BSE and FMD Chaos

by John Melcher, D.V.M.
former United States Senator, Montana

Bovine spongiform encephalopathy (BSE) caused public fear of eating beef in Britain that devastated the beef industry and the same is happening in Europe as BSE was diagnosed in several countries. Recently, Britain is being buffeted again with foot-and-mouth disease in numerous farms; France has one infected herd, while Ireland and Holland are also experiencing two or more outbreaks.

Here in the U.S., the immediate

President Bush, Congress & Secretary Veneman Urged to OK ARS-APHIS Master Plan to Rebuild NVSL, CVB and NADC

USAHA president Dr. Bob Hillman, in letters to President George W. Bush, Secretary of Agriculture Ann M. Veneman, and Congressional leaders, urged approval of the U.S. Department of Agriculture’s ARS-APHIS Master Plan for Facility Consolidation and Modernization. The plan would rebuild USDA’s National Veterinary Services Laboratories (NVSL), the Center for Veterinary Biologics (CVB) and the National Animal Disease Center (NADC) in Ames, Iowa.

$447 million cost

The Association’s membership voted unanimously in favor of a resolution supporting the Master Plan during its 104th annual meeting in Birmingham, Alabama, in October 2000. Implementation of the plan is essential to maintaining and improving the quality of health care delivered to the 1.7 billion-plus animals living daily in the United States. (See adjacent table.)

The Master Plan proposes the
President’s Corner

DURING the 104th annual meeting of USAHA in Birmingham, Alabama, last October, our Association determined that modernization, upgrading and consolidation of the USDA-ARS and APHIS labs currently located at Ames, Iowa, would be our number one priority for 2001.

To this end, 17 of our committees shaped and endorsed an Association resolution that supports the USDA ARS-APHIS Master Plan for Facility Consolidation and Modernization. This resolution was unanimously approved by our membership and has been sent to the President, Secretary of Agriculture, and Congressional leaders accompanied by a letter requesting support for the modernization plan.

This special edition of our newsletter is dedicated to the laboratory issue and is intended to help gain support for this critical endeavor.

Our current laboratories are in deplorable condition and are unable to meet the mandates of national animal health programs, safeguarding of animal agriculture in America from foreign and emerging pathogens and meet the needs of animal agriculture in the 21st century.

One has to look no further than the front pages of numerous prominent newspapers to grasp the great need for improvement in our laboratory system. BSE in Europe; foot-and-mouth disease in Asia, the United Kingdom and South America; West Nile virus in the northeastern and eastern United States; classical swine fever in Haiti and the Dominican Republic; chronic wasting disease in the western United States; brucellosis, tuberculosis and/or pseudorabies in wild and feral animal populations in several areas of the United States; Johne’s disease and its alleged link to Crohn’s disease in man; exotic ticks that have the capability to harbor serious vector-borne diseases on imported exotic animals; fever tick issues along the buffer zone in Texas; PRRS in swine; avian influenza and Newcastle disease in wildfowl; and a number of food-borne pathogens of animal origin are routinely written about in our newspapers and reported on national television news shows.

Several of the articles in this

National Veterinary Services Laboratories Is First to Isolate West Nile Virus in Western Hemisphere

Caused 1999 fatal encephalitis outbreak in humans and animals in northeast

by Beverly Schmitt, Chief Diagnostic Virology Laboratory, USDA, APHIS, NVSL, Ames, Iowa

In August 1999, residents in the New York City (NYC) area noticed that crows were dying in the streets. Many of these birds were picked up and sent to the New York State Department of Environmental Conservation (NYS). At the same time, several different species of birds at the Bronx Zoo began to demonstrate clinical signs of encephalitis.

Bronx Zoo pathologist Dr. Tracey McNamara, aware that there were human deaths in the New York City area attributed to St. Louis encephalitis, called Dr. Brundaban Panigrahy of USDA’s Diagnostic Virology Laboratory (DVL), a unit of the National Veterinary Services Laboratories (NVSL) in Ames, Iowa, about the situation. Both veterinarians agreed that the crow and zoo bird deaths were very unusual and suspected they might be related to the human deaths from encephalitis. Crow specimens from the NYS and samples from the Bronx zoo birds were forwarded to NVSL for diagnostic testing.

When the samples arrived at NVSL on September 9 and 10, they were immediately processed according to established protocols and inoculated into embryonated chicken eggs and cell cultures. Serum

USAHA Newsletter, Vol. 28, No. 2, June, 2001
International Experts Review Master Plan & Visit NVSL, CVB and NADC Laboratories in Ames, Iowa

Endorse ARS-APHIS Master Plan ... astounded by the inadequacy of some facilities ... need is urgent
by Dick McCapes

A team of international animal health experts visited USDA’s national animal health laboratories located in Ames, Iowa, on January 9 and 10, 2001, at the request of the Secretary of Agriculture. The facilities visited by the team were the APHIS National Veterinary Services Laboratories (NVSL) and Center for Veterinary Biologics (CVB) and the ARS National Animal Disease Center (NADC).

The team consisted of:

- Dr. Norm Willis, Executive Director, Canadian Science Center for Human & Animal Health, Winnipeg, Canada.
- Dr. Yoshihiro Ozawa, Advisor, OIE Regional Representation for Asia and the Pacific, Tokyo, Japan.
- Dr. Chris Bostock, Director, Institute for Animal Health, Compton Laboratory, Compton, United Kingdom.
- Dr. Alex Ardans, Department Head, University of California - Davis, California Veterinary Diagnostic Laboratory, Davis, California.

The visitors were asked to view the current facilities and provide an analysis of the scope and need for the planned facilities. Consideration was to be given to:

- current and future roles in production, trade, and food supply;
- new standards for animal care, health and safety, quality assurance, and the environment; and
- response to new disease threats.

The team toured various facilities and received program overviews from local USDA personnel as well as from Drs. Alfonso Torres, Deputy Administrator, and Dr. Chris Bostock, Director, for the Animal Health Laboratory at the University of California - Davis.

Task Force Mandated by Congress Urges Integration of NVSL, CVB & NADC

1999 study reviewed all USDA, ARS research facilities ... report states bio-containment facilities are imperative for high-risk, animal disease research ... gives priority to NADC renovation
by Dick McCapes

As directed by the Federal Agriculture Improvement and Reform Act of 1996, the Secretary of Agriculture established the “Strategic Planning Task Force” in 1997 to review current and planned agriculture research facilities, funded in whole or in part by federal monies, to ensure that a comprehensive research capacity is maintained.

The major food, agriculture, and forestry research facilities owned or funded in part by the federal government are overseen by the Agricultural Research Service (ARS), the Forest Service and the land grant university system.


The report expressed a new vision for agricultural research, 14 supporting principles and 47 specific recommendations flowing from these principles. The end result is a 10-year strategic plan that “can make U.S. food, agriculture and forestry research and education facilities a model of first-rate science and efficiency well into the 21st century.”

The report states “Our vision is of world-class scientists in food, ag-

USAHA Newsletter, Vol. 28, No. 2, June, 2001
What Is the ARS-APHIS Master Plan?

Consolidates and modernizes outdated, inefficient animal health facilities of the NVSL, CVB and NADC in Ames, Iowa.

The USDA Agriculture Research Service (ARS)-Animal and Plant Health Inspection Service (APHIS) Master Plan for Facility Consolidation and Modernization requests new facilities for USDA’s national animal health laboratories located near Ames, Iowa, to meet urgent national needs for research, diagnosis and vaccine evaluation.

The plan consolidates and modernizes outdated and inefficient health facilities of the APHIS National Veterinary Services Laboratories (NVSL) and Center for Veterinary Biologics (CVB) and the ARS National Animal Disease Center (NADC) located on 471 acres of land just east of Ames, Iowa.

