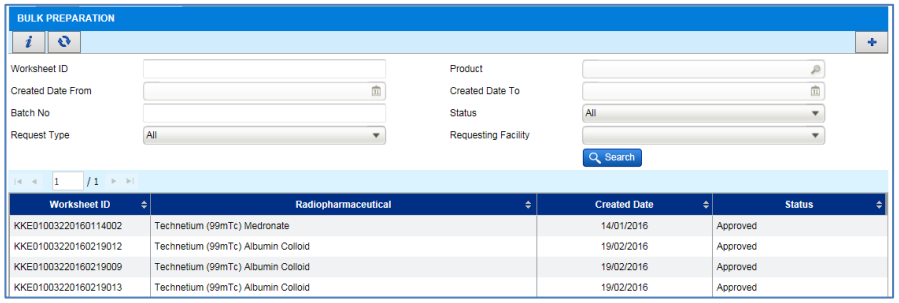
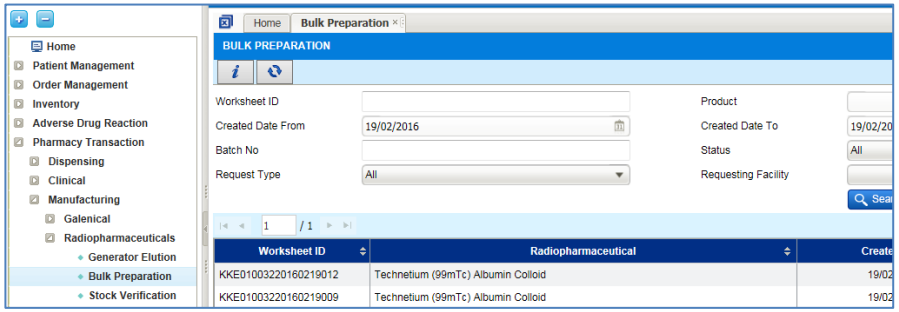
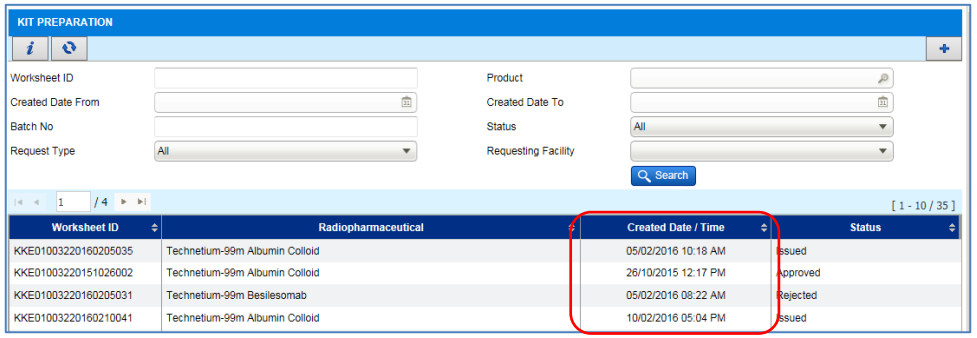
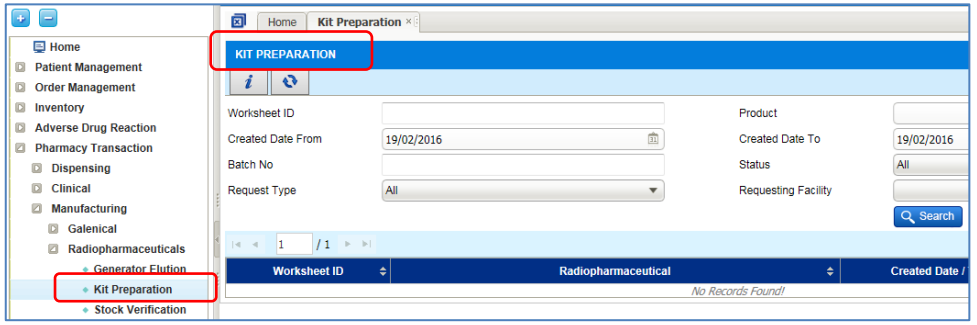
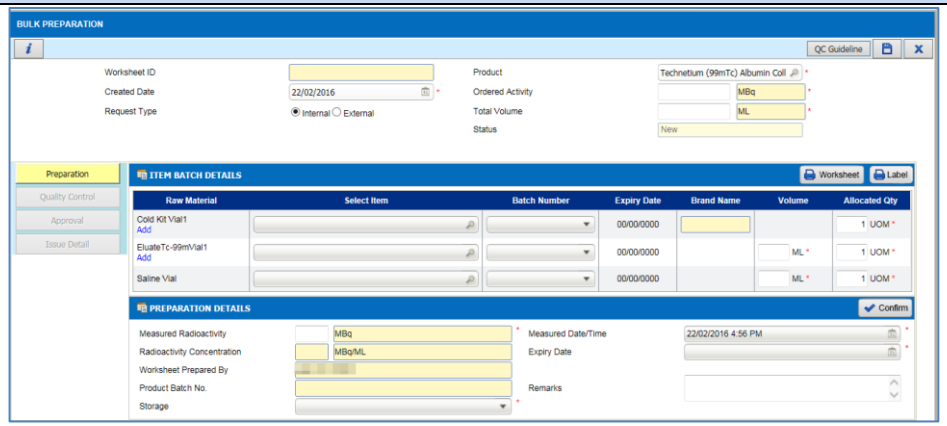
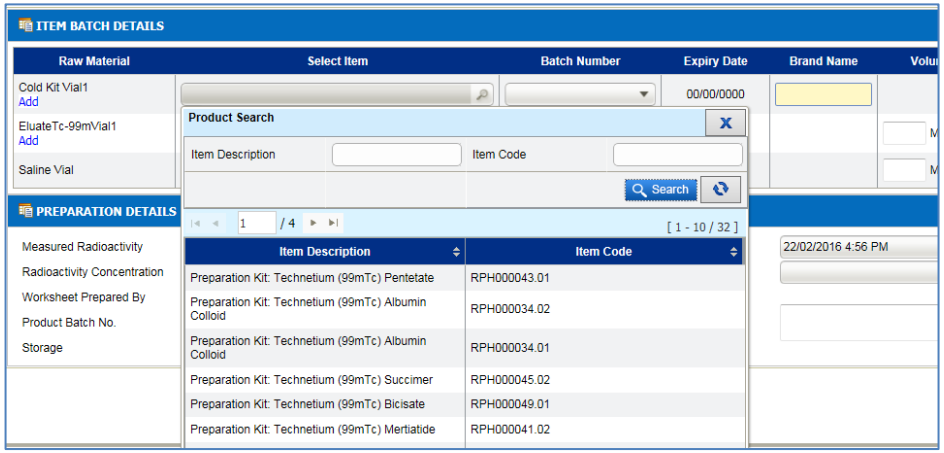
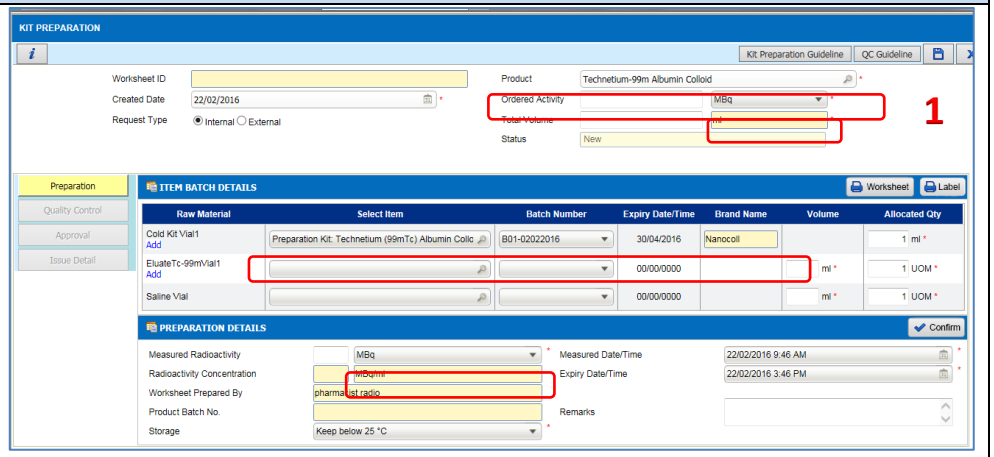
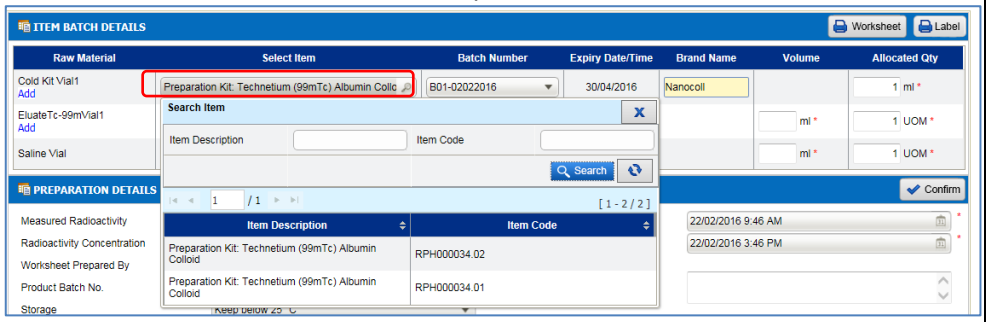
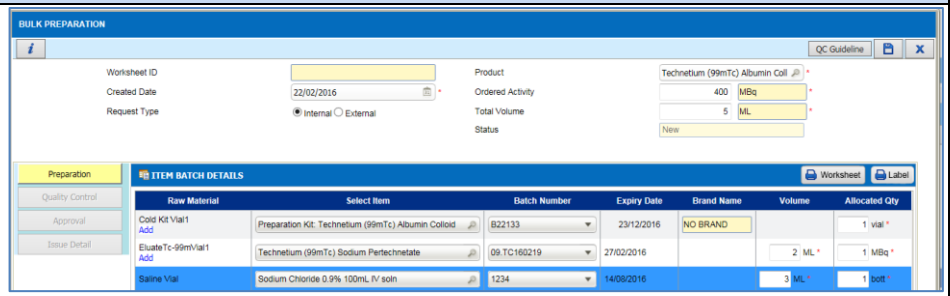
Proposed Solution

