Bracco CardioGen-82 Recall
Frequently Asked Questions

Q1. Why did the CardioGen-82 recall occur?

A1. It has been reported that strontium breakthrough from generators used to administer Rubidium (Rb-82) occurred at two separate sites. The reason for the problem is still under investigation by the U.S. Food and Drug Administration (FDA). All factors are being investigated, including manufacturing procedures and quality control procedures at individual facilities.

Q2. What is an Rb-82 generator?

A2: The radionuclide Rb-82 is a radioactive tracer that allows physicians to track blood flow to the heart. A device called a generator uses the decay of a strontium source to produce the Rb-82 that is used by the physician. When working properly, there is very little strontium in the Rb-82 that is extracted from the generator.

Q3: How many patients were exposed to higher than normal radiation?

A3. Only two patients are known to have been exposed to higher than normal radiation levels.

Q4. How much radiation did these two patients receive?

A4. The FDA released a statement on July 16 estimating that patients received 90 mSv of radiation.

Q5. Is this amount of radiation harmful?

A5. At this time, the FDA believes that the risk of harm from this exposure is minimal, although any unnecessary exposure to radiation is undesirable. The estimated amount of excess radiation the two patients received is similar to that other patients might receive with cumulative exposure to other types of heart scans. It would take much more radiation to cause any severe adverse health effects in patients.
Q6. Is it likely that more than two patients were exposed to higher than normal radiation levels?

A6. It is possible that more patients were exposed, but at this time no other cases have been identified. As with all radionuclide imaging, proper quality control measures should prevent this from occurring.

Q7. What is the name of the clinic or hospital where the problem occurred?

A7. That information has not been released by regulatory agencies, pending further investigation.

Q8. How many patients have PET myocardial perfusion imaging studies with Rb-82 produced by CardioGen generators each year?

A8. The exact number of patients is unknown, but approximately 160-200 generators are used each month in the United States. Each generator is capable of dispensing multiple doses per day.

Q9. What should patients do if they have had an Rb-82 PET myocardial perfusion imaging study and are concerned about radiation exposure?

A9. Patients should consult their physician. Patients should also be aware that the FDA requires laboratories that perform Rb-82 PET myocardial perfusion imaging to perform daily quality control procedures and to maintain documentation of the results for compliance and safety purposes. By contacting their physician’s office, patients can ensure that these quality control requirements were met and that their study was performed with the highest degree of clinical care and safety.

Q10: Why would a patient have had this test?

A10: The study likely was ordered because it was the best test to determine whether a patient has blocked coronary arteries and, if so, to determine the severity of the problem.

Q11. Should patients be worried if they had an Rb-82 PET myocardial perfusion imaging study within the last year?

A11. No. As long as the generator is functioning properly, it produces Rb-82 with only minimal traces of strontium. Each site that provides Rb-82 testing is required to verify that the amount of strontium in the tracer is less than the FDA specification limit. The problem the FDA is investigating was first detected in June 2011. Subsequent
investigations indicate the radiation exposure occurred in February and March 2011. There is no evidence to suggest that any problems existed before this time. At this time, it is unknown whether this safety issue is due to a product problem involving generator failure, user error, or a combination of both factors. The FDA is continuing to investigate the root cause of these incidents.

Q12. Should patients be concerned if they had any kind of myocardial perfusion study using radioactive material, for instance a SPECT myocardial perfusion imaging study?

A12. No. Various radioactive materials are used for evaluating the heart and there is no concern about procedures using other radioactive materials. All procedures using radioactive materials are considered safe as approved by the FDA. Myocardial perfusion imaging has been used for more than 30 years with an excellent safety record.

Q13. What are the alternatives for patients who need an Rb-82 PET myocardial perfusion imaging study?

A13. Patients should consult their physician. There are many procedures that can be used to evaluate the heart, each having unique advantages and limitations. PET myocardial perfusion imaging is a very accurate, non-invasive test to evaluate the presence and severity of coronary artery disease. When this type of study is the first choice for a patient, it may be possible to perform the test with N-13 ammonia—another type of radioactive material approved by the FDA for use with PET scanning—where available. Physicians who do not have access to N-13 ammonia should use their best clinical judgment as to which, if any, alternative diagnostic modalities, such as SPECT myocardial perfusion imaging, are appropriate based on the patient’s individual clinical indications.

Q14. When will CardioGen-82 be available again?

A14. The answer is not known at this time. Regulatory agencies and the manufacturer understand the adverse impact on patients caused by the voluntary recall of CardioGen-82 and are working as expeditiously as possible to resolve all issues while ensuring patient safety.