CLAIMS

1. A mobile radioisotope generator system comprising:

a movable platform carrying an infusion tubing circuit, an activity detector, a dose calibrator, a computer, and a shielding assembly containing a strontium/rubidium radioisotope generator configured to generate a radioactive eluate via elution of an eluant,

the infusion tubing circuit including a tubing line connected between the strontium/rubidium radioisotope generator and the dose calibrator and configured to supply a portion of radioactive eluate to the dose calibrator,

the activity detector being positioned downstream of the strontium/rubidium radioisotope generator and configured to measure an activity of the radioactive eluate flowing through the infusion tubing circuit, and

the computer being electronically coupled to the dose calibrator and configured to execute automated quality control testing using the dose calibrator.

2. The system of claim 1, wherein the automated quality control testing comprises breakthrough testing, and the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

3. The system of claim 2, wherein the allowable limit includes a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by an activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

4. The system of claim 1, wherein the computer is configured to collect and store quality control test parameters and results.

5. The system of claim 1, wherein the computer is configured to automatically transfer quality control test information to one or more remote computers.

6. The system of claim 1, wherein

the movable platform further carries a waste reservoir and the infusion tubing circuit further includes a waste tubing line and a divergence valve, the waste tubing line being configured to provide fluid communication between the strontium/rubidium radioisotope generator and the waste reservoir via the divergence valve, and

the computer is configured to receive activity measurements from the activity detector, control the divergence valve to direct eluate to the waste reservoir until the activity detector measures a threshold amount of radioactivity in the eluate, and, upon receiving an indication from the activity detector that the eluate has the threshold amount of radioactivity, control the divergence valve to direct eluate to the dose calibrator.

7. The system of claim 6, wherein

the movable platform further carries a pump electronically coupled to the computer and connected to a supply of eluant,

the computer is configured to control the pump to supply the eluant to the strontium/rubidium radioisotope generator and generate the portion of radioactive eluate, and

the computer is configured to execute the automated quality control testing by controlling the pump, the divergence valve, the dose calibrator, and the activity detector.

8. The system of claim 1, wherein the movable platform further carries a printer configured to provide a printout of quality control test information.

9. The system of claim 1, wherein the dose calibrator is at least one of integrated into the shielding assembly or contained within a well of the shielding assembly.

10. The system of claim 1, wherein the computer is configured to execute automated quality control testing by at least receiving activity data from the dose calibrator and calculating at least one of breakthrough test results and calibration coefficient results.

11. The system of claim 1, wherein the computer is configured to execute automated quality control testing by at least receiving a first activity measurement from the dose calibrator at a first time, receiving a second activity measurement from the dose calibrator at a second time later

than the first time, and calculating breakthrough test results using the first activity measurement and the second activity measurement.

12. The system of claim 1, where the computer is configured to execute automated quality control testing by receiving activity data from the dose calibrator and calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82.

13. The system of claim 1, wherein the movable platform further carries a touch screen display and the computer is further configured to indicate via the display if results of the quality control testing are within allowable limits.

14. The system of claim 1, wherein the dose calibrator comprises a removable sample collection reservoir configured to receive the portion of eluate.

15. The system of claim 1, wherein the computer is electronically coupled to the dose calibrator via one of a wired or wireless connection.

16. The system of claim 1, wherein the movable platform rests on wheels configured to roll and swivel.

17. The system of claim 1, further comprising an eluant reservoir containing saline as the eluant, the eluant reservoir being connected to the movable platform and positioned outside of the shielding assembly.

18. The system of claim 17, further comprising an encoded information reader configured to read encoded information from at least one of the eluant reservoir, the infusion tubing circuit, and the strontium/rubidium radioisotope generator, and wherein the computer is further configured to receive information read from a label attached to the at least one of the eluant reservoir, the infusion tubing circuit, and the strontium/rubidium radioisotope generator.

19. The system of claim 1, further comprising a pressure sensor in communication with the computer and configured to measure pressure of the eluate within the infusion tubing circuit.

20. The system of claim 1, wherein the computer is configured to connect to a removable computer readable storage device and transfer quality control information to the removable computer readable storage device.