No.	Ticket #	Description	Requests	Proposed Solution
1.	I-PhIS012795015S	Radiopharma Kit Preparation - Remove mandatory for pH value	To remove mandatory for pH value	• Remove mandatory for pH value. • Worksheet: To update Strip calculation. Add value to enter BG Reading, update calculation based on BG Reading. • Worksheet: i. Add Manufacturer Name on Cold Kit Brand Name. ii. Add Expiry Date for Cold Kit Vial, Eluate Tc-99m Vial & Saline Vial. iii. Rename Labelling Time to 'Measured Date/Time'. iv. When record is approved, in worksheet Approval section, to update checklist as Yes only. Currently display as Yes/No. v. Worksheet change to Landscape and add portion to paste label.
	I-PhIS012792615S	Worksheet: To update Strip calculation. Add value to enter BG Reading, update calculation based on BG Reading. Value BG display as Background	Worksheet: To update Strip calculation. Add value to enter BG Reading, update calculation based on BG Reading. Value BG display as Background	
	I-PhIS012795615S	Worksheet: i. Add Manufacturer Name on Cold Kit Brand Name ii. Add Expiry Date for Cold Kit Vial, Eluate Tc-99m Vial & Saline Vial iii. Rename Labelling Time to 'Measured Date/Time' iv. Worksheet: When record is approved, in worksheet Approval section, to update checklist as Yes only. Currently diplay as Yes/No v. Worksheet change to Landscape and add portion to paste label"	Worksheet: i. Add Manufacturer Name on Cold Kit Brand Name ii. Add Expiry Date for Cold Kit Vial, Eluate Tc-99m Vial & Saline Vial iii. Rename Labelling Time to 'Measured Date/Time' iv. Worksheet: When record is approved, in worksheet Approval section, to update checklist as Yes only. Currently diplay as Yes/No v. Worksheet change to Landscape and add portion to paste label"	

