PrOFS Application: User Guide

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Revision Details

Version	Date	Revised by	Change Details
01	25-Sep-12	C Harland	This is a new document.
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Conventions

There are a number of text conventions used in this manual, as follows:

Example	Uses
PrOFS Application	This is a term that is defined in the Glossary at the end of the manual.
https://<dbname>.	This is example data or a field entry example.
Orders > Submit Order	This typeface is used for names of specific PrOFS objects such as menu options, field names or page names.
Proceed .	This is used to denote a button shown on the PrOFS pages.
	This is seen in the left margin and shows a note drawing attention to a specific feature, business rule or convention used in PrOFS.
	This is seen in the left margin and shows where there is an icon available for a specific PrOFS function.

Chapter 1
Introduction

This chapter discusses PrOFS overview, infrastructure, the Order life cycle and user interface conventions.

This user manual describes how to use PrOFS effectively to process client orders for radiopharmaceutical products. PrOFS stands for Product Order Fulfilment System. It is designed to provide a web-based system for processing client orders for short half-life radiopharmaceutical products used in medical scanning applications such as Positron Emission Tomography (PET) scanners.

PrOFS has two user interfaces; the **PrOFS Application** is a Windows PC based component used by the manufacturer to process orders submitted by their clients. The clients use the web browser-based **PrOFS web client** to submit orders, manage product deliveries and access order and product data.

As the order life cycle includes the release of pharmaceutical products, this system is designated a GMP-critical application. With this in mind, it has been designed and validated to meet international Good Manufacturing Practice (GMP) regulations, as well as those concerning regulated electronic records and signatures (**RERS**).

The Order Life Cycle

PrOFS has been designed around a life cycle model for orders as shown in *Figure 1-1* Orders are submitted by clients using the PrOFS web client. These orders are received by the manufacturer. The orders can be amended or cancelled by the client (or amended on their behalf by the manufacturer) until the orders are locked, just prior to manufacture. An order submission report can be printed by both parties as a record of their order.
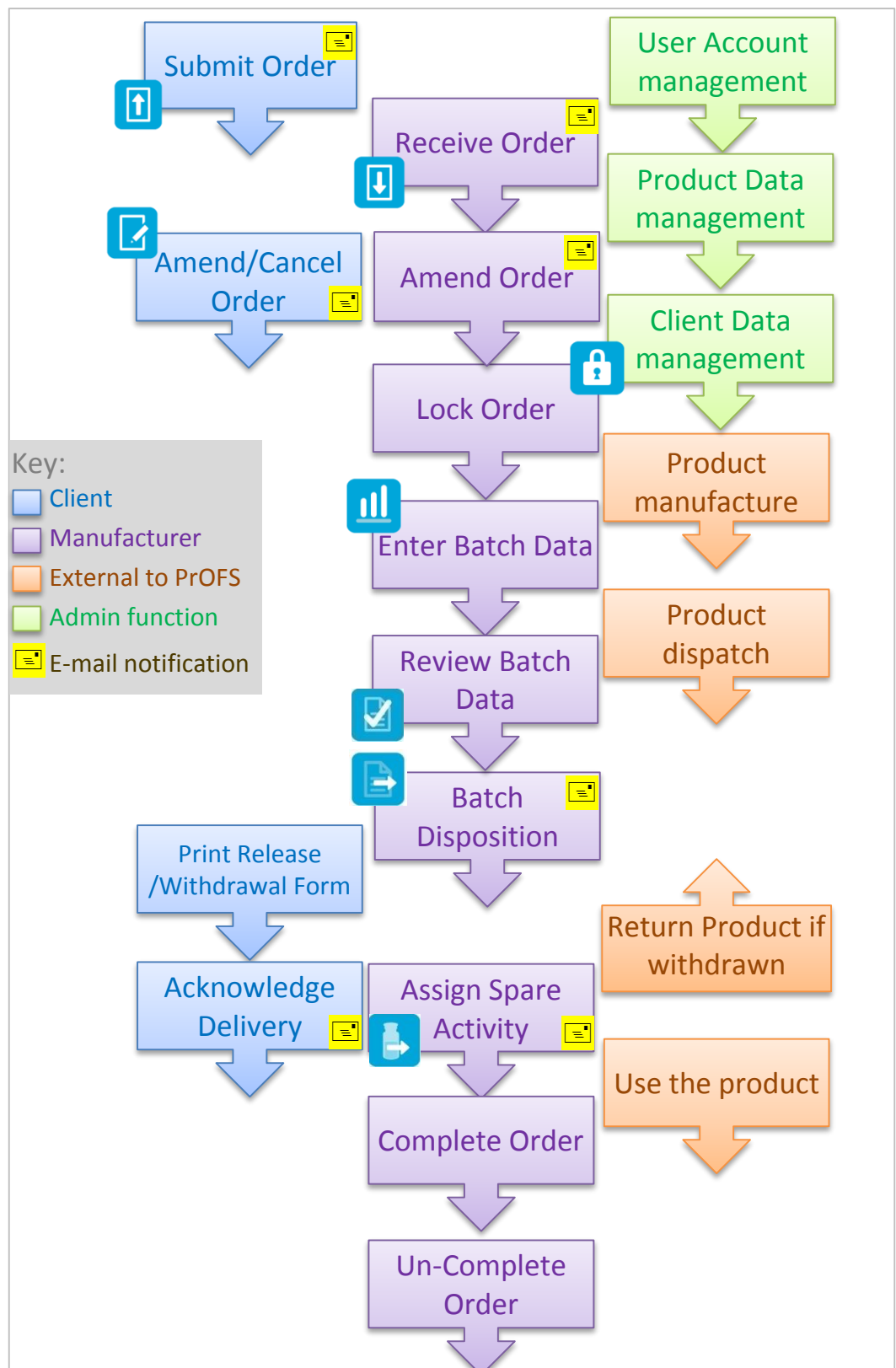
Figure 1-1 - Order Life cycle

External to the system, the manufacturer then commences manufacturer of the product, assumed to be in vials. From the batch manufacturing documentation, data

is entered into PrOFS application about the batch and the vials. Vials are assigned to any orders submitted, or may remain unassigned. A review of the batch data entered is carried out (by someone independent of the user who entered the batch data), and the batch may then be dispositioned by the **Qualified Person**, typically for release, but may be withdrawn if the batch does not meet appropriate quality standards. Because of the nature of short half-life radiopharmaceuticals, they are typically delivered under quarantine to clients soon after manufacture so that the radioactivity is at the appropriate level when the doses are administered. The product remains in quarantine at the client and is only released for use when the appropriate **Release Form** has been received from the manufacturer after approval by a **Qualified Person**.

The client user will be able to access the product **Release Form** via the PrOFS web client as soon as the batch has been dispositioned, which can be viewed on the screen and printed. The client then checks the product delivered against the **Release Form** to confirm it is suitable for use. They formally acknowledge this action using the PrOFS web client, then the product may be administered. In the case of a product withdrawal, a **Withdrawal Notice** is generated instead of a **Release Form**. The product remains in quarantine whether it is *en route* or has arrived at the client facility. If already delivered to the client, it is collected and returned to the manufacturer. If the product is still being delivered then the courier is intercepted by the manufacturer so that the product is not delivered to the client but returned directly to them for disposal.

There is provision in the system to allow unassigned vials (termed **spare activity**) to be assigned to an existing order, then delivered to a client who may require additional doses on the day due to, for example, equipment failure, staff availability or has added patients to their clinic.

At an appropriate point e.g. the next working day, orders may be closed out (**completed**) by the manufacturer and the number of billable doses assigned to the order, to help with the client billing process. Subsequently, orders may be re-opened (**un-completed**) by the manufacturer to amend the billable doses assigned to the order.

There are variations allowed in the order life cycle. For orders of unlicensed products, where these must be assigned to specific patients, it is possible to prevent disposition of individual vials until they have been assigned to a specific order, which must contain the patient identification and doctor's name for each dose. Doses used to calibrate scanning instruments (**calibration doses**) do not require disposition. After data review, they are available to the client to acknowledge on delivery.

Users gain access to the **PrOFS Application** and the **PrOFS web client** by logging on, where they must correctly enter their personal User Name and password. Multiple incorrect attempts at log in results in the user's account being locked by the system. User accounts are used to configure specific permissions for each system function, to allow actions to be restricted to those necessary for the user to perform their role in PrOFS.

At key points in the order life cycle there is an option to send e-mail notifications to other PrOFS users, as an additional communication mechanism that some event has

occurred. Such notifications can be sent at order submission, order amendment/cancellation, order receipt, disposition, assigning spare activity and delivery acknowledgement. These notification events can be configured for each user as part of the User Account set-up. All e-mail services are operated independently by PrOFS and do not require the use of existing e-mail applications for sending the notifications.

PrOFS Infrastructure

PrOFS is a web-based system – see *Figure 1-2*. Communications are performed using a secure internet communications protocol, which is encrypted. Each PC or laptop used for the *PrOFS Application* or *PrOFS web client* communicates with a PrOFS database, which is stored on the PrOFS server. The database stores all PrOFS data related to user accounts, products, clients, orders and batches manufactured. Manufacturers and clients therefore must have readily available internet access to operate PrOFS. As all data is stored in the database on the server, PrOFS cannot be operated if internet access is interrupted.

If there is a history or known likelihood of internet disruptions at your facility it is suggested that having a backup means of accessing the internet access for operating PrOFS is considered, such as a mobile broadband dongle from a mobile network provider, providing the facility has sufficient signal strength.

The specifications for PCs and laptops to operate *PrOFS Application* are:

- Operating System - Microsoft Windows XP/Vista/7 machine
- Internet Connection (Recommend broadband speeds of 100kbps/user)
- Minimum 1GB RAM memory
- Minimum 1024 x 768 (XGA) Monitor resolution

Note: PrOFS Application is not designed to operate on Apple computers or operating systems for portable devices, such as Android

The specifications for PCs and laptops to operate *PrOFS web client* are:

- Operating System - Microsoft Windows XP/Vista/7 machine*
- Web browser: Mozilla Firefox 3.6 or later, Microsoft Internet Explorer 9 or later*
- Application to view PDF documents (e.g. Adobe Acrobat Reader)
- A minimum processor equivalent of a 1GHz Pentium IV is recommended with 512MByte RAM.
- Minimum 1024 x 768 (XGA)Monitor Resolution
- Minimum 256 kilobit Broadband connection

* Other operating systems (e.g. Android) and web browsers (e.g. Google Chrome) may operate PrOFS web client successfully, but these have not currently been tested by the system supplier so correct operation is not guaranteed.
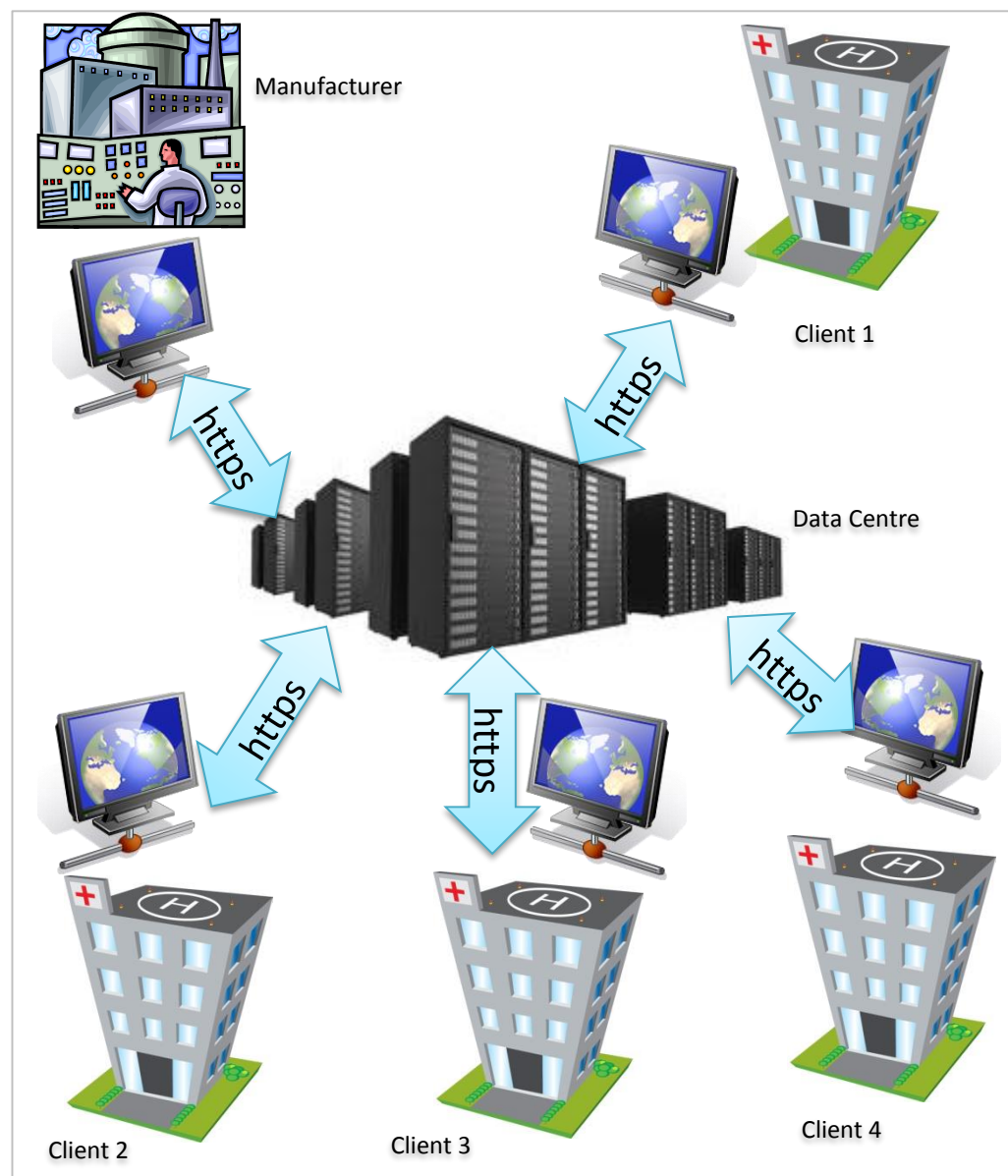

Figure 1-2 - PrOFS communication infrastructure

The system prints reports on standard monochrome or colour printers that have drivers for the above Microsoft Windows operating systems, connected either locally or via a wireless/cabled networked.

Any organisation using PrOFS must ensure that suitable PC anti-virus software and/or network firewalls are installed, operable and are updated to ensure that the PrOFS system and data integrity is maintained.

Other Considerations before using PrOFS

As PrOFS is a GMP-critical system there are a number of other considerations in using the system in your business.

- There is a regulatory expectation that all users will have appropriate training for their use of the system, and this should be documented. This is the responsibility of the manufacturer who operates the system for their products.

- The system utilises electronic signatures for key actions. All users must be aware that the e-signature is the legally binding equivalent of their handwritten signature. It is recommended that each user must agree to this in writing, for example by signing a declaration on the form completed when setting up their user account.

- In order to aid compliance with electronic record regulations, the system records key actions for system access, orders and batch data in an audit trail, which records who did what, when, what changed and the reason for doing so, where appropriate. This implies that the system must be able to identify each user. This occurs by the system recording the User Name, entered at login, for each action. It is therefore critical that each user account is traceable to an individual user, which means that:

  a) The User Name must be linked to the recognisable full name of the user (used when printing reports)

  b) It is therefore not permitted to have generic logon accounts that may be used by more than one user.

  c) As a condition of use, each user is responsible for keeping their logon password confidential.

  It is highly recommended that these points are included in the training of each user.

- The exception to point b) above is the default account created when the PrOFS instance is created. As part of the initial system configuration, once specific User Accounts are created, at least one of which has permission to edit User Account information, the default account must either be locked or permissions be restricted to only those functions in PrOFS which do not modify critical data.

User Interface Conventions

The *PrOFS Application* uses standard Windows features in the design of the user interface. The main window is a fixed size and is divided into three sections, the header ❶, the main body ❷ and the footer ❸ – see *Figure 1-3*. The header contains function access tools such as key function icons ❶ and a menu ❷, as well as current user information ❸.
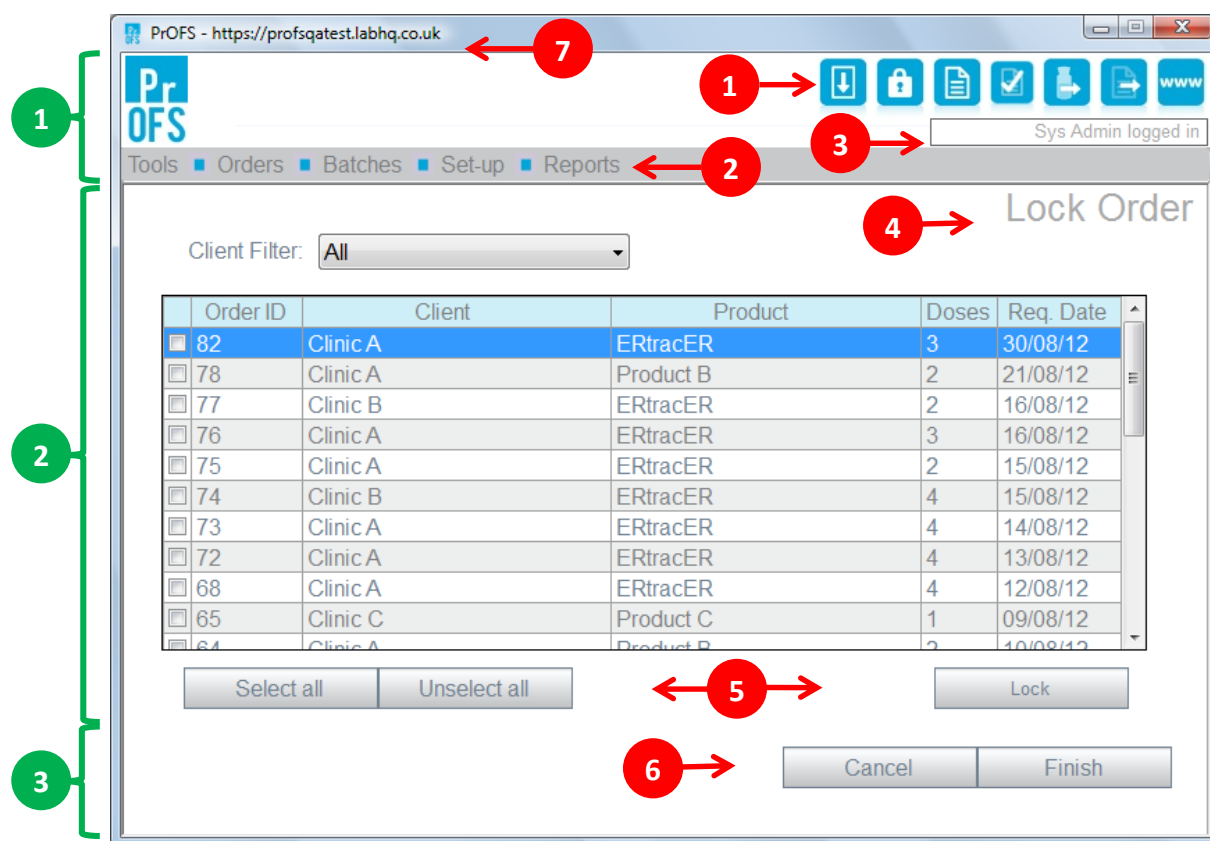
Figure 1-3 - Application User Interface features

The main body is situated below the menu bar and its content is function-specific, though each page typically has a title ❹ and function-specific action buttons ❺. The footer generally contains only navigation buttons ❻ to end the current function, such as Cancel, Finish etc. though may also contain function specific buttons for certain pages where there is many data fields to be displayed..

The title bar of the window contains the address of the PrOFS system currently being used ❼. It is in the form *https://<dbname>.labhq.co.uk*, where *<dbname>* is the unique name of the specific PrOFS system.

By default the main body displays the ***Orders Dashboard*** when no other function pages are open (see Chapter 3).

Questions, warnings and confirmations are typically displayed as pop-up dialog windows, which are conventionally navigated using Yes, No, OK or Cancel buttons.

Header features

The icons are used as a quick, one-click means of accessing key functions in the Order life cycle. The number of icons displayed will depend on the current user's permissions. Hover the cursor over the icon to pop up a function description.

The menu options are laid out in a logic manner, grouping the functions according to the data to which they relate. Like the icons, the menu options displayed will be dependent on the current user's permissions.

