

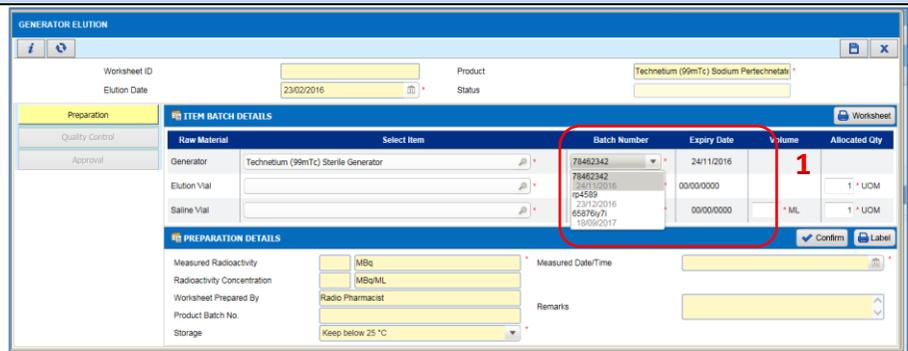
Proposed Solution

No.	Ticket #	Description	Requests	Proposed Solution
1.	I-PHIS012793715S	Saline Vial to not mandatory based on generator brand. Volume mandatory, saline vial not mandatory to select.	Saline Vial to not mandatory based on generator brand. Volume mandatory, saline vial not mandatory to select.	<ul style="list-style-type: none"> • Product Batch No.: i. Generate based on generator code & year ii. Generator code add in stock verification for user to specify code for each generator batch iii. Rename Product Batch No, eg: 'Tc151118', not 'TC151118'. Example of new batch number:01.01Tc151118. (Generator Code).(Running No)Tc(Date) • Saline Vial to not mandatory based on generator brand. • Quality Control: Add UOM dropdown for Measured MO-99 Activity (KBq @ µCi) & MO-99 Breakthrough (KBq/MBq @ µCi/mCi). Default selection based on UOM in Preparation screen. • To auto generate Expiry Date based on generator brand and move Expiry Date field to Preparation screen. • Label: i. To add drop down menu for Checked By. ii. Rename Labelling Date/Time to 'Elution Date/Time'. Add search box to search user from user profile. Field display in preparation screen, move from print label. • Worksheet: i. Rename ' Measured Radioactivity' to 'Measured Activity' ii. Rename 'Technetium (99mTc) Sodium Pertechnetate' to 'Sodium Pertechnetate Tc-99m' iii. Add date on Worksheet Prepared By & Preparation Done By iv. Date value take from Prepared Date, field name remain Date" • To update record in Stock Verification screen once done Approval.

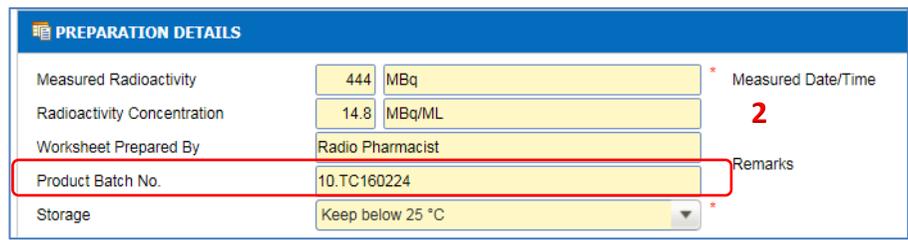


Function Flow
1. Generator Batch Code and Product Batch No

Radiopharma Generator Elution in current Version 1.3.8

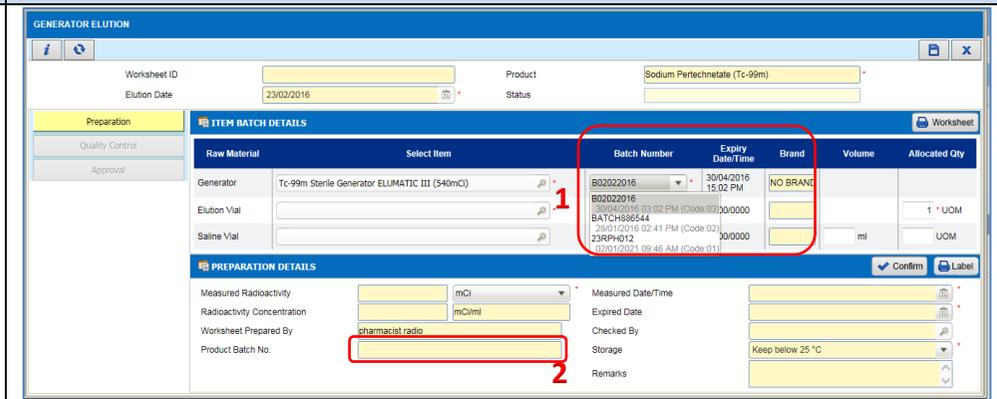


1. Once Generator item is selected, batch number is auto default based on 'First Expiry First Out'. Batch Number list display the Batch No and the Expiry Date.
2. Fill in all details, save and click Worksheet button. Confirm the record. Once confirmed, system auto-generate Product Batch No based on format below:

