



PrOFS Version 1

Web Client: User

Guide

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Conventions

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

Example	Uses
<i>PrOFS Application</i>	This is a term that is defined in the Glossary at the end of the manual
<i>https://<dbname>.</i>	This is example data or a field entry example
<i>Orders > Submit Order</i>	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.

PrOFS Introduction

This user manual describes how to use PrOFS effectively to process client orders for radiopharmaceutical products. PrOFS stands for Product Orders 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.

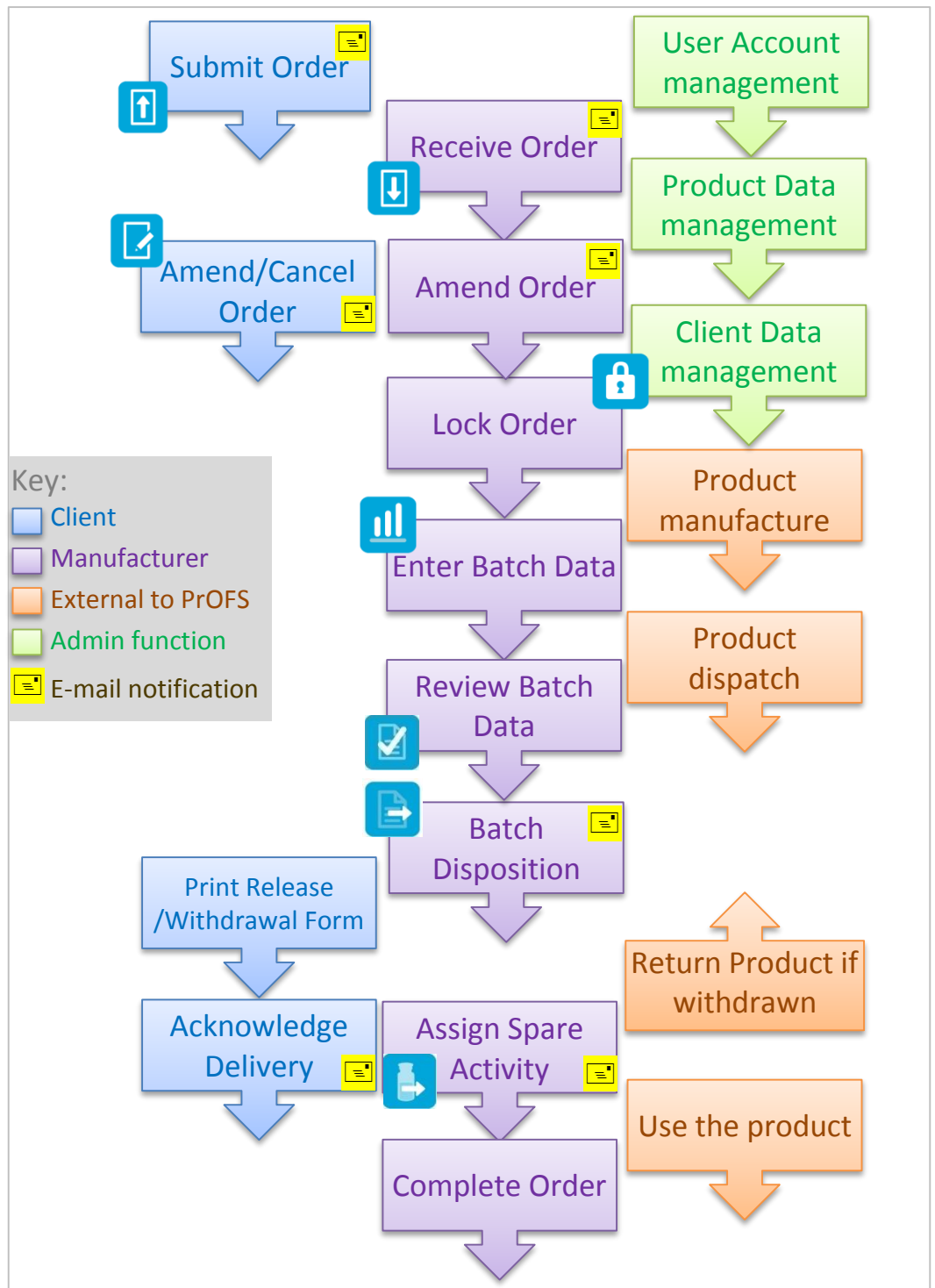


Figure 1-1 - Order Life cycle

External to the system, the manufacturer then commences manufacture 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.

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. For doses used to calibrate scanning instruments (*calibration doses*), these do not require disposition. After data review, they are available to the client to acknowledge on delivery.

Users gain access to both 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 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 256Kbit 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.