Through new construction, remodeling and demolition, the existing 527,000 sq. ft. of space is increased 20 percent to 630,000 sq. ft. of shared, combined-agency (NVSL-CVB-NADC) space.

The added space accommodates new program requirements including wildlife, state-of-the-art technologies, such as genomics and proteomics, and higher levels of biocountermeasure. Laboratory and office facilities currently leased in the city of Ames will be vacated. A preliminary estimate of cost is projected at $447 million over nine years.

The President’s 2001 budget included $9 million for planning the new animal biocountermeasure research facilities and improving the infrastructure. Final approval is pending Congressional action.

Why is this facility needed?

In addition to an increased demand for current services, issues related to animal health have changed dramatically since the existing facilities were constructed in the 1960s and 70s.

These changes profoundly impact the ability of the current facilities to meet their mission. And, the current facilities seriously restrict USDA’s ability to serve the potential needs of the nation, let alone be a world leader.

The changes include:

- The emergence of significant new animal diseases around the world that threaten the U.S. livestock industry and public health, like bovine spongiform encephalopathy, foot and mouth disease and Nipah virus.
- Increasing consumer concerns related to food safety and the need for intensive research on agents, such as salmonella and E. coli.
- Changes in international trade practices, including the need for documented and validated evidence of “freedom from disease” prior to export of livestock and livestock products.
- Development of new international laboratory standards for biocountermeasure, animal welfare and handling, health, safety, and quality assurance.

It is critical that the United States be equipped to meet these new demands. The value of livestock produced in the United States in 1999 was $96 billion. And the competition for the agricultural animal and animal-product export market is intense, with our country exporting $10 billion in 1999.

Other countries, such as Australia, Canada, Germany, Spain and India have, or are constructing, major new national animal disease facilities to meet animal health demands.

Role of the national veterinary programs in Ames, Iowa

The ARS-APHIS national veterinary programs in the Ames area:

- Serve as the national diagnostic reference laboratory.
- Research the most important domestic animal diseases.
- License, inspect and test all veterinary biologics produced or imported in United States.
- Prevent the introduction of foreign animal diseases.
- Monitor for new and emerging diseases.
- Support other animal health laboratories by providing certification, training, reagents and test confirmation.
- Develop vaccines and diagnostics to control disease.
- Discover the causes of disease

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Table 2

<table>
<thead>
<tr>
<th>Preliminary Phasing and Cost Estimates (Shive-Hattery)*</th>
<th>ARS-APHIS Master Plan for Facility Consolidation and Modernization</th>
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<tbody>
<tr>
<td>FY</td>
<td>Description</td>
</tr>
<tr>
<td>2001</td>
<td>Design BL-3Ag &amp; BL-2 large animal research facility. (See r1, n1 &amp; n2, pages 6, 7)</td>
</tr>
<tr>
<td>2002</td>
<td>Construct BL-3Ag large animal research facility. (See r1, n1, pages 6, 7)</td>
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<tr>
<td>2003</td>
<td>Construct BL-2 large animal research facility: Design laboratory/office facility. (See n2, n4, pages 6, 7)</td>
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<tr>
<td>2004</td>
<td>Construct Phase 1 laboratory/office building; Construct utility plant. (See n4, r2, pages 6, 7)</td>
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<tr>
<td>2005</td>
<td>Construct Phase 2 laboratory/office building; Design and construct animal receiving facility (see n4, n3, pages 6, 7)</td>
</tr>
<tr>
<td>2006</td>
<td>Continue construction of Phase 2 laboratory/office building (see n4, pages 6, 7)</td>
</tr>
<tr>
<td>2007</td>
<td>Design and construct infrastructure</td>
</tr>
<tr>
<td>2008</td>
<td>Design and remodel existing administrative/regulatory facilities. (See r3, n5, pages 6, 7)</td>
</tr>
<tr>
<td>2009</td>
<td>Demolition of obsolete facilities (see d, page 6)</td>
</tr>
<tr>
<td>Total</td>
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</table>

* Final phasing and cost estimates were not available at time of publication.
What is the Master Plan?

and how they are transmitted.

Facility status summary

Constructed in the early 1960s, the NADC is the oldest of the Ames' facilities. The NVSL Central/CVB-L building, constructed in the late 1970s, was intended to fulfill the space needs of the entire APHIS diagnostics and biologics programs in Ames. However, only the first phase of the project came to fruition, and construction was limited to what is now mostly accommodations for Biosafety Level-2 laboratory for CVB, leaving other APHIS testing and regulatory functions in separate leased facilities spread across the city of Ames.

Today, the three programs remain scientifically strong and well-focused, but many of the facilities have now reached the end of their design and structural life span. Investments have been made for repair and maintenance, but virtually every critical system is antiquated.

NVSL's diagnostic testing for transmissible spongiform encephalopathies, anthrax, E. coli and salmonella is conducted in leased space at a downtown strip mall. The status of these facilities seriously restricts USDA's world leadership role in animal health and diagnostic needs.

CVB's Inspection and Compliance and Licensing and Policy Development staffs are located in rented office space, 5 miles away from the CVB-Laboratory staff, inhibiting collaborative work and the ability to share common resource and regulatory information.

APHIS has always recognized the need to consolidate its facilities and completed a master plan for renovation, expansion and consolidation in 1995. A 1992 report documented the serious facility problems at NADC and, in 1997, ARS independently began developing a master plan for the renovation of NADC. The total of the separate NVSL and NADC master plans was projected to exceed $450 million (1997 dollars).

ARS-APHIS collaboration

In 1998, both agencies recognized an opportunity to create a single new combined-agency facility encompassing work of the NVSL, CVB and NADC. During 1998-99, the Bernard Johnson Young, Inc. firm completed the Master Plan, including overall function, phasing and cost estimates totalling $379 million (1999 dollars), a savings of $71 million over separate plans.

In 2000-01, the Shive-Hattery firm was retained to refine the BIY Master Plan. This plan promises to provide advantages over separate facilities, a shorter time from design to completion at a preliminary cost estimate of $447 million (2001 dollars)¹ (see “Phasing and Cost Estimates,” page 4).

Additional planning to come includes pre-design (program requirements) and design (planning and design of the actual facilities) and final phasing and cost estimates.

Visual overview of the plan

Aerial photographs and preliminary architectural drawings on pages 6 and 7 provide a visual overview of the scope of the Master Plan.

As envisioned, the plan calls for construction of new BL-2 and BL-3Ag bio-containment animal facilities and a new BL-2/BL-3Ag laboratory building (see r1, n1, n2, n4, pages 6, 7).

The recently constructed BL-3Ag necropsy/incinerator facility would be retained as part of the new animal facility complex (see r1, page 6, 7). Likewise, the NADC utility plant would be retained and remodeled (see r2, page 6, 7).

The NVSL Central/CVB-L building would be retained and remodeled into the administrative and regulatory headquarters (See r3, n5, pages 6, 7).

Finally, existing obsolete facilities will be demolished (See d, page 6).

¹ The $447 million cost, nine-year phasing, and square footage are preliminary Shive-Hattery estimates for the Master Plan. We anticipate these estimates will change, however, final official figures were not available when this newsletter went to press.

Note: Excerpts from USDA publications were utilized in this article. We thank NADC, NVSL & CVB personnel for their assistance.

Lab Biosafety Levels

• Biosafety Level - 1 (BL-1). Microbiological agents are not known to cause disease in healthy adult humans or in animals and are of low risk to the environment. Basic microbiology laboratory of conventional design without special engineering features for containment. Potential hazards readily controlled by standard microbiological practices.