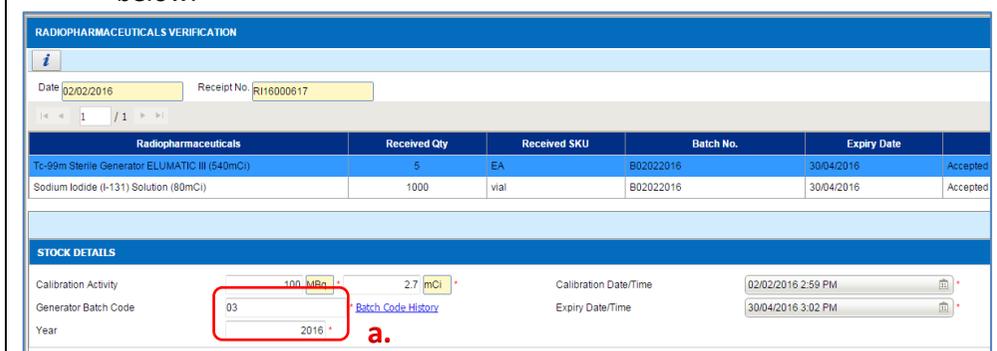


Product Batch No format: (Running number).TC(current system date)

Radiopharma Generator Elution in new Version 1.4.1

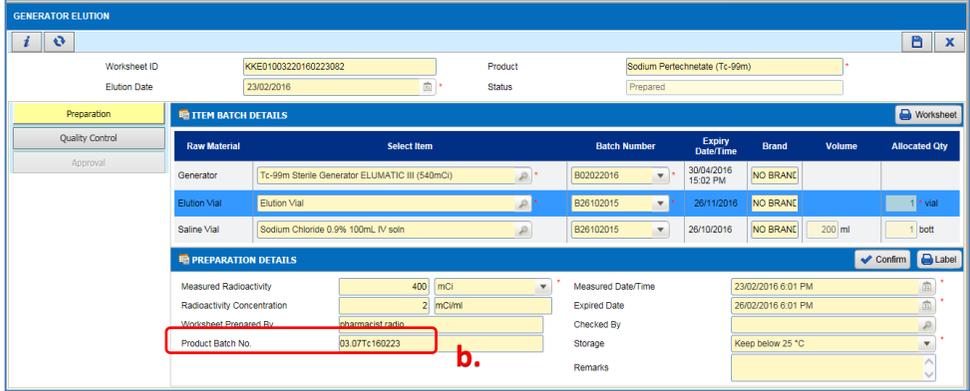


1. When Generator item is selected, batch number is auto default based on 'First Expiry First Out'. Batch Number list updated to display the Batch No, Expiry Date/Time, Batch Code and Brand.
2. Generator batch code is **mandatory to set in Stock Verification** screen before using the batch in Generator Elution screen. The batch code will be used when generate new batch no for the Generator Elution product.
3. For example, in Stock Verification generator batch code is updated as below:



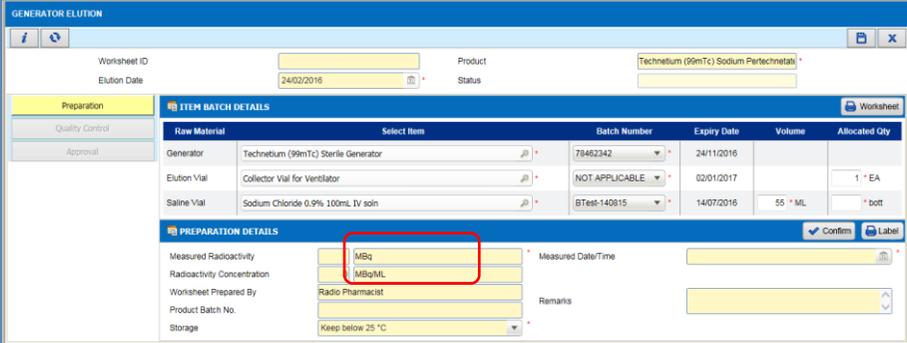
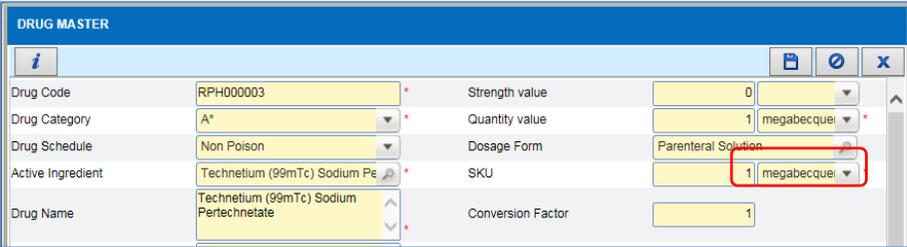
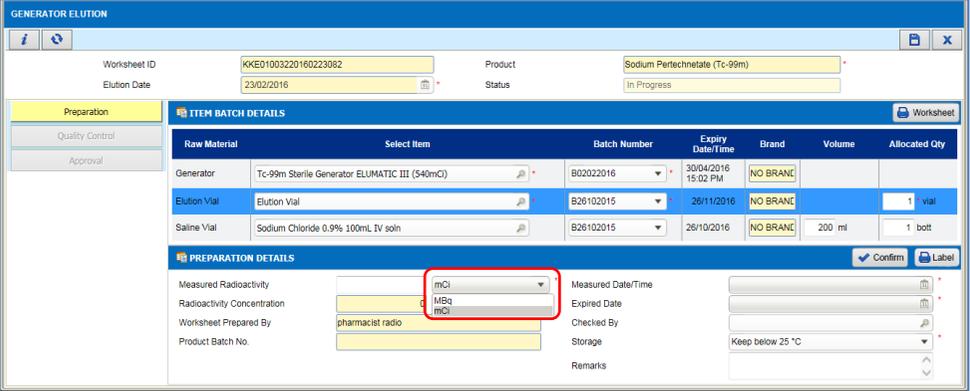
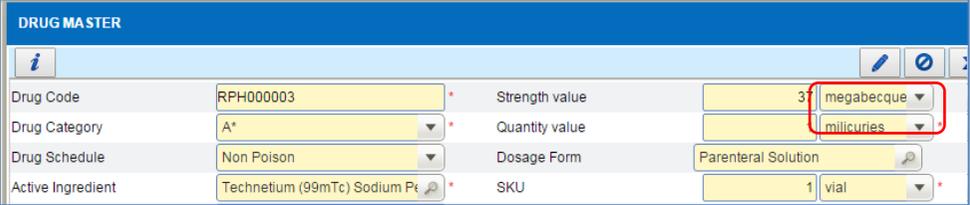
- a. Batch Code = 03 in year 2016. Batch Code is restricted to only integers with maximum up to only 2 characters. In the same year, there is validation that should not have duplicate batch code entered.
- b. In Generator Elution screen, after Confirm the Preparation record (status