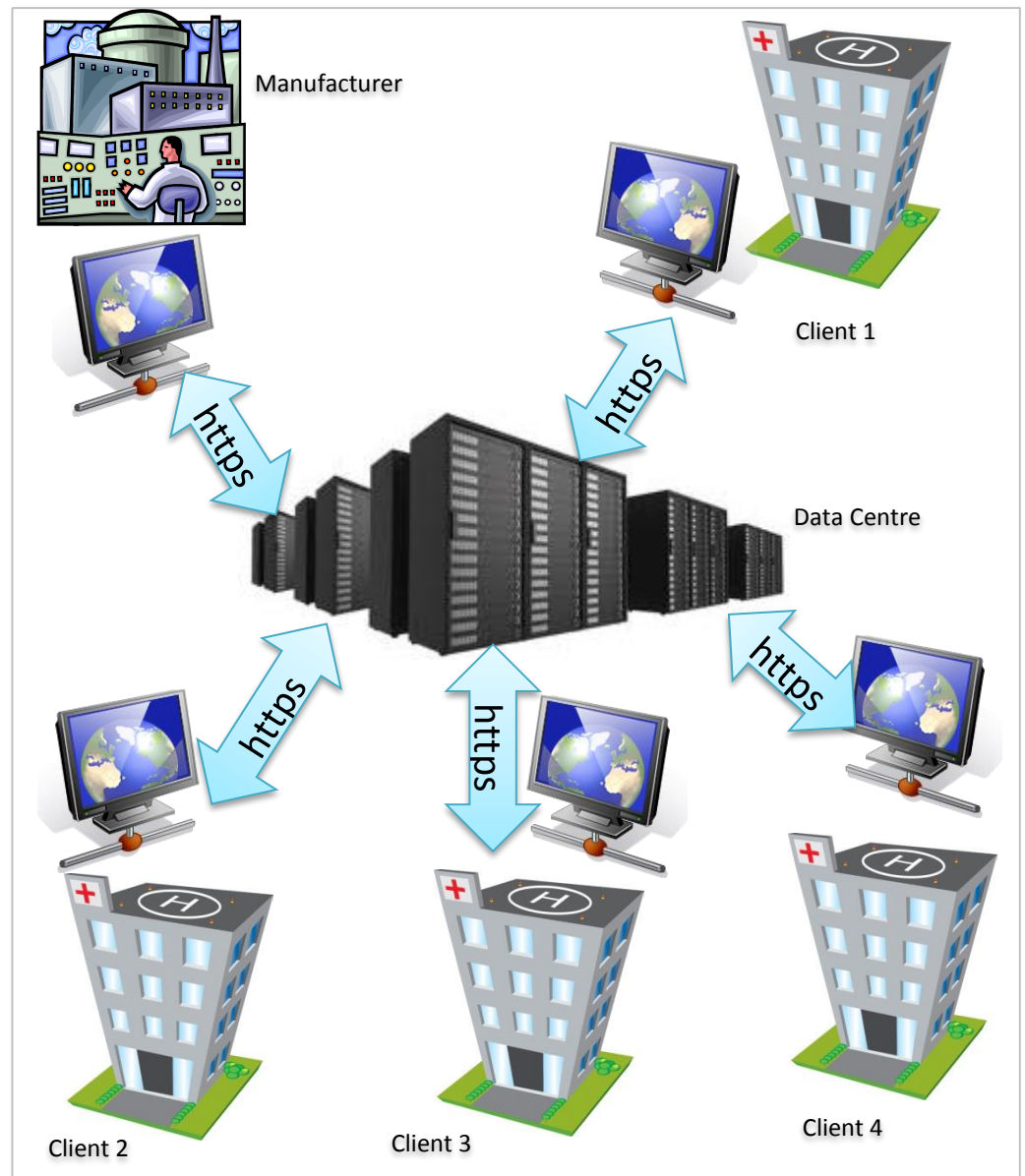


Figure 1-2 - PrOFS communication infrastructure

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.

User Interface Conventions

The *PrOFS Web Client* uses standard browser features. The main page consists of three main areas, the header ❶, the main body ❷ and the footer ❸. See example in *Figure 1-1*.

The header contains icons ❹ for quick access to functions and the menu bar ❺, both of which are configured depending on the user's permissions. The main body is situated below the menu bar and its content is function-specific, though each page typically has a title ❻. The footer generally contains only navigation buttons 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 address bar of the browser 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.

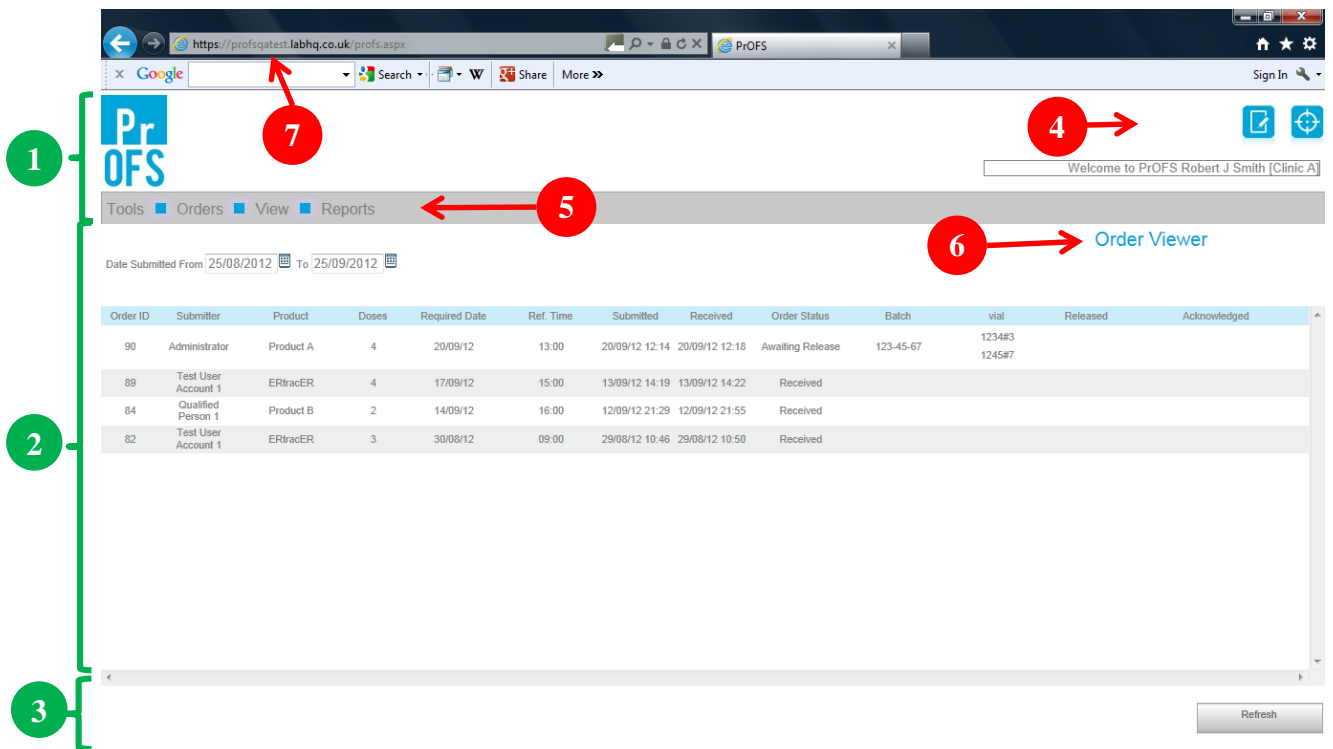


Figure 1-3 – Web Client User Interface features

By default the main body displays the *Orders Viewer* when no other function pages are open though this depends on the user’s permissions.

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

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 install Adobe Acrobat or similar application which can then be set up as your default pdf reader application, while also providing these features.

Installation

The PrOFS Web Client runs entirely using a browser window so there is no installation required. To access the web client, enter the appropriate address in the browser's address window. It is recommended that a desktop shortcut is created.

Chapter 2

Access Management

This chapter describes the logon process to access the web client.

Log on to PrOFS

Access to the *PrOFS Web Client* 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.