Main body features

This area typically contains a data grid or a series of data entry fields (or both), depending on the function.
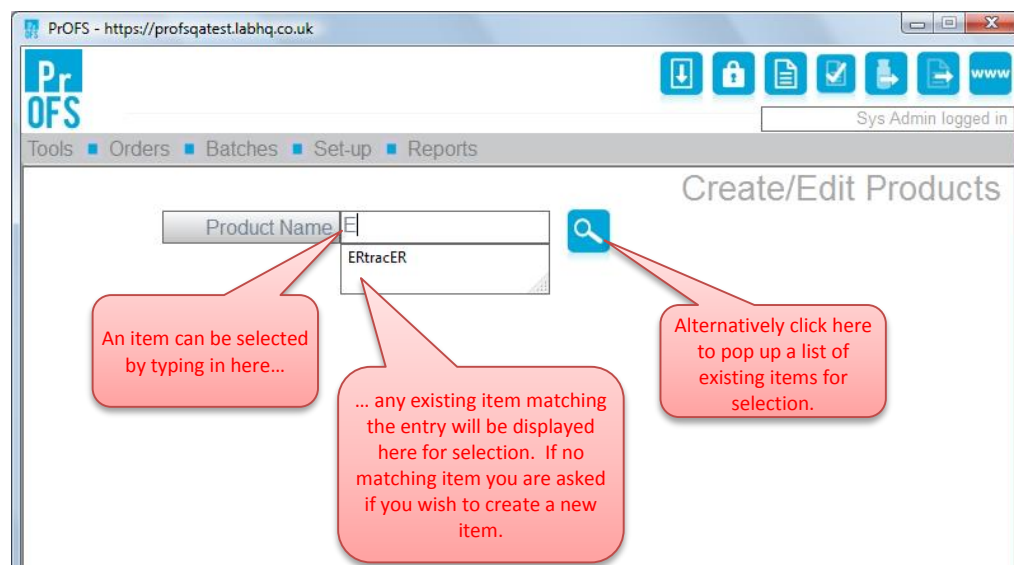

Figure 1-4 - Item selection methods for Set-up pages

Data grids may have selection check boxes where multiple rows of data are to be selected (see the order data in *Figure 1-3* for example)In this case, there are usually Select all and Unselect all buttons, sometimes labelled Set All and Unset All, to facilitate quicker selection. The Set-up data pages require an item to be selected first, such as a specific user, product or client. See *Figure 1-4*. The item may be selected either by typing in the name of the item in the entry field, in which case matching items are listed below as you type, or use the search button, shown a magnifying glass icon. This will pop up a list of items for selection. Typing in a name that is not already in use will prompt if a new item is to be created.

Some Set-up data pages have tabbed sub-pages where there are several stacked pages of data – see *Figure 1-5*. These can be navigated by clicking on the tab header or using Previous and Next buttons.
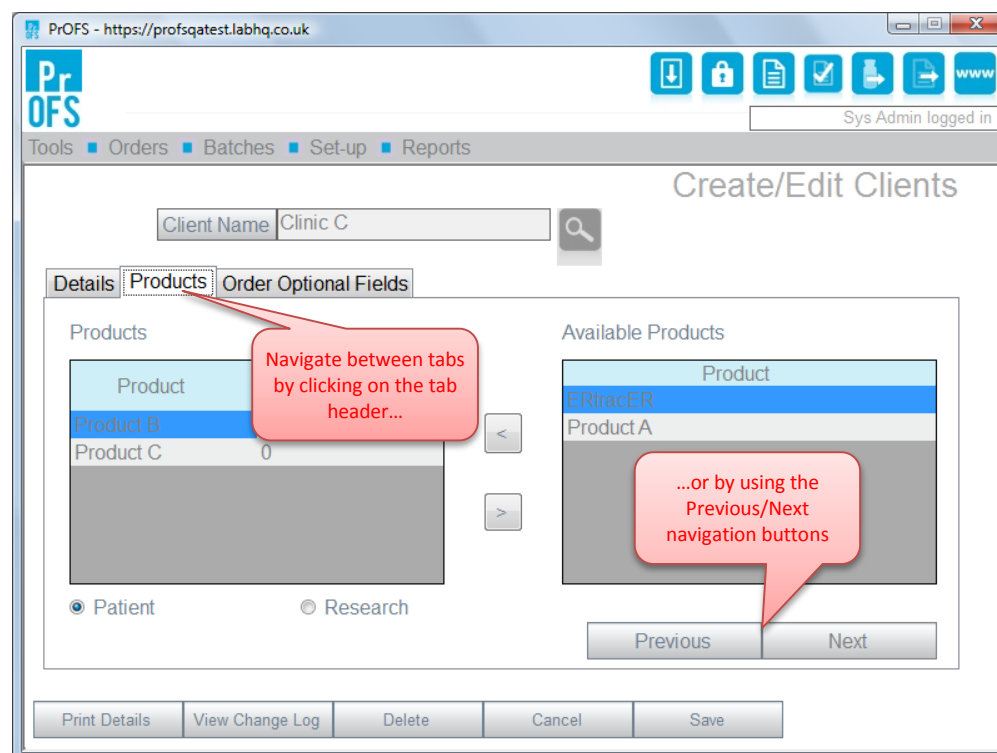
Figure 1-5 - Example of tab pages

Footer features

The footer typically contains only buttons to navigate away from the current page though some pages also place specific function buttons in this area.

The general buttons seen here are:

Finish – used to complete the specific function, close the child page and display the *Orders Dashboard*.

Cancel – used to close the child page, usually ignoring any data selection, entry or changes, and returns to the previous page or *Orders Dashboard*.

Save – used where data has been entered or modified to save the data, then usually returns to the previous page or *Orders Dashboard*.

PrOFS Reports

PrOFS generates data in the form of reports. These are generated in real time as pdf documents; they are not stored in the system. They are initially displayed in a separate window by your default pdf reader application. You can then retain or communicate the report either by printing a hard copy, saving as a file or e-mailing to another person. The availability of print, save and e-mail functions and how they work will be dependent on which pdf reader application is used by default on your computer. In the case of e-mail, this does not use PrOFS e-mail notification system, so you must have a suitable e-mail application if you wish to send the report as an attachment e.g. Microsoft Outlook.

By default, the system does not apply any security to the pdf reports as it is anticipated that these will be mostly printed immediately. If you require these features in order to save or e-mail the pdf, then you will need to install Adobe Acrobat or a similar pdf reader application which can then be set up as your default pdf reader, while also providing these features.

Many reports also give the option to alternatively export the report data into a file format that can be opened in Microsoft Excel. This may be useful if there is a need to use the data in another document or perform further analysis or processing of the data. Depending on the report, it may be necessary to filter out or remove page header and footer information from the exported data before processing and formatting can be performed.

Note that once report data has been exported it is no longer controlled by PrOFS security features, so data integrity is not guaranteed and must be manually controlled as required.

Chapter 2
Installation and Set Up

This chapter describes the PrOFS installation process and the initial set-up required.

Installation Process

Client users who only require use of the *PrOFS web client* require no installation; the interface operates entirely in a web browser session. It is suggested that the web address is retained as a shortcut on the user's desktop or as a Favourite in the browser application.

The *PrOFS Application* runs an application program which is stored on the PC, so the application must first be installed. This is performed by accessing SkySource Limited's PrOFS web site via the internet from a web browser. The web address is system-specific and will be supplied by the supplier on request. The installation is facilitated by a wizard which leads the installer through the installation process.

Note: In order to complete the installation process, the installer must have appropriate access privileges to install an application on the computer e.g. PC Administrator level access.

If PrOFS has previously been installed, it is recommended that this version is first removed by uninstalling using Windows. Note: You may need PC administrator privileges to perform this action. Press the Windows start button and in the Start Search field, type *Programs*. The Search results should display a program called Programs and Features – select this. This will display a list of installed applications on the PC. Select PrOFS then the Uninstall menu option. You may be prompted to confirm you wish to uninstall PrOFS. On completion, PrOFS is removed from the list of installed programs.

As PrOFS is a GxP-critical application, it may be necessary to install the *PrOFS Application* in a formal, documented manner. Please consult the system owner or your Quality Assurance representative on this.

In the example here, the PrOFS instance will be called *profsmain* but this would be substituted by the name of the PrOFS instance you will mainly use.

Open a browser window and type

https://profsmain.labhq.co.uk/install/profssetup.msi

You may get prompted to confirm if you wish to Run or Save – select Run . Depending on your version of Windows and your system's security settings, you may also be warned that the program is not commonly downloaded and may harm your computer. Select Actions and select *Run Anyway*. The installation wizard will load and display the start page (*Figure 2-1*). This shows the version of PrOFS that is appropriate for your system.
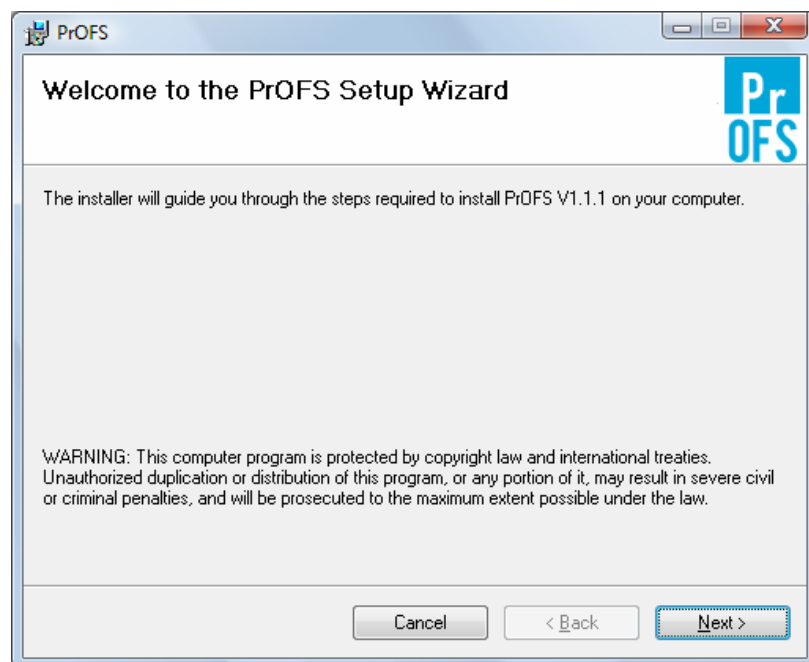
Figure 2-1 - Opening page of the installation wizard

You can halt the installation process at any point by using Cancel .

Select Next > to display the next wizard page (*Figure 2-2*). There are a couple of decisions to be made here. The page shows the default location to store the PrOFS files, but you have the option to change the default folder using Browse... . Unless there is a good reason for doing so, go with the default options.

The second choice is to decide whether to install PrOFS so that it is available to all users of the PC, or just the current user account. If you share the PC with a number of PrOFS users then select Everyone.
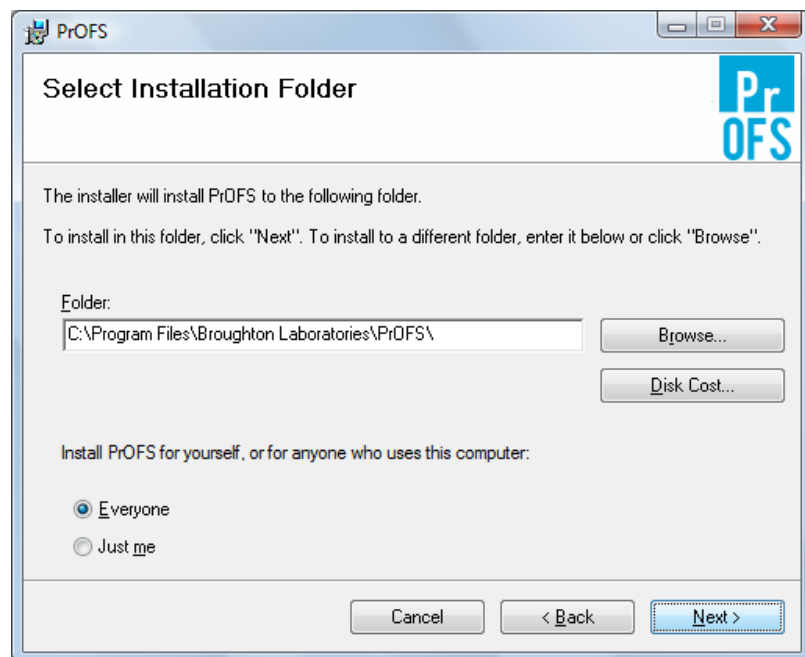
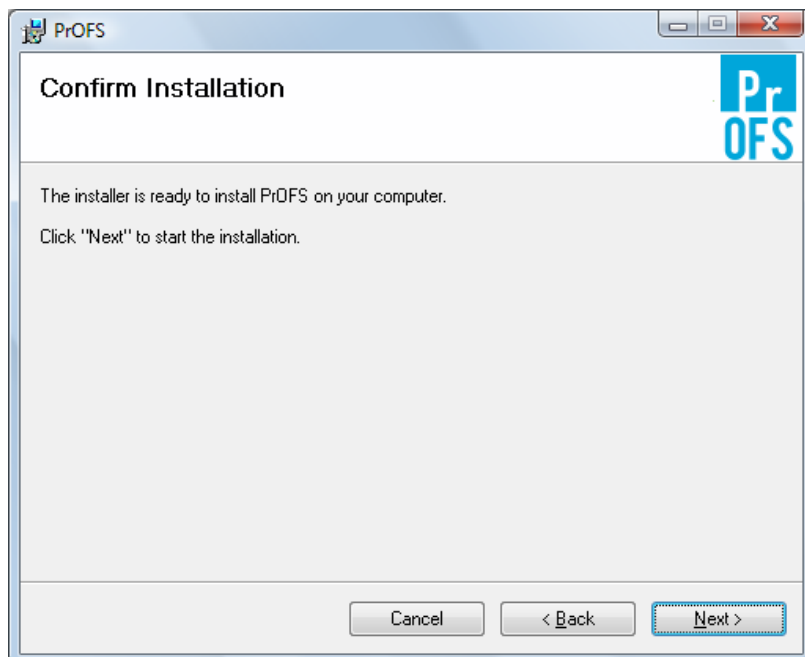*Figure 2-2* - Page 2 of the Installation Wizard

Figure 2-3 - Page 3 of the Installation Wizard

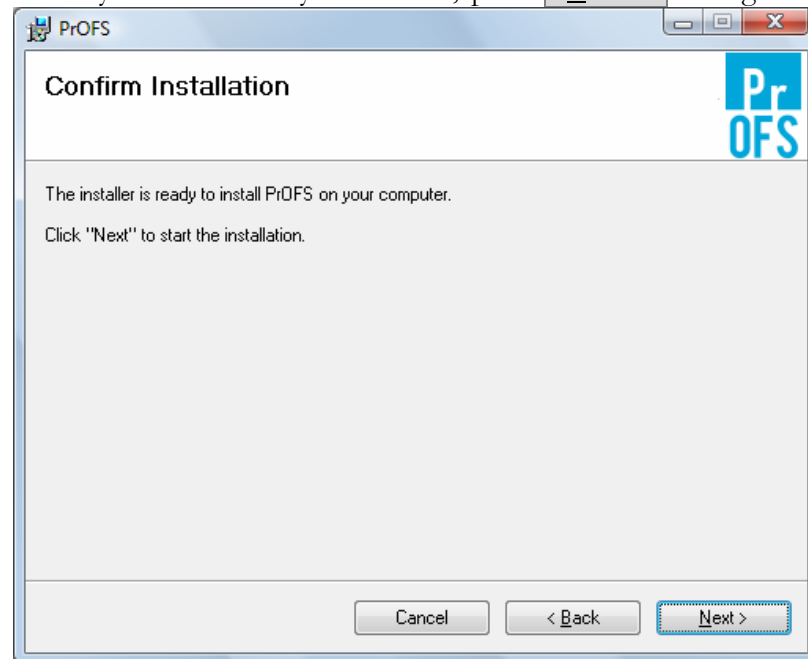When you have made your choices, press [Next >] . Page 3 of the wizard (

Figure 2-3) prompts you to confirm you wish to proceed with the installation. Press [Next >] to proceed or [Cancel] to cancel the installation.

On proceeding with the installation, page 4 of the wizard is displayed while the installation takes place (*Figure 2-4*).
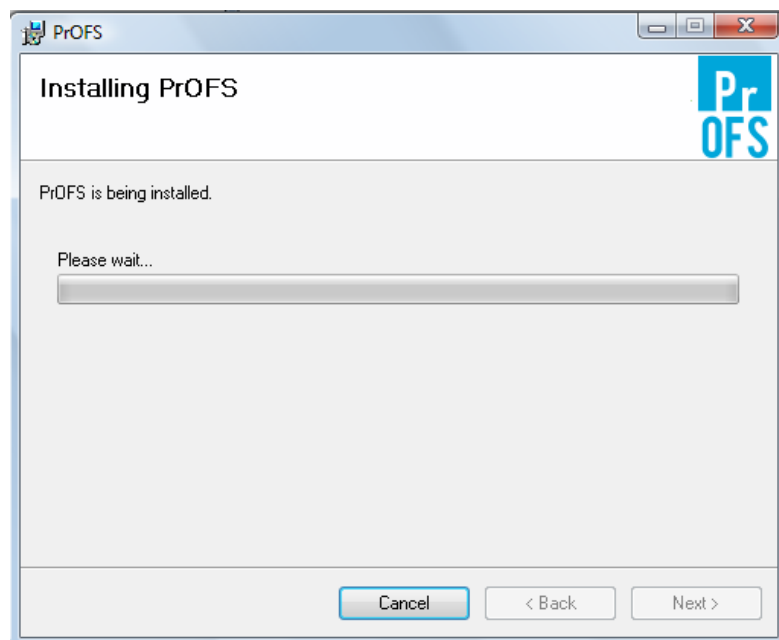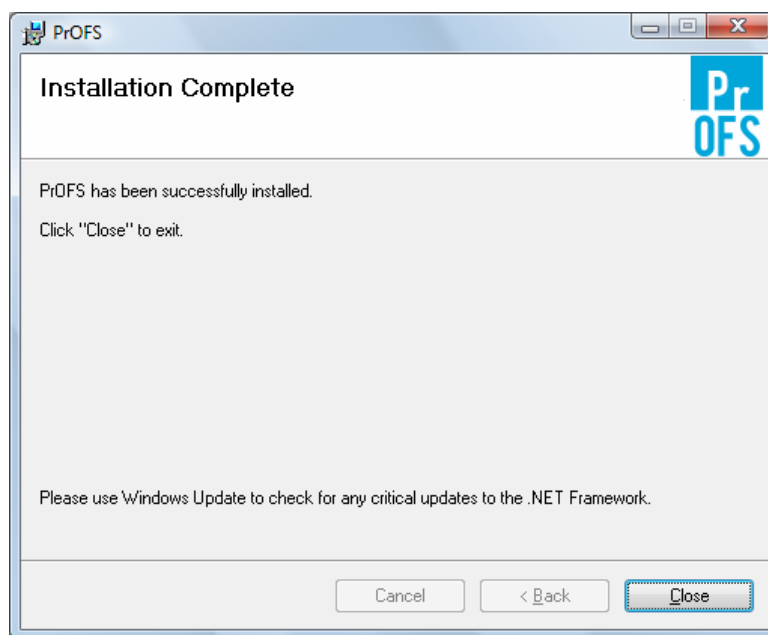

Figure 2-4 - Wizard page during installation

Figure 2-5 - Final installation wizard page

The progress bar shows how the installation progresses, though this typically only takes a few seconds on a broadband connection. At the end of the installation, the last wizard page is displayed (*Figure 2-5*).

Press | Close | to end the installation process.

There should now be a Windows desktop shortcut for the ***PrOFS Application***. The application may also be accessed from the Start menu, by pressing *Start > All Programs > PrOFS*.

PrOFS uses pop-up windows for warnings and information prompts. Before you start PrOFS, ensure your browser is configured to accept pop-up windows by adding *.labhq.co.uk* as a web site that is allowed to use pop-up windows. The browser's pop-up blocker tool varies between browsers, but is usually accessed from the browser's Tools menu.

Initial Set-up

On starting the ***PrOFS Application*** after installation, there will be a prompt to set the web address for the PrOFS database (see *Figure 2-6*). When you press | OK | the Settings page is displayed (see *Figure 2-7*). Enter the address you have been given for the PrOFS database you wish to use. This is typically the first part of the address used for installation. For example, it would be

https://profsmain.labhq.co.uk
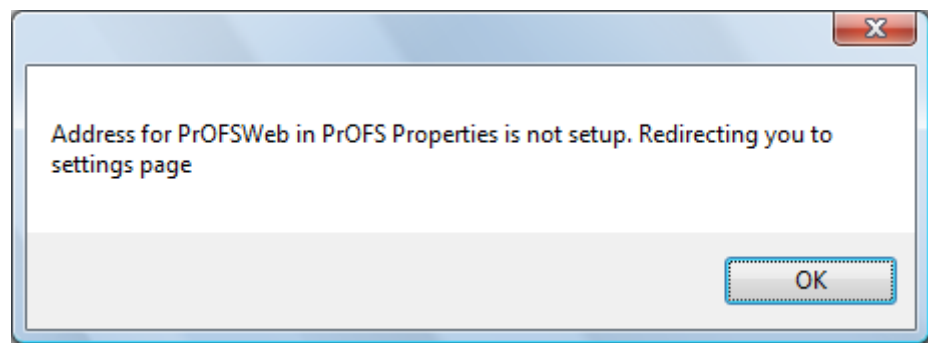
if the database is called profsmain.