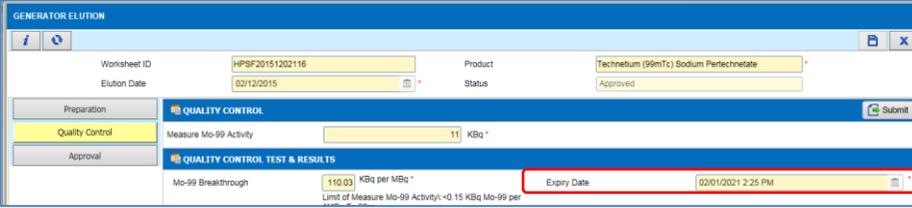
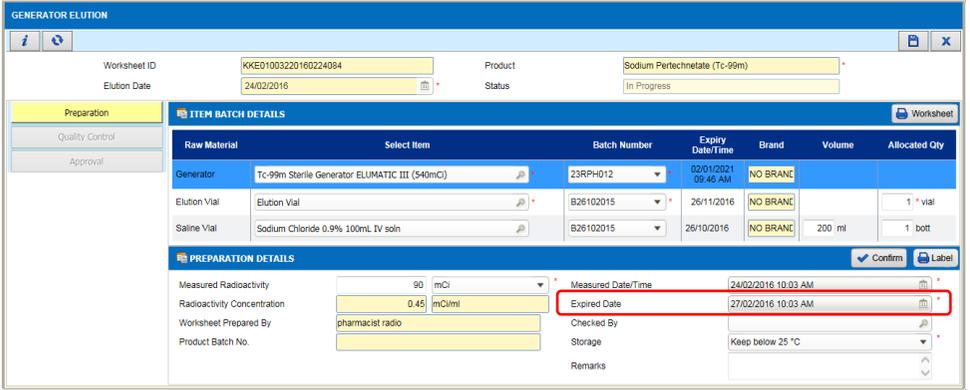
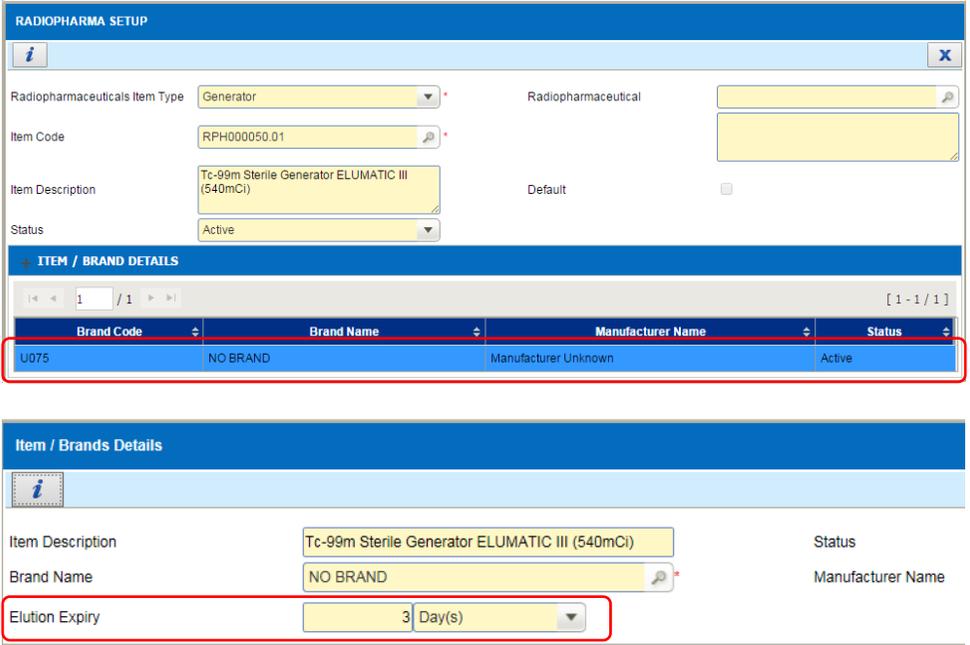
Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1																				
		<p>= Prepared), Product Batch No is generated as '03.07Tc160223':</p>  <p>c. Updated the format to generate the Product Batch No as below:</p> <ol style="list-style-type: none"> (Generator Code).(Running No)Tc(Date). Example of new batch number: 01.01Tc151118 For Generator Code - based on the selected generator batch no set in Stock Verification screen. For Running No - Accumulate the running number based on Generator Code and Year. Example as below: <table border="1" data-bbox="1296 971 2148 1197"> <thead> <tr> <th>Generator Batch No</th> <th>Generator Batch Code</th> <th>Year 2015</th> <th>Year 2016</th> </tr> </thead> <tbody> <tr> <td>BN1234</td> <td>01</td> <td>01.01Tc151118</td> <td>01.01Tc161118</td> </tr> <tr> <td></td> <td>01</td> <td>01.02Tc151118</td> <td>01.02Tc161118</td> </tr> <tr> <td>BNABC</td> <td>02</td> <td>02.01Tc151118</td> <td>02.01Tc161118</td> </tr> <tr> <td></td> <td>02</td> <td>02.02Tc151118</td> <td>02.02Tc161118</td> </tr> </tbody> </table>	