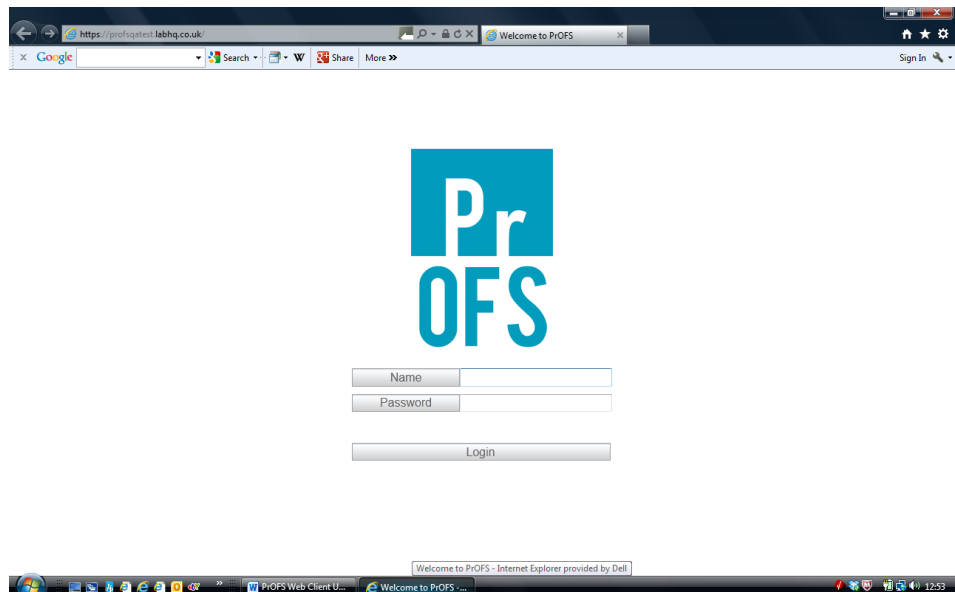


Figure 2-1 - PrOFS Web Client logon page

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 Web Client* is started, the logon page is displayed (see *Figure 2-1*). Both *User Name* and *Password* field are case-sensitive, so a User Name of *rjsmith* cannot 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 has 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 a system administrator.

Normally the web client user will be for a specific client so will only have access to that client's data. When any user has access to more than one client they will then be prompted to select the client (see *Figure 2-2*). Select the client from the selection list.



The image shows a login form for PrOFS. At the top is the PrOFS logo, which consists of a blue square containing the letters 'Pr' in white, with 'OFS' in blue below it. Below the logo are four input fields: 'Name' with the text 'rjsmith', 'Password' with ten dots, 'Client' with a dropdown menu showing 'Clinic A', and a 'Login' button.

Figure 2-2 - Client selection at logon

When a user's initial log in or after their password has been manually reset, they will be prompted to enter a new password. (see *Figure 2-3*). The password must be different from the current value. 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.

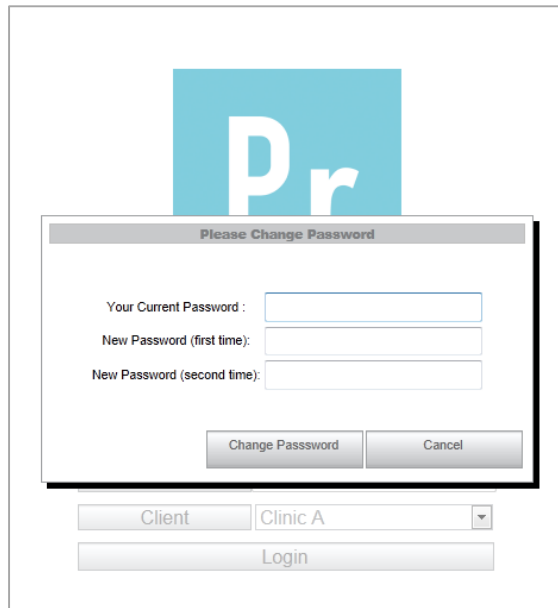


Figure 2-3 - Password Change page

On successful login, the main page, showing either the PrOFS logo or the *Order Viewer*, will be displayed, depending on the user's permissions. While the *PrOFS Web Client* is running, the page header provides information on who is logged on and for which client (see *Figure 2-4*).

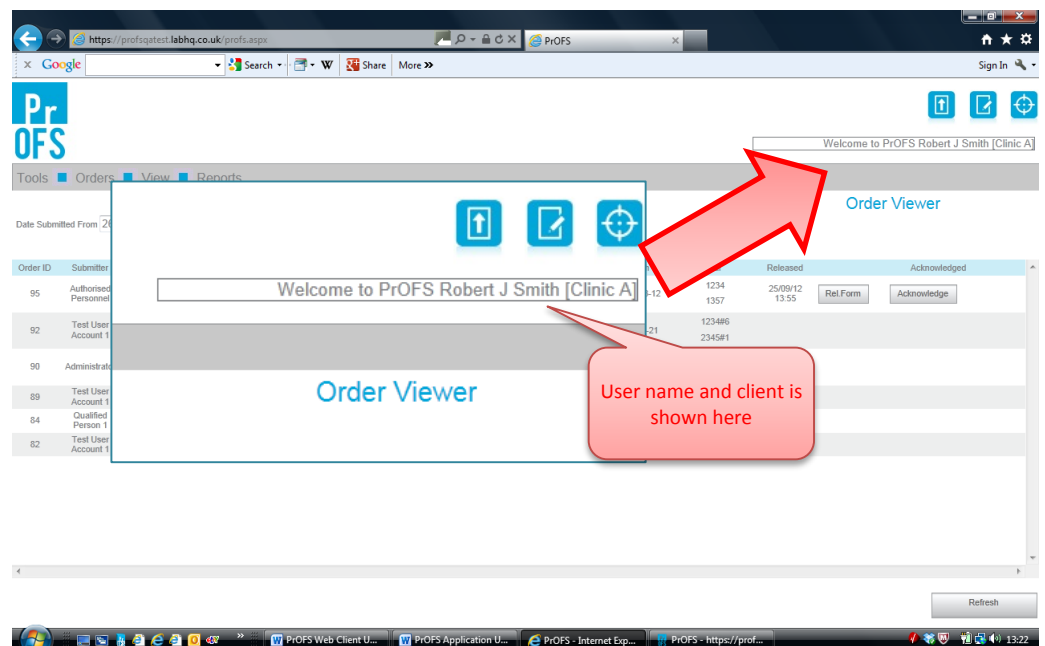


Figure 2-4 - Current user identity

Chapter 3

Order Submission

This chapter describes the order submission process.

Order Submission



This is the first step in the order life cycle, performed by the client. The function is accessed by using the *Submit Order* icon or from the menu using *Orders > Submit Order*. To access this function the user must have the *Submit Orders* permission.

On choosing this option, the *Order Details* page is displayed (see *Figure 3-1*).