Figure 2-6 - Web address set-up prompt

On pressing ⬚ Save ⬚ you will be directed to the logon page. See *Chapter 3, Access Management* for a description of the login process. The Settings page is the only function that is available before logging onto the system, to allow access to different PrOFS databases, should this be required. This is accessed by selecting *Tools > Settings* from the logon page.
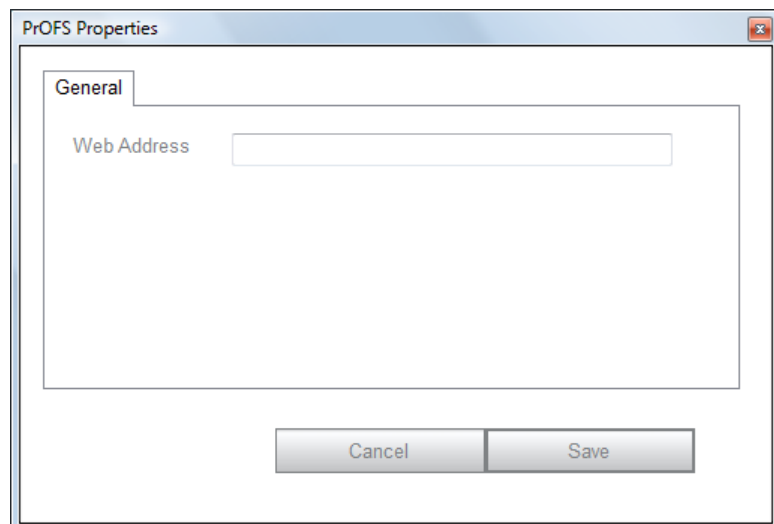

Figure 2-7 - The Settings page

Initial Configuration Activities

The initial set-up of a PrOFS system involves the following activities:

Creating one or more products – see Chapter 4, *Product Data Management*

This chapter describes how client product information is created and configured.

Products in PrOFS

Product data is required by PrOFS to allow selection at order submission. Also, information on product expiry must be known to allow batch data checks to be performed and to guide how and when product can be assigned to orders.

Clinics order calibration doses for use in calibration the scanning equipment. PrOFS matches calibration orders against a special product created on PrOFS which is

designated as a *calibration product*. This implies that orders for calibration doses must be made independently of patient or research doses, irrespective of the source of the material used for a calibration dose.

Creating a Product in PrOFS

Product set-up is performed by PrOFS Application users with Edit Products permission and is accessed from the PrOFS menu using *Set-up > Products*.

On selecting this option the Create/Edit Products start page is displayed (see *Figure 4-1*). To create a new product just type in a Product Name that does not already exist in this PrOFS instance. NB Products are unique to each instance of PrOFS so must be created for each instance to which they have access. Also the Product Name field is a unique identifier for the product so may not be changed once saved, so it should be chosen and checked for spelling errors when entered before saving the record.

As you type, any matching values will be displayed for quicker selection, so typing *P* will match any accounts where the Product Name starts with P. If the Product Name typed is matched exactly then it already exists and when you press Enter (↵) the existing product data will be displayed. Finish ends the function and returns to the Main Page.

On entering a new Product Name you will be prompted to confirm you wish to create a new product. On selecting Yes the main Create/Edit Products page is displayed (see *Figure 4-2*).
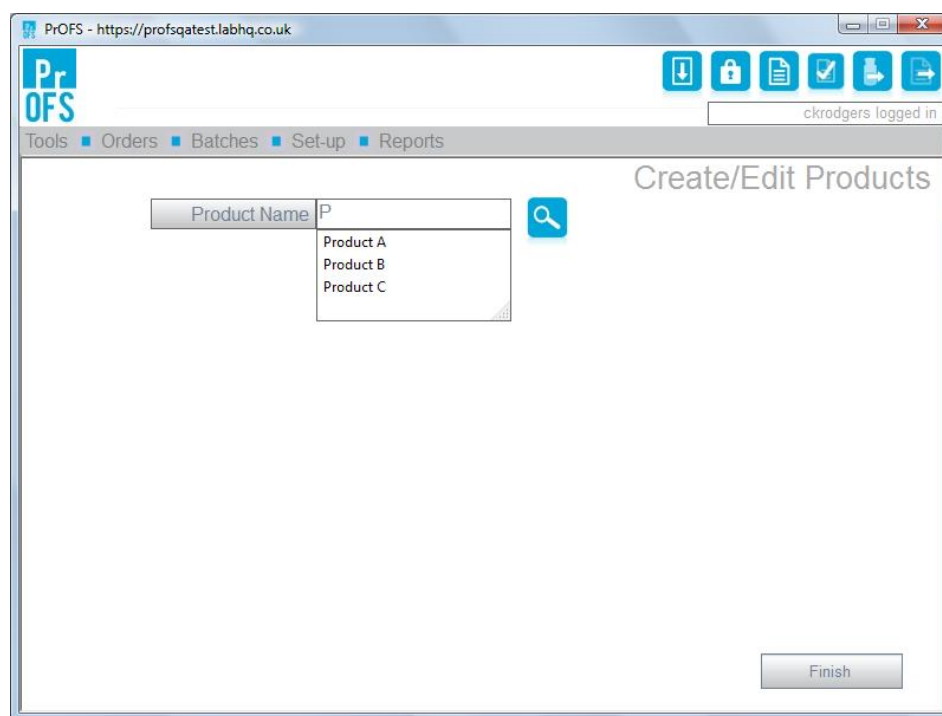

Figure 4-1 - Create/Edit Products start page

The *Description* field is optional and allows a fuller description of the product, which can be referenced in a report if required.

The *For Calibration* check box is checked when creating a product that is used to order calibration doses. It is possible to have multiple products designated as **calibration products**, for example if clients insist on a specific name for the **calibration product**, though typically only one is required for each system.

The *Expiry/Shelf life* field is used to enter the time to expiry (or shelf life) of the product from the defined start point, which is typically End of Synthesis. Due to the short half-lives of these radiopharmaceuticals, this value is entered in units of hours. This must be specified for any product though is ignored for a **calibration product**.

The *Allow release prior to assignment* check box is used when it is desirable to release a product vial even though it is not assigned to a specific order. It is therefore possible for a QP to release a batch of vials, but some of these may be later assigned to late orders or as **spare activity**. The main use of this field is to leave it unchecked for unlicensed products, where typically there must be a named patient/prescription for release of the product vial.

Figure 4-2 - Create/Edit Products main page.

Similarly, the *Include Patient Information on Orders* flag is checked for unlicensed products which forces the person submitting the order to enter a patient identifier and doctor name for each dose ordered. For licensed products this would generally remain unchecked unless the client wishes to enter the data so that it is formally recorded and printed on the Order Submission report.

The *Default Report* field may be used to assign an alternative report template to that used as the default report used for the **Release Form**/ **Withdrawal Notice** for this

product only. If this feature is to be used, then the alternate report template must have been developed and loaded into the system using the Report Management function (see *Chapter 16, Report Management* for more details). This report template would then be listed in the drop-down list. The default value of *No report* means that the system default report template is used.

The product data entered is saved by pressing Save . The creation of the product may be discarded before saving by using Cancel . Either button will return PrOFS to the Create/Edit Products start page.

Changing Product Data

The modify the product data, an existing product is selected at the Create/Edit Products start page.

Figure 4-3 - Selecting an existing product for editing

A product is selected by starting to type the Product Name and select from the list of matches, or by selecting the magnifying glass icon to pop up a list of products for selection – see *Figure 4-3*.

The existing product details will then be displayed (see *Figure 4-4*) and may be modified in the same manner as creating the product, described in the previous section. Use Cancel to cancel the modification process and Save to save the changes made. On saving modified data, the user will be prompted to enter a reason for change and this will be recorded in the audit trail event. The entry must be a minimum of six characters to be accepted, but should adequately describe the reason for changing the product record.

In addition there are a number of other option buttons:

 Print Details - generates a report of the product configuration. The report is generated in a separate window as a pdf file (no export option).

View Change Log - generates an audit trail report for the product record. The report is generated in a separate window as a pdf file (no export option).

Delete - retires the product so that it may no longer be used (the record is not actually deleted from the system). A reason for deleting the product must be entered. It is not possible to reinstate a retired product, therefore before deleting a product from the system, ensure that there are no outstanding orders for that order requiring completion or cancellation, or any batches that have not expired.

Figure 4-4 - Create/Edit products main page - modifying a product

Create Similar - this button allows a new product to be created based on the same data as the current product record. This is a shortcut to creating new products when they are similar in the settings. The user is prompted to enter a new Product Name (must be unique) then the product record is opened so that any of the data fields can be modified.

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Client Data Management

Chapter 3
Access Management

*This chapter describes getting logged on and
how user accounts are managed, permissions
set and notifications configured.*

Log on to PrOFS

Access to the PrOFS Application is controlled by entering a User Name and a
password associated with the user's PrOFS account. The User Name must be
unique to each user and the password is known only to the user. The system owner
will likely have agreed on a convention for the User Name.
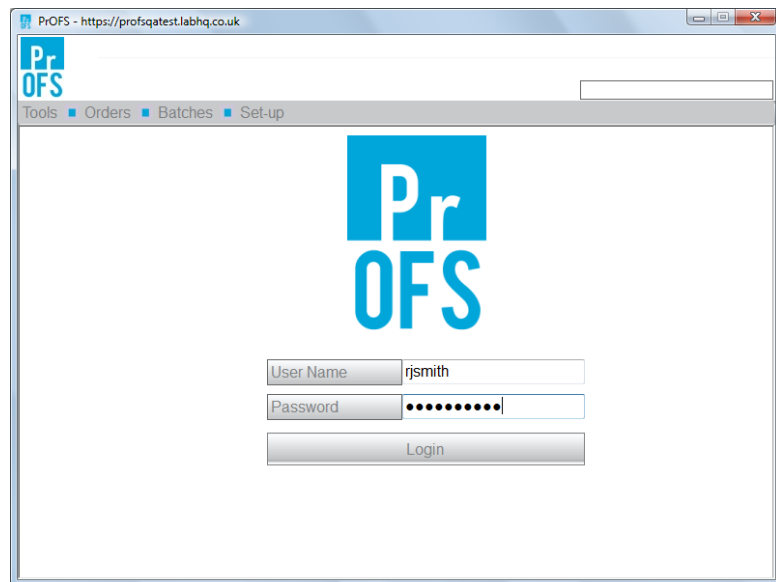
Figure 3-1 - PrOFS Application logon page

In the examples in this chapter the convention of using one or more initials and
surname, all in lower case characters will be used e.g. rjsmith.

When PrOFS is started, the logon page is displayed (see *Figure 3-1*). Both User Name
and Password field are case-sensitive, so a User Name of *rjsmith* can not be entered
as *RJSmith*. By convention, the characters entered for the password are obscured on

the page for security. A user's initial password will be provided by a system administrator or line manager.

Pressing ⌊ Login ⌋ will cause the system to check the user credentials are valid. If either the User Name or password have been entered incorrectly, a warning will be displayed to this effect and another attempt will be permitted. As part of the system configuration, there is likely to be a limit on the number of attempts; if this is exceeded the user account will be automatically locked and must be unlocked by an account administrator (a user with Edit User permissions).

When a user first logs in or after their password has been manually reset, they will be prompted to enter a new password. (see *Figure 3-2*). The password must be different from the current value. The Strength indicator gives a value based on the length and complexity of the password. Depending on the system configuration, the password may be rejected if it is not strong enough. The new password must be entered then re-entered for verification. There is no specific limit to the length of the password, but it needs to be practical. A combination of upper and lower case characters and numbers will make a stronger password.

Figure 3-2 - Password Change page

On successful login, the main application page, showing the Orders Dashboard, will be displayed. While the PrOFS application running, the window title bar and page header provide information on which database is being accessed and who is logged on respectively (see *Figure 3-3*).
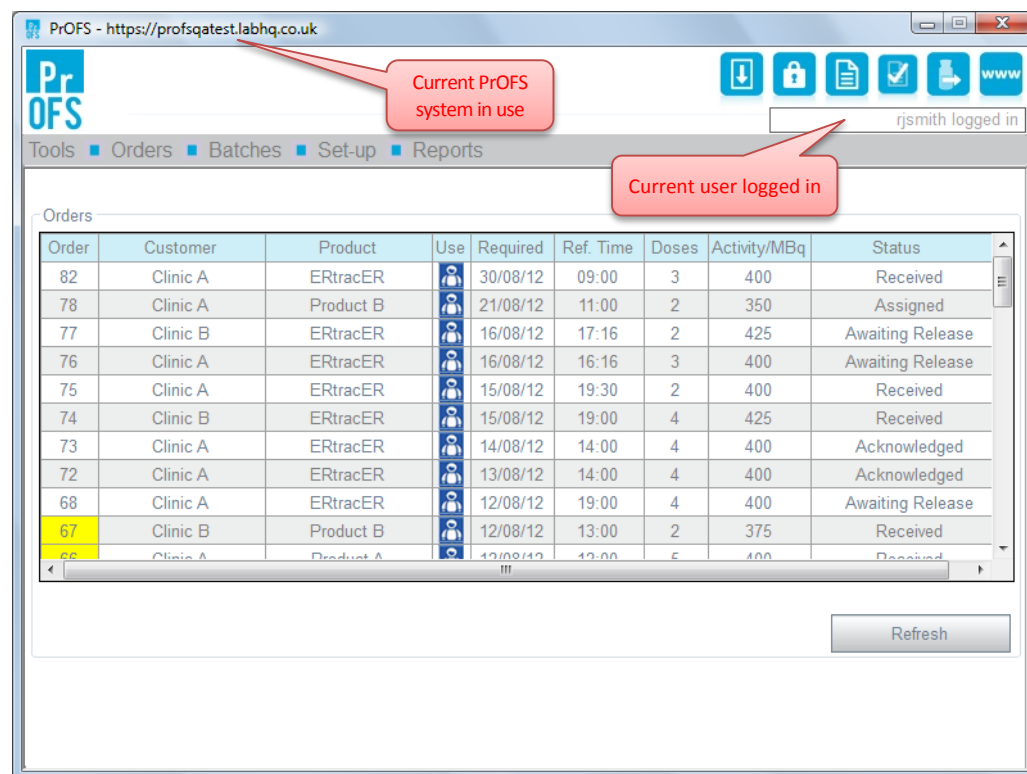
Figure 3-3- Main Page showing the Orders Dashboard

Creating a User Account

User Accounts can be created and modified by those PrOFS users with Edit User permissions and is accessed from the PrOFS menu using *Set-up > Users*.

On selecting this option the Create/Edit Users start page is displayed (see *Figure 3-4*). To create a new user account just type in a User Name that does not exist on this system. NB User Accounts are unique to each instance of PrOFS so users must be created for each instance to which they have access. Also note that the User Name field is the unique identifier for this user account and may not be changed, so must be chosen carefully.

As you type, any matching values will be displayed for quicker selection, so typing *A* will match any accounts where the User Name starts with A, such as *Administrator*, *ajones* etc. If the User Name typed is matched exactly then it already exists and when you press Enter (↵) the existing account details will be displayed. | Finish | ends the function and returns to the Main Page.

On entering a new User Name you will be prompted to confirm you wish to create a new user account. On selecting | Yes | the main Create/Edit Users page is displayed (see *Figure 3-5*).

Figure 3-4 - Create/Edit Users start page

User Account data is entered using tabbed pages; there are three displayed initially – the Client tab is added on selecting the permission for web access.

Figure 3-5 - Create/Edit Users main page

The *Details* tab is where the basic user information is entered. The information fields are described in *Table 3-1*.

Field	Description
Full Name	This should contain the full name of the user, as this field is referenced on any report when an action is identified with a user, such as Submitted By, Amended By or Released By. It is a mandatory field; the User record cannot be saved unless it is completed.
Password	This is where the initial password is entered and re-entered to confirm, or when a password is manually reset. Password entry is as described in the previous section. This field is mandatory.
Job Title	This is an optional field but should be entered, especially for anyone dispositioning a batch as it is printed on the *Release Form*.
Email	The e-mail field is optional but a valid e-mail address must be entered if e-mail notifications are used.
Internal User	This should be selected if the user account is created for an internal user of the system. (e.g. employees of the manufacturer).
External User	This should be selected if the user account is created for an external user of the system. (e.g. employees of the client ordering product from the manufacturer). If selected, Application Access is not available for the user account.
Account Locked	This may be optionally checked during account creation to lock the account from being used e.g. if the account is created prior to the user competing their PrOFS training.

Table 3-1 - Details tab fields

The *Permissions* tab is where the functions permitted for the user are assigned (see *Figure 3-6*). Check *Application Access* if the user belongs to the manufacturer. Check *Web Access* if access to the web client is also required for the user. Web Access may be required for example, by a support member who needs to see the client view, or for a manufacturer user if orders are to be cancelled by the manufacturer. If *Web Access* is checked then a tab labelled *Clients* will be added.

A list of permissions will be displayed for each Access option that is checked. These are described in *Table 3-2* and *Table 3-3*. Permissions are set by checking the appropriate item, either individually or using Set All . They are deselected by unchecking the item or using Unset All .

Permission	Gives access to…
Administrator	…system configuration and report management.
Amend Orders	…amend orders from the PrOFS Application
Batch Deletion	…remove a batch from the system if created in error
Batch Disposition	…release or withdraw a batch
Batch Entry/Edit	…create/modify the batch data

Permission	Gives access to…
Batch Review	…review the batch data for accuracy and completeness
Batch Un-Release	…rescind the batch disposition decision
Complete Orders	…mark an order as closed and add billing data
Edit Clients	…create or modify client data
Edit Products	…create or modify product data
Edit Users	…create or modify user accounts
Lock Orders	…lock orders to prevent amendment or cancellation
Receive Orders	…acknowledge order submission, amendment or cancellation
Set Out of Hours	…set/clear a warning to client users that the manufacturer is unable to acknowledge orders submitted or amended
Spare Activity Assignment	…assign spare vials of released product to existing orders or request
Un-Complete Order	…mark an order as un-complete
Unlock Orders	…unlock orders to allow amendment or cancellation
View Reports	…access all reports from the Report menu.

Table 3-2 - Application Permissions

Figure 3-6 - Permission tab

Permission	Gives access to...
Accept Delivery	...acknowledge the *Release Form* or *Withdrawal Notice*
Amend Order	...amend an existing order
Cancel Order	...cancel an existing order
Print Acknowledgement Form	...generate the Acknowledgement Form for the *delivery*
Print Release Form	...generate the *Release Form* or *Withdrawal Notice* for the *delivery*
Submit Orders	...submit an order for product or calibration dose
View Orders	...access the View Order page in the *PrOFS Web Client*

Table 3-3 - Web Client Permissions

The *Client* tab is displayed when *Web Access* is checked and allows the selection of which client(s) the user will have access to (see). The typical case is that client user accounts will only have access to a single client as this is the mechanism PrOFS uses to preserve client confidentiality. Manufacturer users, system support staff or third parties, for example, who may submit orders on behalf of multiple clients, may require access to several (or all) clients.
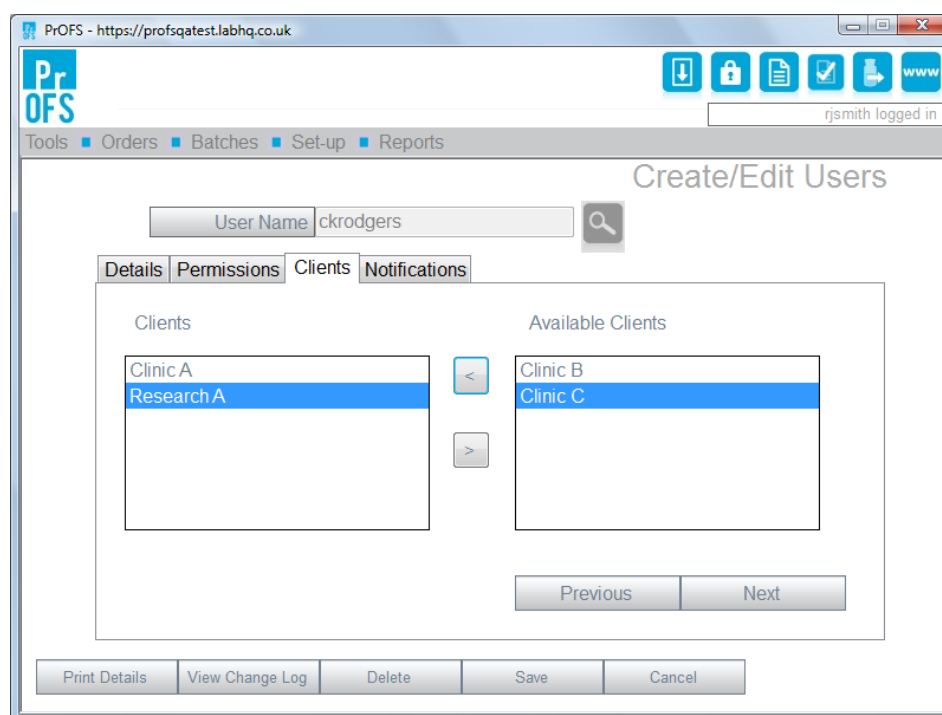
Figure 3-7- Clients tab

Note that the Web Access permissions selected will be applied equally to all clients chosen. Also note that a user with Web Access must have at least one client selected.