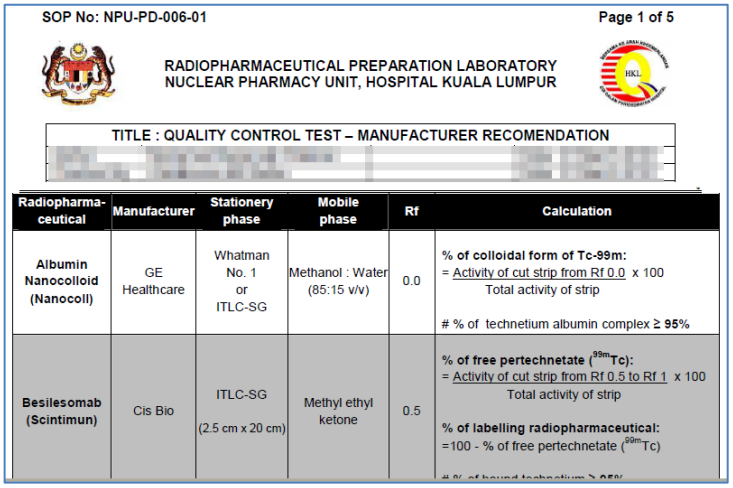
Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
1. Rename screen to Kit Preparation	<u>Bulk Preparation listing screen</u>  <u>Bulk Preparation screen</u>  Screen and menu name is Bulk Preparation.	<u>Kit Preparation listing screen</u>  Add Time value for Created Date/Time. <u>Kit Preparation screen</u>  Screen and menu name updated to Kit Preparation.

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
2. Kit Preparation screen function	 1. Select Product and proceed to select the Cold Kit, Eluate and Saline Vial batch number. 2. Ordered Activity and Measure Radioactivity UOM based on SKU UOM in drug master. Only one UOM option available.  3. When search Cold Kit vial, all item specified as Cold Kit (setup in Radiopharma Setup screen) displayed in the list.	 1. Once Product is selected, Cold Kit Vial 1 and batch number is auto selected based on the default Cold Kit set in Radiopharma Setup maintenance screen. 2. Ordered Activity and Measured Radioactivity UOM is displayed as drop down. User able to choose MBq or mCi UOM.  3. Only Cold Kit that linked to the selected Product will display in the Cold Kit Vial 1 list. Setting is done in Rediopharma Setup screen.

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1



4. Able to view QC Guideline only. On click of the button, document in PDF is displayed as below:



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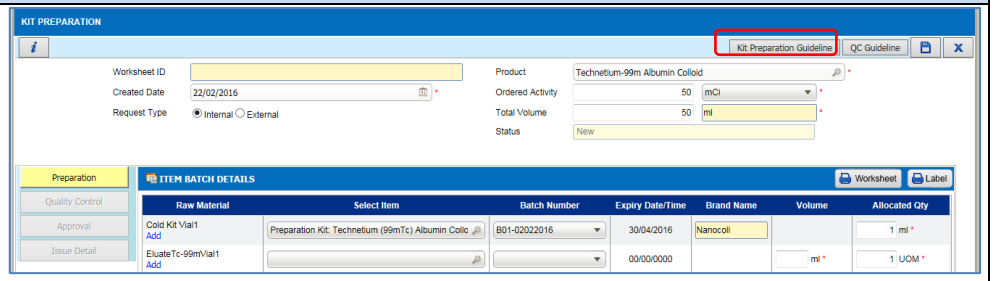
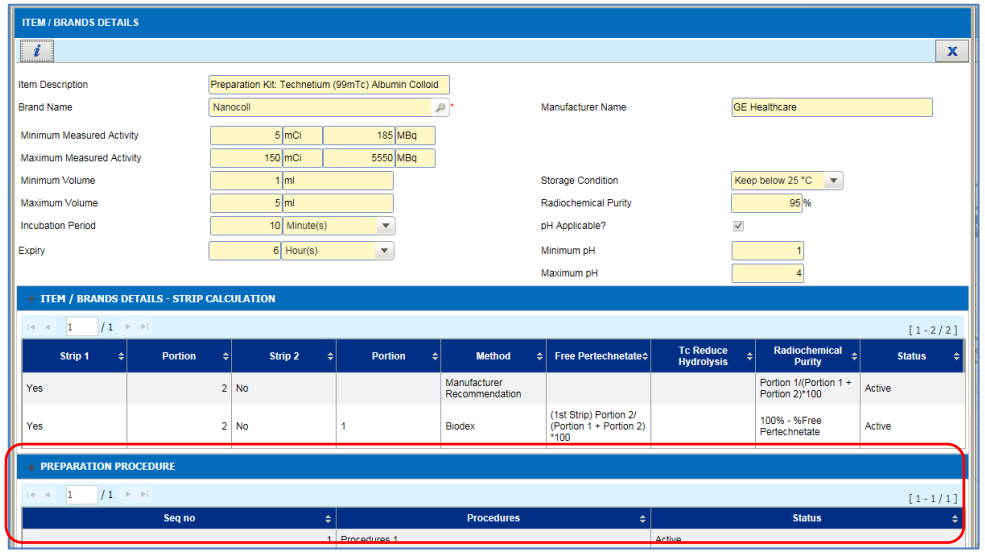
RADIOPHARMACEUTICAL PREPARATION LABORATORY
NUCLEAR PHARMACY UNIT, HOSPITAL KUALA LUMPUR