• Biosafety Level - 2 (BL-2). Microbiological agents are of moderate risk to humans, animals, or the environment. Similar in design to biosafety level-1 facility except that access to the laboratory is restricted and work that may cause splashes or aerosol generation is conducted in primary containment equipment (biological safety cabinets). Plants and animals not related to research project are not allowed in the laboratory and laboratory clothing, gloves and eye protection may be required for wear by personnel that work in the laboratory.

• Biosafety Level - 3 (BL-3). Microbiological agents which may cause serious disease in humans from exposures by inhalation. The laboratory is separated from remainder of the building, often by a personnel change room (shower optional). Access to the laboratory is restricted. Biological safety cabinets and personal protective equipment are used. The laboratory should be constructed to allow it to be sealed for gas decontamination. The ventilation system is designed to provide directional air flow from uncontaminated to potentially contaminated areas. Air is not recirculated. Filtration of exhausted air is optional.

• Biosafety Level - 3 Agriculture (BL-3Ag). Required for certain high risk microbiological agents that infect livestock or plants. Mandatory building design includes personnel change rooms with showers; personnel and equipment air locks; a double door autoclave; single pass, directional, and pressure gradient air system; HEPA filtration (or equivalent) on supply and exhaust air with electrical interlocks to prevent pressurization of the laboratory during electrical or mechanical breakdowns; central liquid/solid waste sterilization; and sealed interior surfaces. The facility requires special testing and certification procedures.

• Biosafety level - 4 (BL-4). Required for extremely hazardous biological agents with high risk to human life. The distinguishing characteristic of this type of facility from the biosafety level-3 agriculture facility is the provision of a secondary barrier for workers (one piece positive pressure personnel suits ventilated by life support system to prevent human exposure). The Agricultural Research Service does not have this level of facility.
The Master Plan consolidates and modernizes the existing facilities of APHIS’ National Veterinary Services Laboratories (NVSL) and Center for Veterinary Biologics (CVB) and ARS’ National Animal Disease Center (NADC) located on 471 acres of land east of Ames, Iowa.

Through new construction, remodeling and demolition, the existing 527,000 sq. ft. of space is increased 20% to 630,000 sq. ft. of shared, combined-agency (NVSL/CVB/NADC) space. Preliminary estimate of cost is $447 million over nine years.*

- Photographs
  NOW (above) - Looking north at existing NVSL/CVB and NADC facilities; Now: View II - Looking southeast at existing NADC facilities.
  PROPOSED (page 7) - Looking north at new, combined-agency facilities; Proposed: View II - Looking southeast at new, combined-agency, BL-3Ag and BL-2 animal research buildings**; Proposed: View III - Looking southeast at new, combined-agency, laboratory/office, administrative and central receiving facilities. (Preliminary drawings)

- Symbol definitions (pages 6 & 7)
  A, B - Fixed geographic reference points shared by photographs to assist viewer orientation.
  r1 - Existing NADC BL-3Ag, necropsy/incinerator facility to be retained and incorporated into new, combined-agency BL-3Ag animal research facilities.
  r2 - Existing NADC utility plant facility to be retained and remodeled.
  r3 - Existing NVSL/CVB-L laboratory and office facility to be retained and remodeled.
  d - Existing NADC laboratory, animal research and administrative facilities to be demolished.
  n1 - New, combined-agency BL-3Ag animal research buildings.
  n2 - New, combined-agency BL-2 animal research buildings.
  n3 - New, combined-agency central receiving facility.
  n4 - New, combined agency laboratory facility.
  n5 - New training facility.


** See “Lab Biosafety Levels,” page 5.
PROPOSED
New, combined-agency (NVSL/CVB/NADC), facilities

USDA, ARS-APHIS Master Plan for Facility Consolidation and Modernization

Proposed: View II
New, combined-agency (NVSL/CVB/NADC), BL-3Ag & BL-2 animal research facilities

Proposed-View III
New, combined-agency (NVSL/CVB/NADC), laboratory and office facilities


Nation’s premier lab for domestic & foreign animal disease diagnosis

The National Veterinary Services Laboratories (NVSL) is part of USDA-Animal and Plant Health Inspection Service (APHIS)-Veterinary Services and is this nation’s premier animal disease diagnostic laboratory. It is a critical component of our ability to defend our animal populations from domestic and foreign animal diseases.

• **Mission** - NVSL’s mission is "To protect the health of animals and contribute to public health by providing timely, accurate, and reliable laboratory support to our customers."

The NVSL performs animal disease testing for Veterinary Services and is the only laboratory system in APHIS dedicated to the testing of diagnostic specimens for domestic and foreign animal diseases (FAD). It provides analytical services, disseminates scientific information and conducts developmental activities.

As a national reference laboratory, it sets the standards for testing procedures and transfers that knowledge to many domestic diagnostic laboratories through training and the use of proficiency panels. It also works closely with APHIS' International Services office to provide consultation, reagents and training for foreign governments.

It is a world resource and certified by the OIE and FAO as a reference laboratory for 19 diseases. NVSL is an OIE Collaborating Centre for the Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas.

Laboratory support services are provided for many APHIS activities, including brucellosis, tuberculosis, animal and bird quarantine, foreign animal products importation, Salmonella serotyping, horse importation, scrapie, bovine spongiform encephalopathy surveillance, the National Animal Health Monitoring System, the National Poultry Improvement Plan, training for domestic and foreign animal diseases and fraudulent blood testing.

NVSL tests over 50,000 accessions each year. Its clients and stakeholders include state, federal, university and foreign laboratories, and other groups that support animal industries, both domestic and foreign.

What is the National Veterinary Services Laboratories?

What is the Center for Veterinary Biologics?

Responsible for licensing safe & effective vaccines for all animals

The Animal and Plant Health Inspection Service (APHIS) Veterinary Biologics Program is part of USDA-APHIS-Veterinary Services and is based at the Center for Veterinary Biologics (CVB) in Ames, Iowa.

• **Mission** - CVB’s mission is to implement the provisions of the Virus-Serum-Toxin Act to ensure that veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent and effective. Veterinary biologics include vaccines, bacterins, immunotherapeutics and commerical diagnostics.

This mission mandates the use of sound scientific technology to: 1) ensure that biologics are free of disease-producing agents, especially foreign animal diseases; 2) develop appropriate standards and procedures for product release; 3) issue licenses and permits; 4) monitor and inspect products and facilities; and 5) control field tests and release of veterinary biologics.

The CVB plays a vital role in regulating products that diagnose, prevent, or treat animal diseases. The Center uses scientific information and regulatory processes to assure its customers that the veterinary biological products available for use are of high quality. It encourages open communication with stakeholders as new products and standards are developed. The Center promotes the use of quality assurance processes that inherently result in the production of pure, safe, potent and effective veterinary biologics and diagnostics.

The CVB provides leadership in the development and international harmonization of standards for veterinary biological products and is a member of the Institute for International Cooperation in Animal Biologics, an OIE Collaborating Centre for the Diagnosis of Animal Diseases and Vaccine Evaluation in the Americas.

There are nearly 2,500 biological products licensed by CVB, including combinations for over 190 different animal diseases, and 110 licensed establishments involving 180 manufacturing sites. Of these, 40 are located in foreign countries (Canada, Australia, New Zealand and Europe). CVB oversees the release of more than 17,000 serials (batches) of biologics per year.
What is the National Animal Disease Center?

USDA’s major research center for domestic & emerging animal disease

The National Animal Disease Center (NADC), an arm of the Agricultural Research Service (ARS), is the major U.S. Department of Agriculture (USDA) center for research on livestock and poultry diseases that occur in the United States. It is one of the world’s largest animal health research facilities.

- **Mission** - NADC’s mission is to conduct basic and applied research on selected diseases of economic importance to the U.S. livestock and poultry industries.