Figure 3-1 - Order Details page

On opening this page the default product is shown in the *Product* field. This can be changed by selecting another product from the list of products that can be ordered by the current client.

There are a number of default entry fields for key order data. These are mandatory fields but some may already contain a value where these are fixed, depending on the product's use and the product type. See *Table 3-1* below for the variations here.

Field	Description	Use ⁴		
		Patient	Research	Calibration
Activity (per patient)	The standard radioactivity per dose in MBq	Fixed ¹	Entered	Entered
Doses	The number of doses required	Entered	Fixed at 1	Fixed at 1
Date Required	When the order is required to be delivered for use	Entered ²	Entered ²	Entered ²
Ref Time	The time the first dose is scheduled to be used.	Entered ³	Entered ³	Entered ³

Table 3-1 - Order field variations

Notes:

- ¹ The *Activity* value for patient use is set at the value agreed contractually between manufacturer and client.
- ² The *Date Required* may not be set before the current date.
- ³ The *Ref Time* may not be set before the current time when the *Date Required* is the current date.
- ⁴ Use of products for Patient or Research purposes is configured and fixed for each client. Calibration use is determined by selecting the product designated as the *calibration product*.

The *Notes* field is optional and can be used to add any order specific information e.g. additional instructions for the manufacturer.

There may also be client optional fields if these have been configured for the client. There are up to five of these fields available, but entering a value for these fields is not mandated. The *Purchase Order No.* field in *Figure 3-1* is an example of an optional field.

For products configured to require patient details, there is an additional table to complete by entering the patient identifier and consultant details for each dose. This is typically used for unlicensed or prescription-only products. The correct number of entry rows will be displayed when the *Doses* field has been entered. See *Figure 3-2* as an example. If the *Doses* value is reduced patient rows may be deleted by pressing ✕ at the end of the required rows. The entry fields will take any characters so that numeric patient identity codes or names can be entered as seen in the example page. Entry of a value in these fields is mandatory when they are displayed.

Figure 3-2- Order Submission with Patient Information

The order submission can be cancelled at any time before pressing **Submit** by using the **Cancel** option.

When all the required data has been entered press **Submit** to save the order information. The submitter will be prompted to enter their user account password as a signature to confirm they are submitting the order (see *Figure 3-3*).

Figure 3-3 - E-signature prompt for order submission



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 Web Client* will be immediately closed without saving the order as a security measure. It will be necessary for a PrOFS system user administrator to reset the account, and if necessary reset the user password.

A prompt will be displayed to ask if e-mail notifications are to be sent. If **Yes** is pressed the e-mail notification page will be displayed (see *Figure 3-4*).

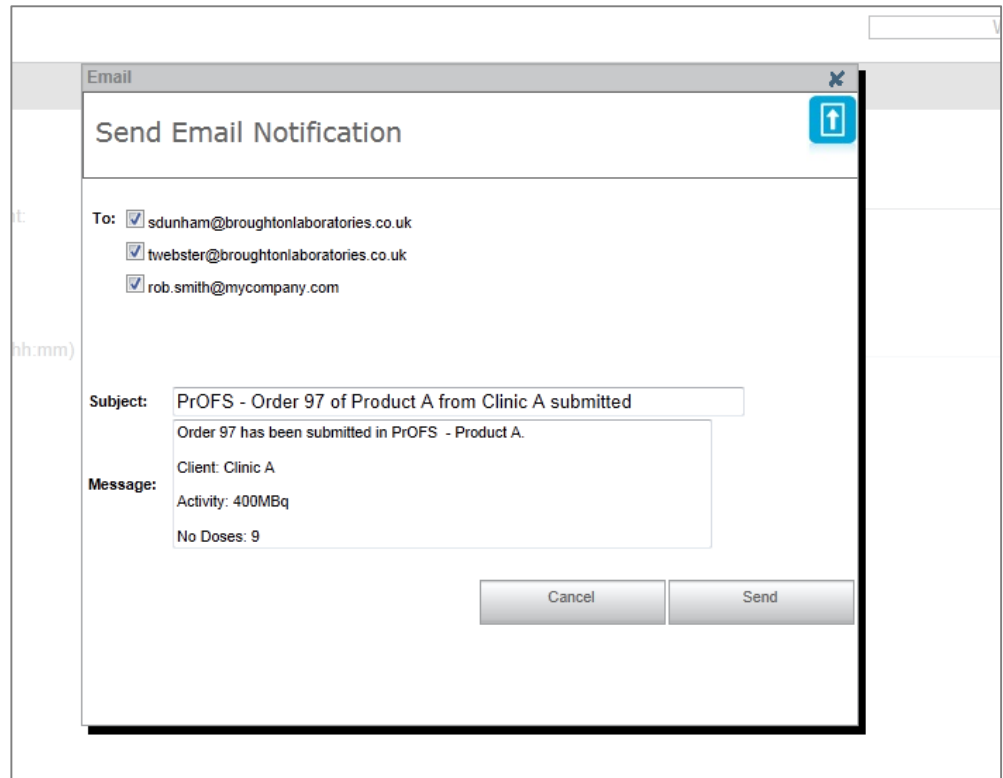


Figure 3-4 - Order Submission e-mail notification page

The upper region of the page will list the e-mail address of all users from the manufacturer and the current client that have the *Order Submission* 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 information related to the order. Both of these fields are editable to allow additional information to be added if required.

Press **Send** to send the e-mail notification; a prompt will be displayed to confirm the e-mail has been sent. Press **Cancel** to cancel the e-mail notification (not the order submission).

Next a prompt is displayed asking if the *Order Submission report* is to be printed. If the response is **Yes** then the report is displayed. This may then be printed as a pdf document and retained if hard copy is required. Note: the report can be printed at a later date or time if required (see *Chapter 6, Reports*). The *Order Details* page is then closed.

Out of Hours

When selecting to submit an order, an *Out of Hours Warning* may be displayed (see *Figure 3-5*).