TITLE : QUALITY CONTROL TEST – MANUFACTURER RECOMENDATION

Radiopharma-ceutical	Manufacturer	Stationery phase	Mobile phase	Rf	Calculation
Albumin Nanocolloid (Nanocoll)	GE Healthcare	Whatman No. 1 or ITLC-SG	Methanol : Water (85:15 v/v)	0.0	**% of colloidal form of Tc-99m:** = Activity of cut strip from Rf 0.0 x 100 / Total activity of strip # % of technetium albumin complex ≥ 95%
Besilesomab (Scintimun)	Cis Bio	ITLC-SG (2.5 cm x 20 cm)	Methyl ethyl ketone	0.5	**% of free pertechnetate (^{99m}Tc):** = Activity of cut strip from Rf 0.5 to Rf 1 x 100 / Total activity of strip **% of labelling radiopharmaceutical:** =100 - % of free pertechnetate (^{99m}Tc)

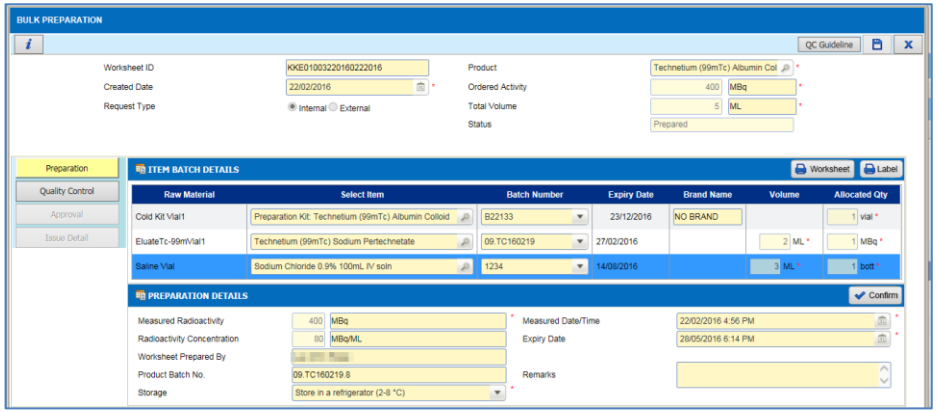
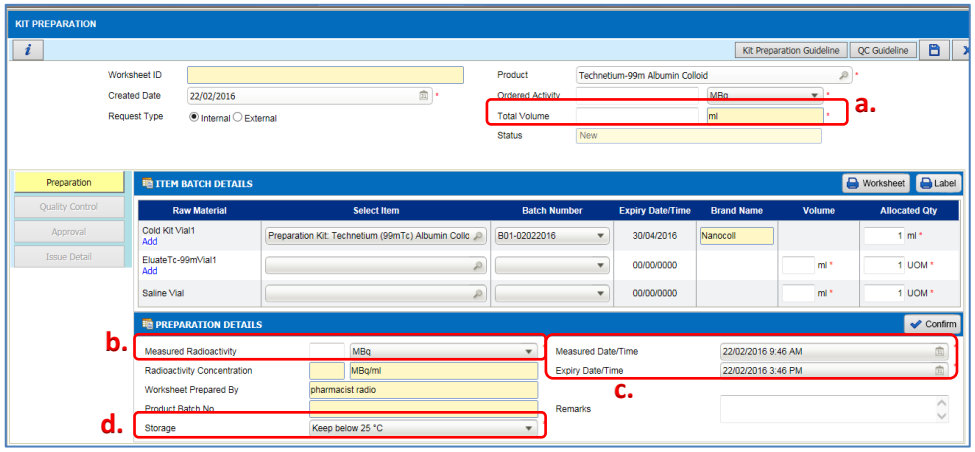
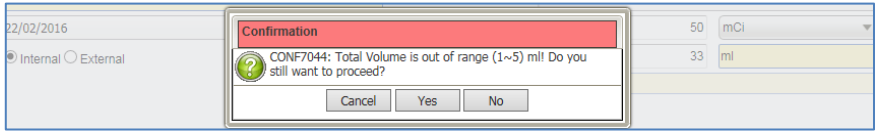
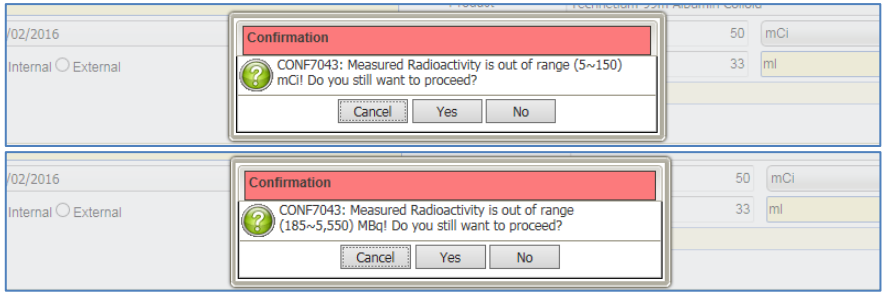