21. A mobile radioisotope generator system comprising:

a shielding assembly configured to contain a strontium/rubidium radioisotope generator that generates radioactive eluate via elution of an eluant and an infusion tubing circuit comprising an eluate tubing line configured to convey eluate from the strontium/rubidium radioisotope generator;

means for measuring an activity of the eluate flowing through the eluate tubing line;

means for receiving eluate from the eluate tubing line and calculating breakthrough activity within the eluate; and

means for receiving activity data from the means for measuring the activity of the eluate and also receiving breakthrough activity data from the means for receiving eluate and calculating breakthrough activity and controlling the mobile radioisotope generator system based on the received activity data and breakthrough activity data.

22. The system of claim 21, wherein the means for receiving activity data, receiving breakthrough activity data, and controlling the mobile radioisotope generator system is configured to prevent a patient infusion procedure if breakthrough activity data exceeds an allowable limit.

23. The system of claim 21, wherein the means for receiving activity data, receiving breakthrough activity data, and controlling the mobile radioisotope generator system is configured to electronically transfer quality control test information and infusion information to one or more remote computers.

24. The system of claim 21, wherein

the shielding assembly is configured to further contain a waste reservoir and the infusion tubing circuit further includes a waste tubing line and a divergence valve, the waste tubing line being configured to provide fluid communication between the strontium/rubidium radioisotope generator and the waste reservoir via the divergence valve, and

the means for receiving activity data, receiving breakthrough activity data, and controlling the mobile radioisotope generator system is configured to control the divergence valve to direct eluate to the waste reservoir until the activity data indicates a threshold amount of radioactivity in the eluate, and, upon receiving an indication that the eluate has the threshold amount of radioactivity, control the divergence valve to direct eluate to the means for receiving eluate from the eluate tubing line and calculating breakthrough activity within the eluate.

25. A method comprising:

delivering eluant to a strontium/rubidium radioisotope generator carried by a movable cart and thereby generating radioactive eluate via elution;

measuring, with an activity detector carried by the movable cart, an activity of the eluate within a tubing line of an infusing tubing circuit;

delivering a portion of eluate via the tubing line to a dose calibrator carried by the movable cart, and

performing quality control testing on the eluate delivered to the dose calibrator.

26. The method of claim 25, wherein performing quality control testing on the eluate comprises conducting breakthrough testing, and further comprising preventing, via a computer carried by the movable cart, a patient injection procedure if a breakthrough test result exceeds an allowable limit.

27. The method of claim 25, further comprising storing, on a computer carried by the movable cart, quality control testing information.

28. The method of claim 27, further comprising transmitting, via the computer carried by the movable cart, quality control information to one or more remote computers.

29. The method of claim 27, further comprising transferring, via the computer carried by the movable cart, quality control information to a removable computer readable storage device.

30. The method of claim 25, wherein delivering the portion of eluate via the tubing line to the dose calibrator comprises delivering the portion of eluate to a removable sample collection reservoir.

31. A system comprising:

a shielding assembly configured to contain a radioisotope generator that generates radioactive eluate via elution;

a computer carried by the shielding assembly, wherein the computer is configured to receive a user input and, responsive to receiving the user input, control the radioisotope generator to generate a sample of eluate via elution during breakthrough testing; and

a dose calibrator electronically coupled to the computer and configured to measure an activity of the sample of eluate generated during breakthrough testing,

wherein the computer carried by the shielding assembly is configured to receive the activity data from the dose calibrator and calculate breakthrough test results.

32. The system of claim 31, wherein the radioisotope generator comprises a strontium-rubidium generator configured to generate rubidium-82 by decay of strontium-82.

33. The system of claim 31, wherein the computer is configured to calculate the breakthrough test results by at least calculating a ratio of an activity of strontium-82 divided by an activity of rubidium-82 and a ratio of an activity of strontium-85 divided by the activity of rubidium-82.

34. The system of claim 33, wherein the computer is further configured to indicate if the breakthrough test results are within allowable limits.

35. The system of claim 34, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

36. The system of claim 31, wherein the computer is further configured to prevent a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

37. The system of claim 31, further comprising an activity detector.

38. The system of claim 37, wherein the computer is configured to divert eluate generated via elution to a waste bottle until the activity detector detects a given level of activity.