This tab displays a list of all active clients on the right-hand side, and a list of chosen clients on the left-hand side. A client is selected by highlighting their name and pressing < . A client is similarly deselected by using > .

The last data tab in Users set-up is *Notifications* (see *Figure 3-8*). Notifications can be sent by the PrOFS e-mail service at important events, as an additional means of communication. These are entirely optional. The notifications are described in *Table 3-4* and are chosen by checking those required.

Notification	Occurs when…
Delivery Accepted	…the client acknowledges the *Release Form* or *Withdrawal Notice*
Order Amendment	…the client amends an order
Order Assigned	…a batch is dispositioned or spare activity is assigned
Order Cancelled	…an order is cancelled
Order Received	…an order submission, amendment or cancellation is received by the manufacturer
Order Submission	…an order is submitted by the client

Table 3-4 - Notification events

When chosen the user's e-mail address is shown at the e-mail prompt for that specific event, where it may still be cancelled if necessary.

The user data entered is saved by pressing Save . The creation of the user account may be discarded before saving by using Cancel . Either button will return PrOFS to the Create/Edit Users start page.

Changing User Accounts

To modify a user account, an existing user is selected at the Create/Edit Users start page.

A user is selected by starting to type the User Name and select from the list of matches, or by selecting the magnifying glass icon to pop up a list of user accounts for selection – see *Figure 3-9*.

Figure 3-8 - Notifications tab

The existing user details will then be displayed and may be modified. Note that the User Name field is the unique identifier for this user account and may not be changed. Use Cancel to cancel the modification process and Save to save the changes made. On saving modified data, the user will be prompted to enter a reason for change and this will be recorded in the audit trail log. The entry must be a minimum of six characters to be accepted, but should adequately describe the reason for changing the user account record.

Figure 3-9 - Select Existing User page

When modifying an existing user account, a feature is that on the *Details* tab, in place of the password entry fields there is a button labelled | Reset Password |. This may be used by the current user to reset the password for the selected user account if the password has been forgotten. When the button is pressed the password fields are displayed to enter and confirm a new password.

In addition there are a number of other option buttons:

| Print Details | - generates a report of the user account settings. The report is generated in a separate window as a pdf file.

| View Change Log | - generates an audit trail report for the user account. The report is generated in a separate window as a pdf file.

| Delete | - retires the user account (the record is not actually deleted from the system). A reason for deleting the user account must be entered. It is possible to reinstate a retired account by typing in the original User Name (does not appear in the selection list after being retired). On confirmation that the account is to be reinstated, it is displayed for modification if required, or to be saved.

| Create Similar | - this button is located on the *Details* tab and allows a new user account to be created based on the same data as the current user. This is a shortcut to creating new user accounts when they are similar in permissions, notifications etc. The user is prompted to enter a new User Name (must be unique) then the account is opened so that any of the data fields can be modified. The password and e-mail address fields must be completed as a minimum.

This *Edit User* function must also be accessed to manually lock a user's account if it is to be temporarily disabled, or to unlock a user's account if it has previously been locked either manually or by the system following the maximum attempts at entering log on credentials. Locking and unlocking are achieved by checking/unchecking the *Account Locked* option respectively.

Changing Your Password

A user may change their own password at any time by selecting *Tools > Change Password*. The page displayed is the same as when first logging on – see *Figure 3-2*.

Additionally, depending on your system configuration, passwords are given an expiry period, after which you are forced to change your password at the next log-on. Similarly if your password has been reset by a system administrator, you will also be required to change your password.

Chapter 4
Product Data Management

*This chapter describes how client product
information is created and configured.*

Products in PrOFS

Product data is required by PrOFS to allow selection at order submission. Also, information on product expiry must be known to allow batch data checks to be performed and to guide how and when product can be assigned to orders.

Clinics order calibration doses for use in calibration the scanning equipment. PrOFS matches calibration orders against a special product created on PrOFS which is designated as a *calibration product*. This implies that orders for calibration doses must be made independently of patient or research doses, irrespective of the source of the material used for a calibration dose.

Creating a Product in PrOFS

Product set-up is performed by PrOFS Application users with Edit Products permission and is accessed from the PrOFS menu using *Set-up > Products*.

On selecting this option the Create/Edit Products start page is displayed (see *Figure 4-1*). To create a new product just type in a Product Name that does not already exist in this PrOFS instance. NB Products are unique to each instance of PrOFS so must be created for each instance to which they have access. Also the Product Name field is a unique identifier for the product so may not be changed once saved, so it should be chosen and checked for spelling errors when entered before saving the record.

As you type, any matching values will be displayed for quicker selection, so typing *P* will match any accounts where the Product Name starts with P. If the Product Name typed is matched exactly then it already exists and when you press Enter (↵) the existing product data will be displayed. ⬚Finish⬚ ends the function and returns to the Main Page.

On entering a new Product Name you will be prompted to confirm you wish to create a new product. On selecting Yes the main Create/Edit Products page is displayed (see *Figure 4-2*).

Figure 4-1 - Create/Edit Products start page

The *Description* field is optional and allows a fuller description of the product, which can be referenced in a report if required.

The *For Calibration* check box is checked when creating a product that is used to order calibration doses. It is possible to have multiple products designated as **calibration products**, for example if clients insist on a specific name for the **calibration product**, though typically only one is required for each system.

The *Expiry/Shelf life* field is used to enter the time to expiry (or shelf life) of the product from the defined start point, which is typically End of Synthesis. Due to the short half-lives of these radiopharmaceuticals, this value is entered in units of hours. This must be specified for any product though is ignored for a **calibration product**.

The *Allow release prior to assignment* check box is used when it is desirable to release a product vial even though it is not assigned to a specific order. It is therefore possible for a QP to release a batch of vials, but some of these may be later assigned to late orders or as **spare activity**. The main use of this field is to leave it unchecked for unlicensed products, where typically there must be a named patient/prescription for release of the product vial.

Figure 4-2 - Create/Edit Products main page.

Similarly, the *Include Patient Information on Orders* flag is checked for unlicensed products which forces the person submitting the order to enter a patient identifier and doctor name for each dose ordered. For licensed products this would generally remain unchecked unless the client wishes to enter the data so that it is formally recorded and printed on the Order Submission report.

The *Default Report* field may be used to assign an alternative report template to that used as the default report used for the **Release Form**/**Withdrawal Notice** <u>for this product only</u>. If this feature is to be used, then the alternate report template must have been developed and loaded into the system using the Report Management function (see *Chapter 16, Report Management* for more details). This report template would then be listed in the drop-down list. The default value of *No report* means that the system default report template is used.

The product data entered is saved by pressing Save . The creation of the product may be discarded before saving by using Cancel . Either button will return PrOFS to the Create/Edit Products start page.

Changing Product Data

The modify the product data, an existing product is selected at the Create/Edit Products start page.

Figure 4-3 - Selecting an existing product for editing

A product is selected by starting to type the Product Name and select from the list of matches, or by selecting the magnifying glass icon to pop up a list of products for selection – see *Figure 4-3*.

The existing product details will then be displayed (see *Figure 4-4*) and may be modified in the same manner as creating the product, described in the previous section. Use Cancel to cancel the modification process and Save to save the changes made. On saving modified data, the user will be prompted to enter a reason for change and this will be recorded in the audit trail event. The entry must be a minimum of six characters to be accepted, but should adequately describe the reason for changing the product record.

In addition there are a number of other option buttons:

Print Details - generates a report of the product configuration. The report is generated in a separate window as a pdf file (no export option).

View Change Log - generates an audit trail report for the product record. The report is generated in a separate window as a pdf file (no export option).

Delete - retires the product so that it may no longer be used (the record is not actually deleted from the system). A reason for deleting the product must be entered. It is not possible to reinstate a retired product, therefore before deleting a product from the system, ensure that there are no outstanding orders for that order requiring completion or cancellation, or any batches that have not expired.

Figure 4-4 - Create/Edit products main page - modifying a product

Create Similar - this button allows a new product to be created based on the same data as the current product record. This is a shortcut to creating new products when they are similar in the settings. The user is prompted to enter a new Product Name (must be unique) then the product record is opened so that any of the data fields can be modified.

Chapter 5
Client Data Management

*This chapter describes how client
information is created and configured.*

How is Client Data used in PrOFS?

PrOFS uses client information for several purposes:

- It is used to segregate order data so that client users have access only to the order data relevant to their organisation.

- It is used to restrict which products can be ordered by each client, and the dose per patient ordered for each product, as this may be restricted by license or technical agreement.

- It is also used to determine whether clients use the product for patients or animal research; the current version only permits either one or the other, but not both.

- PrOFS stores client contact information, such as postal address and telephone number so that this may be included on reports.

- Lastly, client configuration allows the creation of custom fields that can hold data of relevance to that client which can be entered and recorded at order submission, and generated on reports.

Creating a Client in PrOFS

Client set-up and modification by PrOFS Application users with Edit Clients permission and is accessed from the PrOFS menu using *Set-up > Clients*.

On selecting this option the Create/Edit Clients start page is displayed (see *Figure 5-1*). To create a new client just type in a Client Name that does not already exist in this PrOFS instance. NB Clients are unique to each instance of PrOFS so must be created for each instance to which they have access.
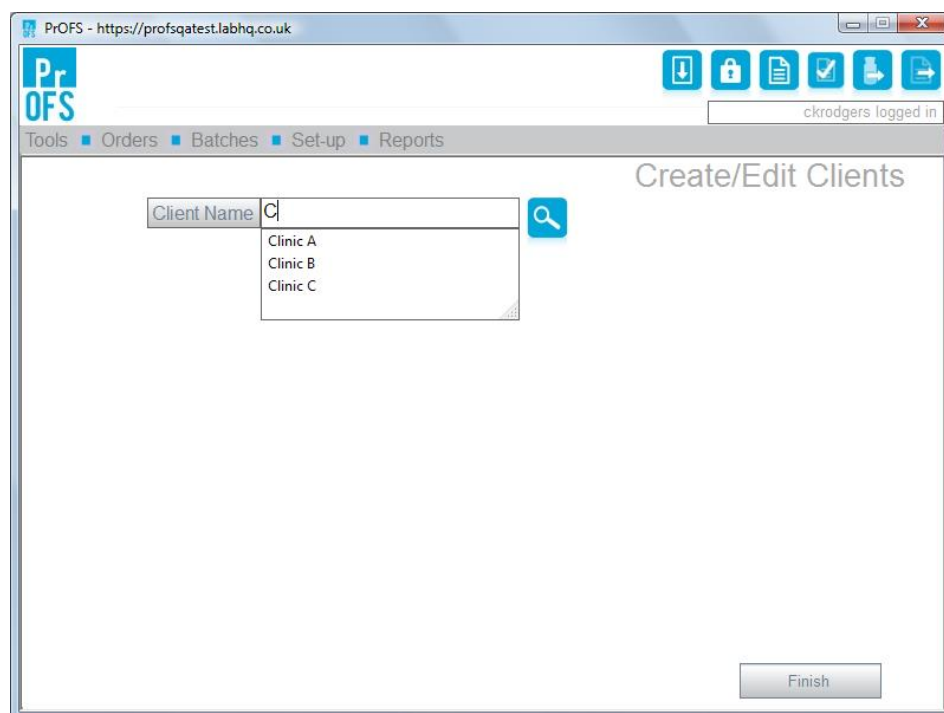
Figure 5-1 - Create/Edit Clients start page

As you type, any matching values will be displayed for quicker selection, so typing *C* will match any accounts where the Client Name starts with C. If the Client Name typed is matched exactly then it already exists and when you press Enter (↵) the existing client data will be displayed. Finish ends the function and returns to the Main Page.

On entering a new Client Name you will be prompted to confirm you wish to create a new client. On selecting Yes the main Create/Edit Clients page is displayed (see *Figure 5-2*). Client data is entered using three tabbed pages.

The *Details* tab permits entry of client contact information, postal address fields, telephone number and an e-mail address. All of these fields are optional, but the address fields should be completed in order that the client address is included on reports such as the **Release Form**.

The *Product* tab is used to specify product data for the client (see *Figure 5-3*). On the right-hand side is a list of available products, and the left-hand side displays a list of products available to the current client.

Figure 5-2 - Create/Edit Clients main page showing the Details tab

Figure 5-3 - Create/Edit Clients showing the Products tab

Select either *Patient* or *Research* to designate whether the client uses products for human patients or for animal research.
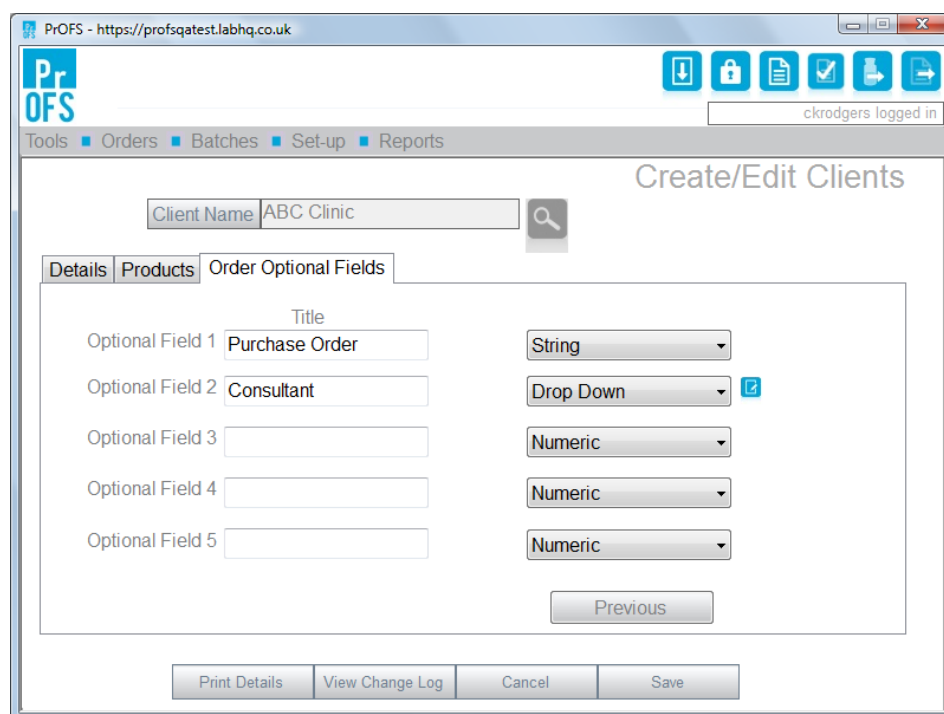
Select each product in turn on the right then use < to add it to the client's products list. To remove a product from the client's list use > .

The default activity value (value is 0 when selected) is entered for each selected product in units of megabecquerels (MBq) and this value is the agreed dose per patient, which is displayed but cannot be changed when submitting an order for patient. Where products are used for research or as a calibration dose (see *Chapter 4, Product Data Management*) a default value may be entered here if required, but this can be modified when submitting or amending an order, as it is likely to be more variable.

At least one product must be defined to save the client record.

The *Order Optional Fields* tab is used to configure data fields which may need to be recorded as part of the order data submitted by the client (see *Figure 5-4*).

Figure 5-4 - Create/Edit Clients page showing Order Optional Fields tab

An example of where an optional field is useful is if the client wishes to record a purchase order number when submitting an order so that it may be linked to their purchasing system.

There are up to five optional fields available for use. These fields are usually discussed and defined prior to the client is introduced to PrOFS.

Data type	Description
Numeric	Only allows numeric characters to be permitted
String	Allows any combination of alphanumeric characters to be entered
Drop Down	Allows the selection of a value from a pre-defined list of choices

Table 5-1 - Order Optional Field data types

An identifier is entered in the Title field for each optional field then the data type is selected from the list of options (see *Table 5-1*).

When the Drop-Down data type is selected, a small list icon appears to the right of the row. Click on this to pop up a page to enter the list of values (see example in *Figure 5-5*).

Figure 5-5- List creation for Drop-Down data type

The client data entered is saved by pressing Save . The creation of the client may be discarded before saving by using Cancel . Either button will return PrOFS to the Create/Edit Clients start page.

Changing Client Data

To modify a client configuration, an existing client is selected at the Create/Edit Clients start page.
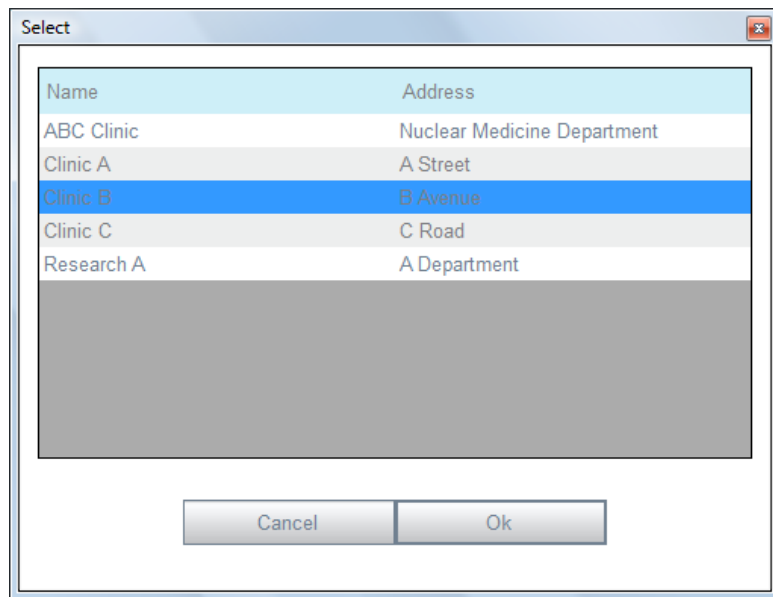
Figure 5-6 - Selecting an Existing Client

A client is selected by starting to type the Client Name and select from the list of matches, or by selecting the magnifying glass icon to pop up a list of clients for selection – see *Figure 5-6*.

The existing client details will then be displayed and may be modified in the same manner as creating the client, described in the previous section. Use | Cancel | to cancel the modification process and | Save | to save the changes made. On saving modified data, the user will be prompted to enter a reason for change and this will be recorded in the audit trail event. The entry must be a minimum of six characters to be accepted, but should adequately describe the reason for changing the client record.

In addition there are a number of other option buttons:

| Print Details | - generates a report of the client configuration. The report is generated in a separate window as a pdf file (no export option).

| View Change Log | - generates an audit trail report for the client record. The report is generated in a separate window as a pdf file (no export option).

| Delete | - retires the client so that it may no longer be used (the record is not actually deleted from the system). A reason for deleting the client must be entered. It is not possible to reinstate a retired account, therefore before deleting a client from the system, ensure that there are no outstanding orders for completion or cancellation.

Chapter 6
System Settings

This chapter describes the system administration settings and their configuration.

System Configuration Settings

The system configuration settings are accessed using *Tools>Administration>Settings*. This requires the user to have the Administrator permission. The settings are spread across five tabbed pages.

The General tab

The General tab includes general system settings, which includes the fields as described below:

The *Password Strength* field is a value set between 0 and 100 and represents the minimum strength a password must have to be accepted by the system. 0 is no password required and 100 is the strongest level of password. The higher the setting the longer and more complex the password must be, including the use of non-alphabetical and non-numeric characters. The algorithms used to calculate the password strength are described in *Table 6-1*.

Rule #	Description
1	Any score above 75 is classed as strong. The maximum score is 100.
2	If password is 1 character score = 1
3	If password is equal to username score = 2
	Otherwise score is made up as follows:
4	Score = length of password * 4
5	Score increased if no repetition of letters/words

Rule #	Description
6	Score increased by 5-20 if password includes combination of lower and upper case or special characters (e.g. * , @).
7	Score increased by 10 if password contains letters and numbers
8	Score increased by 10 if password contains letters and spaces
9	Score decreased if password contains username.