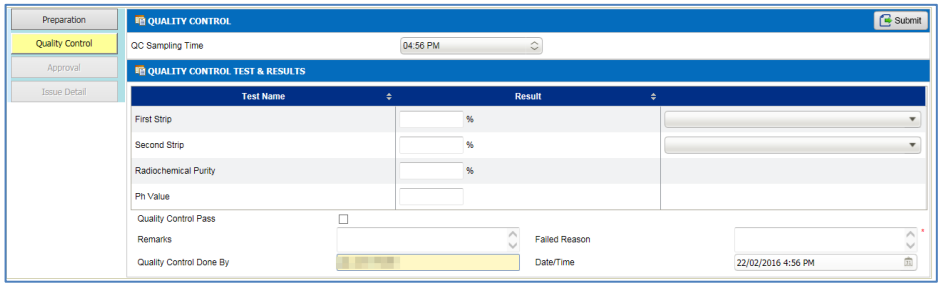
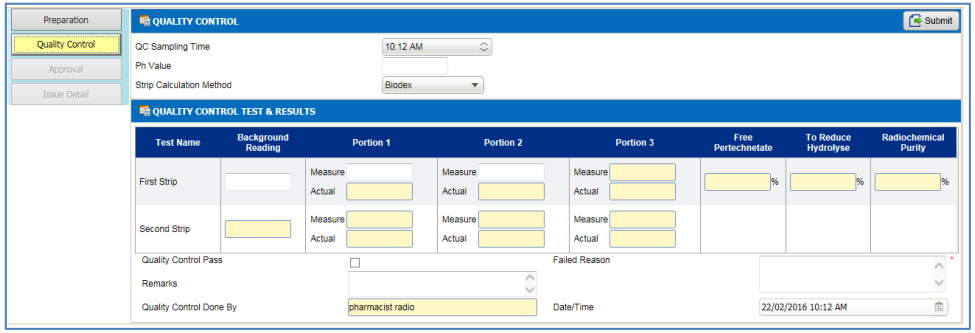
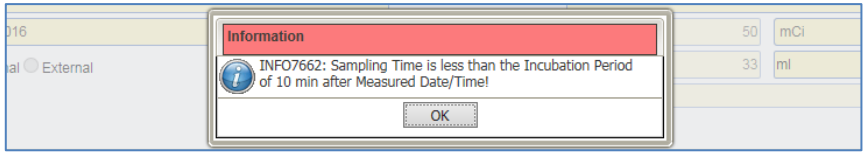
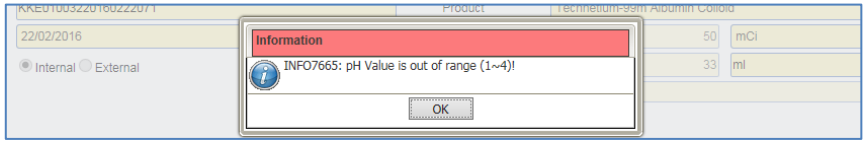
4. Added new button, Kit Preparation Guideline. On click of this button, screen is below is displayed:

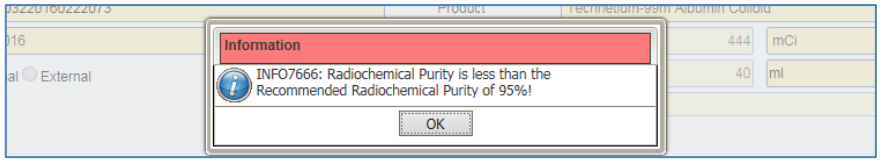
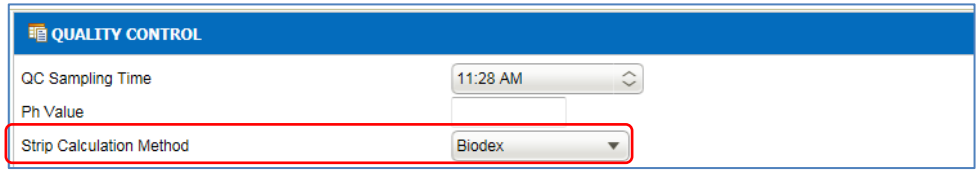
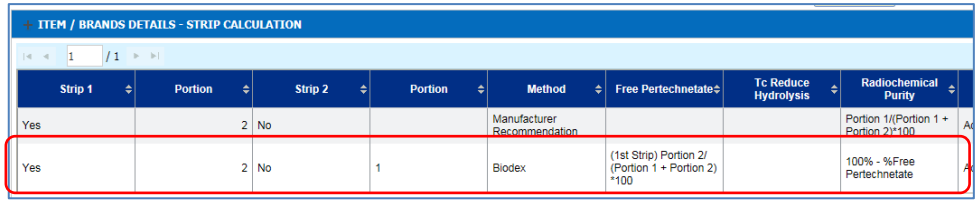


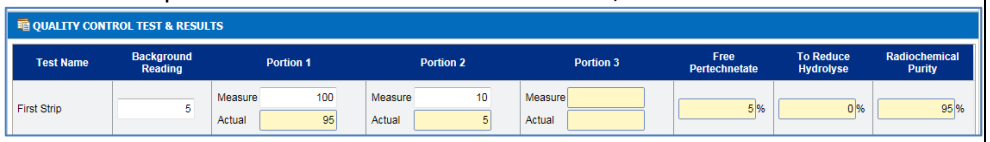
5. Kit Preparation Guideline is displayed as read-only based on the Radiopharma Setup screen. Cold Kit Batch Number and Brand is mandatory to select before user can open this screen.

6. In this guideline, user able to view the Preparation Procedures is any setup is done in the Radiopharma Setup screen by HQ.

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
	5. In Bulk Preparation screen, there is no validation involved for all fields. No minimum or maximum value validation and no default value for Expiry Date/Time and Storage.  6. Confirm the Preparation record and proceed to Quality Control screen.	7. Based on the Kit Preparation Guideline, the validations involved are:  i. Minimum/Maximum Total Volume: If the entered value is not within the range, alert will pop up but user still able to proceed.  ii. Minimum/Maximum Measured Activity: Of the entered value is not within the range, alert will pop up but user still able to proceed. Alert will display based on the selected UOM of MBq or mCi. 

