- Source location checks can be recorded.
- Sources can be transferred off-site, and a consignment is created.
- Sources can be disposed of in a specified waste container.
- Sources can be designated as waste items when they are no longer of use.
- Photos and documents of any type can be attached to a source.
- Free text can be recorded to indicate any other event relating to a source.
- A decay table can be displayed for any source.
- Labels can be printed for any source in a format and layout defined in the setup.
- Colour is used to show sources with tests overdue and to highlight sources exempt from licences.
- There are search options to display sources belonging to a department or user, within a specific location, or a particular nuclide, as well as free-text searches of source names, serial numbers, and model numbers. The list can also show items overdue tests, or exempt from licences, marked as waste, etc.
- All transactions are recorded with the date/time and user.

Licences/limits/regulations

- IsoStock (Cloud) contains checks for total activity of stock (holding), disposals, accumulations (waste containers), acquisitions and sealed sources.
- IsoStock (Cloud) can be set up with the limits imposed by the regulatory authority.
- Limits can be defined by a single nuclide, multiple nuclides, beta group, alpha group or another nuclide group as defined in the setup.
- Limits for disposal can also be categorised by waste type, and/or by disposal route, either totalled as a group, totalled by route, or just selected routes.
- Disposal limits can be set for daily, monthly, and annual totals.
- Accumulation limits can also be specified by waste type, and can be set for activity, time, and volume.
- Sealed source limits are for total activity, number of sources at a given activity, weight, or activity/D value (Category 5) calculation.

- Sealed source limits can be grouped into separate licences.
- Limits of activity can be specified in Bq or Ci, and ALI, Re or Equiv MBq.
- Limits can be set per site, and optionally per department.
- The format of the Overview summary report directly reflects the limits that have been defined.
- Where a limit is not specified but a total is required, the limit can be recorded as "calculate only".
- The system can notify when approaching limits at a predetermined percentage.

Set-up and security

- Any number of security levels can be created. There are over 300 options to select from, allowing or disallowing user functions.
- An audit trail accompanies all edits. When an edit is made, the user is presented with the changes and
 asked to enter the reason for the change (default reasons can be configured). The changes are
 recorded, along with the user, reason, date and time, previous data, and new data. Audits can be
 displayed on the screen or as a generic list for a given period.
- All data can be edited by the user, subject to the user's access level. Where an edit would influence a
 subsequent entry, there are options to freeze the more recent transactions and re-edit or recalculate
 them after the edit is made.
- Historical records can be edited, and decay correction will be correct as if entered at that time.
- Limits can be placed on users to restrict editing of records after a given time. You can define which security levels this applies to.
- All setup options are fully editable by the Supervisor.
- Nuclides can be selected from the master list and can be allocated for use in open or sealed sources.
 Any additional nuclides not on the 180+ list will be added on request.
- A default list of suppliers can be configured.
- The site can be divided into any number of departments. Compounds are then allocated to users within departments. A department has an RPO and deputies for reporting, who receive notifications when their users exceed limits.
- Departments can be grouped for reporting purposes.
- Locations can be defined in a hierarchy of 3 levels. These could be, e.g., top-level labs or rooms. Second level fridges, freezers, stores. Third level shelves within stores.
- Locations can be specified as usable for open sources, sealed sources, waste containers, waste collection points, temporary holding areas for receipt, decay stores, radiopharmacy, dosing. Or any combination of these.
- Locations can be defined as accessible by the site, a department, or multiple departments.
- Locations can be grouped for reporting purposes.

- A default list of commonly used compounds can be defined along with supplier, catalogue code, name, pack size (if in different quantities), nuclide, activity, quantity and concentration. The most common compounds can be listed at the top, with all others listed alphabetically by catalogue code beneath.
- All disposal routes licensed for use can be defined. These are categorised by direct routes (i.e. drains), container types, collection contractors, incinerators, land fill, and non-waste transfers.
- Container types specify their waste type (solid, aqueous, organic, low-level, exempt, sealed source), the maximum time they should ideally be kept in the department or decay store, whether they are generally mixed nuclides, and their default size in litres or kilograms.
- Disposal routes can be sorted to list the most used first.
- Protocols can be defined to group compounds.
- Quick disposals can be defined to allow proportions to be allocated to different waste streams simply by selecting a disposal type from the list.
- Tasks can be defined and allocated to security groups to prompt them to perform given tasks at specified intervals. A report shows the tasks outstanding by the users.
- Personal settings can be defined to specify how some screens are displayed, and the type of summary report that is given as the user logs in.
- General preferences allow for setting the base units for reports, currency, date format, the site RPO, the default periods for sealed source leak tests, calibrations, and location checks, as well as the default periods for waste analysis.
- Reference codes are automatically produced. The format can be specified individually for compounds, orders, waste, consignments and sealed sources. The format can be composed of years, months, days, free text, and counters.
- Subsample reference format can be specified in several formats.
- Users can be allocated to a single department, multiple departments, or the entire site, at a specified security level.
- Where a company has multiple sites, a list of sites and relevant servers can be entered for switching between sites/licences.