39. The system of claim 38, wherein the given level of activity is approximately 1.0 millicurie per second.

40. The system of claim 31, further comprising a display configured to display the breakthrough test results.

41. The system of claim 40, wherein the computer is configured to control the display to provide an indication of progress of the breakthrough testing.

42. The system of claim 31, further comprising a cabinet structure, wherein the shielding assembly is positioned inside the cabinet structure and the computer is carried by the cabinet structure.

43. The system of claim 31, wherein the dose calibrator is configured to physically receive the sample of eluate generated during breakthrough testing.

44. A method comprising:

generating, with a radioisotope generator contained within a shielding assembly, a radioactive eluate via elution of an eluant;

measuring, with a dose calibrator electronically coupled to a computer carried by the shielding assembly, an activity of the radioactive eluate; and

determining, with the computer, an activity of rubidium-82 within the radioactive eluate.

45. The method of claim 44, further comprising determining, with the computer, an activity of strontium-82 and an activity of strontium-85 in the radioactive eluate.

46. The method of claim 45, further comprising determining, with the computer, a ratio of the activity of strontium-82 divided by the activity of rubidium-82 and a ratio of the activity of strontium-85 divided by the activity of rubidium-82.

47. The method of claim 46, further comprising determining, with the computer, if the ratio of activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 are within allowable limits.

48. The method of claim 47, wherein the allowable limits include the ratio of the activity of strontium-82 divided by the activity of rubidium-82 and the ratio of the activity of strontium-85 divided by the activity of rubidium-82 each being less than 0.02 microcurie / millicurie.

49. The method of claim 44, further comprising displaying breakthrough test results determined by the computer.

50. The method of claim 44, further comprising preventing, with the computer, a patient infusion procedure if a breakthrough test result exceeds an allowable limit.

51. The method of claim 44, further comprising measuring, with an activity detector electronically coupled to the computer, an activity of the radioactive eluate.

52. The method of claim 51, further comprising controlling, with the computer, a diverter valve to divert the radioactive eluate to a waste bottle until the activity detector detects a given level of activity.

53. The method of claim 52, wherein the given level of activity is approximately 1.0 millicurie per second.

54. The method of claim 44, wherein the shielding assembly is positioned inside a cabinet structure and the computer is carried by the cabinet structure.

We claim:

1. A method for creating an image of an organ of a patient by operating a system that generates and infuses a radiopharmaceutical into a patient, the system comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer including a computer interface, the infusion tubing circuit including an eluant line coupled to the pump and to the generator, a waste line coupled to the generator and to the waste bottle, and a patient line coupled to the generator, the method comprising:

entering, into the computer, via the computer interface, a command to activate the pump in order to generate an eluate from a portion of a volume of eluant pumped through the generator, via an elution within the generator;

receiving an indication, from the computer, via the computer interface, that the elution is completed, when the pump has completed pumping the portion of the volume of eluant;

receiving an indication, from the computer, via the computer interface, of time lapsed since the elution was completed; and

creating an image of the organ of the patient.

2. The method of claim 1, further comprising:

entering, into the computer, via a computer interface, the volume of eluant contained in the reservoir, prior to the elution; and

receiving, from the computer interface, an indication of a volume of eluant in the reservoir, based upon tracking the portion of the volume of eluant that is pumped from the reservoir.

3. The method of claim 1, further comprising:

directing flow of the eluate through the patient line of the infusion tubing circuit to a first shielded test vial, in order to collect a first sample of the eluate during the elution;

measuring an activity of the first sample; and

transferring the measured activity of the first sample and a time between completion of the elution and the measuring of the activity to the computer, according to the received indication of time lapsed, so that the computer may calculate a breakthrough of the generator.

4. The method of claim 3, further comprising:

selecting a breakthrough test procedure of the computer, via the computer interface, prior to entering the command to activate the pump, and

receiving instructions from the computer interface to couple the patient line to the first shielded test vial, after selecting the breakthrough test and prior to entering the command to activate the pump.