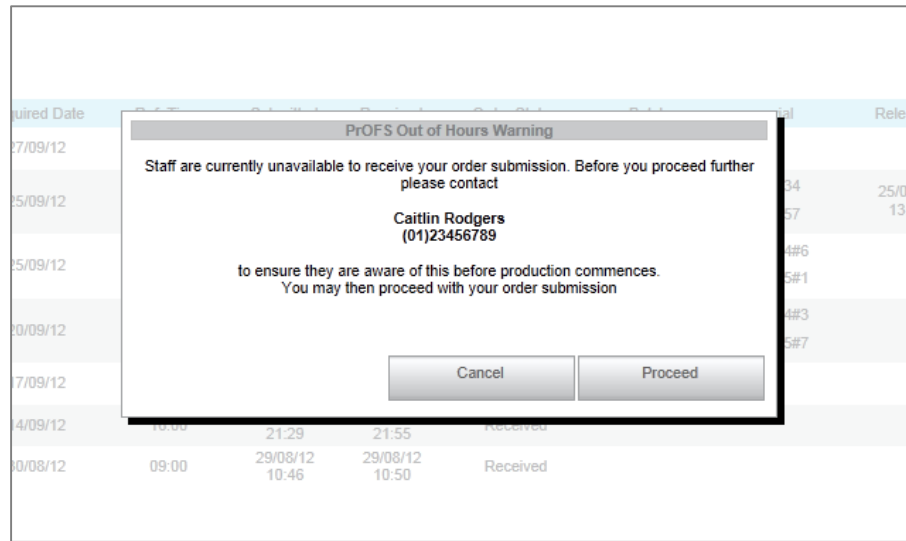


Figure 3-5 - Out of Hours Warning

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 contact (typically the Operations Manager or designated deputy) directly by telephone 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.

Once the manufacturer has been contacted, press **Proceed** to continue to the Order Details page or **Cancel** to cancel the order submission activity.

Chapter 4

Order Amendment

This chapter describes how to amend existing orders.

Amending Orders



Active orders can be amended providing they have not been locked by the manufacturer. To access this function use either the *Amend Orders* icon or the menu option *Orders > Amend Order*. The user must have the *Amend Order* permission to use this function.

On selecting this function the user is prompted to enter the Order Number. On entering a valid order number the Amend Order page is displayed. If it is outside the manufacturers hours of business, a warning may be initially displayed to contact them directly by telephone before amending the order. The warning will give the contact details (see *Figure 4-1*). Press **Proceed** after contacting the manufacturer or cancel the action using **Cancel**.

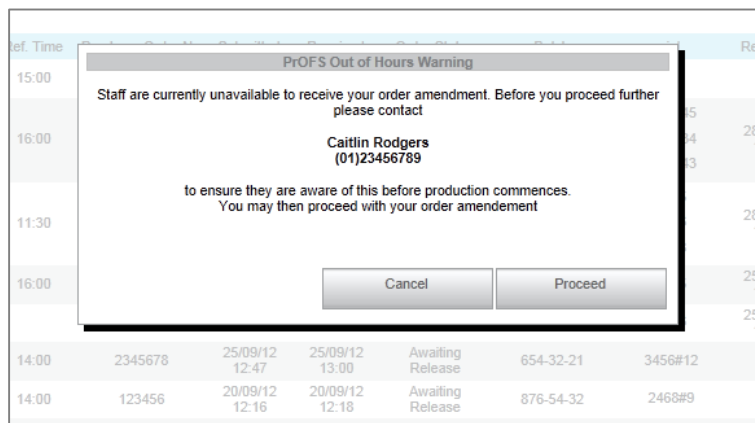


Figure 4-1 - Amend Orders - Out of Hours warning

If the order is currently locked then there will be a warning indicating this and the order record will be viewable only (see *Figure 4-2*).

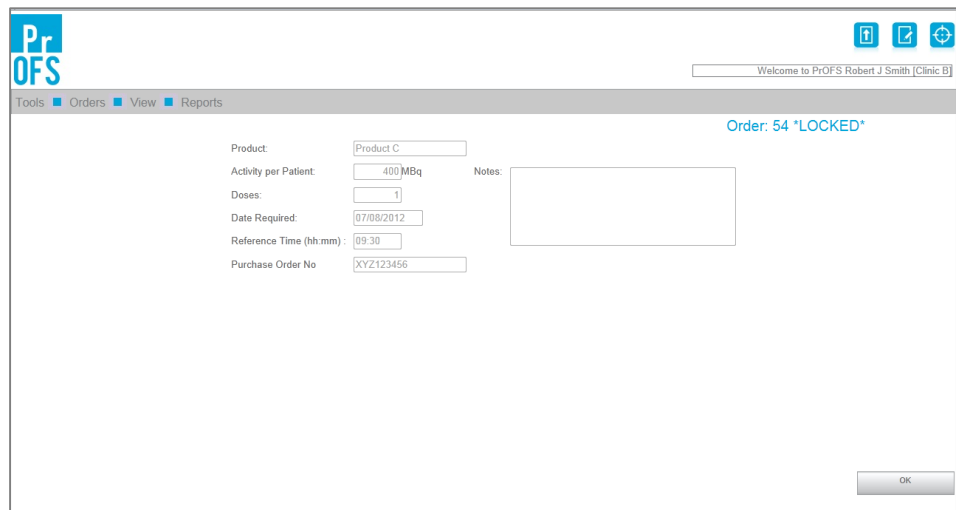


Figure 4-2 - Amend Order page showing a locked order

If the order is not locked then the record is displayed and can be modified (see Figure 4-3). The fields that can be modified are similar to order submission except that the product may not be changed. If the wrong product was selected at order submission then the order must be cancelled and a new order raised.

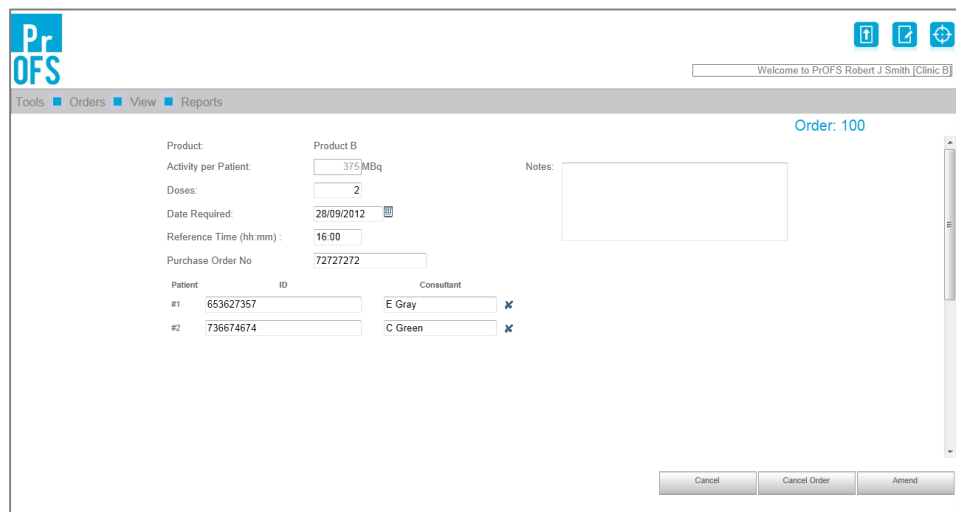


Figure 4-3 - Amend Order page

The order amendment action can be cancelled any time by pressing **Cancel**. Select **Amend** when the amendments have been made to save the updated order record. The user will be prompted to enter a reason for the amendment 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 described the reason for changing the order details.