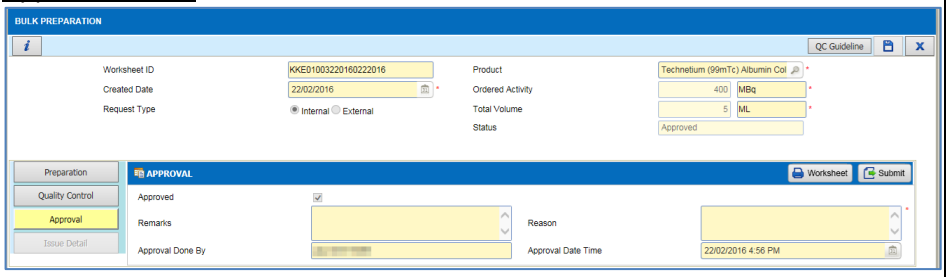
Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
	Quality Control screen  7. All fields are for data recording purposes only, no validation or calculation involved. User enter any value, select Pass/Fail checkbox and click Submit. Status will update to QC Pass or QC Fail. Then, proceed to Approval screen.	iii. Expiry: Expiry Date/Time is auto-generated based on Measured Date/Time and the Expiry Duration as saved in Radiopharma Setup screen. iv. Storage Condition: Storage Condition is auto default based on value saved in Radiopharma Setup screen. Quality Control screen  v. Incubation Period: If the QC Sampling Time is not AFTER the Incubation Period, alert will display when user click on QC Pass and Submit the record. User unable to proceed unless edit the Sampling Time or Fail the QC record.  vi. Minimum/Maximum pH: If the entered pH value is not within the range, alert will display when user click on QC Pass and Submit the record. User unable to proceed unless edit the pH value or Fail the QC record. 

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
		vii. Radiochemical Purity and Strip Calculation: Radiochemical Purity should be more than the value set in Radiopharma Setup. Alert will display when user click on QC Pass and Submit the record. User unable to proceed unless edit the value or Fail the QC record.  8. Radiochemical Purity is calculated based on the calculation below: a. Based on the selected calculation method,  b. Refer to the formula in Kit Preparation Guideline, for example: 

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
		c. Example of the calculated value is as below,  - Enter value for Background Reading (if necessary) - Enter value for Portion 1:Measure and Portion 2:Measure - Portion 1:Actual and Portion 2:Actual is calculated based on, 'Measure – (minus) Background Reading' - Free Pertechnetate = (**1st Strip:Actual**) Portion 2/(Portion 1 + Portion 2)*100 - Radiochemical Purity = 100% - %Free Pertechnetate ***Note: The calculation for Radiochemical Purity, Free Pertechnetate and Tc Reduce Hydrolysis depends on the setting in Radiopharma Setup screen.*

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1

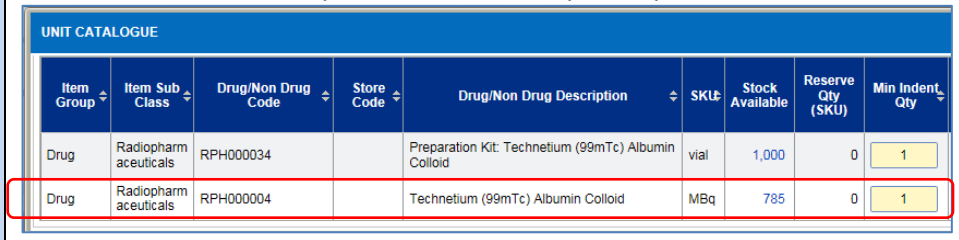
Approval screen



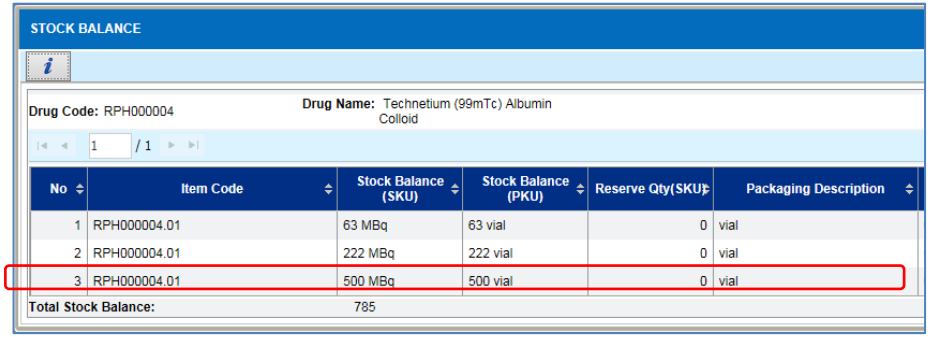
Select Approved checkbox and click on Submit button, status will update to Approved. If checkbox not selected, status will update as Rejected.

Once record is Approved:

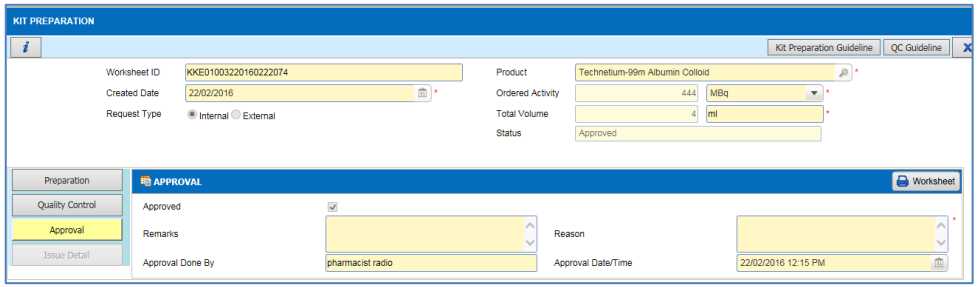
1. In Unit Catalogue, new batch is created with the same batch number, with Available Qty = Measured Activity in Prep details;



- Click on the Stock Available hyperlink to view screen below,



Approval screen

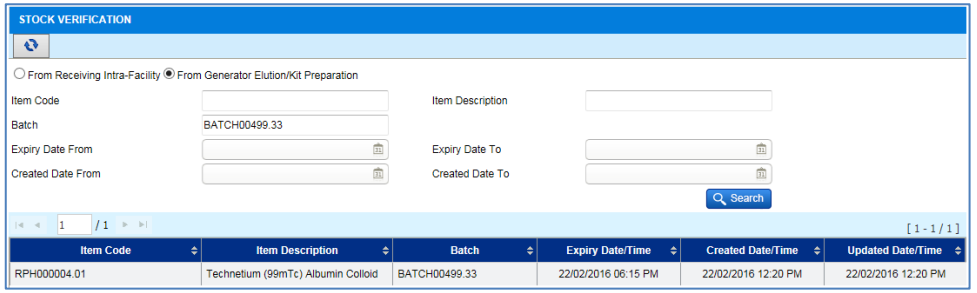


Select Approved checkbox and click on Submit button, status will update to Approved. If checkbox not selected, status will update as Rejected.