5. The method of claim 3, further comprising:

exchanging the patient line of the infusion tubing circuit for a first new patient line, after collecting the first sample;

directing flow of the eluate through the first new patient line to a second shielded test vial;

repeating the steps of claim 1, after exchanging the patient line, wherein the pump is activated a second time and a second elution takes place, in order to fill the second vial with a second sample of the eluate from the first new patient line;

measuring an activity of the second sample; and

transferring the measured activity of the second sample and a time between completion of the second elution and the measuring of the activity of the second sample to the computer, according to the received indication of time lapsed, so that the computer may calculate a calibration coefficient for the infusion system based on the measured activity of the second sample and an activity of the eluate detected, during the second elution, by the activity detector of the system.

6. The method of claim 5, further comprising:

selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump for the second time; and

receiving instructions from the computer interface to couple the first new patient line to the second shielded test vial, after selecting the calibration procedure and prior to entering the command to activate the pump for the second time.

7. The method of claim 5, further comprising:

exchanging the first new patient line of the infusion tubing circuit for a second new patient line, after the computer calculates the calibration coefficient;

coupling the second new patient line to the patient;

repeating the steps of claim 1, after exchanging the first new patient line for the second new patient line, wherein the pump is activated a third time and a third elution takes place; and

directing flow of the eluate through the patient line, once an activity of the eluate, as detected by the activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate to the patient from the second patient line for diagnostic imaging.

8. The method of claim 7, further comprising receiving a report from the computer, upon completion of the third elution, the report including a patient identification number and at least one quantification related to the activity of the dose of the eluate.

9. The method of claim 1, further comprising:

directing flow of the eluate through the patient line to a shielded test vial in order to collect a sample of the eluate from the patient line during the elution;

measuring an activity of the sample; and

transferring the measured activity of the sample and a time between completion of the elution and the measuring of the activity to the computer, according to the received indication of time lapsed, so that the computer may calculate a calibration coefficient for the infusion system based on the measured activity and an activity of the eluate detected, during elution, by the activity detector of the system.

10. The method of claim 9, further comprising:

selecting a calibration procedure of the computer, via the computer interface, prior to entering the command to activate the pump; and

receiving instructions from the computer interface to couple the patient line to the shielded test vial, after selecting the calibration procedure and prior to entering the command to activate the pump.

11. The method of claim 1, further comprising:

coupling the patient line of the infusion tubing circuit to the patient;

directing flow of the eluate through the patient line, once an activity of the eluate, as detected by the activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate into the patient for diagnostic imaging; and

receiving a report from the computer, upon completion of the elution, the report including a patient identification number and at least one quantification related to the activity of the dose of the eluate.

12. The method of claim 1, further comprising:

entering, into the computer, via the computer interface, a command to set a waste bottle level indicator to zero, when the waste bottle is empty and prior to entering the command to activate the pump; and

receiving, from the computer, via the computer interface, an indication that the waste bottle needs to be emptied, based upon the computer tracking a volume of the eluate that is diverted, from the generator, through the waste line of the infusion tubing circuit.

13. The method of claim 1, further comprising:

coupling the patient line of the tubing circuit to the patient;

directing flow through the patient line, once an activity of the eluate, as detected by the activity detector, has reached a prescribed threshold, in order to inject a dose of the eluate into a coronary artery of the patient for diagnostic imaging;

collecting parameters defining an activity profile of the injected dose; and

transferring the parameters to another system for analysis.

14. The method of claim 1, wherein the pump is activated to pump the portion of the volume of eluant through the generator at a constant flow rate; and further comprising collecting, into the computer, a plurality of activity measurements of the eluate, over time, from the activity detector, while the pump is pumping, the collected plurality of activity measurements comprising a baseline activity profile, so that the computer may calculate a flow rate profile that corresponds to a desired activity profile, the flow rate profile for controlling a speed of the pump, upon a subsequent activation.

15. The method of claim 14, wherein the subsequent activation of the pump is for pumping another portion of the volume of eluant through the generator, to generate a dose of eluate, via another elution within the generator, for a patient injection.

16. The method of claim 14, wherein:

the subsequent activation of the pump follows a second activation of the pump;

the second activation of the pump is for pumping a second portion of the volume of eluant through the generator, to generate a dose of eluate, via another elution within the generator; and

the subsequent activation of the pump is for pumping a third portion of the volume of eluant though a tubing line that by-passes the generator at a higher flow rate than that achieved by the second activation of the pump, the third portion of the volume of eluant for injecting the dose of eluate into a patient.

