Regadenoson (Lexiscan®) and Updated Labeling Changes

- On March 17, 2009, the Food and Drug Administration (FDA) approved a labeling revision for Regadenoson (Lexiscan®) to include adverse events reported post-marketing.
- Regadenoson (Lexiscan®) is an intravenous (IV) radionuclide stress agent that received FDA approval in April 2008 for use in myocardial perfusion imaging (MPI).
- Regadenoson (Lexiscan®) works as an A(2A) adenosine receptor agonist that produces coronary vasodilation and increases coronary blood flow.
- Changes to the WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections of the package insert include:
  - **Cardiovascular**
    Heart block (including third degree block), asystole, symptomatic hypotension, transient ischemic attack [see Warnings and Precautions (5)], and syncope requiring intervention with fluids and/or aminophylline have occurred.
  - **Gastrointestinal**
    Abdominal pain, occasionally severe, has been reported a few minutes after Lexiscan administration, in association with nausea, vomiting, or myalgias; administration of aminophylline, an adenosine antagonist, appeared to lessen the pain. Diarrhea and fecal incontinence have also been reported following Lexiscan administration.
  - **Musculoskeletal**
    Musculoskeletal pain has occurred, typically 10-20 minutes after Lexiscan administration; the pain was occasionally severe, localized in the arms and lower back and extended to the buttocks and lower legs bilaterally. Administration of aminophylline appeared to lessen the pain.
  - **Respiratory**
    Dyspnea and wheezing have been reported following Lexiscan administration. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to Lexiscan exposure.

REFERENCES

ACTIONS:
- **Facility COS:** Forward this document to all appropriate providers who prescribe/use/handle this agent (e.g., cardiologists and nuclear medicine clinicians as well as nurses and technicians who work in imaging settings, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).