Once record is Approved:

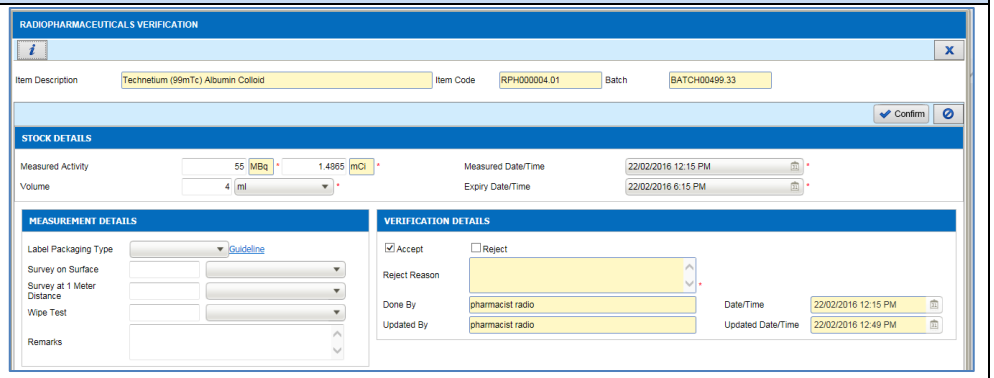
1. Stock Verification screen is updated with the batch, measured activity, measured date/time, total volume and expiry date/time. Record will always updated as Accepted.

- When open Stock Verification as below,able to search the newly created batch:

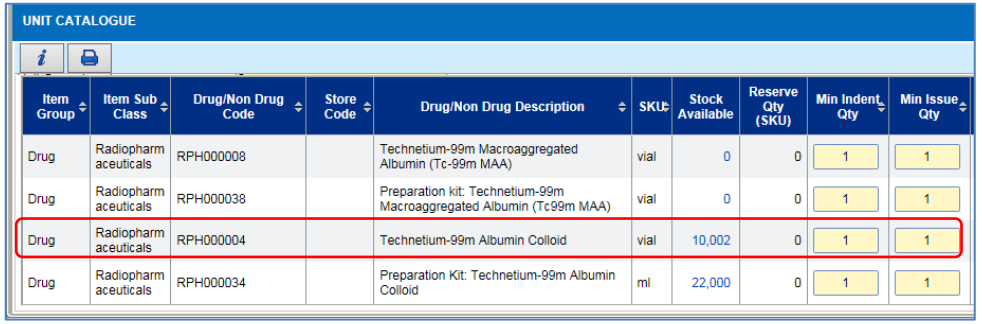


- Record is auto created once Approved the Kit Preparation record. Able to edit the value in Stock Verification if necessary.

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1

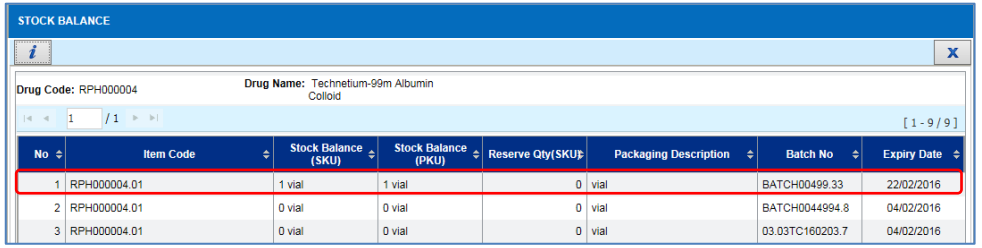


2. In Unit Catalogue, new batch is created with the same batch number, with Available Qty = 1 vial;



Item Group	Item Sub Class	Drug/Non Drug Code	Store Code	Drug/Non Drug Description	SKU	Stock Available	Reserve Qty (SKU)	Min Indent Qty	Min Issue Qty
Drug	Radiopharmaceuticals	RPH000008		Technetium-99m Macroaggregated Albumin (Tc-99m MAA)	vial	0	0	1	1
Drug	Radiopharmaceuticals	RPH000038		Preparation kit: Technetium-99m Macroaggregated Albumin (Tc99m MAA)	vial	0	0	1	1
Drug	Radiopharmaceuticals	RPH000004		Technetium-99m Albumin Colloid	vial	10,002	0	1	1
Drug	Radiopharmaceuticals	RPH000034		Preparation Kit: Technetium-99m Albumin Colloid	ml	22,000	0	1	1

- Click on the Stock Available hyperlink to view screen below,



No	Item Code	Stock Balance (SKU)	Stock Balance (PKU)	Reserve Qty(SKU)	Packaging Description	Batch No	Expiry Date
1	RPH000004.01	1 vial	1 vial	0	vial	BATCH00499.33	22/02/2016
2	RPH000004.01	0 vial	0 vial	0	vial	BATCH0044994.8	04/02/2016
3	RPH000004.01	0 vial	0 vial	0	vial	03.03TC160203.7	04/02/2016

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
3. Worksheet	Bulk Preparation Worksheet is displayed as below:	Kit Preparation Worksheet is updated as below:

RADIOPHARMACEUTICALS WORKSHEET

MINISTRY OF HEALTH
Klinik Kesihatan Bandar Maharani

Bulk Preparation records for Technetium (99mTc) Albumin Colloid
Batch No: 09.TC160219.11
Worksheet ID: KKE01003220160222019