17. A system that generates and infuses radiopharmaceuticals comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle and a computer; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, a by-pass line coupled to the eluant line, via a divergence valve, and to the patient line, the by-pass line accommodating flow of eluant to the patient line, when the divergence valve is set to direct the flow to by-pass the generator; and wherein:

the patient line is coupled to the eluate line and to the by-pass line downstream of the activity detector; and

the computer is coupled to the pump, to the divergence valve and to the activity detector, and is pre-programmed to collect information, from the pump and the activity detector, and to execute a method for controlling the divergence valve and the pump according to a method, the method comprising:

activating the pump a first time, to pump a portion of a volume of eluant from the reservoir, through the eluant line and through the generator at a first flow rate, in order to generate eluate in the eluate line, via an elution within the generator;

diverting flow of the eluate into the patient line, thereby pushing a dose of the eluate into the patient line, upon receipt of feedback from the activity detector, the feedback indicating detection by the activity detector of a desired activity of the eluate in the eluate line;

setting the divergence valve to direct flow of eluant through the by-pass line, once the dose of the eluate has been pushed into the patient line; and

activating the pump a second time, to pump a second portion of the volume of eluant from the reservoir, through the eluant line, through the by-pass line and into the patient line, at a second flow rate that is higher than the first flow rate, in order to inject the dose out from the patient line.

18. The system of claim 17, wherein the first flow rate is less than approximately 70mL/minute and the second flow rate is greater than approximately 70mL/minute.

19. A method for purging a tubing circuit of an infusion system with air, the system comprising a pump coupled to the tubing circuit, a radioisotope generator, a waste bottle and a computer including a computer interface, the method comprising:

receiving instructions from the computer, via the computer interface, to disconnect the pump from an eluant reservoir of the system, and to by-pass the generator by disconnecting an eluant line and an eluate line, of the tubing circuit, from the generator, and connecting the eluant line to the eluate line; and

entering, into the computer, via the computer interface, a command to perform an air purge of the tubing circuit, the air purge being automated, via the computer, to perform purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit;

wherein a first valve, of the two divergence valves, is located between a first portion of the eluate line and two downstream portions of the eluate line, a first of the two downstream portions extending to a waste bottle of the system and a second of the two downstream portions extending to a vial outside the system;

a second valve, of the two divergence valves, is located between a first portion of the eluant line, extending from the pump, and two downstream portions of the eluant line, a first of the two downstream portions of the eluant line being connected to the first portion of the eluate line, and a second of the two downstream portions of the eluant line being connected to the second of the two downstream portions of the eluate line.

20. The system of claim 17, further characterized in that the pre-programmed method of the computer further comprises the steps of:

calculating a flow rate profile, that corresponds to a desired activity profile, using a baseline activity profile, the baseline activity profile being comprised of a plurality of detected activity levels, received from the activity detector, for the eluate in the eluate line, prior to diverting the flow of eluate into the patient line; and

controlling a speed of the pump, according to the calculated flow rate profile, when activating the pump the second time.

21. A system that generates and infuses radiopharmaceuticals comprising an eluant reservoir, a pump coupled to the reservoir, an infusion tubing circuit, a radioisotope generator, an activity detector, a waste bottle, a computer and a computer interface; the infusion tubing circuit including an eluant line coupled to the pump and to the generator, an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, via a first divergence valve, a waste line coupled to the eluate line, via the first divergence valve, a by-pass line coupled to the eluant line, via a second divergence valve, and to the patient line, the by-pass line accommodating flow of eluant to the patient line, when the second divergence valve is set to direct the flow to by-pass the generator; and the system being characterized in that:

the patient line is coupled to the eluate line and to the by-pass line downstream of the activity detector; and

the computer is coupled to the pump, to the first and second divergence valves and to the computer interface, the computer being pre-programmed to execute a method for an automated air purge of the tubing circuit, the method comprising the steps of:

providing instructions to a user of the system, via the computer interface, the instructions instructing the user to disconnect the pump from the eluant reservoir and to by-pass the generator by disconnecting the eluant line and the eluate line from the generator and connecting the eluant line to the eluate line; and

performing air purges of individual portions of the tubing circuit, in sequence, via control of the pump and of two divergence valves of the tubing circuit.