The user must then enter their account password as an electronic signature to verify that they have reviewed the data (see Figure 4-4).

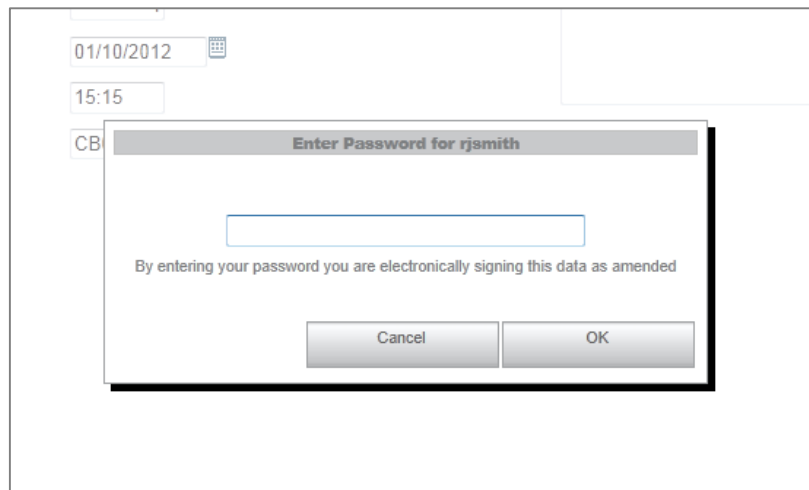


Figure 4-4 - E-signature prompt on amending an order



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 Web Client* will be immediately closed without completing the amendment as a security measure.

The user is then asked if an e-mail notification is required. If the response is the e-mail notification page is displayed (see Figure 4-5).

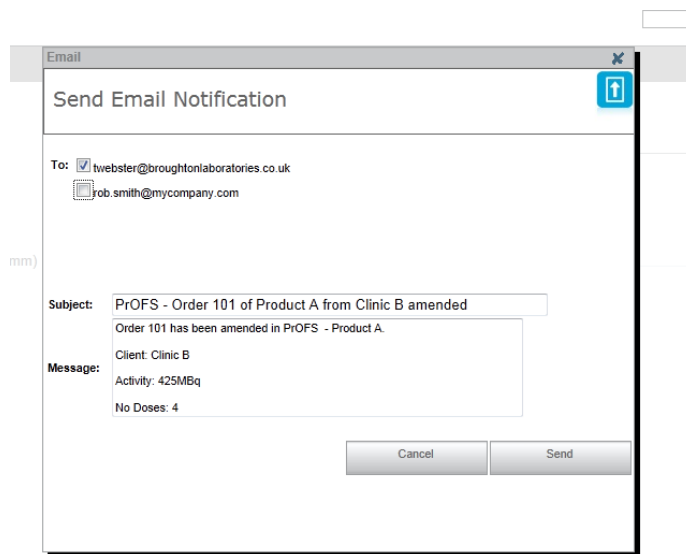


Figure 4-5 - Amend Order - e-mail notification

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.

The *Subject field* and *Message body* will contain the information related to the order. Both of these fields are editable to allow additional information to be added if required.

Press to send the e-mail notification; a prompt will be displayed to confirm the e-mail has been sent. Press to cancel the e-mail notification (not the order amendment).

Next a prompt is displayed asking if the *Order Submission report* is to be printed. If the response is then the report is displayed showing the amended order details. This may then be printed as a pdf document and retained if hard copy is required. Note: the report can be printed at a later date or time if required (see *Chapter 6, Reports*). The *Amend Order* page is then closed.

Cancelling Orders

If the client no longer wishes to receive the product ordered, for example, due to a scanner malfunction, then an order may be cancelled, provided it has not been locked. Note: If it is necessary to cancel a locked order then the client must contact the manufacturer by telephone so they can unlock the order if appropriate.

The order cancellation function is accessed via the Amend order function (see above) but requires the *Cancel Order* permission (in addition to the *Amend Order* permission).

Once the required order is visible on the page, use to cancel the order. You will be required to confirm you wish to cancel the order. On selecting you will be prompted to enter a reason for the amendment 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 described the reason for changing the order details.

The user must then enter their account password as an electronic signature to verify that they have reviewed the data (see *Figure 4-6*).



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 Web Client* will be immediately closed without completing the cancellation as a security measure.

The user is then asked if an e-mail notification is required. If the response is the e-mail notification page is displayed (see *Figure 4-7*)



Figure 4-6 - E-signature prompt for order cancellation

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 Cancelled* 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 information related to the order. Both of these fields are editable to allow additional information to be added if required.

Press **Send** to send the e-mail notification; a prompt will be displayed to confirm the e-mail has been sent. Press **Cancel** to cancel the e-mail notification (not the order cancellation action). The *Cancel Order* page will then be closed.

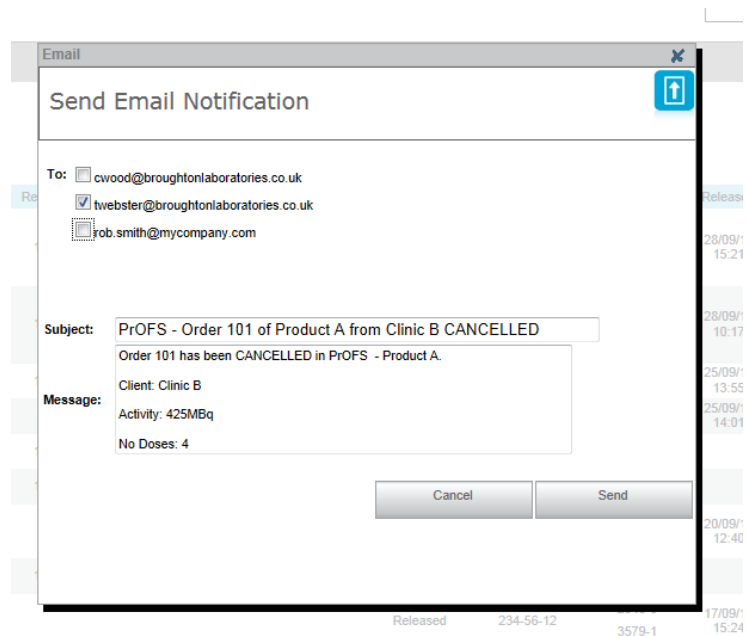


Figure 4-7 - Cancel Order e-mail notification page

Chapter 5

Delivery Acknowledgement

This chapter describes how deliveries are acknowledged by the client.

