Pharmaceutical Failure Mode and Effects Analysis
Regadenoson (Lexiscan®)

· Step 1:

Describe how the intended product will be procured and used, from acquisition through administration.

Who will prescribe the drug and for what type of patient?
Lexiscan® will be prescribed by physicians as a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress.

Where will the drug be stored?
Drug will be stored in the inpatient pharmacy storeroom, room temperature.

Who will prepare and dispense it?
The drug will be prepared by the pharmacy technician and dispensed to the patient by the pharmacist.

How will it be administered?
The drug will be administered by rapid IV push.

· Step 2:

Identify potential failure modes (how and where systems and processes may fail) while considering how the product will be used.

Could the drug be mistaken for another similarly packaged product?
No. Lexiscan® is packaged in a white rectangular box with purple lettering.

Does the label clearly express the strength or concentration?
Yes.

Does the name sound or look like another drug on the formulary?
Adenosine.

Are dosing parameters complex?
No. Single predetermined dose.

Is the administration process error prone?
No - we are purchasing the single bolus dose pre-filled syringe eliminating volume calculations or extra manipulations.

· Step 3:

Once failure modes have been identified, determine the likelihood of
making a mistake and the potential consequences of an error.

What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate?

Fatal cardiac arrest, life threatening ventricular arrhythmias, and myocardial infarction may result from the ischemia induced by pharmacologic stress agents.

· **Step 4:**

Identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.

A nurse checks the medication prior to administration of drug. The patient is monitored during the stress test. The availability of Lexiscan® is limited to Nuclear Medicine.

· **Step 5:**

If failure modes could cause errors with significant consequences, what actions could be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences? (A few examples include: using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders).

The use of patient identifiers prevents administration to wrong patient. The medication is purchased as a prefilled syringe minimizing any manipulations. The dose is standardized to 0.4 mg/5 ml (one syringe). The availability of Lexiscan® is limited to Nuclear Medicine.