

## **CASE STUDY: MANAGING LOW-LEVEL RADIOISOTOPES AS PART OF A COMPANY'S TOTAL LIFECYCLE OF CHEMICALS AND RADIOACTIVE MATERIALS**

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Chiron Corporation is one of the world's leading biopharmaceutical companies with businesses in biopharmaceuticals, vaccines and blood testing. In addition to manufacturing facilities, Chiron has an extensive research and development organization, which works with chemicals and radioactive materials.

Under Federal, State and Local regulations, as well as corporate operating procedures, Chiron is required to implement programs that track and optimize the use of chemicals, biohazardous materials, radioactive materials and hazardous waste. As with all organizations that use radioisotopes, Chiron is required to have an extensive mechanism to track the acquisition, storage, use and disposal of isotopes that it is licensed to use at its facilities. Chiron has a Broad Scope License issued by the State of California. Under this license, principal investigators and biochemists are authorized to use specific isotopes in defined quantities and locations for their research and operations.

In 2000, Chiron implemented RTS, the Chiron Radioisotope Tracking System (RTS), as a tool to manage radioactive materials in its Emeryville facilities. This tool has proven to be a cost-effective tool that helps manage data efficiently. In 2005, Chiron partnered with Chemical Safety Software, a technology company that already provided Chiron with chemical management and regulatory compliance systems, to integrate RTS into its enterprise software.

The Radioisotope Tracking System (RTS) program is designed to help manage the flow of radioactive isotopes from purchasing through waste disposal in a multi-user and multi-facility environment. RTS has been integrated into Chemical Safety's Environmental Management Systems (EMS) as a unique component to manage Isotope purchase, use and disposal, all within the context of the regulatory framework under which Chiron is required to operate, and all in real-time. It is designed to assist both the Radiation Safety Officer (RSO) and/or compliance officer within the Chiron organization, as well as Biochemists and Principal Investigators, meet industry and regulatory requirements for Radioisotope use.

Chiron's RTS system incorporates the following 6 components:

### **1. People**

- Track, monitor and manage employees that use or come in contact with radioactive material.
- Set-up processes and controls to authorize employee use and track their exposure.
- Incident and accident tracking

- Employee training
- 2. Facilities and Locations (Labs)**
  - Track, monitor and locate isotopes within facilities, laboratories, company departments, and/or projects.
  - Maintain, display and print facility and lab diagrams with isotope inventory links for easy access and view.
  - Schedule and monitor vial transfer (including history)
  - Schedule and monitor disposition (including history)
- 3. Isotopes**
  - Manage inventory, control and record use
    - Barcode scanners – wireless and wired handheld devices
    - Through RFID
  - Searchable databases
    - Molecular Structure search fields
    - Chemical Formula search fields
  - Manage half-life and automated tracking from radioactive to biohazard
  - Schedule and monitor transfer (including history)
  - Schedule and monitor disposition (including history)
- 4. Purchase Order and Receipt**
  - Automated ordering and authorization with linkage to EMS Task Management Module
    - Real time validation against RUA constraints (People, Locations and Activity Levels)
  - Automated and scheduled reordering
  - Searchable databases of available isotopes
    - Molecular Structure search fields
    - Chemical Formula search fields
  - Receiving
    - Transportation label tracking
    - Contamination measurement statistic tracking
    - Shipping capabilities with linkage to EMS' Bill of Lading module
- 5. Waste**
  - Waste type – tracking and management barcode labels and RFID tags for wireless and wired handheld devices
    - Dry
    - Absorbed Liquid
    - Liquid
  - Current and historical record management
- 6. Reporting**
  - Standard and customizable reporting
    - Isotope possession Report
      - Facility
      - Lab
      - Department
      - Project

- User
  - Purchase Order Report
  - Transfer Report
  - Waste Drum Report
  - Disposition Report

Good safety practices as well as regulations require that radioisotope use be managed down to its smallest denomination. By dynamically decaying isotopes in real-time, the Radiation Safety Officer has a real-time view of isotope activity at each of Chiron's facilities, buildings and Radioactive Use Authorizations (RUAs). The system automatically alerts the RSO and Environmental Health and Safety staff via email when an event occurs that has or may cause an issue of compliance or safety. This includes:

- Unauthorized purchases
- Potential Storage or Use Violations
- Warning of use by unauthorized individuals or at unauthorized locations
- Potential Employee training deficiencies

Other features of Chemical Safety / Chiron's Radioisotope Tracking System's include capabilities that further insure precise inventory management and tracking which in turn simplifies safety regulations and reporting, such as:

- **RTS Setup.** Manages Material Licenses, Isotopes, Isotope Decay, Labs, Personnel and Facilities
- **Radioactive Use Authorization (RUA) Management.** Manages authorized use by Project, Location, Isotope(s) and Authorized Personnel. Includes real-time Isotope decay capabilities, on-the-spot adjustments and usage reports.
- **Isotope Purchasing and Receiving.** Manages all aspects of Isotope Purchasing and Receiving, including monitoring of potential license or RUA exceedence that a purchase or transfer to a particular RUA or location may cause.
- **Isotope Waste.** Manages Isotope waste storage and disposal and generates manifests, labels and other appropriate paperwork. Includes real-time Isotope decay capabilities, on-the-spot adjustments and Isotope disposal reports.
- **RTS Human Resources.** Manages training requirements for Isotope users.
- **Transaction History.** RTS maintains detailed history of every transaction, activity, event, modification or amendment made to any of the RTS tables. This information can be queried and reported as required.
- **Regulatory and Ad-hoc (Management) Reporting.** RTS produces all required reports for Local, State and Federal Authorities, and has a powerful reporting tool that allows users to generate and export a variety of organization specific reports.
- **Automatic Email Notification.** RTS includes automatic email notifications of unauthorized purchase or RUA requests, potential Material License violations and re-training tickler notifications.

In addition to safety improvements and constant compliance monitoring, RTS, as part of Chemical Safety's Environmental Management Systems, reduces isotope purchasing and

disposal costs. Chiron's partnership with Chemical Safety has had long-term benefits for the company. The model used by Chemical Safety for its technology has been adopted from the Chemical Management Services (CMS) model, which is a market-based approach to reducing chemical use and costs. Under the CMS model, formerly conflicting incentives are aligned. To the further this understanding, one can look at the Chemical Lifecycle:

➔ Total chemical lifecycle costs = chemical purchase costs + management costs

By improving chemical management Chiron has reduced "total" costs through maintaining smaller inventory as well as purchasing, managing and disposing of fewer chemicals. Moreover, improved chemical management has served to enhance production quality and efficiency as well as improve safety and environmental protection. Other benefits have included:

- Freed up floor space through inventory reduction
- Improved management of chemicals on-site
- Improved data management and environmental reporting

What's more, combined with Chemical Safety's EMS (Environmental Management Systems), RTS completes the corporate requirement for total lifecycle management of chemicals and radioactive materials for Chiron. The EMS software is powerful and comprehensive system that includes components for Chemical Inventory, Tracking and Management, MSDS and Chemical Information Management, Hazardous Waste Management, and Compliance Management and Reporting.

The integrated chemical tracking and management has helped reduce chemical purchasing, management, compliance and disposal costs by streamlining chemical acquisition and on-site tracking and management. Individuals within the company have access to accurate, up-to-date chemical information that allows users to maximize the use of the chemicals on-site.

EMS has managed compliance aspects of the facility and the entire company. Data in all modules have been brought together to create user-defined management reports. Regulatory reports and documentation have been generated to meet local and state regulations in addition to federal laws and regulations.

Recent world events and threats have reinforced the need for security, accountability, compliance and safety. September 11, 2001, in particular raised fears and questions about where, when and how terrorists will and can attack. There has been concern for chemicals and radioactive materials getting into the wrong hands. With proper management and tracking of these materials that involves the most detailed tasks and safety regulation reporting, these fears and concerns can finally be addressed.

Successful radiation safety and compliance program depends on the cooperation and support by all individuals and groups within the organization, including researchers, the

Radiation Safety Committee, Environmental Health and Safety, Purchasing, Receiving and Executive management. Using an integrated software tool in RTS, all stakeholders at every step of the way have the opportunity to update, monitor, validate and review procedures and activities related to safe and efficient radioactive use on site. Regulators and the community at large also have the ability to monitor and inspect the company's practices.

The Radioisotope Tracking System Chiron and Chemical Safety have developed incorporates every component necessary for complete radioisotope management and security. This not only allows for comprehensive safety compliance, but has helped reduce chemical and radioisotope use and cost for the company. With the complicated procedures, safety precautions, guidelines and standard practices that must be followed with usage of any chemical, streamlining chemical and radioisotope management has cut valuable time, made better use of and cut costs nearly in half. The Radioisotope Tracking System simplifies material management and helping to increase efficiency of environmental management operations, sequentially increasing productivity, reducing costs, and ultimately increasing Chiron Corporation's profitability.

More information about these systems can be found at [www.chemicalsafety.com](http://www.chemicalsafety.com).

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