Order Acknowledgement Process

Product is typically sent by the manufacturer under quarantine to the client in order that it is available in time to administer it to their patients as scheduled. The product may not be administered until the batch release disposition has been made by the **Qualified Person**. This is indicated to the client in PrOFS on the **Order Viewer** page; the status of the order will change to either Released or Withdrawn. Occasionally there may be more than one delivery against an order, for example, when the order is fulfilled from more than one batch, or if **spare activity** has been requested after the initial delivery has left the manufacturer.

If the product is released, the client will print the **Release Form** for the delivery and check the details of the vials on the form against the physical product to ensure that the correct items have been delivered. This is conveyed to the manufacturer by acknowledging that this has been done.

If the product delivered has been withdrawn then the client must still print the **Withdrawal Notice** and indicate whether the product has actually been delivered (it may still be in the process of being transported to the client) and, if this is the case, confirm they acknowledge the withdrawal notice and will retain the product in quarantine until it can be returned to the manufacturer.

Figure 5-1 shows an example of the **Order Viewer** with orders that have been dispositioned and are awaiting acknowledgement. In this example, the product despatched for orders 99 and 100 has been withdrawn, as indicated by the **Order Status** value and the coloured button **With.Form** which is used to print the **Withdrawal Notice** for the respective deliveries.

Tools ■ Orders ■ View ■ Reports													
													Order Viewer
Date Submitted From <input type="text" value="01/06/2012"/> To <input type="text" value="01/10/2012"/>													
Order ID	Submitter	Product	Doses	Required Date	Ref. Time	Purchase Order No	Submitted	Received	Order Status	Batch	vial	Released	Acknowledged
100	Administrator	Product B	2	28/09/12	16:00	72727272	28/09/12 14:55	28/09/12 14:59	Withdrawn	CCR0019-B	18-2345 19-1234 19-6543	28/09/12 15:21	<input type="button" value="With Form"/> <input type="button" value="Acknowledge"/>
98	Administrator	Product B	2	28/09/12	11:30	345678	28/09/12 09:31	28/09/12 09:32	Withdrawn	456-78-12	2345 3456 4578	28/09/12 10:17	<input type="button" value="With Form"/> <input type="button" value="Acknowledge"/>
96	Authorised Personnel	Product B	2	25/09/12	16:00	986774532	25/09/12 13:37	25/09/12 13:39	Released	1425-43-12	2345	25/09/12 13:55	<input type="button" value="Rel. Form"/> <input type="button" value="Acknowledge"/>
									Released	1425-43-12	3456	25/09/12 14:01	<input type="button" value="Rel. Form"/> <input type="button" value="Acknowledge"/>
93	Authorised Personnel	Product A	4	25/09/12	14:00	2345678	25/09/12 12:47	25/09/12 13:00	Awaiting Release	654-32-21	3456#12		
91	Administrator	Product B	2	20/09/12	14:00	123456	20/09/12 12:16	20/09/12 12:18	Awaiting Release	876-54-32	2468#9		
									Released	876-54-32	2345#8	20/09/12	<input type="button" value="Rel. Form"/> <input type="button" value="Acknowledge"/>

Figure 5-1 - Order Viewer showing dispositioned orders

Order 96 has two deliveries; the product has been released and the **Rel.Form** button is used to generate the *Release Form*. Order 93 has not yet been dispositioned so there is no option to generate a *Release Form/Withdrawal Notice* or acknowledge the delivery.

The *Order Viewer* automatically refreshes the data every minute but can be manually updated using **Refresh**.

Acknowledging A Released Delivery

Access to both the relevant disposition form and delivery acknowledgement are controlled for each user account by the *Print Release Form* and *Print Acknowledgement Form* permissions respectively.

On selecting **Acknowledge** for a released batch, the user is required to enter their account password as e-signature for the acknowledgement (see *Figure 5-2*).



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 Web Client* will be immediately closed without completing the acknowledgement 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 (see *Figure 5-3*).

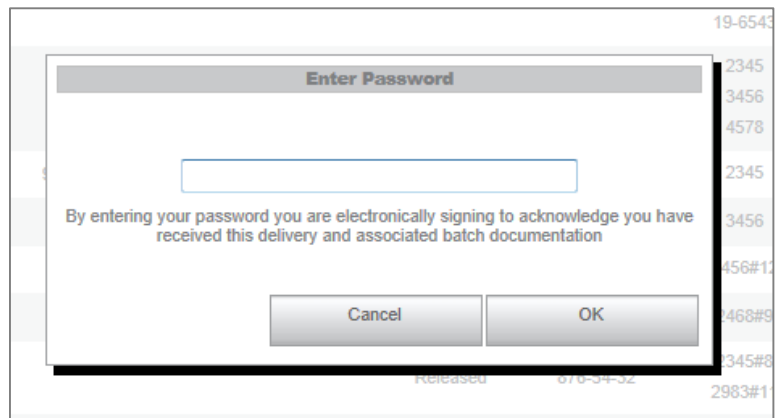


Figure 5-2- E-signature for Released Delivery Acknowledgement

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 Cancelled* 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.

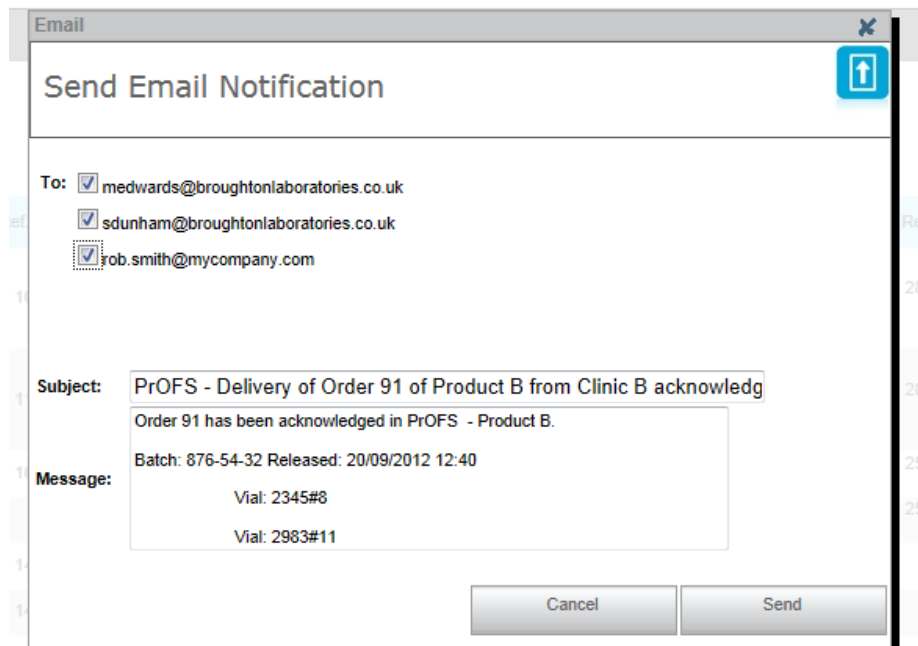


Figure 5-3 - Order Acknowledgement e-mail notification

The *Subject field* and *Message body* will contain the information related to the order. Both of these fields are editable to allow additional information to be added if required.