- The goal of its research program is to produce research knowledge and technology to:
  - Reduce economic losses of the livestock and poultry industries and the associated rural agricultural community from infectious, genetic, and metabolic diseases.
  - Reduce or eliminate pre-harvest contamination and/or infection of livestock and poultry with food-borne human pathogens.
  - Prevent suffering and death caused by diseases in agriculturally important livestock and poultry.

- **Budget, personnel, facilities** - The NADC reports to the ARS midwest field administration and management area office located in Peoria, Illinois.

  The NADC became operational in 1961. It is a large facility, consisting of 83 buildings on 318 acres of land just east of Ames, Iowa, that includes 260,730 sq. ft. of laboratory and office space and 228,507 sq. ft. of other buildings. It is located just north of and adjacent to the 153-acre main premises of the National Veterinary Services Laboratories (NVSL) and the Center for Veterinary Biologics (CVB), USDA-APHIS.

  It operates on an annual budget of $23 million. The Center is staffed by some 300 personnel, including 56 scientists. The NADC cares for and provides housing for animals used in research. The current research animal census is 300 mice, 200 cattle, 200 turkeys, 200 rats, 150 swine, 75 sheep, 50 white-tail deer, 35 bison, 30 chickens, 20 elk, 18 goats, 15 rabbits, eight raccoons, and two horses.

- **NADC webpage** - www.nadc.ars.usda.gov

- **Organization**

  Dr. Keith Murray, Director of the NADC, oversees NVSL and Veterinary Biologics Division (currently the Center for Veterinary Biologics-CVB) were allocated 10 percent of the space in the NADL.

  In 1967, the President of the National Association of State Departments of Agriculture recommended to Congress that the diagnostic and biologics support services be moved to a new location, separate from the NADL disease research program.

  After consideration of several sites, Ames, Iowa, was chosen. In 1974, the Iowa state legislature and the Ames community provided funds for the purchase of 153 acres immediately south of the NADL on which to build new facilities for diagnostic and biologics activities.

  A design contract was awarded in 1974, construction began in 1976, and the new NVSL (which included veterinary biologics laboratory functions) was completed in August 1978.

Note: Prepared from a summary of an article in the CIEDA Science Review, Vol. 5, No.1, Fall, 1993, and information on the NADC website. We thank NADC, NVSL and CVB personnel for their assistance.

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**96 Years: A History of USDA’s Animal Health Laboratories in Ames, Iowa**

In 1905, USDA established the Hog Cholera Research Station on 35 acres of land near Ames, Iowa. The station conducted research and diagnostic services on hog cholera until 1961.

In 1955, USDA-ARS closed unsafe animal health research laboratory facilities in the Washington, D.C., area. A USDA committee was appointed to recommend a site for new laboratory facilities in 1956. One hundred institutions expressed interest in the laboratory and 34, including Iowa State College, presented proposals. Following hearings, nine were visited.

On July 9, 1956, the Iowa state legislature, with the urging of Iowa State College, provided funds to buy 318 acres of land for the new USDA laboratory near the original site of the Hog Cholera Research Station. The following day, Secretary of Agriculture Benson approved the recommendation of the committee to locate the laboratory in Ames.

On July 27, 1956, President Eisenhower signed an appropriation bill containing $16,250,000 to construct the new National Animal Disease Laboratory-NADL (renamed the National Animal Disease Center-NADC in 1974).

The laboratory officially opened in 1961. The functions of the Animal Health Diagnostic Services Division (currently the National Veterinary Services Laboratories-NVSL) and Veterinary Biologics Division (currently the Center for Veterinary Biologics-CVB) were allocated 10 percent of the space in the NADL.

In 1967, the President of the National Association of State Departments of Agriculture recommended to Congress that the diagnostic and biologics support services be moved to a new location, separate from the NADL disease research program.

After consideration of several sites, Ames, Iowa, was chosen. In 1974, the Iowa state legislature and the Ames community provided funds for the purchase of 153 acres immediately south of the NADL on which to build new facilities for diagnostic and biologics activities.

A design contract was awarded in 1974, construction began in 1976, and the new NVSL (which included veterinary biologics laboratory functions) was completed in August 1978.
What is the NVSL?
from page 8

- NVSL webpage - The address is: www.aphis.usda.gov/vs/nvsl

- Budget, personnel and location - The NVSL operates on a $15 million annual veterinary diagnostic appropriation budget and has approximately 220 employees, of which 60 are scientists. Its facilities are located in four locations in the Ames, Iowa, area and on Plum Island, New York.

- NVSL Office of the Director - Dr. William Buisch, Acting Director, is supported directly by offices of Engineering and Facilities Management, Administrative and Program Management Services, Quality Assurance and Information Resources Management Services. He reports directly to the Deputy Administrator for Veterinary Services, APHIS.

This office is in the NVSL Central/CVB-L Building, which is located on APHIS’ main premises.

The Director oversees the operations of the four units of the NVSL: 1) Diagnostic Virology Laboratory; 2) Diagnostic Bacteriology Laboratory; 3) Pathobiology Laboratory and the; 4) Foreign Animal Disease Diagnostic Laboratory.

- NVSL Diagnostic Virology Laboratory (DVL) - Dr. Beverly J. Schmitt serves as Chief of this service, which provides laboratory support for diagnosis of domestic diseases by virus isolation and identification, serological testing and surveillance of domestic and certain exotic diseases, import/export testing, reference and reagent production and bench training.

Some of the viruses worked on include West Nile encephalitis, swine influenza, porcine respiratory and reproductive syndrome, exotic Newcastle disease, vesicular stomatitis, highly pathogenic avian influenza, chlamydia, pseudorabies, Venezuelan equine encephalitis, bluetongue, equine viral ateritis, epizootic hemorrhagic disease, equine infectious anemia, bovine leucosis, bovine viral diarrhea and infectious bovine rhinotracheitis.

DVL Facilities - The DVL activities are carried out in leased, BL-3 laboratories and animal facilities located in the A wing of the National Animal Disease Center’s (NADC) Building #2-Main Laboratory and in NADC’s Building #3-Animal Isolation Facilities. These facilities were constructed in circa 1960. (See photo, page 17 and Lab Biosafety Levels, page 5.)

DVL space at NADC Building #2-Main Laboratory - This well maintained building has never been renovated. Biosafety level standards are more stringent now than when the building was constructed and there is concern that the space does not meet current standards. Currently, equipment and storage cabinets line the walkways within the laboratory module creating poor working conditions and safety hazards—there are some places where it is literally “one-way traffic.”

DVL space at NADC Building #3-Animal Isolation Facilities - These facilities were also constructed in circa 1960 and have not been fully renovated. The 1960’s incinerator, while still functioning, is nearing the end of its operational life.

Easily containerized waste, primarily from small animals and birds, is currently transported to newer incinerators in nearby buildings in order to reduce its use.

Other concerns about this facility are the lack of protective barriers between animals and people, an inadequate ventilation system, and overcrowded work spaces.

- NVSL Diagnostic Bacteriology Laboratory (DBL) - Dr. Thomas Bunn serves as Chief of this service, which provides support through the isolation and identifica-
tion of pathogenic bacteria from animal tissues and fluids and through serologic examination for evidence of exposure to diseases caused by bacteria and protozoa.

Some of the microorganisms worked on include salmonella, *E. coli* O157: H7, *Mycobacterium bovis* and *paratuberculosis*, brucella, anaplasma, mycoplasma, leptospira, clostridia, pasteurella, and the agents of anthrax, dourine, glanders, tuleremia and contagious equine metritis.

**NVSL-DBL facilities** - The DBL activities are carried out in four buildings in the Ames area: a leased commercial building located in the Lincoln East Commercial Center strip mall near downtown Ames; leased space in NADC Buildings #2-Main Laboratory and #3-Animal Isolation Facilities; and the NVSL Central/CVB-L building on the APHIS main premises.