Table 6-1 - Password strength algorithms

Figure 6-1 - System settings showing the General tab

The *Force password change every n days* field is used to set the interval between mandatory password changes for all users, starting from date of the last password change (or creation for a new user account). Values of 0 to 999 are permissible where a value of 0 disables the function.

Max Logins defines number of allowable attempts before the user account is locked and the user cannot gain access to the **PrOFS Application** or **Web Client** until the account is unlocked (see *Chapter 3, Access Management*).

Password Signature Required is checked to enforce electronic signature functionality required for the key actions: Submission, amendment and cancellation of Orders, Batch data Review, Disposition and rescinding, Batch Deletion and Delivery Acknowledgement. If not checked there is no password entry enforced for any of these actions.
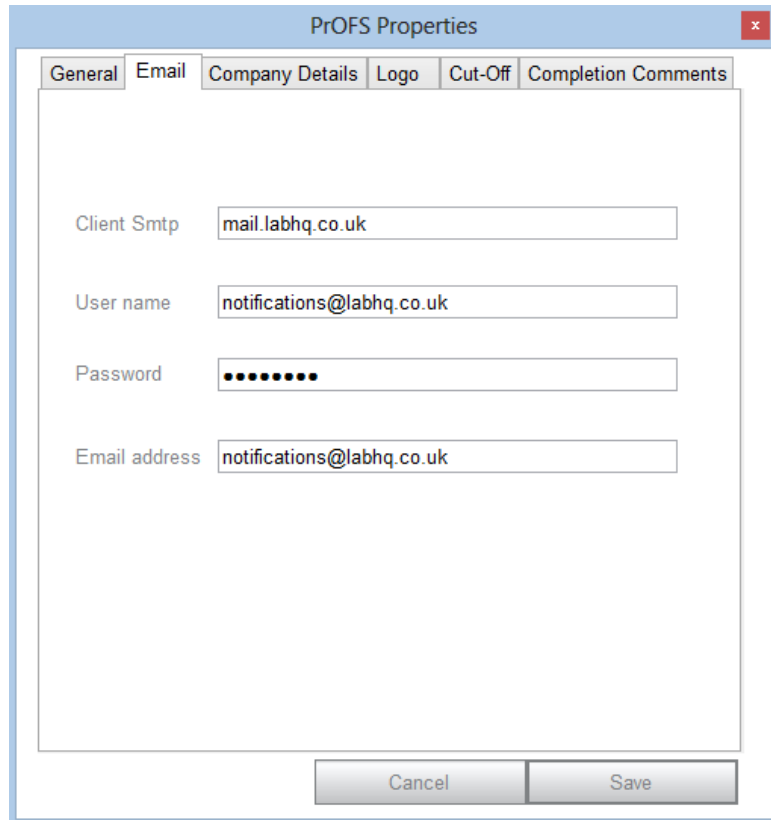
Check Expiry on Batches is checked to perform a check at Batch Data Entry that the difference in date/times recorded and entered for End of Synthesis and Expiry are the same as the Expiry period stored for that product, to the nearest minute. See *Chapter 10, Batch Data Entry* for more details.

Allow release of unassigned vials setting is checked to permit batch disposition for product vials that have not been assigned to an order. If not checked then only vials assigned to an order may be dispositioned. This works in conjunction with the Allow release prior to assignment field for each product, so that unassigned vial release can be product-specific. This feature is included so that licensed and unlicensed products may be controlled differently to help comply with regulations regarding release of unlicensed products in the European Union.

The *Default Product* field is used to define which product is selected by default at order submission and batch data entry. It requires the user to select the default product from the drop-down list of available products. This is included as a shortcut where the majority of orders are for a specific product. It may also be set to Undefined.

The E-mail tab

The purpose of the e-mail tab is to define the configuration of the PrOFS e-mail service used to send e-mail notifications (see *Figure 6-2*). These values are set when the PrOFS instance is created and should not be altered unless specifically indicated by the PrOFS support team at the supplier.

Figure 6-2 - the E-mail tab

The Company Details tab

This tab is entirely optional. It is used to allow the recording of the manufacturer contact details – postal address, telephone, e-mail address, web site etc. so that they be included in a report if necessary (see *Figure 6-3*). These fields are not included in any of the default report templates and are not used anywhere else in PrOFS but could be accessed for use in custom reports.

Figure 6-3 - Company Details tab

The Logo tab

This option can be used to define an image file which is then displayed in the web client (when not obscured by the *Order View* page). It is entirely optional and can be used to add corporate branding to the **Web Client** display. See *Figure 6-4*.

Use UpLoad to select an image file; the function supports most common image file formats such as jpg, bmp, png, gif etc. The image is displayed in a fixed window on the main web client page so it may necessary to crop or expand the width of the image to retain its aspect ratio. When an image has been loaded, it can be replaced by uploading another image or removed using Delete .
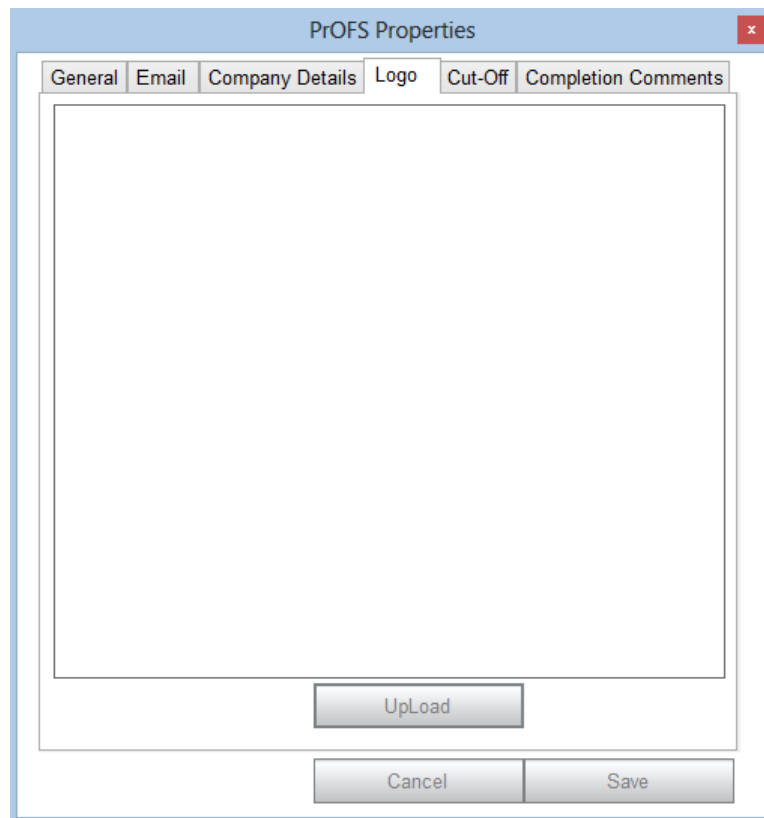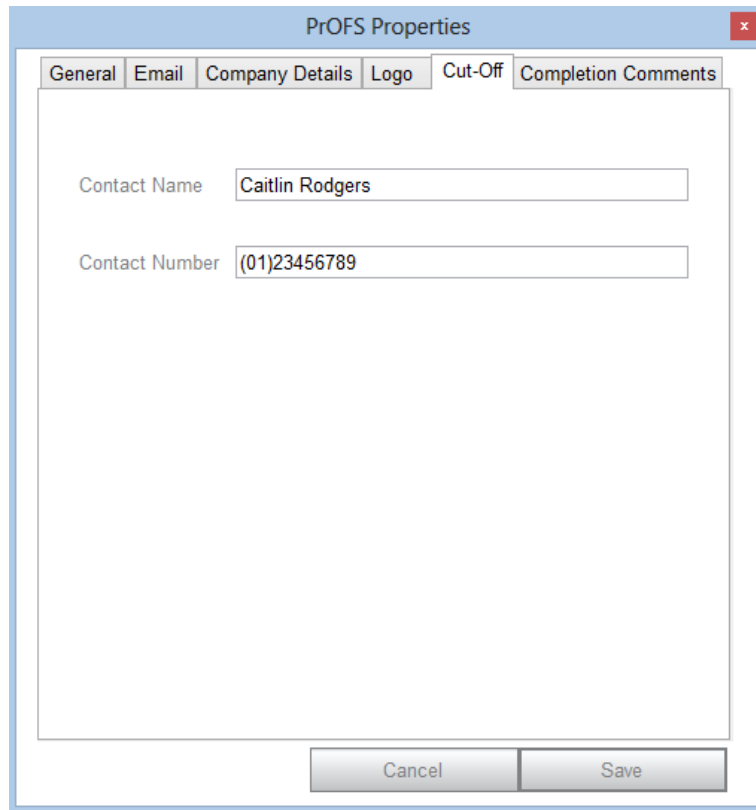
Figure 6-4 - the Logo tab

The Cut-Off tab

This tab allows entry of the data displayed in the warning for clients which can be set during out of office hours (see *Chapter 8, Order Controls* for further details on the warning). It allows entry of a contact name and a contact telephone number, which are stored in the system as the default values. Note these values can be edited when setting the Out of Hours flag but is included here so that be modified at other times.
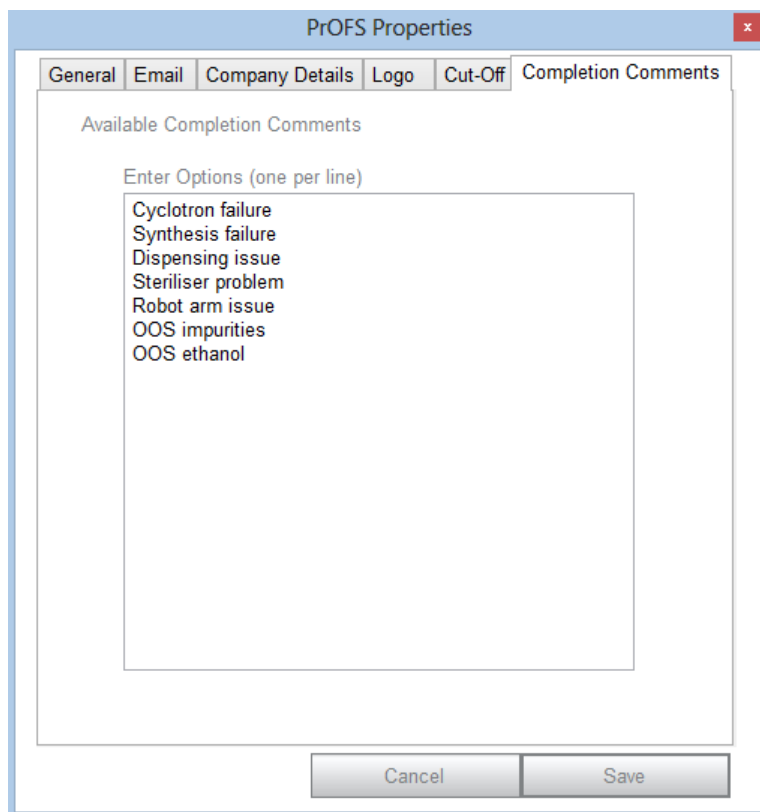
Figure 6-5 - the Cut-Off tab

When settings have been added or modified on any or all tabs, use Save to store the settings, else Cancel to discard any changes and return to the main page. When saving changes, a reason for change must be entered (a minimum of 6 characters).

The Completion Comments tab

This tab allows entry of data for selection within a drop down menu in the comment field when completing orders (see *Chapter 12, Order Completion).* It allows entry of options as one per line.

Figure 6-6 - the Completion Comments tab

When settings have been added or modified on any or all tabs, use Save to store the settings, else Cancel to discard any changes and return to the main page. When saving changes, a reason for change must be entered (a minimum of 6 characters).

Chapter 7

Receiving Orders

This chapter describes the Orders
Dashboard, receipt of orders and order
changes.

What is the purpose of Order Receipt?

Order receipt serves two purposes in PrOFS; it is a formal point in the system when the manufacturer acknowledges a new or modified order has been received by them. It also may be used to communicate the receipt of the order to the client. It is an integral step in the order life cycle, such that unless an order has been receipted it is not available for selection when assigning vials to orders at batch data entry.

As inferred above, an order must be receipted at order submission, but also when an existing order changes i.e. if it amended or cancelled by the client, so it is clear that the change has been acknowledged.

The Orders Dashboard

The manufacturer can keep up to date with new and changed orders by viewing the **Orders Dashboard** (see *Figure 7-1*). This page is displayed when starting the **PrOFS Application** and is the default page when not accessing specific PrOFS functions.

The Orders Dashboard displays all current orders i.e. those that have not been cancelled or completed. The order data is automatically refreshed approximately every minute and may be manually refreshed using Refresh .

As each order is submitted, it is assigned an incremental order number which is unique to the specific order. Each order is displayed in a separate row. When the screen becomes full there is a vertical scroll bar to view older orders. The orders are sorted so that the newest orders or changes are at the top.

Each row also displays the client, the product ordered, its intended use, when it is required, Reference Time, number of doses required and their activity. The order status is also displayed.

Figure 7-1 - The Orders Dashboard

The intended use is displayed as an icon. These include patient, research and calibration. Hover the cursor over an icon to display the meaning textually.

Order status informs the user at what stage in the order life cycle each order is currently at – see *Table 7-1* for an explanation of the status values.

If an order is locked the order number is highlighted with a yellow background – see orders 9, 10 and 11 in *Figure 7-1* for example.

Status	Description
Awaiting receipt	The order has been submitted but has not yet been formally received by the manufacturer.
Received	The order submission or change has been noted and received by the manufacturer.
Amended	The order has been modified by the client – this is highlighted with an amber background.
Cancelled	The order has been cancelled by the client (or on their behalf from the Web Client). This is highlighted with a red background. Cancelled orders remain on the dashboard until the next calendar day after the Required Date.
Assigned	There are vials assigned to the order but these have not yet been reviewed or released.
Awaiting Release	The batch data for the vials assigned to the order has been reviewed but has not been dispositioned.

Status	Description
Released	The vials assigned to the order have been released and are now available to the client for printing the *Release Form* and delivery acknowledgement.
Withdrawn	The vials assigned to the order have been withdrawn; the client can see this and can print the *Withdrawal Notice* and acknowledge this.
Acknowledged	The release or withdrawal of the vials assigned to the order has been acknowledged by the client.
Part acknowledged	This is displayed when there are multiple deliveries against the order and at least one delivery has been acknowledged.
Complete	This indicates that the manufacturer has closed out the order. It is included here for completeness but is never displayed on the Orders Dashboard, as completed orders are excluded from the dashboard immediately on perform the complete action.

Table 7-1- Order Status values

Receive Orders

Access to the Receive Order function is either via selecting the Receive Order icon (see left) or from the menu via *Orders > Receive*. To access this function the user must have the *Receive Orders* permission.

On selecting this function the *Receive Orders* page will be displayed (see *Figure 7-2*). The default view shows all orders that have a status of Awaiting Receipt or Amended, sorted in descending Order Number.

If there are many orders to receive then there is a client filter so that only orders for a specific client are displayed. The default value of the filter is *All*.

The user must select all the orders that are to be received. This can be done by checking the check box next to each order, or using Select All or Unselect All .

You can cancel the Receive Order action at any time before pressing Receive by using Cancel . When all orders are selected, press Receive . A prompt will be displayed to ask if e-mail notifications are to be sent. If you press Yes the e-mail notification page will be displayed (see *Figure 7-3*).

The *Send to* region will list the e-mail address of all users from the manufacturer and the order's client that have the Receive Order notification configured in their user account. Note that only PrOFS users can be e-mailed. If the list of users is long a scroll bar will appear. By default all of these users will be checked to receive the notification, but they may be individually deselected.

Figure 7-2 - Receive Order page

The *Subject field* and *Message body* will contain default information related to the order and its receipt. Both of these fields are editable to allow additional information to be added if required. Please note: the layout of the default data in the message body field may look unusual but when received in the e-mail each item is shown on a separate line – this is a limitation of the current text control that displays the message body text.

Press Send to send the e-mail notification. Press Cancel to cancel the e-mail notification.

Next a prompt is displayed asking if **Order Submission reports** are to be printed. If the response is Yes then a report is displayed for each order received in a single window. These may then be printed as pdf documents.

Figure 7-3 - Order Receipt E-mail notification page

The received orders will be removed from the page. When you have finished receiving orders, press Finish to return to the *Orders Dashboard*. On returning to the dashboard, these orders will be displayed with a status of *Received* at the next data refresh.

Chapter 8
Order Controls

This chapter describes the order locking mechanism and the Out of Hours Notice.

The Purpose of Order Controls

Order Controls are used to ensure that order submissions, amendments and cancellations are managed effectively, by limiting when clients can change orders or warning them to contact the manufacturer by phone when submitting or changing orders out of the manufacturer's normal hours of business. This will help the manufacturer optimise their next batch production in a timely manner, as due to the radioactive nature of the material, only sufficient product is typically made to cover the quantities ordered with little spare capacity.

Locking Orders

This is typically performed after orders are received and just prior to the start of the manufacturing process, so that customers are unable to change orders without direct contact with the manufacturer. The feature is accessed either using the Lock Orders icon, or from the menu using *Orders > Lock*. To access this function the user must have the *Lock Orders* permission.

The *Lock Order* page lists all unlocked orders that have been received in order of descending Order Number (see *Figure 8-1*).

If there are many orders which can be locked then there is a client filter so that only orders for a specific client are displayed. The default value of the filter is *All*.

The user must select all the orders that are to be locked. This can be done by checking the check box next to each order, or using Select All or Unselect All .
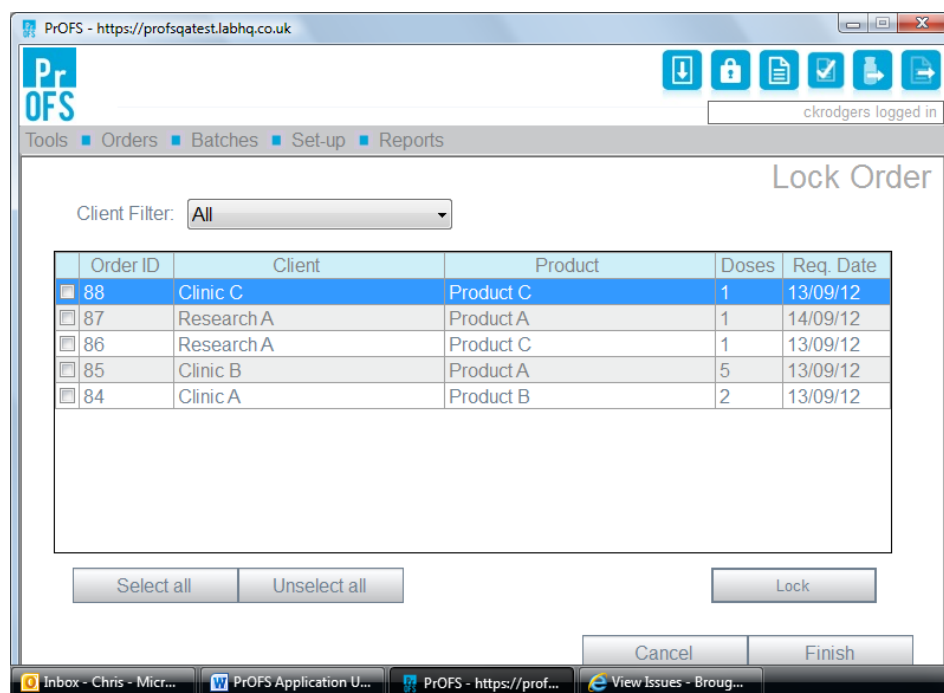
Figure 8-1 - The Lock Order page

You can cancel the Lock Order action at any time before pressing Lock by using
 Cancel . When all orders are selected, press Lock . The page will be updated to
remove the locked orders, leaving any that are still unlocked for selection.

When you have finished locking orders, press Finish to return to the *Orders
Dashboard*. On returning to the dashboard, the locked orders will be displayed
with a yellow highlight to the Order Number at the next data refresh. These orders
will no longer be able to be amended or cancelled unless they are unlocked.

Unlock Orders

This function may be used to unlock orders so that they be amended or cancelled by
the client after communication with the manufacturer. The feature is accessed from
the menu using *Orders > UnLock*. To access this function the user must have the
UnLock Orders permission.

This page works in the same way as the Lock Orders page except the orders displayed
are those which are already locked.

If there are many orders which can be unlocked then there is a client filter so that
only orders for a specific client are displayed. The default value of the filter is *All*.

The user must select all the orders that are to be unlocked. This can be done by
checking the check box next to each order, or using Select All or Unselect All .

You can cancel the UnLock Order action at any time before pressing Un-Lock by
using Cancel . When all orders are selected, press Un-Lock . The page will be
updated to remove the unlocked orders, leaving any that are still locked for further
selection.