Press **Send** to send the e-mail notification; a prompt will be displayed to confirm the e-mail has been sent. Press **Cancel** to cancel the e-mail notification (not the acknowledgement action).

Next a prompt is displayed asking if the *Order Acknowledgement report* is to be printed. If the response is **Yes** then the report is displayed showing the order

acknowledgement details. This may then be printed as a pdf document and retained if hard copy is required. Note: the report can be printed at a later date or time if required (see *Chapter 6, Reports*).

Chapter 6


Other Features

This chapter describes the Reports and Tools menu options in the web client.

Reports

Currently there is only one report option available, other than those on the [Order Viewer](#). The Order Submission report can be accessed for any current client's orders using *Reports > Order Submission*. This function requires the *View Orders* permission.

On selecting this option, you are prompted to enter an order number. On completing this action, the report will be displayed. An example is given in *Figure 6-1*. This may then be printed as a pdf document and retained if hard copy is required.




Order Submission 

Product: Product A

For: Clinic B
B Avenue
Blackrock

Purchase Order No 2345678

Order Comments:

Order:85
Date Required:17-Sep-2012
Activity per Patient:425 MBq

Ref Time:13:30

Doses:5

Order Submitted by: Qualified Person 1

Title: Qualified Person

Order Amended by: Robert J Smith

This order has been submitted by electronic signature, which the above uses as the legally-binding equivalent of their hand-written signature.

Order Date: 12-Sep-2012 21:30:58

Amended Date: 17-Sep-2012 09:40:46

Figure 6-1 - Order Submission Report - Amended Order Example

Tools Menu Options

There are a number of miscellaneous options available on the *Tools* menu (see *Figure 6-2*) which do not fit into the other menu option groups. Some of these may not be present depending on the current user's permissions. There is a brief description of each given in *Table 6-1*.

Menu Option	Description
Change Client	If a PrOFS user has been configured to access more than one client e.g. a manufacturer user, then there is a menu option to quickly switch between client's accounts without closing and re-opening PrOFS. The client required is selected from the list of clients configured for the current user and then press <input type="button" value="OK"/> to log on to the new client account.
Logout	This option allows the user to log out when finished the current session or to allow another user to access PrOFS.
Help	This will give access to the PrOFS Help web pages.

Menu Option	Description
About	This displays a page which shows the current version details of PrOFS and its components (see example in <i>Figure 6-3</i>).
Change Password	This allows the current user to change their password at any time while logged in. See <i>Chapter 2</i> .

Table 6-1 - Tools Menu options

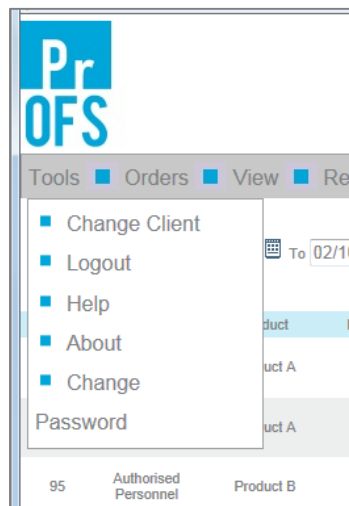


Figure 6-2 – Tools menu options

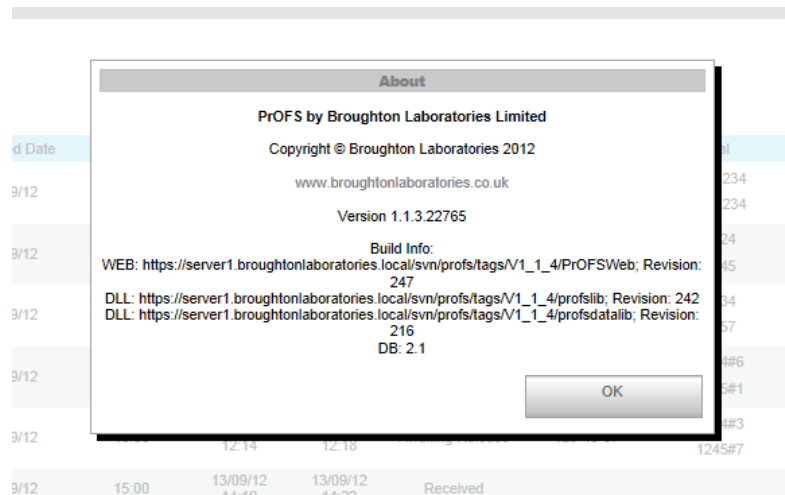


Figure 6-3 - Tools About page

Chapter 7

Glossary

Term	Meaning
<i>Calibration dose</i>	A unit of product used solely for calibration of scanning equipment
<i>Calibration product</i>	A product configured in PrOFS that is used when ordering <i>calibration doses</i>
<i>Completed</i>	In PrOFS this is the final status of orders when all activities have been performed and when billing data is entered.
<i>Delivery</i>	In PrOFS a delivery occurs when vials are made available to the client, which is at disposition
<i>Order Acknowledgement report</i>	The report generated to provide the data on when an delivery acknowledgement was performed and by whom.
<i>Order Submission report</i>	The report generated to provide the data related to order submission or amendment.
<i>Order Viewer</i>	The default display in the <i>PrOFS Web Client</i> that summarises the client's orders and their status.
<i>PrOFS Application</i>	The PrOFS program used by the manufacturer to manage their part of the order life cycle
<i>PrOFS Web Client</i>	The PrOFS program used by the client to manage their part of the order life cycle
<i>Qualified Person</i>	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.
<i>Release Form</i>	This report is generated to report the details of a <i>delivery</i> available for use by the specified client.

Term	Meaning
<i>Selection criteria</i>	These are filters used when selecting data to be reported.
<i>Spare activity</i>	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.
<i>Withdrawal Notice</i>	This report replaces the <i>Release Form</i> if a product batch does not meet the required quality standard.