**DBL strip mall building** - BL-2 laboratory activities are carried out in the strip mall building including isolation and identification of bacterial agents, such as salmonella, *E. coli*, and clostridia. Serological testing for antibodies to brucella, anaplasmosis, piroplasmosis and Johne’s disease are also conducted in this building.

The building, which has been leased by NVSL for 27 years, has significant deficiencies, such as inadequate heating and cooling, poor ventilation and ground water seepage. Even though the building owners have recently painted the interior, there are still problems of dust falling from the ceiling, roof leakage in the winter and insect and rodent incursion.

**What is the NVSL?**

In 1994, the USDA Office of Inspector General determined that these satellite facilities were not constructed to the recommended safety standards for handling some human pathogens. Interim steps have been taken to mitigate these issues. These included moving brucella and mycobacteria isolation and identification typing to temporary space at the NVSL Central/CVB-L Building’s BL-3 laboratory section and the NADC Building #3-Animal Isolation Facilities.

Another concern is that specimens from the field first go to the NVSL Central/CVB-L Building on the APHIS main premises and then are delivered to the DBL strip mall building by courier. Likewise, microbiological media used in the strip mall DBL facility is delivered from the NVSL Central/CVB-L Building.

**DBL space at NADC buildings #2 and #3** - The DBL occupies space in these buildings with the DVL. The status of this space is similar to that described under "DVL space at NADC Buildings #2 and #3," page 10. In addition, DBL occupies renovated animal facility space in NADC Building #3 that was renovated for laboratory use.

**DBL space in NVSL Central/CVB-L building** - This building was completed in 1978 and was designed to house APHIS’ biologics testing activities of that era. However, only the first phase of the project was completed. Consequently, no space was built for diagnostics and the building’s laboratory space is occupied principally by the biologics programs. Most of the laboratories are BL-2 with one small BL-3 section.

The DBL activities in this building include bacterial isolation and serology work with agents, such as pasteurella, leptospira and salmonella in the BL-2 section and with brucella in the BL-3 section. Support work, such as media preparation, is also carried out in this building by DBL.

Even though it is a well maintained, pleasant building with large windows throughout, renovations to this building have been few and limited since its construction. Inadequate bench space, higher biosafety level standards and the need for more BL-3 space in this building necessitate significant renovation.

The DBL also utilizes some of the animal facilities located on the APHIS main premises.

**NVSL Pathobiology Laboratory (PL)** - Dr. Arthur J. Davis serves as Chief of this service.
PL facilities - The PL diagnostic activities are carried out in two buildings in the Ames area: a leased commercial building located in the same Lincoln East Commercial Center strip mall as DBL; and the NVSL Central/CVB-L building on the APHIS main premises.

PL strip mall building - With the exception of toxicological and animal care services, all of the PL activities are carried out in the strip mall building. This includes diagnostic pathology support of APHIS surveillance programs for transmissible spongiform encephalopathies (TSE's). (See TSE Diagnosis and Surveillance in previous column.)

With current trends moving towards working with TSE's under higher biosafety levels, the PL strip mall facility is inadequate to meet these standards. Recently, interim steps have been taken to improve biosafety in working with these agents by leasing adjacent space within the strip mall that is dedicated TSE workspace, along with the addition of new biosafety cabinets; however, as requirements change, these interim steps are likely to be inadequate.

In addition, chemical fumes are a problem due to the common air circulation system in the building, even with the use of fume hoods. Other concerns about the condition of this building are similar to those described under “DBL strip mall building,” page 11.

PL space at NVSL Central/CVB-L building - PL toxicological service activities are carried out in BL-2 laboratory space in this building and include diagnostic testing for pesticides, heavy metals and toxins.

The status of this building is discussed under "DBL space in NVSL Central/CVB-L Building," page 11.

- NVSL Foreign Animal Disease Diagnostic Laboratory (FADDL) - Dr. Tom McKenna serves as Chief of this service, which has broad responsibility in providing diagnostic services for foreign and emerging animal diseases; reagent production, evaluation and distribution; foreign animal disease masterseed and vaccine evaluation and; maintenance of the North American Foot-and-Mouth Disease Vaccine Bank. FADDL also is the nation’s provider of vitally important training courses for veterinarians in the recognition of the signs and lesions of several foreign animal diseases.

FADDL is co-located with the Plum Island Animal Disease Center (PIADC) on Plum Island, New York, and Dr. McKenna serves as Assistant Center Director.
What is the NVSL?

from page 12

FADDL facilitates - The FADDL activities are carried out in BL-2 and BL-3 laboratories and animal isolation facilities located in Buildings #100 - Administrative Complex and #101 - Laboratory Complex of the PIADC. (See photos, page 12.)

Building #101 was constructed in 1957 and FADDL laboratory facilities were upgraded in 1995. Building #100 was constructed in 1995. The Master Plan does not contain funding requests for FADDL facilities.

Note: Excerpts from USDA publications used in this article. We thank NVSL personnel for their assistance.

What is the CVB?

from page 8

The CVB provides biologics expertise and services for all Veterinary Services regulatory programs, including tuberculosis, brucellosis, pseudorabies, and other diseases/areas of concern, such as Johne’s disease, PRRS, rabies, West Nile virus, foot-and-mouth disease and infectious diseases of aquaculture.

The CVB serves agriculture, the public, agricultural organizations, the biologics industry, APHIS and other federal agencies by facilitating communications and regulating the production and distribution of veterinary biological products. It educates biologics manufacturers and users and monitors product performance.

• Public meetings - The CVB holds an annual Veterinary Biologics public meeting in Ames to explain its regulatory initiatives, get stakeholder input, and provide scientific information on biologics issues. Information on past and future meetings can be found on the CVB web site.

• CVB webpage - The address is: www.aphis.gov/vs/cvb

• Budget, personnel and location - The CVB operates on a $11 million annual budget and employs approximately 104 program employees, including 48 scientists, and provides funding for 47 NVSL support personnel. Its facilities are located in two locations in the Ames, Iowa, area.

• CVB organization - The CVB consists of three interdependent units: 1) Laboratory; 2) Inspection and Compliance; 3) Licensing and Policy Development. Each of the three units has a Director. These three Directors work together as a team and report directly to the Deputy Administrator for Veterinary Services.

Although technically independent, the three units of CVB coordinate their respective resources to carry out the mission of the APHIS Veterinary Biologics Program.

• CVB-Laboratory (CVB-L) - Dr. Randall L. Levings is the Director of the CVB-L and oversees the activities of four sections: 1) Biologics Bacteriology, headed by Dr. L. K. Schlater; 2) Poultry Virology, headed by Dr. R. L. Hyde; 3) Mammalian Virology, headed by Dr. L. A. Wilbur and; 4) Cytology and Sterility headed by Dr. G. G. Christianson. There are 47 employees in this unit.

The CVB-L provides testing results to Inspection and Compliance and to Licensing and Policy Development. It is responsible for prelicensing testing of biologics, test methods development, references and reagents, international technical harmonization and post license testing.

Tests ensure that the products are pure, safe, potent and efficacious. In the first half of fiscal year 2001, CVB-L completed 934 serial release tests, 63 tests on master seeds and cells, and...

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What is the CVB? from page 13

401 tests of products for other regulatory purposes. The CVB-L is currently examining strategies for more risk-based testing.

The CVB-L, as a regulatory entity, is not involved in fundamental research. It is involved in applied research or developmental activities related to veterinary biologics issues. The activities involve developing new tests and reagents (e.g., in vitro antigen quantitation assays), learning techniques needed to evaluate new products (e.g., vectored immunogens), and examining safety issues (e.g., virulence markers). Special emphasis is placed on reducing or replacing animal usage and suffering in veterinary biologics evaluation.

