

**U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Enforcement**



**Select Agent Infectious Substance Program
April 2008**

1.0 INTRODUCTION

The Select Agent Infectious Substance Program is established as set forth by the Director of Office of Hazardous Materials Enforcement (OHME) in order to strengthen the focus, enhance the expertise, and ensure the uniform application of inspection and oversight pertaining to the shipments of select agent infectious substances.

2.0 PURPOSE

This program is established in order to develop and implement standardized protocols and procedures and maximize outcomes of OHME's inspections and investigations conducted by the PHMSA OHME **Select Agent Infectious Substance Team (SAIS)**.

3.0 MISSION STATEMENT

The team's mission is to protect the people, property, and environment from the risk inherent in transportation of select agents by all applicable modes of transportation. The SAIS team will accomplish this by inter-agency cooperation in the use of risk based approaches to identify high risk and high consequence select agent shipments and by leveraging the available resources to ensure that noncompliant and/or unsafe industry practices are identified and rectified. The team will also develop coordination mechanisms to share the field observations and lessons learned among team members and enforcement staff. This includes methods to ensure PHH program offices are informed of adverse industry trends and practices, including OHME recommendations for regulatory or outreach changes as warranted.

4.0 SCOPE

In the past several years, the number of incidents involving select agents has increased. In a post 9/11 era, there is an increased awareness of the high consequence potential of such incidents involving select agents. Based on past findings of incorrect packaging, lost shipments, lack of proper training and the direct potential of high consequential risk of diseases and infection to the public and animals, OHME implements a team approach to assess and address the growing issues pertaining to transport of select agents. The team consists of OHME's "resident experts" for the safe shipment of select agents. Their developed expertise will be used to identify unsafe trends and practices. The goal of the

team will be to recommend courses of actions, so that the risks to the general public stemming from these trends and practices will be reduced or eliminated.

5.0 OBJECTIVES

Carry out the functions of the PHMSA OHME National Business Strategy as it relates to the focus and prioritization on high risk/high consequence activities, particularly those pertaining to the transportation of select agents.

6.0 ROLES

a. Leadership

Director, OHME

- Will assign a Select Agents Infectious Substances Team lead from investigative staff.

Region Chiefs

- Supervision of the SAIST leader will be the responsibility of the Region Chief for which the team leader reports in the duty station assigned.
- Each Region Chief will assign at least one Investigator to become a team member of the SAIST.
- Provides direction, guidance, and enables implementation of SAIST activities.
- Communicates and coordinates activities with other Region Chiefs.

b. Select Agent Infectious Substance Team Lead

- The duties of the team lead are to identify, coordinate, prioritize and communicate inspection and investigation activities with team members (direct such activities, when required), maintain a central data base of all inspection activities, set national goals and priorities of the team, ensure that all team members are trained regarding the domestic and international regulations, to include the CFR's, 7- Agriculture, 9- Animals, 42-Public Health & 49-Hazardous Materials, and ensure that team members provide briefs of activities upon inspection/investigation.
- The team lead will be responsible for developing partnerships and be the primary point of contact with the Health & Human Services/CDC, the US Department of Agriculture, modal agencies, other PHMSA offices and industry associations.
- Team lead will be responsible for collecting, consolidating, reviewing and submitting recommendations to all proposed rulemaking pertaining to transport of select agent infectious substances.
- The team lead must also be capable of performing all duties required of team members.
- The team lead will provide timely information concerning inspections and noted trends to the OHME Director, through the Region Chief.

c. Select Agent Team Members

- The duties of the team members are to develop regional partnerships with Federal, State, and local enforcement agencies, and industry stakeholders.
- Through the team leader, each team member will be given names and addresses of inspection entities, identifying select agent activities.
- Each team member must be thoroughly familiar with the current domestic and international regulatory requirements and be capable to lead and conduct inspections of select agent infectious substances transported by all applicable modes.
- Team members will respond, as necessary, to requests for investigative assistance from other agencies or industry and will follow up on all select agent complaints filed with OHME. The members will coordinate these activities with the team leader, as appropriate.
- Team members may be directed to represent OHME in meetings, outreach activities, conferences and work group activities.
- Team members will conduct timely reviews of all proposed rule makings pertaining to transport of select agents and provide comments/recommendations to the team leader for consolidation.
- Team members, by the 5th day of each month will notify the team leader of all SAIST completed inspections and results and post them on the Share Point drive.
- Timely Situation Reports (SITREP) will be submitted, when appropriate, in accordance with OHME Operation Guidance - Accident & Emergency Response & Investigation Policy - dated November 2007.