When you have finished unlocking orders, press Finish to return to the *Orders Dashboard*. On returning to the dashboard, the unlocked orders will be displayed without a yellow highlight to the Order Number at the next data refresh. These orders will now be available for amendment or cancellation.

The Out of Hours Notice

This function was designed so clients are warned when it is outside the manufacturer's working hours, as the manufacturer will be unable to receive new or amended orders and act upon them. The feature does not prevent the submission or changing of orders but reminds the clients that they should contact the manufacturer (typically the Operations Manager or designated deputy) directly to let them know of any late orders or changes before the next production cycle is started. This will typically be set at the close of business each day or at the start of the weekend, shutdown period or public holidays.
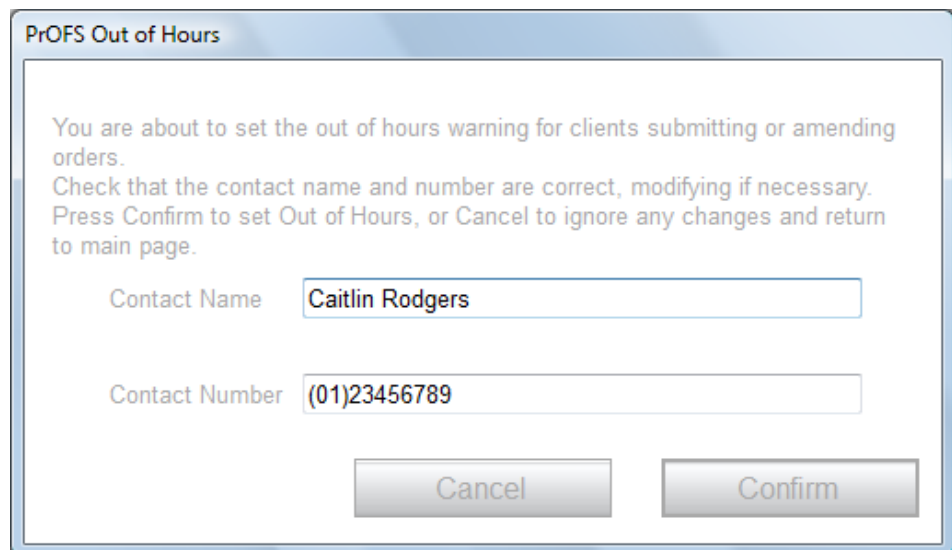
Figure 8-2 - Setting the Out of Hours Notice

To activate the function, select *Orders > Set Out of Hours* from the menu. This requires the user's account to have the *Set Out of Hours* permission. The Out of Hours page is displayed (see *Figure 8-2*).

The name of the contact and a telephone number must be entered. The previous values used will be displayed by default but may be changed if required.

Press Cancel to cancel setting the notice, else press Confirm when the data is correct. The page will be closed. On the main PrOFS Application page there will now be a label showing that Out of Hours Notice is set (see *Figure 8-3*).
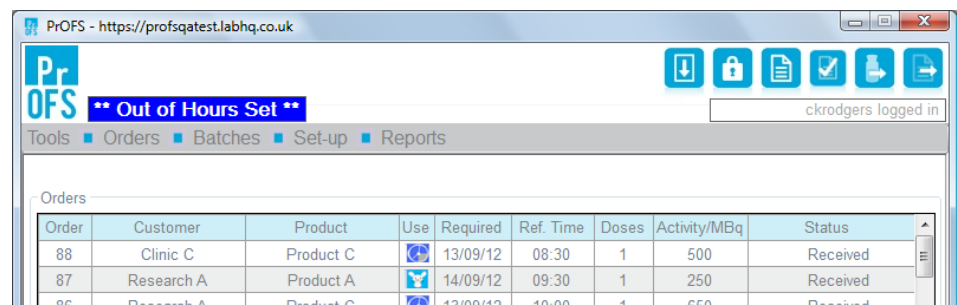
Figure 8-3 - The Out of Hours Notice on the main page

The Out of Hours Notice can be cleared, for example when staff arrive for the next work shift.

This can be done in one of two ways. When logged on, select *Orders > Clear Out of Hours* from the menu, then confirm you wish to clear the notice. Alternatively, once the notice is set, the next time a user with *Set Out of Hours* permission logs on, they are asked if they wish to remove the notice (see *Figure 8-4*). Select No to allow access out of hours while keeping the notice set.
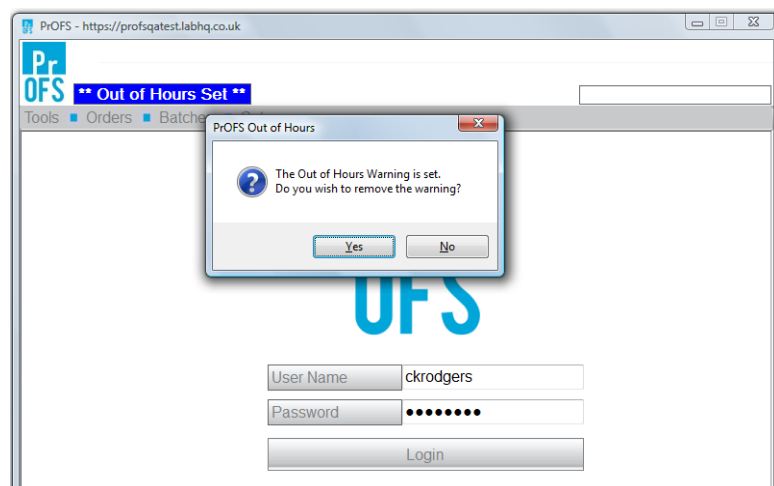
Figure 8-4 - Removing Out of Hours at login

If Yes is selected, then the Out of Hours Notice is cleared. In addition, all unlocked orders required for the current day will be automatically locked (if the user has lock orders permission) as typically, this will be at the start of the production shift and the manufacturer will not want the orders changed by clients. Orders for future dates are not locked. Even though they are now locked, new or modified orders for that day can still be received by the manufacturer. Once the Out of Hours is cleared the label on the main page will no longer be visible.

Chapter 9
Order Amendment

This chapter describes how the manufacturer can amend an order submitted by a client.

Amend Orders

This option is available so that the manufacture may amend an order on behalf of a client, for example, if a client temporarily does not have access to **PrOFS web client**. Users must have *Amend Orders* permission for the Application in order to access this function. The function is accessed by selecting *Orders > Amend*.

An Edit Order page is displayed to permit selection of the order (see *Figure 9-1*).
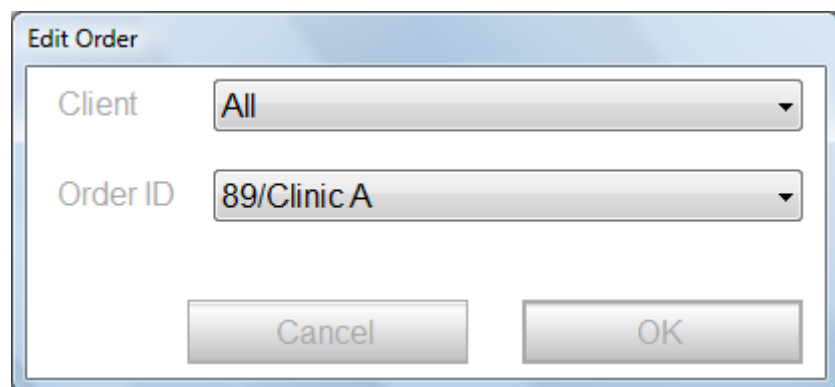
Figure 9-1 - Edit Order selection page.

The order to be amended can be selected from the Order ID list, which displays the orders in descending order number. The order ID and client is displayed in the list to aid selection of the correct order. There is also a Client filter field to pre-filter the order selection list when there are many orders or the order is older and further away from the top of the list.

Once the order is selected press OK . The order will be displayed in the Amend Order page. Note that if the order is locked, the data displayed is read only and a Locked label is shown on the page, indicating it cannot be modified (See *Figure 9-2*). The order would need to be unlocked first (see *Chapter 8, Order Controls*)

Figure 9-2 - Amend Order page for a locked order

The order data is displayed and for unlocked orders can be modified, though the product itself cannot be changed. (If the order is for the wrong product then the order must be cancelled and a new order submitted). Otherwise, the same rules apply as with Order Submission i.e.

- All fields must be completed except for the Note field and any client-specific optional fields.

- Activity field is only editable for calibration doses and research orders

- Date Required and Ref Time cannot be in the past.

- Number of doses is fixed for calibration doses and research orders

Where configured for the product, there must be patient information entered to match the number of doses. For unlicensed products where this information is typically required, use the ✖ at the end of each patient row to remove any patient information. Similarly, if the number of doses is increased, a new row will be added to enter the additional patient information (see *Figure 9-3*).

Figure 9-3 - Amending an order with patient information

Use ⬚Cancel⬚ to exit the function without saving the changes, else press ⬚Save⬚. If any fields are invalid then a warning will be displayed else a reason for change must be entered (a minimum of 6 characters). The user must then enter their account password as an electronic signature to verify that they have amended the data (see *Figure 9-4*).

Figure 9-4 - E-signature prompt for Amend Order function

Note that the same rule applies for password entry as at login; more than the permissible number of incorrect attempts will cause the user account to be locked and the **PrOFS Application** will be immediately closed without saving the changes as a security measure.

A prompt will be displayed to ask if e-mail notifications are to be sent. If you press ⬚Yes⬚ the e-mail notification page will be displayed (see *Figure 9-5*).

The *Send to* region will list the e-mail address of all users from the manufacturer and the order's client that have the *Order Amendment* notification configured in their

user account. Note that only PrOFS users can be e-mailed. If the list of users is long a scroll bar will appear. By default all of these users will be checked to receive the notification, but they may be individually deselected.

Figure 9-5 – Email Notification page for Amend Order function

The *Subject field* and *Message body* will contain the updated information related to the order. Both of these fields are editable to allow additional information to be added if required. Please note: the layout of the default data in the message body field may look unusual but when received in the e-mail each item is shown on a separate line – this is a limitation of the current text control that displays the message body text.

Press Send to send the e-mail notification. Press Cancel to cancel the e-mail notification (not the amendment).

Next a prompt is displayed asking if the ***Order Submission report*** is to be printed. If the response is Yes then the amended report is displayed. This may then be printed as a pdf document. The *Amend Order* page is then closed.

Chapter 10
Batch Data Entry

*This chapter describes how batch data is
entered in PrOFS, how vials are assigned
to orders and how this data can be edited.*

The Purpose of Batch Data in PrOFS

Batch data is the information related to the manufactured products ordered by the clients. It is an integral part of the order life cycle as GMP regulations require that the batch is released by a Qualified Person before it may be used. This is especially important for short half-life radiopharmaceutical products, where they are typically shipped under quarantine to the client before the disposition is complete in order that the doses have sufficient radioactivity when administered.

The batch data includes a batch identifier (batch number) and product identity, then information for each vial produced in the batch; vial identity, activity, volume and Reference Time. Additionally comments may be entered that applies to the batch as whole, or for individual vials. The final piece of information for each vial is the order to which it is assigned, if any.

The batch number must be a unique identifier for each batch; this is a regulatory requirement. The batch number entered in PrOFS is therefore checked for uniqueness when the record is first saved. The exception to this is that a batch number may be re-used if the product selected is configured for calibration doses, as it is likely that a calibration dose vial could be sourced from a batch of product.

The data for vials from a batch assigned to an order is also included on the Release Form and Withdrawal Notice, so that the client can confirm by comparison with the vials received that they are the correct items.

Batch Data Entry

This action is accessed either by using the *Enter Batch Data* icon or from the menu using *Batches > Enter Data*. To access this option the user account must have the *Batch Entry/Edit* permission.

On selecting this option the Enter Batch page is displayed (see *Figure 10-1*).

Figure 10-1 - Enter Batch page

There are two fields labelled *End of Synthesis* and *Expires*. These fields are used to perform a check that the Expiry information on the product label is correct. The user enters the data for each field from the manufacturing record. The difference between the two is then compared with the Expiry/Shelf Life value stored for each product. Unless these match exactly to the nearest minute a warning will be displayed (as it is when the page opens) indicating there is an Expiry Error. These fields are ignored if the product is designated a *calibration product* or the Expiry check feature is disabled in the system configuration (see *Chapter 2, Installation and Set Up*).

By default, the dates for the Expiry check fields are both set to the current date, as this action is normally performed the same day as batch manufacture. The times for the Expiry check fields are both set at 00:00, which is why the Expiry Error label is displayed. Values are entered by clicking on the specific part of the date or time (day, month, year, hour and minutes are all separate entries) and overtyping the default value, or using the roll buttons to increase or decrease the value.

When first displayed the page shows the product configured as the default. Select any other product from the *Product* drop-down list if necessary, then type in the *Batch Number*. Remember that the batch number must be unique in the system unless the product selected is the *calibration product*. Entry of batch number is mandatory.

The batch comment field is optional and provides space to enter any comment that applies to the whole batch. Any text entered here will be included on the **Release Forms** or **Withdrawal Notices**.

The lower part of the page allows entry of the data for each vial manufactured in the batch. Each of the *Vial ID*, *Activity*, *Volume* and *Ref Time* fields are mandatory for each vial. The *Activity* and *Volume* fields must be a numeric entry and *Ref Time* must be a valid time in hh:mm 24-hour format. Warnings will appear if any entries are made in an invalid format.

Figure 10-2- Enter Batch page showing Order assignment

When a vial entry is created, the *Client/Order* field defaults to *Unassigned*. This field is used to assign the vial to an order. The list box will display a list of current orders in the form of order number and client name, for the selected product that are required on that day (see *Figure 10-2*). This will include orders for which there may have already been a delivery from another batch as some orders may need to be filled from more than one batch, depending on the number of doses requested and how many other orders have been submitted for the same product on that day.

The *Comments* field in the vial data grid allows a comment to be entered that is specific to that vial. This comment will be included only on the **Release Form** or **Withdrawal Notice** for the order to which it is assigned.

Batch data entry may be cancelled without saving the data using ⃞ Cancel ⃞. To save the batch data, use ⃞ Save ⃞. The Enter Batch page will be closed if there are no errors and return to the main page. The status of any assigned orders will changed to *Assigned*.

Edit Batch Data

Batch data may be edited until the batch is dispositioned or the batch has expired according to the value in the *Expires* field. This option is accessed by using *Batches > Edit* and requires the user account to have *Batch Entry/Edit* permission.

When this option is selected the Edit Batch page will be displayed (see *Figure 10-3*).

Figure 10-3 - Edit Batch page

This is essentially the same as Enter Batch with the following exceptions:

- Batch number is not editable. By default the most recent batch available for editing will be displayed, but if there are other batches that can be edited they can selected from the drop down list.

- The product name is displayed only; the product cannot be modified.

All other fields can be modified in the same way as on the Enter Batch page.

Batch data editing may be cancelled without saving the data using Cancel . To save the modified batch data, use Save . On saving modified batch data, the user will be prompted to enter a reason for change and this will be recorded in the audit trail event. The entry must be a minimum of six characters to be accepted, but should adequately describe the reason for changing the batch record. The *Edit Batch* page will then be closed.

Chapter 11
Batch Review and Disposition

*This chapter describes how batch data is reviewed,
how the batch is dispositioned and how this can
be rescinded, if necessary.*

Batch Data Review

The purpose of batch data review is to perform an *independent* check that the batch data is correct and vials have assigned to the correct orders. This means that any user who performs batch data entry or edits batch data may not perform the review. This is an essential step in the order life cycle and must be performed before batch disposition or **calibration product** is released.

To access this function use either the *Review Batch* icon or from the menu via *Batches > Review*. The user account must have the *Batch Review* permission. On selecting this function the *Review Batch* page is displayed (see *Figure 11-1*). The exception to this is when there are no batches to review when a message to this effect will be displayed.

By default, the most recent batch that is awaiting review is displayed. If there is more than one batch for review then the others may be selected from the *Batch Number* selection list. In this function, none of the fields can be edited. If any of the fields require correction then the Batch Edit function must be used (preferably by the user who entered or edited else the current user will no longer be able to review). You can exit *Review Batch* without completing the review using Cancel .

Next to each vial there is a check box to select the vials to be reviewed. Select All and Deselect All can be used to aid vial selection. Note: If the current user was involved the entry or editing of the batch data displayed, then this page is a read-only view and the vial selection check boxes, buttons and Verify will not be displayed to prevent review.

Figure 11-1 - Review Batch page

Once the data has been checked and vials have been selected, press [Verify] to complete the review. The user must then enter their account password as an electronic signature to verify that they have reviewed the data (see *Figure 11-2*).
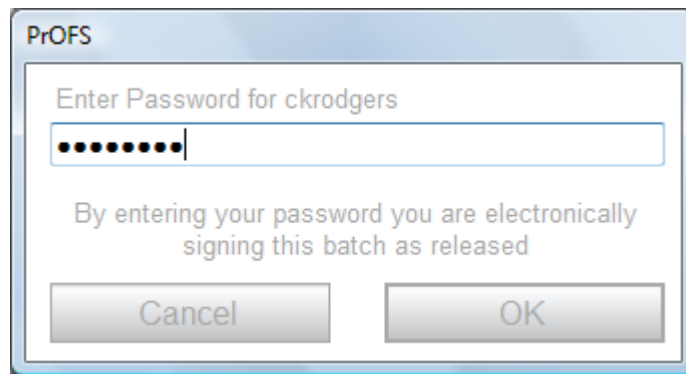

Figure 11-2 - E-signature prompt for Batch review

Note that the same rule applies for password entry as at login; more than the permissible number of incorrect attempts will cause the user account to be locked and the **PrOFS Application** will be immediately closed without completing the review as a security measure. On successful password entry the *Review Batch* page is closed. The status of orders assigned to the reviewed vials will change to *Awaiting Release*.

For **calibration products**, the completion of batch review makes the product available in the **PrOFS web client**; it does not require to be dispositioned.

Batch Disposition

Batch disposition is the formal decision made on the suitability of the product to be administered. It is performed by the **Qualified Person**, after review of the batch manufacturing and quality control documentation. This is the key step in the order life cycle. In PrOFS the disposition is performed for each vial though they may be all dispositioned at the same time. The disposition results in the decision to either release the product or withdraw the product.

To access this function, either use the *Batch Disposition* icon or from the menu via *Batches > Disposition*. If there are batches available to disposition the Batch Disposition page will be displayed (see *Figure 11-3*).

Figure 11-3 - Batch Disposition page

By default the most recent batch will be displayed. If there is more than one batch to be dispositioned, then other batches are available from the Batch Number drop-down list. The Expiry data and vial data is read-only; only the batch comment and vial comment fields may be modified.

Each vial that is available to be dispositioned will have a check box at the left-hand end of the row. Note: Not all vials may be available to be dispositioned. For example, an unlicensed product may be configured so that it requires an order with patient identity to be assigned to the vial before it can be dispositioned (see *Chapter 4, Product Data Management*).

Select All and Deselect All can be used to facilitate vial selection.

Before completing the disposition process there are a number of other options for the Qualified Person to use. A preview of the Release Form or Withdrawal Notice

can be displayed using Release Form . If chosen, the user is prompted to choose whether the preview should be for release or withdrawal. On making this choice the forms will be displayed for all selected vials (one form for each different order). These will be marked to indicate they are preview versions and will not contain any e-signature information.

The audit trail for the current batch may be reviewed by selecting Print Audit . The audit trail is displayed as report and may be printed. The batch disposition action may be cancelled at any point before release or withdrawal by selecting Cancel .

If the batch is to be released this is done by select Release . Conversely if the batch is to be withdrawn, select Withdraw . In either case, the user is prompted to enter their user account password as their e-signature to confirm they are releasing or withdrawing the batch (see *Figure 11-4*).

Figure 11-4 - E-signature prompt at batch release

Note that the same rule applies for password entry as at login; more than the permissible number of incorrect attempts will cause the user account to be locked and the **PrOFS Application** will be immediately closed without saving the changes as a security measure.

The user is then asked if an e-mail notification is required. If the response is Yes the e-mail notification page is displayed once for each separate order associated with the dispositioned vials (see *Figure 11-5*).

The *Send to* region will list the e-mail address of all users from the manufacturer and the order's client that have the *Order Assigned* notification configured in their user account. Note that only PrOFS users can be e-mailed. If the list of users is long a scroll bar will appear. By default all of these users will be checked to receive the notification, but they may be individually deselected.

Figure 11-5 - Disposition e-mail notification page

The *Subject field* and *Message body* will contain the updated information related to the order. Both of these fields are editable to allow additional information to be added if required. Please note: the layout of the default data in the message body field may look unusual but when received in the e-mail each item is shown on a separate line – this is a limitation of the current text control that displays the message body text.