CVB-L is an international reference center for biologics testing methodology and reference standards. The lab provides training in laboratory evaluation of biologics to U.S. and international personnel. It maintains 290 standard reference preparations and test reagents for anaerobic and aerobic bacterial products (64) and virus products (226). The CVB-L will soon seek accreditation to the ISO standard 17025. The quality assurance of laboratory processes, documentation, references and equipment is being improved.

CVB-L facilities - The laboratory bench and office activities of CVB-L are carried out in one building, the NVSL Central/CVB-L Building, on the APHIS main premises. CVB-L is the primary occupant of this building (80 percent of the laboratory testing modules) and shares space with NVSL-DBL and PL. (See photos, pages 10, 13.) Animal testing is performed in animal facilities on the APHIS main premises and in the NADC Building #3-Animal Isolation Facilities. (See photos, pages 11, 17.)

The status of NVSL Central/CVB-L Building is discussed under “DBL space in NVSL Central/CVB-L Building” on page 11. As noted, this building was constructed in 1978 specifically for biologic testing, which at that time was primarily microbiological in nature.

Today and in the future, molecular biology will be a primary technology in biologics, which, in turn, necessitates more specialized chemistry and other laboratory space for CVB-L. Sufficient space for this purpose is lacking in this building.

The condition of the NADC Building #3-Animal Isolation Facilities is described under "DVL space at NADC Buildings #3" on page 10.

• CVB Inspection and Compliance (CVB-IC) - Mr. Steven A. Karli is the Director of CVB-IC, which is divided into four teams: 1) Product Inspection, headed by R. M. Schnurr; 2) Facilities Inspection, headed by J. R. Mittel; 3) Compliance, (position vacant); and 4) Product Monitoring and Information, (position vacant). There are 24 employees in this section.

The mission of CVB-IC is to ensure that veterinary biological products are produced and maintained in compliance with the Virus-Serum-Toxin Act.

This unit of CVB inspects all licensed or permitted veterinary biologics manufacturers and products to assure that worthless, dangerous, contaminated or harmful products are not distributed in the United States.

Its specific responsibilities are: serial (batch) release; facilities inspection; post-release product surveillance; and compliance. In addition, CVB-IC conducts an average of 70 facility inspections each year. CVB’s Consumer Information Hotline number is (800) 752-6255.

Supervision of the release of serials and batches of biologics is one of the main activities, with CVB-IC approval required of each of the 17,000 serials released each year. CVB-IC works closely with CVB-L in this process.

It also oversees the Animal Immunobiologic Vigilance Program, which is an ongoing surveillance of adverse events associated with animal vaccines and other biologics, in cooperation with the veterinary profession and the veterinary biologics industry. This unit conducted 11 investigations and issued 41 regulatory actions for violations of the Virus Serum Toxin Act.

CVB-IC facilities - The activities of this unit of CVB are carried out in a leased section of one of the
What is the CVB? from page 14

Aspen Business Park commercial buildings located in Ames, Iowa. CVB-IC shares this space with CVB-LPD. This is a new building that has two other occupants besides CVB. It is approximately five miles from the CVB-L, which is located on the APHIS main premises. (See photos, page 14.)

This is the site for storage of CVB confidential business information files, which are shared by CVB-L, CVB-IC and CVB-LPD. There is concern about record security due to the off-site location of CVB-L.

• CVB Licensing and Policy Development (CVB-LPD) - Dr. Richard E. Hill, Jr. is the Director of CVB-LPD, which is divided into five sections: 1) Biometrics, headed by Dr. J. Tanner; 2) Biotechnology and Diagnostics, headed by Dr. L. Henderson; 3) Bacteriology and Poultry Virology, headed by Dr. B. E. Rippke; 4) Mammalian Virology and Antibody Products, headed by Dr. D. M. Gatewood; and 5) Operational Support, headed by A. Morgan. There are 33 employees in this unit.

CVB-LPD's specific responsibilities are to license and register veterinary biologics, establish program standards and policy and, issue permits to import veterinary biologics.

It reviews license applications for production facilities and biological products; reviews applications for permits for importation of products; establishes licensing, testing and permit requirement and procedures and; reviews production methods, labels and supporting data involved in the licensing and permit process.

CVB-LPD facilities - Activities of this unit of CVB are also carried out in the leased building in the Aspen Business Park. The status of this building has been discussed in “CVB-IC facilities” on page 14.

Note: Excerpts from USDA publications were used for parts of this article. We appreciate the assistance of CVB personnel.

Plant-Derived Vaccines

CVB gearing up to evaluate transgenic plants for production of animal biologics

by Louise Henderson, Head, Biotechnology & Bacteriology Section, CVB-LPD

Several firms have indicated to the USDA-APHIS-VS-Center for Biologics (CVB) that they intend to pursue product license applications for plant-derived biologics. The Animal Health Institute, an association of veterinary biologics manufacturers, has developed a Working Group for Transgenic Plants.

The CVB has already received proposals for conducting environmental assessments and pre-licensing information for some of these products, and has visited proposed field production sites and/or facilities for some of these firms.

The CVB must hire personnel with the expertise to deal with the unique issues involving plant-derived biologics and add the needed equipment and facilities to enable the adequate evaluation and testing of these novel products, which may be derived from engineered plants or engineered plant viruses used to transfect non-GMO crops.

All three CVB units will have issues that need to be addressed and the resources of all three will be severely strained.

The CVB-Laboratory will need to develop methods for testing Master Seeds/Constructs and products; develop reagents and develop potency and safety test assays. Greenhouse facilities may be needed.

The CVB-Inspection & Compliance will need to develop guidelines for inspecting plant-derived biologics firms. The scope of inspections will take on a whole new meaning when fields, storage facili-

Reduction of Animal Testing

CVB program saves 1,200 cattle, 200 cats and 8,000 mice in first year

by Renee Schnurr, Team Leader, Product Inspection, CVB-Inspection & Compliance

The Center for Veterinary Biologics (CVB) codified requirements for the use of in-vitro potency testing of veterinary biologics in May 1997, with enforcement of these regulations to begin on or before May 1999. These regulations were implemented to reduce the use of animals in potency testing of veterinary biologics.

It was estimated in the first year of implementation approximately 1,200 cattle, 200 cats and more than 8,000 mice have been saved. Unfortunately, requalifying reference material has not allowed for an over-all reduction in the use of host or laboratory animals in the short term. The manufacturing firms are required to periodically conduct challenge or serological studies in host animals or laboratory animals to demonstrate the continued stability of their in vitro references. National References prepared, tested and supplied by the CVB would eliminate the need for each manufacturer to perform these studies at times of qualification and recertification. Also, National References would eliminate the need for stability testing in animals of the immunogen by each manufacturer.

The CVB needs the appropriate animal facilities for host and laboratory animals to conduct the required testing of a National Reference. As a regulatory agency of the USDA, CVB is taking the lead in implementing a Reference Standard program that is in the interest of the U.S. veterinary biologics manufacturing firms. This program will continue to assure the efficacy of veterinary biological products, while contributing to animal welfare advances.

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What is the NADC?
from page 9

all operations and ongoing research activities. Six major units report directly to him, including a Program Support Unit and five Research Units.

• Program Support

The Assistant Director for Program Support, Scott Rusk, is responsible for the vast physical plant of the NADC. Reporting to him are: Environmental Safety & Support; Facilities Engineering; Biosafety & Animal Welfare; Farm Management and; Laboratory Resources.

• Five Research Units

The NADC’s five animal health research units and 18 ongoing research projects are as follows:

1. Virus and Prion Diseases of Livestock Research Unit

William L. Mengeling, DVM, Ph.D. is the Research Leader.