Preparation of Technetium (99mTc) Albumin Colloid			Cold Kit Brand Name :
Date	22/02/2016		NO BRAND
Expected Activity	200 MBq		
Raw Material	Batch Number	Volume	Remarks :
Cold Kit Vial	B22133	Total : 5 mL	
Eluate Tc-99m Vial	09.TC160219	2 mL	
			Worksheet Prepared By : Signature,Name,Time
Saline Vial	1234	3 mL	
Measured Activity Date/Time	200 MBq		Worksheet Checked By : Signature,Name,Time
Labelling Time	22/02/2016		
Radioactivity Concentration	40 MBq/ML		Preparation Done By : Signature,Name,Time

Quality Control of Technetium (99mTc) Albumin Colloid					Approval of Technetium (99mTc) Albumin Colloid	
QC Sampling Time		18:37		Remarks :	Checklist for approval :	
		Measure	Actual	%		
First Strip	BG Reading	55			Preparation done accordingly	Yes/No
	1st Portion				QC done accordingly and pass	Yes/No
	2nd Portion				Label done accordingly	Yes/No
Second Strip	BG Reading	55			Remarks :	
	3rd Portion					
	4th Portion			Quality Control Done By	Approved By :	
Radiochemical Purity		55		Pass/Fail	Signature,Name,Time	Signature,Name,Time

RADIOPHARMACEUTICALS WORKSHEET

MINISTRY OF HEALTH
Klinik Kesihatan Bandar Maharani

Kit Preparation records for Technetium-99m Albumin Colloid
Batch No: BATCH00499.33
Worksheet ID: KKE01003220160222074

2

Preparation of Technetium-99m Albumin Colloid				Cold Kit Brand/Manufacturer Name:	
Date	22/02/2016	Expected Activity	444 MBq	Nanocoll - GE Healthcare	Worksheet Prepared By : pharmacist radio
Raw Material	Batch Number/Expiry		Volume		
Cold Kit Vial	B01-02022016 - 30/04/2016		Total : 4 ml		Worksheet Checked By :
Eluate Tc-99m Vial	BATCH00499 - 24/02/2016		1 ml	Remarks :	
Saline Vial	B26102015 - 26/10/2016		3 ml		Preparation Done By :
Measured Activity	55 MBq				
Measured Date/Time	22/02/2016 12:15 PM				
Radioactivity Concentration	13.75 MBq/ml				

II.

Quality Control of Technetium-99m Albumin Colloid						Label
QC Sampling Time		1:15 PM			Remarks :	
		Measure	Actual	%		
First Strip	BG Reading	5				
	1st Portion	100	95	5.26		
	2nd Portion	10	5			
Second Strip	BG Reading	N/A				
	3rd Portion	N/A	N/A	N/A	Quality Control Done By	
	4th Portion	N/A	N/A		pharmacist radio	
Radiochemical Purity		95		Pass/Fail		

3

Approval of Technetium-99m Albumin Colloid	
Checklist for approval :	
Preparation done	Yes
QC done accordingly and	Yes
Label done accordingly	Yes
Remarks :	
Approved By : pharmacist radio	

4

1. Updated worksheet format and orientation changed to Landscape.
2. Preparation section:
   i. Updated based on the Preparation details on screen.
   ii. Added Manufacturer Name together with Brand Name.
   iii. Worksheet Prepared By refers to user who print the worksheet.
   iv. Worksheet Checked By and Done By: Manually sign.
3. Quality Control and Label section:
   i. Updated based on Quality Control details on screen.
   ii. % is calculated based on:
   % = (Actual 2nd Portion / Actual 1st Portion) * 100
   iii. Quality Control Done By is based on user clicks on Submit button in QC screen.
   iv. Label: Empty space provided to paste the printed label.
4. Approval section: All checklist will update to 'Yes' once Approval record is Approved and 'No' once record is Rejected.

Function Flow	Radiopharma Bulk Preparation in current Version 1.3.8	Radiopharma Kit Preparation in new Version 1.4.1
4. Label	In Preparation section, Click on Print label button and label in PDF is displayed as below:	Updated label design as below:

NUCLEAR PHARMACY UNIT
Klinik Kesihatan Bandar Maharani

Caution : Radioactive Material

PRODUCT NAME : Technetium (99mTc) Albumin Colloid
BATCH NO. :
RADIOACTIVITY : nullMBq VOLUME : 30mL
CONCENTRATION : nullMBq/mL
LABELLING DATE/TIME : 29/02/2016 5:44 PM
PREPARED BY : Radio Pharmacist
CHECKED BY : Radio Pharmacist
EXPIRY :
STORAGE :

NUCLEAR PHARMACY UNIT
Klinik Kesihatan Bandar Maharani

Caution : Radioactive Material

PRODUCT NAME : Technetium (99mTc) Albumin Colloid
BATCH NO. :
RADIOACTIVITY : nullMBq VOLUME : 30mL
CONCENTRATION : nullMBq/mL
LABELLING DATE/TIME : 29/02/2016 5:44 PM
PREPARED BY : Radio Pharmacist
CHECKED BY : Radio Pharmacist
EXPIRY :
STORAGE :

Klinik Kesihatan Bandar Maharani

Caution : Radioactive Material

Product Name : Technetium-99m Besilesomab
Batch No. : BATCH00499.35
Radioactivity : 300 MBq **Volume** : 11 ml
Concentration : 27.27 MBq/ml
Elution Date/Time : : 29/02/2016 5:42 PM
Prepared By : rp 1
Checked By : rp 1
Expiry : 22/02/2016 5:28 PM
Storage : Keep below 25 °C

Klinik Kesihatan Bandar Maharani

Caution : Radioactive Material

Product Name : Technetium-99m Besilesomab
Batch No. : BATCH00499.35
Radioactivity : 300 MBq **Volume** : 11 ml
Concentration : 27.27 MBq/ml
Elution Date/Time : : 29/02/2016 5:42 PM
Prepared By : rp 1
Checked By : rp 1
Expiry : 22/02/2016 5:28 PM
Storage : Keep below 25 °C