Press ⏐ Send ⏐ to send the e-mail notification. Press ⏐ Cancel ⏐ to cancel the e-mail notification (not the disposition).

On completing the disposition, the Batch Disposition page is closed and the Orders Dashboard will be displayed (if no other pages are open). The status of the orders just dispositioned will change to *Released* or *Withdrawn* at the next refresh.

Rescinding Batch Disposition

There may be circumstances where it is necessary to rescind batch disposition, for example, withdraw a batch that has been released. It is possible to do this in PrOFS for batches dispositioned in the last 24 hours by selecting *Batches > Un-Release*. A user account must have *Batch Un-Release* permission to use this function.

On selecting this function the *Batch UnRelease* page is displayed (see *Figure 11-6*).

Figure 11-6 - Batch UnRelease page

The most recent batch dispositioned in the last day will be displayed by default. If there are other batches then these may be selected from the *Batch Number* drop-down list. As with review and disposition the action operates on individual vials but all vials may be selected using Select All and Deselect All . Individual vials may be selected using the check box adjacent to each vial ID. All data fields are read-only. The option to display or print the batch audit trail is available using Print Audit . The function can be discarded by pressing Cancel .

When the vials have been selected, press Un Release . The user must then enter a reason for changing the batch disposition. The user must then enter their user account password as their e-signature to confirm they are rescinding the disposition of the batch (see *Figure 11-7*).

Note that the same rule applies for password entry as at login; more than the permissible number of incorrect attempts will cause the user account to be locked and the **PrOFS Application** will be immediately closed without saving the changes as a security measure.
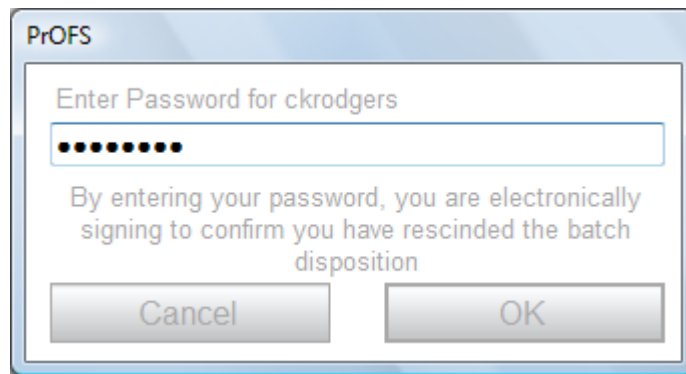
Figure 11-7 - E-signature prompt for rescinding batch disposition

On completing the e-signature the Batch Disposition page is immediately displayed so that the opposite disposition may be performed.

Chapter 12
Post-Disposition Activities

*This chapter includes the activities performed after
disposition – assigning spare activity and
completing orders.*

Assigning Spare Activity

Any vials that have not been assigned to an order during batch entry or prior to disposition may be subsequently assigned to a new or existing order for that product. This is termed assigning *spare activity*. This is only allowed while the product batch is still within its shelf life and for orders that have not been *completed*. If the vial assigned is already dispositioned then it is immediately available on the PrOFS web client; otherwise the vial will need to follow the review and disposition process as discussed in the previous chapter.

This function is accessed either by selecting the *Spare Activity* icon or from the menu using *Batches > Spare Activity*. Only users with *Spare Activity Assignment* permission can access this function.

On selecting this function, if there are any valid batches with unassigned vials, the *Spare Activity* page is displayed (see *Figure 12-1*). The most recent batch is displayed by default but if there other batches with spare activity they may be selected using the *Batch Number* drop-down list. Only vials that are unassigned are displayed.

The data fields are all read-only with the exception of the batch comment and vial comment fields. The Client/Order field is active for selecting the order from a list of orders for the product that are required today.

Once assigned, use Save to update the batch and order assignment. The spare activity function may be closed without saving assignments by using Cancel .

Figure 12-1 - Spare Activity page

On saving the assignment data, if the vial is already dispositioned, there is a prompt to ask if e-mail notification is required. On selecting Yes the e-mail notification page is displayed (see *Figure 12-2*), one for each order to which spare activity is assigned.

The *Send to* region will list the e-mail address of all users from the manufacturer and the order's client that have the *Order Assigned* notification configured in their user account. Note that only PrOFS users can be e-mailed. If the list of users is long a scroll bar will appear. By default all of these users will be checked to receive the notification, but they may be individually deselected.

The *Subject field* and *Message body* will contain the updated information related to the order. Both of these fields are editable to allow additional information to be added if required. Please note: the layout of the default data in the message body field may look unusual but when received in the e-mail each item is shown on a separate line – this is a limitation of the current text control that displays the message body text.

Press Send to send the e-mail notification. Press Cancel to cancel the e-mail notification (not the spare activity assignment). If there is another order assigned to spare activity then another e-mail notification will be displayed.

When completed, the *Spare Activity* page is closed. The status of the order will either be *Released* or, if not yet dispositioned, then the status will be *Assigned*.

Figure 12-2 - E-mail notification page for Spare Activity

Order Completion

Orders are completed in PrOFS for three reasons:

- It tells the system that the order no longer needs to be displayed in the Orders Dashboard, so tidies it up so that it focusses on current orders.

- It allows the number of billable doses to be entered for each order to contribute to the client billing process via the ***Billing Report***.

- It allows the number of billable doses to be entered for each order to contribute to the client billing process via the ***Billing Report***.

Access to this function is via the menu option Orders > Complete and requires the user account to have *Complete Orders* permission. On selecting this function the Complete Order page is displayed if there are any orders to complete (see *Figure 12-3*). Only orders that have been acknowledged by the client will be displayed for completion.

If there are many orders to complete then there is a client filter so that only orders for a specific client are displayed. The default value of the filter is *All*. Orders are displayed by default with the most recent at the top.

Figure 12-3 - Complete Order page

The user must select all the orders that are to be completed. This can be done by checking the check box next to each order, or using Select All or Unselect All .

The data fields are all read-only with the exception of the Billable doses column and the Comment column. The Billable doses value for each order is set by default to the number of doses originally requested but may be changed if appropriate. The Comment for each order can be selected from a customizable drop down list (see *Chapter 6, The Completion Comments tab)*.

You can cancel the Complete Order action at any time before by using Cancel . When all orders for completion are selected, press Mark as Complete . This will remove these orders from the page. When you have finished using the page then press Finish to close the page and return to the Orders Dashboard. Any orders completed will be removed from the dashboard at the next refresh.

Order Un-Completion

Orders are un-completed in PrOFS for three reasons:

- It tells the system that the order is not complete, and will therefore be displayed in the Orders Dashboard.

- It allows the number of billable doses to be amended for each order to contribute to the client billing process via the ***Billing Report***.

- It allows the completion comments to be amended for each order which also contributes to the client billing process via the ***Billing Report***.

the user account to have *Un-Complete Orders* permission. On selecting this function the Un-Complete Order page is displayed (see *Figure 12-34*). Only orders that have been completed will be displayed for un-completion.

There is a client filter so that only orders for a specific client are displayed. The default value of the filter is *All*. Orders are displayed by default with the most recent at the top.

Figure 12-4 – Un-Complete Order page

The user can select one or all the orders that are to be un-completed. To select all orders, check the box next to each order, or use Select All or Unselect All .

The data fields are all read-only.

You can cancel the Un-Complete Order action at any time by using Cancel . When all orders for un-completion are selected, press Mark as Un-Complete . This will remove these orders from the page. When you have finished using the page then press Finish to close the page and return to the Orders Dashboard. Any orders un-completed will appear in the dashboard at the next refresh.

Chapter 13
Administrative Reports

This chapter describes the reports available in PrOFS Application to help administer the system.

Use of Administrative Reports

The administrative reports supplied with the system provide summary information for the **static data** stored in the system and is also the location of the **Billing Report**.

Any user with View Reports permission can access these reports by selecting *Reports > Administration*. There is another sub-menu which displays the administrative reports as listed in *Table 13-1* - Administrative Reports available.

Sub-menu option	Description
Clients	Provides a summary of all client records and their status
Users	Provides a summary of all user accounts and their status
Products	Provides a summary of all product records and their status
Billing	Generates the billing report

Table 13-1 - Administrative Reports available

With the exception of the Billing Report and Users Report, these reports have no fields to select so are displayed in a new window when selected.

The client and product summary reports display the key data related to each record and in addition indicate whether the record has been deleted. Note: The records are not physically deleted but are no longer accessible by PrOFS with the exception of user accounts, which may be reinstated (see *Chapter 3, Access Management*).

Figure 13-1 - Example of a Client Summary Report

Figure 13-2 - Example of a Product Summary report

Billing Report

The *Billing Report* has a number of input parameters that can be defined to restrict the data included in the report. These are termed the *selection criteria*. On selecting the *Billing Report* it's selection criteria are displayed (see *Figure 13-*).

Figure 13-3 - Selection Criteria for Billing Report

The user may filter the data included in the report by defining the *selection criteria*:

- The *Client* field allows the data to be restricted to a specific client. The default value is *All*.

- The *Use* field allows the records to be restricted to Animal Research, Patient or Calibration use (these may attract a different billing rate for example). The default value is *All*.

- The *Start Date* and *End Date* fields may be used together to restrict the date range for the report, based on the Required Date. By default the *End Date* is today and the *Start Date* is a calendar month in the past.

- The product field allows the data to be restricted to a specific product. The default value is *All*.

The fields may be used in any combination to suit the user.

A common feature in PrOFS reports is that for any that have *selection criteria*, the report may be generated in the standard pdf format or in a Microsoft Excel-compatible format. The *Billing Report* has this option.

Press OK to generate the report or Cancel to cancel the report.

An example of the Billing report is given in *Figure 13-4* . All completed orders that conform to the selection criteria are displayed. They are grouped by client if all clients is selected. For each group the total requested and billable doses are shown in the group footer.

The report also includes any cancelled orders that fit the *selection criteria*, as these may be important for discussion with the client and, depending on the reason for cancellation, may or may not be included for billing purposes. Cancelled orders are shown in italics and include the reason for their cancellation.

Order	Product	Date Submitted	Required Date	Requested Doses	Billed Doses	Cancelled Reason
			Clinic A			
79	ERtracER	21-Aug-12	21-Aug-12	1	2	
83	*Product A*	*12-Sep-12*	*12-Sep-12*	*4*	*-*	*User manual development*
			Total Doses:	5	2	
			Clinic B			
80	ERtracER	21-Aug-12	21-Aug-12	1	2	
			Total Doses:	1	2	
			Research A			
81	ERtracER	21-Aug-12	21-Aug-12	1	2	
			Total Doses:	1	2	

Note: Cancelled orders are shown in italics.

Figure 13-4 - Example of a Billing report

Users Report

The *Users Report* has a number of input parameters that can be defined to restrict the data included in the report. These are termed the *selection criteria*. On selecting the *User Report*, it's selection criteria are displayed (see *Figure 13-5*).

Figure 13-5 - Selection Criteria for User Report

The user may filter the data included in the report by defining the *selection criteria*:

- The *Client* field allows the data to be restricted to one or more specific client(s). The default value is *All*.

- The *User Type* field allows the records to be restricted to Internal or External. The default value is *All*.

The fields may be used in any combination to suit the user.

A common feature in PrOFS reports is that for any that have *selection criteria*, the report may be generated in the standard pdf format or in a Microsoft Excel-compatible format. The *User Report* has this option.

Press OK to generate the report or Cancel to cancel the report.

An example of the User report is given in *Figure 13-6*. All user accounts that conform to the selection criteria are displayed. They are displayed in alphabetical order.

Figure 13-6 – Example of a User Report

Chapter 14
Quality-based Reports

This chapter describes the reports available in PrOFS Application related to quality and compliance.

Use of Quality-based Reports

This category of reports are associated with the quality compliance aspects of the system. They are mostly based on data recorded by PrOFS and stored in audit trail records. These would typically be used to review how the system is being used and to help diagnose any atypical events.

Any user with View Reports permission can access these reports by selecting *Reports > Quality*. There is another sub-menu which displays the quality-based reports as listed in *Table 14-1.*

Sub-menu option	Description
Batch Audit	The audit trail for a specified batch
Order Audit	The audit trail for a specified order
Login Log	The log for any recorded user access actions
Change Log	The audit trail view looking at changes to data records in a given period, by a specific user or for specific types of change
Version Log	The audit trail for a specific static data record (client, product, user)
Deleted Log	The audit trail showing deletion actions for a specific record type, by a specific user or during a specific period.

Table 14-1 - Quality-based reports

All of these reports require some *selection criteria* to be chosen before they are generated.

Batch Audit Report

This report generates a list of all activities recorded in the audit trail for the specified batch. On selecting this report the *selection criteria* page is displayed (see *Figure 14-1*).

Figure 14-1 - Batch Audit selection criteria

There are fields to select the product then the batch number. The product field will default to the product designated as the default product. Batches are listed with the most recent at the top and will include any deleted batches.

On selecting OK the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-2*.

Figure 14-2 - Example Batch Audit report

The report has a layout common for audit reports. The date and time of each event is shown together with the user associated with this. A description of the event is given and includes old and new values where appropriate. Where a modification or deletion is made, the reason for change is also displayed. Records are shown in chronological order with the most recent at the end.

Order Audit report

This is similar to the batch audit report but reports the audit trail record for a specified order. On selecting this option a selection criteria page is displayed to select the order (see *Figure 14-3*).

Figure 14-3 - Order Audit Selection Criteria

As the list of orders will grow over time, it can be pre-filtered by first selecting the client. By default the *Client* field is set to *All* and the most recent order is displayed. The orders are listed with the most recent at the top. On selecting OK the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-4*.

Date	Time	Event type	User Name	Change	Comment
21/Jun/2012	12:50	Order edited	Admin	Order 20 submitted	
21/Jun/2012	12:53	Order edited	QP1	Order 20 received	
21/Jun/2012	12:54	Order edited	QP1	Order 20 locked	
21/Jun/2012	13:09	Order edited	QC1	Order:20 Vial:1234#5 assigned	
21/Jun/2012	13:09	Order edited	QC1	Order:20 Vial:2345#6 assigned	
22/Jun/2012	14:03	Order edited	Auth	Order 20 Batch:BN 6.2.5 Vial:1234#5 delivery acknowledged	
22/Jun/2012	14:03	Order edited	Auth	Order 20 Batch:BN 6.2.5 Vial:2345#6 delivery acknowledged	
22/Jun/2012	14:40	Order edited	QP1	Order 20 complete. 1 billable doses	

Figure 14-4 - Example of an Order Audit report

Login Log

This audit trail report includes data recorded in the audit log that relates to access to the system and e-signature events. On selecting this option the selection criteria page is displayed (see *Figure 14-5*).

Figure 14-5 - Login Log selection criteria showing event types

The *Start Date* and *End Date* fields can be used to restrict the date range as there will be many access records in the audit trail. These fields are set by default to the last month. The *Event Type* field allows some of the more common login-related events to be selected but is set to *All* as default. On selecting OK the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-6*.

User Access Log

10 Sep 2012 - 19 Sep 2012   Event Type: All

Date/Time	Location	User name	Status
10-Sep-2012 13:44	Laboratory Application	Sys Admin	Logged In
10-Sep-2012 14:00	Laboratory Application	Sys Admin	Logged Out
10-Sep-2012 14:10	Laboratory Application	SYS ADMIN	Login Failed
10-Sep-2012 14:11	Laboratory Application	sys admin	Login Failed
10-Sep-2012 14:16	Laboratory Application	Sys Admin	Logged In
10-Sep-2012 14:21	Laboratory Application	Sys Admin	Logged Out
10-Sep-2012 14:44	Laboratory Application	rjsmith	Logged In
11-Sep-2012 8:58	Laboratory Application	ckrodgers	Login Failed

Figure 14-6 - Example of Login Log report

Each record in this report includes the date and time and user name, whether the event was in the application (Laboratory Application) or Web client, and the event type. Events include Logged In, Logged out, Login failed, Password verified, Password failed and Locked Out. The password events relate to e-signature events.

Note: There may not be a logout event to coincide with each login event as the application or web client may be exited without logging out.

Change Log Report

This report focusses on events related to changing a data item in the system. On selecting this report the selection criteria page is displayed as in *Figure 14-7*.

Figure 14-7 - Change Log selection criteria
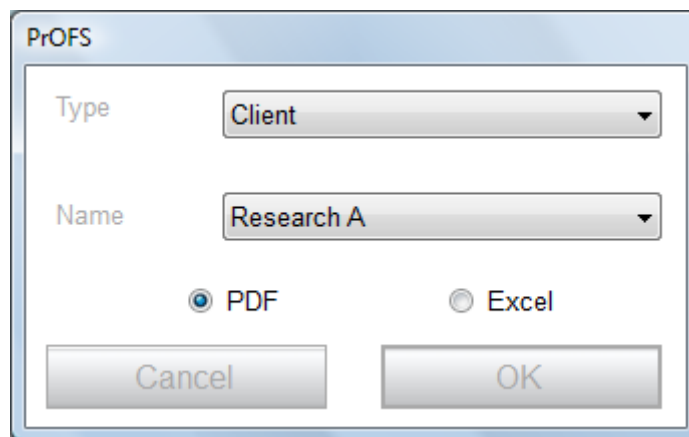
The change events may be filtered by selecting a specific User, a data range or for a specific event type i.e. changes to batches, orders, clients, products, user accounts or system settings. On selecting OK the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-8*.

Date	Time	Event type	User Name	Change	Comment
11/Sep/2012	0:05	User edited	rjsmith	Caitlin Rodgers Permission Spare Activity Assignment added	Added permissions
11/Sep/2012	0:05	User edited	rjsmith	Caitlin Rodgers Permission Unlock Orders added	Added permissions
11/Sep/2012	0:05	User edited	rjsmith	Caitlin Rodgers Permission View Reports added	Added permissions
11/Sep/2012	0:15	User edited	rjsmith	ckrodgers Deleted	User Manual development
11/Sep/2012	8:59	User edited	Sys Admin	ckrodgers Account re-instated	Reinstated account - User Manual development
11/Sep/2012	8:59	User edited	ckrodgers	ckrodgers Password changed	
12/Sep/2012	21:27	User edited	Sys Admin	QP1 Password Reset	Reset password
12/Sep/2012	21:28	User edited	QP1	QP1 Password changed	
13/Sep/2012	15:10	User edited	System	ckrodgers Account Locked: Old Value - Off New Value - On	
13/Sep/2012	15:18	User edited	Sys Admin	ckrodgers Account Locked: Old Value - On New Value - Off	Unlocked account

Figure 14-8 - Change Log Example for User changes

Version Log Report
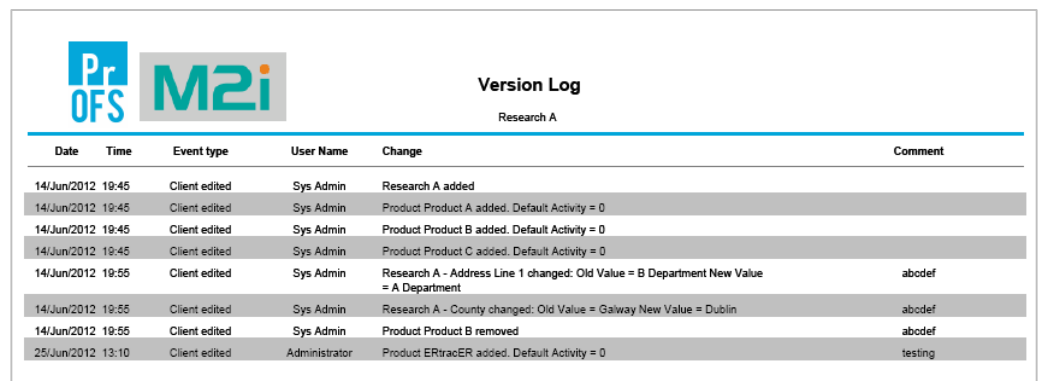
The version log report shows changes made to specific static data objects i.e. Clients, Products or Users. On selecting this option the selection criteria page allows the choice of the data object type, then the specific record within the category. In the example in *Figure 14-9* the user has selected to show changes to the Client record for Research A.

Figure 14-9 - Version Log Selection criteria page

On selecting OK the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-10*.

Figure 14-10 - Example of Version Log report

Deleted Log Report

This report includes events for when any batch, client, product or user account is retired (deleted) or a cancelled order.

On selecting this report option, the data type and a data range can be selected to filter the data. In the example in *Figure 14-11* the user has selected to show any cancelled orders for a 3-month time period.

Figure 14-11 - Deleted Log Selection Criteria

On selecting ⬚ OK ⬚ the report will be displayed in the chosen format (default is pdf). See the example in *Figure 14-12*.

Figure 14-12 - Example of a Deleted Log report

Chapter 15

Order-based Reports

This chapter describes the reports available in PrOFS Application related to orders.