The Virus and Prion Diseases of Livestock Research Unit identifies and characterizes viruses and prions (abnormal disease causing proteins) associated with economically important diseases of livestock and develops methods to control or eradicate these diseases. Unit goals include:

• Develop diagnostic tests.
• Understand the development of specific diseases.
• Develop vaccines to control viral infections.
• Define the prevalence and economic impact of emerging viral diseases.

Current research projects:

• Detection and control of bovine viral diarrhea viruses (BVD).
• Emerging viral diseases of swine.
• Virus-induced respiratory and reproductive diseases of swine.
• Transmissible spongiform encephalopathies (TSE) in animals.

2. Pre-harvest Food Safety & Enteric Disease Research Unit

Irene Wesley, DVM, Ph.D., is the Acting Research Leader.

The Pre-harvest Food Safety and Enteric Diseases Research Unit strives to provide scientific leadership in reducing the prevalence of human food-borne pathogens in livestock and to elucidate the basic mechanisms of selected enteric diseases of hogs. The end goal is to provide basic and applied multidisciplinary research that will benefit the American consumer and the livestock industry.

Current research projects:

• Prevention of losses from colibacillosis and E. coli O157:H7 in cattle and swine.
• Salmonella-host interactions.
• Ecology and epidemiology of salmonella and other food-borne pathogens in livestock
• Antibiotic resistance of enteric bacteria.

3. Bacterial Diseases of Livestock Research Unit

Diana Whipple is the Acting Research Leader.

The Bacterial Diseases of Livestock Research Unit investigates diseases of food-producing animals and wild ruminants caused by brucella, mycobacteria, leptospiroa, and brachyspira.
Current research projects:
- Identification of factors causing immune suppression at parturition.
- Molecular, nutrient and endocrine basis for metabolic disease in the transition dairy cow.
- Microbial factors and pathogenesis of subacute rumen acidosis (SARA) in cattle to assure food safety.

5. Respiratory Diseases of Livestock Research Unit

Kim Brogden, Ph.D., is the Research Leader.

The mission of the Respiratory Diseases of Livestock Research Unit is to investigate and provide innovative approaches to solving bacterial diseases of the respiratory tract of poultry, swine, and cattle. Unit goals include developing diagnostics, therapeutics, and new and/or improved vaccines, as well as identifying new agents and understanding epidemiology, pathogenicity, and virulence.

Current research projects:
- Controlling losses from respiratory diseases in cattle, sheep, and goats.
- Control of porcine respiratory diseases of complex...
What is the NADC? from page 17

- Bacterial and mycotic diseases of poultry.

Iowa State University

The close proximity to Iowa State University, one of America’s foremost land-grant universities, also located in Ames, helps to maintain a creative environment for research. Many NADC scientists hold appointments at the university and frequently teach, serve on graduate committees, engage in cooperative research, coordinate seminars, and participate in many other scholarly activities.

Iowa State’s exceptionally strong teaching, research and service programs in animal health, including its College of Veterinary Medicine and Department of Animal Science, make Ames a particularly attractive site for USDA national animal health laboratories.

The congressionally mandated Strategic Planning Task Force (Task Force) on USDA Research Facilities reported in 1999 that “Co-location of federally supported and conducted research laboratories with colleges and universities should be a goal of the intramural research system.” (See “Task Force,” page 3.)

Facilities status

Researchers at NADC continue to conduct important animal disease research in the 40-year old facility in both a safe and effective manner, addressing, as noted above, a wide spectrum of high-priority animal health issues.

However, the facility needs significant renovation, including updating of existing and construction of new buildings, in order to maintain the availability of facilities required for essential animal disease research of high priority to the nation.

The convergence of three factors is accelerating the need for renovation and new facilities at the NADC.

- First, many of the facilities are simply wearing out.
- Second, laboratory biosafety standards, such as Biosafety Level 3 Agriculture (BL-3Ag), now required for certain types of research, cannot be easily attained in some of the existing facilities. (See “Lab Biosafety Levels,” page 5.)
- Third, new technologies, such as genomics and proteomics, require new, state-of-the-art laboratory facilities.

ARS, for some time, has been studying and planning for the infrastructure needs at NADC. As a result of a 1992 “Facilities Condition Study” conducted by an outside architectural and engineering firm hired by ARS, NADC received additional ARS High Priority Research List funding that has been used to address some of the more immediate needs in the intervening years. The study estimated it would take $103 million to address then current needs (‘92 dollars).

The 1999 Task Force report estimated the 10-year repair and maintain-
The NADC microbiologists Tom Casey (left) and Mark Rasmussen evaluate a laser for use in their fecal contamination detection system for meat carcasses. They are working in the laser lab of Iowa State University collaborator, photochemist Jacob Petrich.

Very contented cows taking a break in the sand stalls inside of NADC’s Barn 125

NADC microbiologists Tom Casey (left) and Mark Rasmussen evaluate a laser for use in their fecal contamination detection system for meat carcasses. They are working in the laser lab of Iowa State University collaborator, photochemist Jacob Petrich.

Named by “R&D Magazine” as one of top 100 promising technologies

A new way to improve the ability of meat inspectors to identify small amounts of fecal contamination not detected visually on carcasses has been developed through collaborative research by NADC and Iowa State University scientists.

The new technology could help the industry meet new food safety regulations designed to control deadly bacteria, such as E. coli 0157:H7.

The researchers received a patent on the technology in the summer of 1999 and it was included in “R&D Magazine’s” top 100 promising technologies of the year 2000.

A prototype designed by the researchers was used in a test at a large Midwestern beef packing plant. The instrument uses specific wavelengths or colors of light to illuminate the carcass (fluorescent spectroscopy). Collected light returned from the carcass is electronically analyzed to determine if fecal matter is present. If fecal matter is detected, the carcass can undergo further sanitation.

The system is based on the dramatic fluorescence of agents in the degradation products of chlorophyll.

Visual inspection and carcass cleaning are the standard tools for reducing the feces containing E. coli and other bacterial contaminants in meat slaughterhouses across the country. But the human eye is not sensitive enough to identify all of the fecal contamination that can be on carcasses, according to Mark A. Rasmussen at the NADC.

USDA’s Food Safety Inspection Service has a zero tolerance standard for fecal contamination on livestock and poultry carcasses. The fecal detection system can help livestock and poultry slaughterhouses meet these federal standards.

Rasmussen, NADC microbiologist Thomas A. Casy, and Iowa State University chemist Jacob W. Petrich invented the prototype, which instantly detects minute amounts of fecal material on carcasses.

Work to commercialize the technology is being conducted under a cooperative agreement with ISU and a commercial company, eMerge Interactive, Inc. of Sebastian, Florida.

Note: Extensive excerpts of articles by Linda McGraw (1999 & 2000) in ARS publications were used as well as comments from Tom Casey. We thank NADC personnel for assistance with this article.
What is the NADC?
from page 19

generated. Five million dollars were allocated for renovation of the waste treatment facility. A total of $13 million is required to complete the necessary update.

Evolution of the Master Plan

In 1997, ARS contracted with Bernard Johnson Young, Inc. of Bethesda, Maryland, to draw up a Master Plan for NADC facility needs. The plan provided an overall look at NADC, its programs and facilities, and made recommendations on renovation, including new construction needs. The final cost was estimated at $328 million (1998 dollars).

The APHIS National Veterinary Service Laboratories and Center for Veterinary Biologics had completed a separate Master Plan in 1995, with an estimated cost of $122 million (1995 dollars).

Subsequently, in 1999, ARS and APHIS began joint, collaborative planning for new, combined-agency facilities for NVSL, CVB and NADC needs, rather than continuing with separate agency plans.