Generator Batch No	Generator Batch Code	Year 2015	Year 2016	BN1234	01	01.01Tc151118	01.01Tc161118		01	01.02Tc151118	01.02Tc161118	BNABC	02	02.01Tc151118	02.01Tc161118		02	02.02Tc151118	02.02Tc161118
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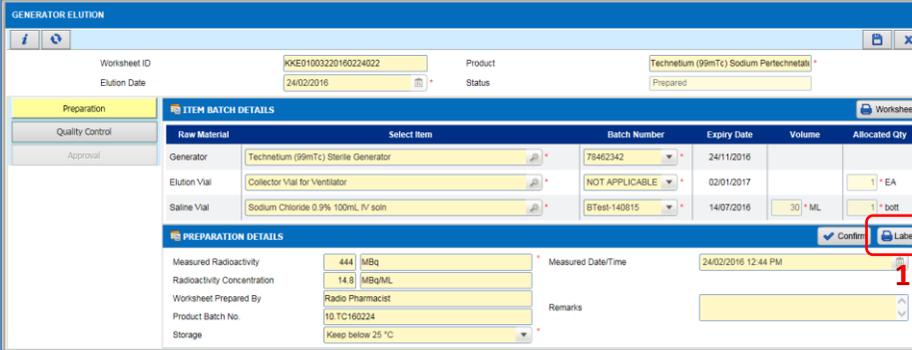
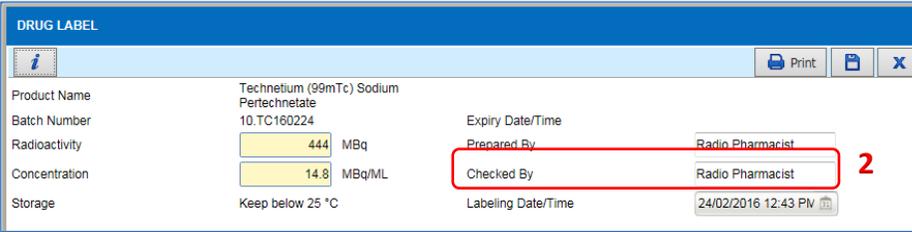
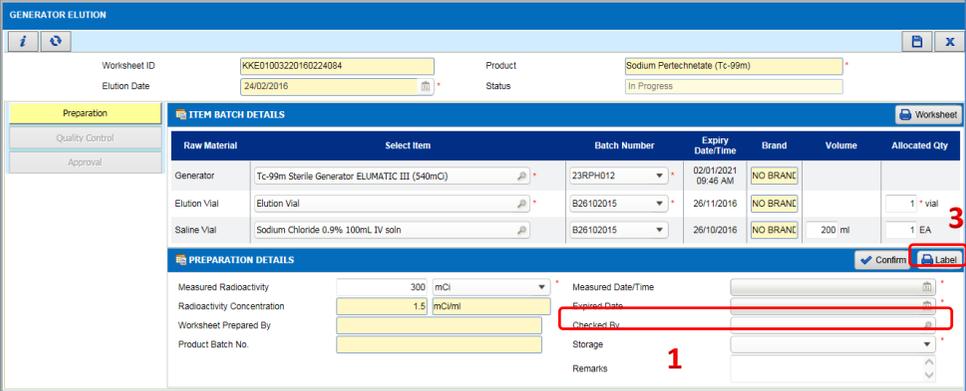
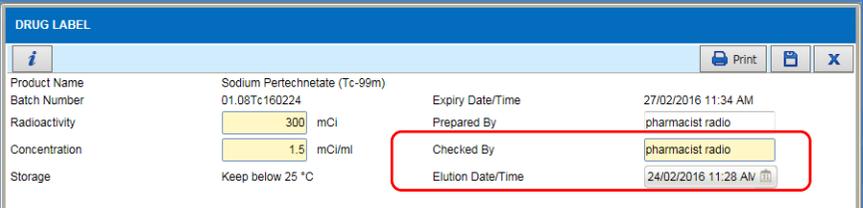
Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
<p>2. Saline Vial is not mandatory</p>	<p>Saline Vial - Mandatory</p> <p>Unable to save record if Saline Vial batch number and allocated qty is not entered:</p>	<p>Saline Vial – Not Mandatory</p> <p>1. Able to save and confirm Preparation details without selecting the Saline Vial item, batch number and allocated qty:</p> <p>2. If Saline Vial item and batch selected but Allocated Qty not entered:</p> <p>Alert will display when click on Save or Worksheet button.</p>



Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
2. Product activity UOM	<p>Measured Radioactivity UOM</p>  <p>Measure Radioactivity UOM is based on SKU UOM in drug master. Only one UOM option available.</p> 	<p>Measured Radioactivity UOM</p>  <p>UOM updated to display UOM from Drug Master – Strength UOM or Quantity UOM. Able to select either MBq or mCi to be used for preparation of the Generator Elution product.</p> 

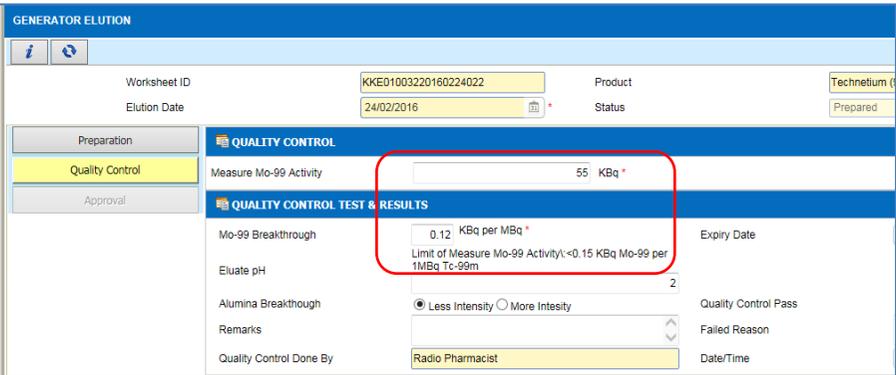
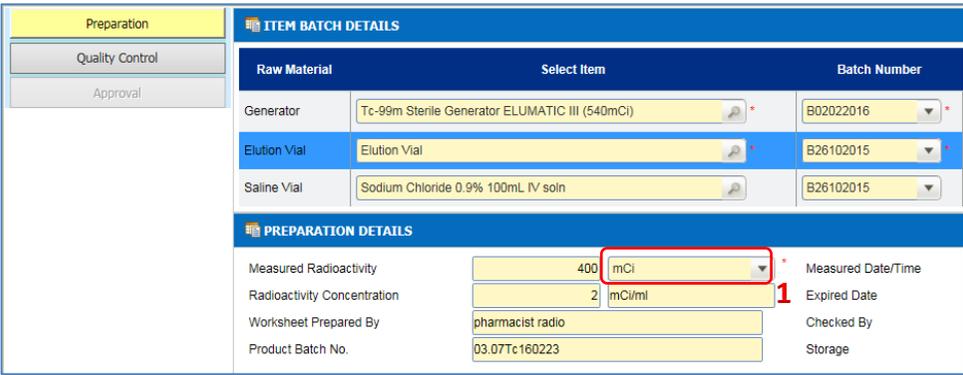
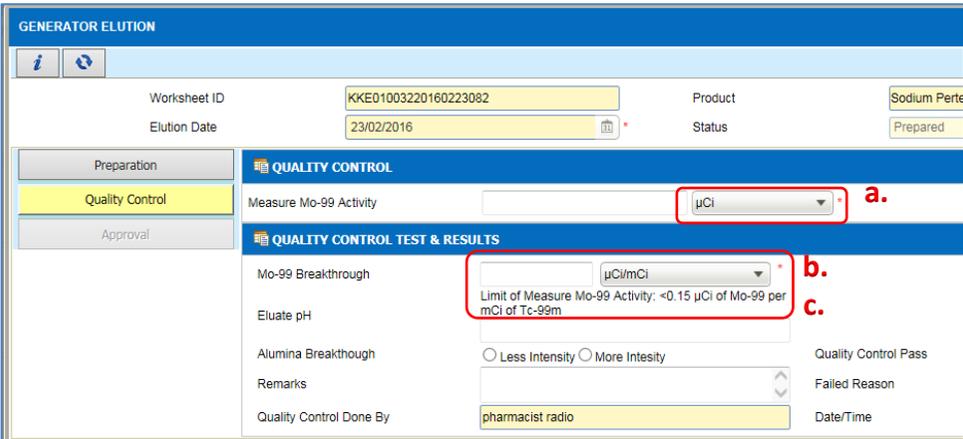


Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
4. Expiry Date	<p><u>Product Expiry Date</u> Current function, expiry date is displayed in Quality Control screen; No default value, user to select date/time for each transaction.</p> 	<p><u>Product Expiry Date</u></p> <ol style="list-style-type: none"> Update to move the Expiry Date field to Preparation screen;  <ol style="list-style-type: none"> Expiry Date is auto generated based on setting by HQ in Radiopharma Setup screen, example setting is as below: 

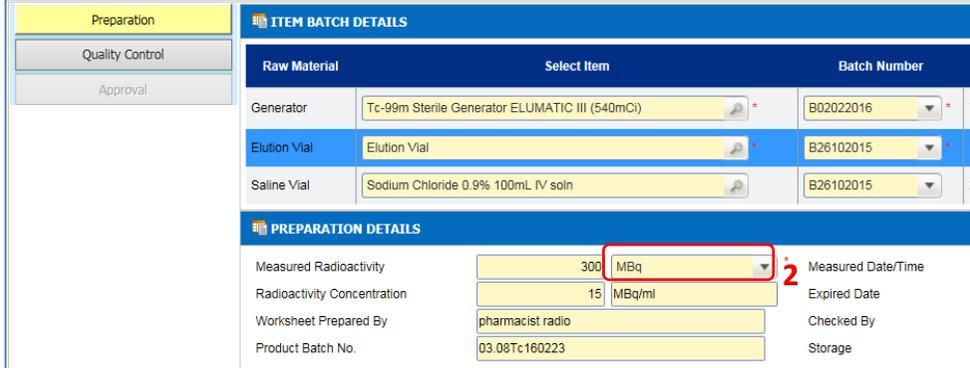
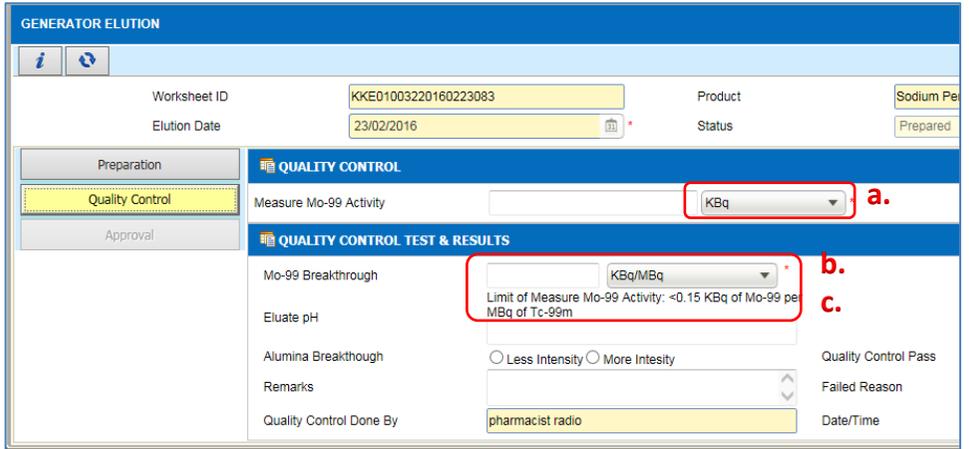
Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
5. Label	<p>Label</p> <ol style="list-style-type: none"> Once Confirm preparation, click on Label button:  <ol style="list-style-type: none"> Checked By field is free text and displayed in drug label screen. 	<p>Label</p> <ol style="list-style-type: none"> In Preparation Details added new field, Checked By.  <ol style="list-style-type: none"> When click on Checked By search field, system display screen as below; User able to search and select any registered user.  <ol style="list-style-type: none"> Once confirm Preparation record, click on Label button and screen as below is displayed:  <ol style="list-style-type: none"> Checked By updated to read-only and display value (User first name and last name) based on selected user in Preparation Details section Rename field to Elution Date/Time, default value to Measured Activity value from Preparation details.

Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
	<p>3. Click on Print label button and label in PDF is displayed as below:</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">  <p>NUCLEAR PHARMACY UNIT Klinik Kesihatan Bandar Maharani</p> <p>PRODUCT NAME : Technetium (99mTc) Sodium Pertechnetate</p> <p>Caution : Radioactive Material BATCH NO. : 10.TC160224</p> <p>RADIOACTIVITY : 444MBq VOLUME : 30mL</p> <p>CONCENTRATION: 14.8MBq/mL</p> <p>LABELLING DATE/TIME : 24/02/2016 12:52 PM</p> <p>PREPARED BY : Radio Pharmacist</p> <p>CHECKED BY : Radio Pharmacist</p> <p>EXPIRY :</p> <p>STORAGE : Keep below 25 °C</p> </div> <hr/> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">  <p>NUCLEAR PHARMACY UNIT Klinik Kesihatan Bandar Maharani</p> <p>PRODUCT NAME : Technetium (99mTc) Sodium Pertechnetate</p> <p>Caution : Radioactive Material BATCH NO. : 10.TC160224</p> <p>RADIOACTIVITY : 444MBq VOLUME : 30mL</p> <p>CONCENTRATION: 14.8MBq/mL</p> <p>LABELLING DATE/TIME : 24/02/2016 12:52 PM</p> <p>PREPARED BY : Radio Pharmacist</p> <p>CHECKED BY : Radio Pharmacist</p> <p>EXPIRY :</p> <p>STORAGE : Keep below 25 °C</p> </div>	<p>4. Updated label design as below:</p> <ol style="list-style-type: none"> a. Added lines b. Added Generator Batch c. Rename to Elution Date/Time <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">  <p style="text-align: center;">Klinik Kesihatan Bandar Maharani</p> <p>Product Name : Sodium Pertechnetate (Tc-99m)</p> <p>Batch No. : 01.08Tc160224</p> <p>Generator Batch : 23RPH012</p> <hr/> <p>Radioactivity : 300 mCi Volume : 200 ml</p> <p>Concentration : 1.5 mCi/ml</p> <p>Elution Date/Time : 24/02/2016 11:49 AM</p> <p>Prepared By : pharmacist radio</p> <p>Checked By : pharmacist radio</p> <p>Expiry : 27/02/2016 11:34 AM</p> <p>Storage : Keep below 25 °C</p> </div> <hr/> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;">  <p style="text-align: center;">Klinik Kesihatan Bandar Maharani</p> <p>Product Name : Sodium Pertechnetate (Tc-99m)</p> <p>Batch No. : 01.08Tc160224</p> <p>Generator Batch : 23RPH012</p> <hr/> <p>Radioactivity : 300 mCi Volume : 200 ml</p> <p>Concentration : 1.5 mCi/ml</p> <p>Elution Date/Time : 24/02/2016 11:49 AM</p> <p>Prepared By : pharmacist radio</p> <p>Checked By : pharmacist radio</p> <p>Expiry : 27/02/2016 11:34 AM</p> <p>Storage : Keep below 25 °C</p> </div>



Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
6. Quality Control UOM	<p>There is no options for user to choose UOM, UOM always as below:</p>  <ol style="list-style-type: none"> Measure Mo-99 Activity = 'KBq' Mo-99 Breakthrough = 'KBq per MBq' Limit of Measure Mo-99 Activity: <0.15 KBq of Mo-99 per MBq of Tc-99m 	<p>1. When measured radioactivity UOM is selected as mCi,</p>  <ol style="list-style-type: none"> Measure Mo-99 Activity default to 'µCi' Mo-99 Breakthrough default to 'µCi/mCi' Update to: Limit of Measure Mo-99 Activity: <0.15 µCi of Mo-99 per mCi of Tc-99m 



Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
		<p>2. When measured radioactivity UOM is selected as MBq,</p>  <p>d. Measure Mo-99 Activity default to 'KBq' e. Mo-99 Breakthrough default to 'KBq/MBq' f. Update to: Limit of Measure Mo-99 Activity: <0.15 KBq of Mo-99 per MBq of Tc-99m</p> 



Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1
7. Approval screen function	<p data-bbox="280 255 1176 454"> </p> <p data-bbox="280 462 1176 534">Select Approved checkbox and click on Submit button, status will update to Approved. If checkbox not selected, status will update as Rejected.</p> <p data-bbox="280 566 1176 598">Once record is Approved:</p> <ol data-bbox="324 606 1176 710" style="list-style-type: none"> In Unit Catalogue, new batch is created with the same batch number, with Available Qty = Measured Activity from Preparation details; <p data-bbox="280 750 1176 965"> </p> <p data-bbox="324 981 1176 1013">- Click on the Stock Available hyperlink to view screen below,</p> <p data-bbox="280 1045 1176 1252"> </p>	<p data-bbox="1220 255 2172 470"> </p> <p data-bbox="1220 478 2172 550">Select Approved checkbox and click on Submit button, status will update to Approved. If checkbox not selected, status will update as Rejected.</p> <p data-bbox="1220 582 2172 614">Once record is Approved:</p> <ol data-bbox="1265 622 2172 790" style="list-style-type: none"> 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. <ul data-bbox="1265 726 2172 790" style="list-style-type: none"> When open Stock Verification as below, able to search the newly created batch: <p data-bbox="1220 798 2172 1093"> </p> <p data-bbox="1265 1101 2172 1173">- Record is auto created once Approved the Generator Elution record. Able to edit the value in Stock Verification if necessary.</p>



Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1																																																		
		<div data-bbox="1205 252 2175 630"> </div> <p data-bbox="1249 638 2128 702">2. In Unit Catalogue, new batch is created with the same batch number, with Available Qty = 1 vial;</p> <div data-bbox="1205 710 2175 877"> <table border="1" data-bbox="1220 758 2161 869"> <thead> <tr> <th>Item Group</th> <th>Item Sub Class</th> <th>Drug/Non Drug Code</th> <th>Store Code</th> <th>Drug/Non Drug Description</th> <th>SKU</th> <th>Stock Available</th> <th>Reserve Qty(SKU)</th> <th>Min Indent Qty</th> </tr> </thead> <tbody> <tr> <td>Drug</td> <td>Radiopharmaceuticals</td> <td>RPH000003</td> <td></td> <td>Sodium Pertechnetate (Tc-99m)</td> <td>vial</td> <td>3,204</td> <td>0</td> <td>1</td> </tr> </tbody> </table> </div> <p data-bbox="1249 885 2016 917">- Click on the Stock Available hyperlink to view screen below,</p> <div data-bbox="1205 925 2175 1173"> <table border="1" data-bbox="1220 1061 2161 1165"> <thead> <tr> <th>No</th> <th>Item Code</th> <th>Stock Balance (SKU)</th> <th>Stock Balance (PKU)</th> <th>Reserve Qty(SKU)</th> <th>Packaging Description</th> <th>Batch No</th> <th>Expiry Date</th> </tr> </thead> <tbody> <tr> <td>31</td> <td>RPH000003.01</td> <td>1 vial</td> <td>1 vial</td> <td>0 vial</td> <td>vial</td> <td>03.09Tc160224</td> <td>27/02/2016</td> </tr> <tr> <td>32</td> <td>RPH000003.01</td> <td>1 vial</td> <td>1 vial</td> <td>0 vial</td> <td>vial</td> <td>03.11Tc160224</td> <td>27/02/2016</td> </tr> <tr> <td colspan="2">Total Stock Balance:</td> <td colspan="6">3,204</td> </tr> </tbody> </table> </div>	Item Group	Item Sub Class	Drug/Non Drug Code	Store Code	Drug/Non Drug Description	SKU	Stock Available	Reserve Qty(SKU)	Min Indent Qty	Drug	Radiopharmaceuticals	RPH000003		Sodium Pertechnetate (Tc-99m)	vial	3,204	0	1	No	Item Code	Stock Balance (SKU)	Stock Balance (PKU)	Reserve Qty(SKU)	Packaging Description	Batch No	Expiry Date	31	RPH000003.01	1 vial	1 vial	0 vial	vial	03.09Tc160224	27/02/2016	32	RPH000003.01	1 vial	1 vial	0 vial	vial	03.11Tc160224	27/02/2016	Total Stock Balance:		3,204					
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Function Flow	Radiopharma Generator Elution in current Version 1.3.8	Radiopharma Generator Elution in new Version 1.4.1																																																																																																						
8. Worksheet	<p>Worksheet is displayed as below:</p> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">RADIOPHARMACEUTICALS WORKSHEET</p> <p style="text-align: center;">MINISTRY OF HEALTH Klinik Kesihatan Bandar Maharani</p> <p style="text-align: center;">Generator Elution records for Technetium (99mTc) Sodium Pertechnetate Eluate Batch No: 10.TC160224 Worksheet ID: KKE01003220160224022</p> <hr/> <p style="text-align: center;">Preparation of Technetium (99mTc) Sodium Pertechnetate Eluate</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>Date</td> <td>24/02/2016</td> <td rowspan="8" style="vertical-align: top;">Remarks :</td> </tr> <tr> <td>Generator BN/Expiry Date</td> <td>78462342 / 24/11/2016</td> </tr> <tr> <td>Elution Vial BN/Expiry Date</td> <td>NOT APPLICABLE / 02/01/2017</td> </tr> <tr> <td>Saline Vial BN/Expiry Date</td> <td>BTest-140815 / 14/07/2016</td> </tr> <tr> <td>Volume</td> <td>30 ML</td> </tr> <tr> <td>Elution BN</td> <td>10.TC160224</td> </tr> <tr> <td>Measured Radioactivity</td> <td>444 MBq</td> </tr> <tr> <td>Measured Date/Time</td> <td>24/02/2016 12:44 PM</td> </tr> <tr> <td>Radioactivity Concentration</td> <td>14.8 MBq/ML</td> <td style="text-align: right;">Signature,Name,Time</td> </tr> </table> <hr/> <p style="text-align: center;">Quality Control of Eluate</p> <table border="1" style="width: 100%; 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1. Updated worksheet format and orientation changed to Landscape.
2. Preparation section: Elution Date display based on Elution Date field from Preparation screen.
3. Approval section: All checklist will update to 'Yes' once Approval record is Approved and 'No' once record is Rejected.
4. Label section: Empty space provided to paste the printed label.