



Water and Pollution Control Department

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Memorandum of Understanding between the National Animal Disease Center, USDA-ARS and the City of Ames, Iowa January 8, 2008

SUBJECT: SCIENTIFIC REVIEW PANEL RECOMMENDATION FOR FORMAL
REPORTING AND AUDIT SYSTEM FOR TSE WASTE DISPOSAL PRACTICES

In the fall of 2006, the National Animal Disease Center (NADC) of the Agricultural Research Service (ARS), United States Department of Agriculture (USDA) and the City of Ames, Iowa jointly convened a Scientific Review Panel to assess practices used at NADC to treat liquid waste generated from facilities where prion disease research is being conducted. The Panel was tasked to identify acceptable prion decontamination methods, assess concerns raised about NADC's methods for prion decontamination, determine the risk posed to humans from possible environmental prion contamination, and provide scientifically sound approaches for corrective action that may be needed. On November 21, 2006, the Panel provided a written report of its findings and recommendations to representatives of the NADC and the City of Ames.

The following excerpts are from the Panel's Hazard Assessment.

"...the NADC wastewater pretreatment facility as designed and operated should be an effective process to inactivate TSE infectivity using heat as previously described. Provided the pretreatment process is operated according to NADC current standard operating procedures, it should effectively inactivate infective material in the liquid stream to below what can currently be detected."

"The current and past methods of treating the waste water at the NADC sufficiently inactivate the potentially prion-contaminated waste from the research laboratories and animal holding facilities to ensure that the exposure of personnel and animals is extremely unlikely. Even if there were residual infectivity remaining in the waste water and that material were to enter the sanitary sewer down stream of the waste water pretreatment plant, the risk of exposure resulting in prion-associated disease would be extremely minimal."

"The procedures in place, when followed, for the personnel conducting animal care and other research-associated activities also make the risk of exposure to prion-associated material, and subsequent human or animal disease, extremely unlikely."

In its conclusion, the Panel noted the following:

"It must be emphasized that the level of any residual infectivity in these solids would be expected to be very low, and it is highly unlikely for animals and humans to be exposed in such a way to cause transmission of disease. Nevertheless, it would be advisable for NADC to limit where possible the level of particulate contamination containing infectivity that is discharged to the drains to maximize the margin of safety."

The Panel offered a number of recommendations upon which the NADC has already acted. For example, the Panel recommended that NADC "collect and pretreat all liquid and particulate wastes from high exposure sites before delivery to the pretreatment plant." The NADC has implemented a practice of using carcass carts to capture necropsy fluids for incineration. A chemical treatment tank is being installed to allow the liquid to be captured and chemically treated before being released for further treatment in the wastewater pretreatment plant. NADC has also instituted a policy of disposing of saw blades after a single TSE necropsy, instead of attempting to decontaminate and reuse the blades.

The Panel noted that "it would be wise for NADC to eliminate potential sources of concern with their operations in the interests of maintaining a positive relationship with the Ames community. It would also be advisable for a formal reporting and audit system to be developed between Ames and NADC whereby NADC would certify the integrity of the isolation of the NADC discharges of water from TSE exposed sites from direct discharge to the Ames sanitary sewer."

Staff members from NADC and the City of Ames both concur with this recommendation and have met on multiple occasions to discuss the possible form for such an audit system. Both parties mutually agree that the most appropriate format would be to include additional audit items to the bi-annual Industrial Inspection checklist. The attached items have been added to the inspection form. Documentation of these items on an ongoing basis will satisfy the intent of the Panel's recommendation related to the formal reporting and audit system.

_____ Date _____
Kurt Zuelke, DVM, Ph.D., Director
National Animal Disease Center
Animal Research Service
United States Department of Agriculture

_____ Date _____
John Dunn, P.E., Director
City of Ames, Iowa
Water and Pollution Control Department

Evaluation of Wastewater Pretreatment System

Please provide a schematic of the operation of the heat treatment system that outlines any design or operational changes since the last inspection.

Does the facility have a quarterly summary of heat treatment records available for inspection?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Since the last inspection, have there been any heat treatment runs that have failed to achieve a temperature equal to or greater than 250° F for 30 consecutive minutes?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If Yes, provide the following information • Number of runs with a minimum temperature below 250°F since last inspection: _____ Dates and actual temperatures achieved: _____ • Number of runs with a minimum pressure below 14.7 psig since last inspection: _____ Dates and actual pressures achieved: _____ • Number of runs with a minimum batch time of less than 30 minutes since last inspection: _____ Dates and actual pressures achieved: _____		
Spot check of Wastewater Pretreatment System operating records Comments: _____		

Necropsy Waste Handling

Does the facility have necropsy waste disposal and decontamination SOP available for inspection?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has the TSE necropsy waste disposal and decontamination SOP changed since the last inspection?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If Yes, please provide a copy of all versions since the last inspection. • Date of most recent necropsy waste disposal and decontamination SOP: _____ • Summary of changes from previous versions: _____ _____ _____		

Employee Training on TSE Waste Disposal

Does the facility have employee training records for proper disposal methods for persons performing TSE research?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the facility have employee training records for necropsy waste disposal and decontamination SOP training?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

During the past 12 calendar months:

Task	Have all Employees Involved With Task Received Training?	Are records documenting training available for review?
TSE Research	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
TSE Necropsies	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
TSE Animal Care	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
TSE Waste Treatment & Disposal	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No