Use of Order-based Reports

These reports all relate to orders submitted on the system and are the routine reports accessed by PrOFS Application users. They are accessed via the menu using *Reports > Order* and require the user to have the *View Reports* permission.

Submission Report

This report documents the details for a specific order when submitted or subsequently amended. On selecting this option the selection criteria page is displayed (see *Figure 15-1*).
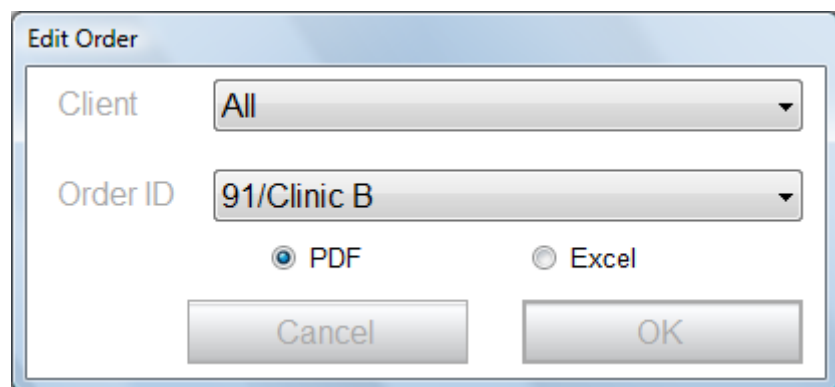
Figure 15-1 - Submission Report selection criteria

The required order is selected from the *Order ID* selection list, which lists all orders. The *Client* selection list allows the order listed to be filtered by client.

On clicking OK the report will be displayed in a new window (see *Figure 15-2* for an example).

Figure 15-2 - Submission report example

Release

This option will generate the **Release Form** or **Withdrawal Notice** depending on the disposition decision for the batch. On selecting this option the selection criteria page is displayed. This function operates in two different modes. The single mode allows a specific order (and delivery if multiple deliveries) to be selected by choosing the order then the batch/delivery. The *Order* selection list will display all orders for

which vials have been dispositioned. The *Batch* selection list will display the batch number, date and time when each delivery is released to help the user choose which delivery to select. See *Figure 15-3* for an example of this mode, which is accessed via the *Single* option (default).

Figure 15-3 - Release selection criteria – Single mode showing multiple deliveries

Figure 15-4 - Release selection criteria - By Date mode

The second mode is to generate all reports for a specified period of time. This is accessed using the *By Date* option. In this case the user enters a start and end date, which default to the current date so that all deliveries for that day can be printed in a single action. See *Figure 15-4* On selecting OK the **Release Forms** and/or **Withdrawal Notices** will be displayed for printing. In *By Date* mode there will be a report page for each delivery in the specified date range.

See *Figure 15-5* as an example of a **Release Form** and *Figure 15-6* for an example of a **Withdrawal Notice**.

Figure 15-5 - Release Form example

Figure 15-6 - Withdrawal Notice example

Chapter 16
Report Management

*This chapter describes the functions available in
PrOFS to manage custom reports.*

Why do I need Report Management?

PrOFS includes a series of default report templates that are used to generate each of the different reports offered by the system. The templates store the layout of each report and information on where to get the specific data each time a report is generated. The system does allow for flexibility in which report templates are used, by allowing alternate report templates to be used for specific purposes. It is therefore possible to configure a custom *Release Form* report for a specific product for one particular client, or to have a common header layout with specific branding for one particular client, for example.

There is a hierarchy in the use of report templates:

- Product-specific report templates only apply to the Release Form/Withdrawal Notice template (both use the same template). These are configured in the product set-up page (see Chapter 4, Product Data Management) but must first be loaded into PrOFS via Report Management. When used they take precedence over any client-specific custom templates or default templates.

- Client-specific templates (or custom templates for all clients) take precedence over default templates.

- If no custom report template is loaded, then the default template is used.

Note: PrOFS reports can currently only be developed by the supplier as they require specific report development tools and knowledge of PrOFS data structure.

The report management function is accessed using *Tools > Administration > Report Management* and requires the user to have *Administrator* permission. On selecting this option the *Report Management* page is displayed (see *Figure 16-1*).
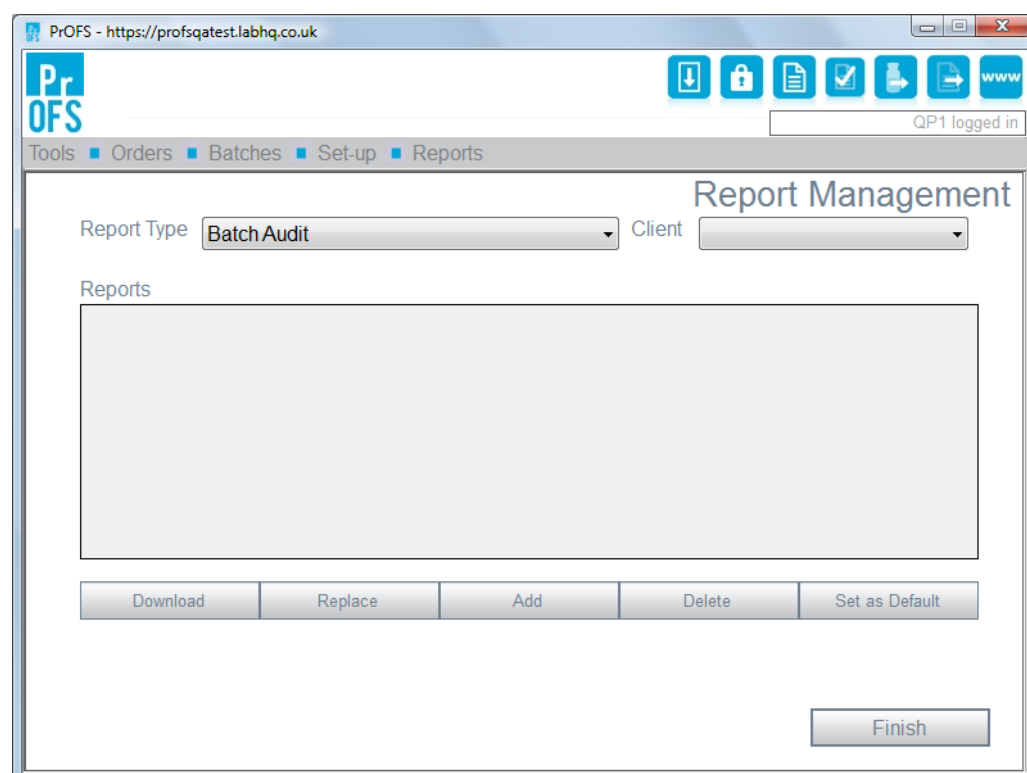
Figure 16-1 - Report Management page

The page has a number of different functions and selection fields as summarised in
Table 16-1.

Function	Description
Report Type	A list of the different report templates available in the system.
Client	A list of clients (or *All*) to specify the scope of a custom report template
Reports	This area displays the template file name and descriptor for any custom reports loaded in the system for the current report type.
Download	Allows a custom report template in the system to be copied to a specified location, used for development or backup only.
Replace	Allows an existing custom report template to be replaced by a new or updated template.
Add	Adds a custom report template to the PrOFS instance
Delete	Removes a custom report template from the PrOFS instance.
Set as Default	Sets the currently selected custom report template as the default template.
Finish	Closes the Report Management page

Table 16-1 - Report Management page functions

Adding Custom Templates

Select the Report Type from the list of available reports in PrOFS. These are described in below:

Report Type	Description
Batch Audit	Generated when selecting the batch audit report option in Quality Reports (See *Chapter 14*)
Billing	The Billing Report template (See *Chapter 13*)
Change Log	Used when generating the Change Log from Quality Reports (See *Chapter 14*)
Client List	Used for creating a summary of Clients in the PrOFS instance (See *Chapter 13*)
Deleted Log	Used to generate the audit trail for retired batches, orders, users etc. (See *Chapter 14*)
Login Log	Used to generate the audit trail for system access actions (See *Chapter 14*)
Order Acknowledgement	The Order Acknowledgement report (See *Chapter 15*)
Order Audit	Generates the audit trail for a specified order (See *Chapter 14*)
Order Submission	Used for the order submission report (See *Chapter 15*)
Product List	Used for creating a summary of Products in the PrOFS instance (See *Chapter 13*)
Product Release	Used to generate the *Release Form*/*Withdrawal Notice* (See *Chapter 15*)
Single Client	Used for the audit trail of the current client in Create/Edit Clients (See *Chapter 4*)
Single Product	Used for the audit trail of the current product in Create/Edit Products (See *Chapter 4*)
Single User	Used for the audit trail of the current user account in Create/Edit Users (See *Chapter 3*)
User List	Used for creating a summary of Users in the PrOFS instance (See *Chapter 13*)
Version Log	Used to create the audit trail for changes to clients, products or users (See *Chapter 14*)

Table 16-2 - Report Types

If the custom report template is to be used for a specific client then select the client from the Clients selection list, else select *All* to use it for all clients in place of the default template.

Press Add to access the report template using a standard Windows Open page (see example in *Figure 16-2*). Template files have a .rpt ending to the file name.
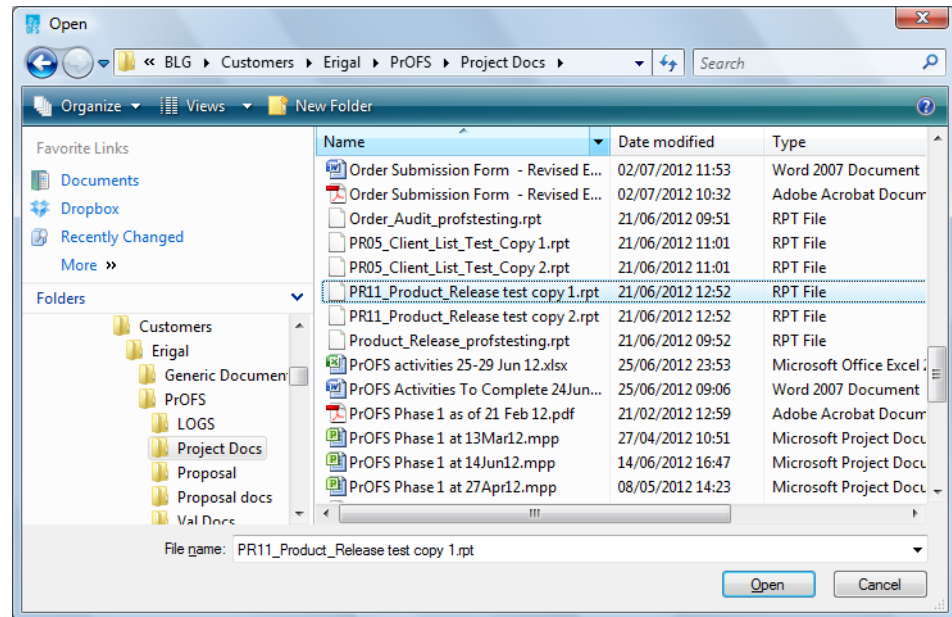

Figure 16-2- File dialog for Adding a template

On selecting the file and pressing Open there is the opportunity to give the template a description; this defaults to the file name. On pressing   OK   the file is uploaded to PrOFS and is displayed in the *Reports* area (see example in *Figure 16-3*). If there is only one custom report template for that report type then it will be automatically selected as the default report template, as shown by the tick mark next to it. If there is more than one custom report template loaded the default can be changed by selecting another custom report in the list shown and pressing Set as Default.

A report template can be replaced by another e.g. when updating a custom template with an updated version, by highlighting the existing custom report template and pressing Replace . This will allow another template to be selected in a similar manner to adding a custom template as described above.

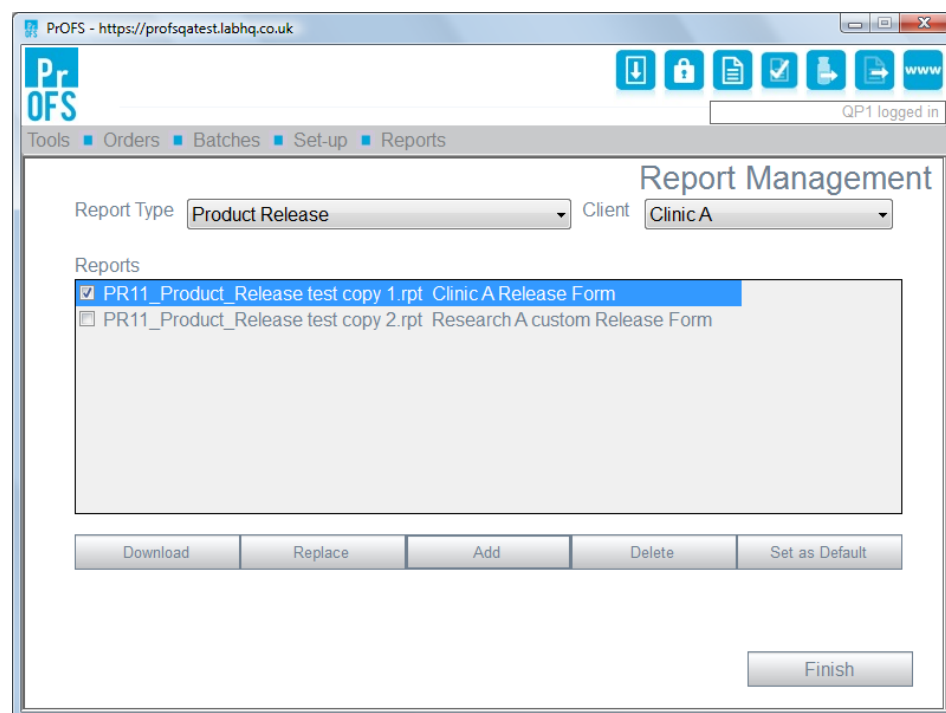*Figure 16-3* - Custom report templates loaded for the Release Form for client Clinic A

The   Download   option allows the template to copied from PrOFS to another location, for example, if creating a local back-up of custom report templates. It allows the user to navigate to a folder where the template is to be stored using a standard Windows Save As page.

Chapter 17
Tools Menu Options

This chapter describes the other functions available on the Tools menu.

The Tools Menu

There are a number of miscellaneous options available on the *Tools* menu, described below in *Table 17-1*, which do not fit into the other menu option groups. (see *Figure 17-1*).
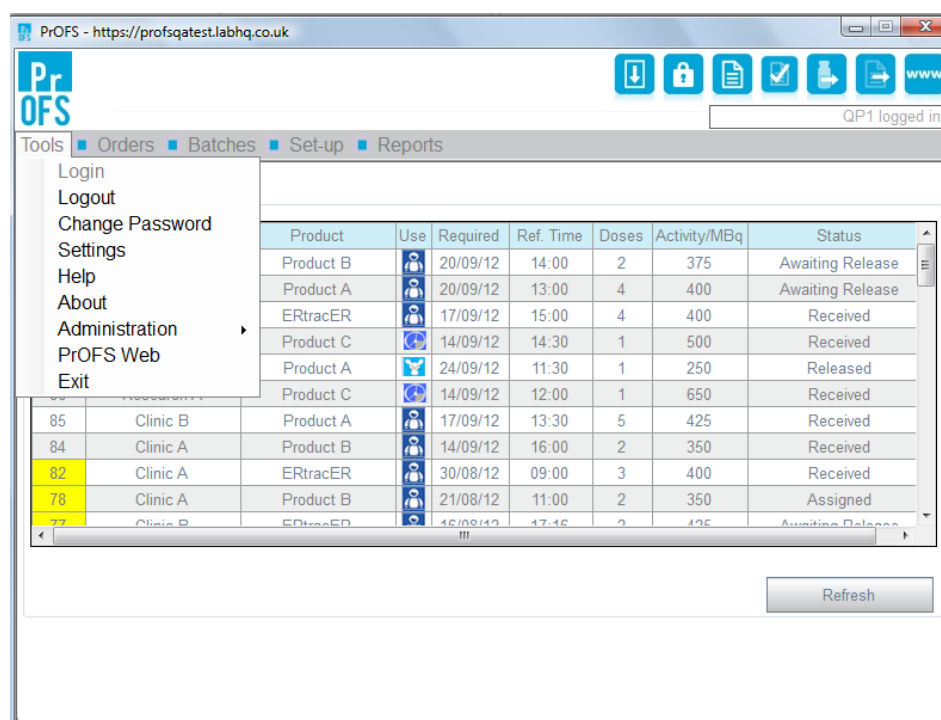

Figure 17-1 - Tools menu options

Some of these may not be present depending on the current user's permissions.

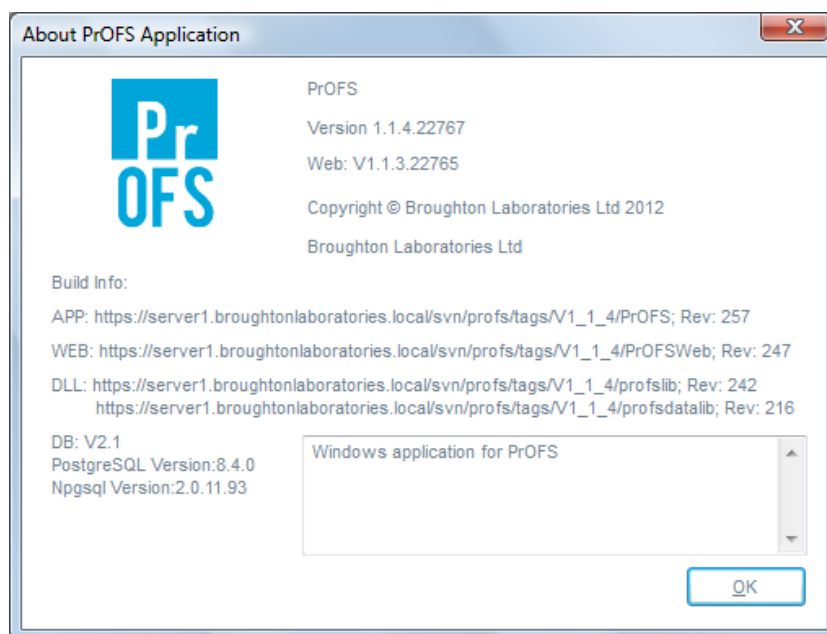| Menu Option	Description
Login/Logout	These options allow the user to login, or to log out when finished the current session or to allow another user to access PrOFS.
Change Password	This allows the current user to change their password at any time while logged in. See *Chapter 3*.
Settings	This allows the user to change the PrOFS instance if they need access to another PrOFS system. See *Chapter 3*.
Help	This will give access to the PrOFS Help web page.
About	This displays a page which shows the current version details of PrOFS and its components (see example in *Figure 17-2*).
Administration	This option gives access to Configuration settings (*Chapter 6*), Batch Deletion (*Chapter 10*) and Report Management (*Chapter 16*) functions, depending on user permissions.
PrOFS Web	Opens the *PrOFS Web Client* if the current user has the permissions to do so, without having to log in again.
Exit	Exit the *PrOFS Application*. This is the same as using Close Window (top-right corner of PrOFS window).

Table 17-1 - Tools menu options

Figure 17-2 - About Page

Chapter 18
Glossary

Term	Meaning
Administrator	A permanent user account that has access to all functions.
Billing Report	The report generated to provide billing data for product orders
Calibration dose	A unit of product used solely for calibration of scanning equipment
Calibration product	A product configured in PrOFS that is used when ordering *calibration doses*
Completed	In PrOFS this is the final status of orders when all activities have been performed and when billing data is entered.
Delivery	In PrOFS a delivery occurs when vials are made available to the client, which is at disposition
Order Submission report	The report generated to provide the data related to order submission or amendment.
Orders Dashboard	The default display in the PrOFS Application that summarises the current orders and their status
PrOFS Application	The PrOFS program used by the manufacturer to manage their part of the order life cycle
PrOFS Web Client	The PrOFS program used by the client to manage their part of the order life cycle
Qualified Person	Qualified person (QP) is a technical term used in European Union pharmaceutical regulations, which specify that no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements.

Term	Meaning
Release Form	This report is generated to report the details of a *delivery* available for use by the specified client.
RERS	Regulated Electronic Records and Signatures – a term used to describe computer-managed GMP records and any associated electronic signatures when used in pharmaceutical manufacture activities (see Eudralex, Annexe 11)
Selection criteria	These are filters used when selecting data to be reported.
Spare activity	Additional capacity of radiopharmaceutical product (vials) which is not assigned to an order initially , but which may be available for clients who require more doses than initially ordered.
Static data	A general term to describe reference data that is not often modified, and refers to Products, Clients and User Accounts.
Un-completed	In PrOFS, this a function to reverse order completion for the purpose of amending billing information or comments.
Users Report	The report generated to provide user account information for one or more clients and for internal or external users.
Withdrawal Notice	This report replaces the *Release Form* if a product batch does not meet the required quality standard.