The ARS-APHIS Master Plan for Facility Consolidation and Modernization, prepared by BJY, was completed in 2000. The BJY plan merged the separate NADC and NVSL-CVB master plans. It proposed new and renovated facilities on the 471-acre combined-agency site at Ames, Iowa, and estimated a cost of $379 million (1999 dollars), a savings of $71 million over separate facilities.

A preliminary refinement of the BJY Master Plan, conducted by the Shive-Hattery firm, estimated a cost of $447 million (2000 dollars) for the combined-agency Master Plan. It is anticipated this cost estimate will change as the plan is finalized.

The new, combined-agency facility will provide the United States with an integrated, multidisciplinary research, diagnostic and biologics center.

Note: Excerpts from USDA publications were utilized in this article. We thank NADC personnel for their assistance.

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Update on Laboratory Accreditation

Ames facilities may not meet requirements ... trade implications for U.S.

In 1996, Congress passed the National Technology Transfer and Advancement Act, which gave the National Institute of Standards and Technology (NIST, Department of Commerce) the responsibility for coordinating conformity assessment in the United States. One of the more complex conformity assessment activities in the U.S. is laboratory accreditation, the mechanism by which the competence of testing and calibration laboratories is assessed.

To address the need for coordination and consistency in this area, NIST, other government agencies, and a number of private entities incorporated the National Cooperation for Laboratory Accreditation (NACLA), in 1998. NACLA is a non-profit organization in which both public and private sectors are involved. NACLA evaluates laboratory accreditation bodies and grants recognition to those that are in compliance with ISO/IEC Guide 58, the standard for competence of accrediting bodies. NACLA bases its operations and requirements on the guidelines developed by the International Laboratory Accreditation Cooperation (ILAC). NACLA is now working to have its recognized accreditors accepted by all participants in the ILAC system.

ILAC is an international cooperation among the laboratory accreditation schemes in almost all nations. It requires accrediting bodies to use ISO/IEC International Standard 17025, “General requirements for the competence of testing and calibration laboratories.” ILAC fosters multilateral recognition among members. The ILAC system is a critical component in global efforts to eliminate technical barriers to trade and to facilitate mutual acceptance of test and calibration data.

ISO/IEC 17025 is therefore the most widely recognized “quality standard” for laboratories worldwide, and, in the global economy, it is expected that accreditation to it by a recognized accrediting body will become more and more of a necessity for both public and private-sector laboratories. ISO/IEC 17025 is a comprehensive and detailed standard. Its requirements include adequate facilities, accurate equipment, qualified staff, appropriately validated test methods, and a comprehensive and effective quality management system. As NIST has recently testified before the House of Representatives, the acceptance of laboratory results for trade will rely more and more on competent verified conformity with voluntary standards such as ISO/IEC 17025, and less and less on compliance with regulations. The impact of this trend on government laboratories in the United States is likely to be that if these laboratories wish to continue to operate, and even to regulate, they must be accredited to ISO/IEC 17025 by an accrediting body recognized by an organization like NACLA. Managers at the National Veterinary Services Laboratories (NVSL) and the Center for Veterinary Biologics (CVB) are concerned that present laboratory facilities in Ames may not meet the requirements of ISO/IEC 17025, and that these laboratories may not pass the assessment required for accreditation.

Note: We thank NVSL & CVB personnel for their assistance with this article.

International Experts from page 3

APHIS Veterinary Services and Anna Hewings, ARS Midwest Area Director. A preliminary draft of the ARS-APHIS Master Plan for Facility Consolidation and Modernization: Ames, Iowa, prepared by the Shive-Hattery architecture and engineering firm, was reviewed.

The team emphasized the urgent need to replace certain current facilities and expressed support for the Master Plan, citing the national and global scope of the animal health programs conducted in Ames.

The team’s report was submitted to the Secretary, to be included in a report to the Congress this spring.

As of the date this special edition of “USAHA” went to press, the report of the external review team had not been publicly released. However, at a meeting in Washington, D.C., earlier this year, it was learned the report would state the following:

• The reviewers fully endorse the Master Plan and state it is advantageous to consolidate the NADC, NVSL and CVB.
• The Master Plan will establish a national and international reference center, which is essential for international recognition and acceptance; provide leadership to focus national collaborations with universities; and enhance necessary linkages between research, diagnostics and regulatory activities.

Individual opinions attributed to the experts, included the following:

• The need is urgent and should be considered an emergency.
• “Astounded by the inadequacy” of some of the facilities.
• Current studies are restricted, with inordinately long periods needed to get results.
• “The status quo is not an option.”
• Addressing the concern is urgent ... 10 years is too long.
• Needs include operating and maintenance funding, as well as construction.
• (New facilities will have) a direct and positive influence on the facilitation of agricultural trade.
• Quality science needs quality facilities to attract a quality staff.
• Big science now demands new biotechnology and biologics for animal diseases.

Plant Derived Vaccines from page 15

The CVB-Licensing and Policy Development will have to deal with a sharp increase in submissions of labels, outlines, protocols, and studies expected when new firms proceed through the initial establishment and product license application procedures.
The 14 principles were categorized under three major headings as follows:

- Expectations of federal research facilities (Principles 1-5).
- Management and operation of federal research facilities (Principles 6-12).
- Networking in federal research facilities (Principles 13-14).

**Task Force Report Addresses Many Aspects of Master Plan**

The USDA “Animal and Plant Health Inspection Service (APHIS) and ARS Master Plan for Facility Consolidation and Modernization at Ames, Iowa (Master Plan),” currently under review by the USDA and Congress, proposes consolidation and modernization of the separate animal health facilities of the APHIS National Veterinary Services Laboratories (NVSL) and Center for Veterinary Biologics (CVB) and the ARS National Animal Disease Center (NADC) located on 480 acres of land, on the east side of Ames, Iowa (See “U.S. Animals at Risk,” page 1).

The Task Force report addresses many aspects of the Master Plan and provides an excellent framework to evaluate the consolidation and modernization proposed by the Master Plan. Excerpts of the report are as follows:

**Principle #7**

**Interaction among disciplines and placement of laboratories to promote effective collaboration are critically important to the creation of improved science.**

Federally supported research systems frequently face decisions regarding placement of new facilities or relocation of current laboratories. Recently, these decisions, almost without exception, have been dictated by politics. The Task Force found that such decisions were at times not in the best interest of the intramural agency nor cost-effective and did not take advantage of potential collaborative opportunities that would result in improved science.

Program justification should always precede facility construction, a matter of function before form.

The Task Force reemphasizes that research laboratories must be concerned about the critical mass of scientists present in a location. There are situations and research topics that lend themselves to virtual laboratories wherein scientists interact through various means of communications ... Other circumstances and research topics are best served when the scientists are co-located and interact on a daily basis. Recommendations:

- Co-location of federally supported and conducted research laboratories with colleges and universities should be a goal of the intramural research system.
- The USDA should request funds to facilitate the consolidation of laboratories, to the extent possible and practical, so that a broad spectrum of scientists representing multiple disciplines is present in any research laboratory.

**Principle #12**

**Bio-containment facilities for conduction research on high-risk, exotic (foreign), and invasive animal and plant pathogens and pests are imperative to the safety of workers and for protecting the environment and productivity of domestic populations.**

Animal health research, including research on foreign animal diseases and human/animal (trans-species) interactions, is and will continue to be a high priority for the future. Bio-containment facilities capable of operating at Level 3 and Level 4 are required for research with pathogens of highest risk. The ARS currently operates four bio-containment facilities for animal diseases (NADC is one of these)¹, each of which is in severe need of renovation to maintain human and animal health security.

Globally, the animal health picture is changing rapidly at this time. U.S. livestock industries are increasingly dependent on international commerce and trading livestock commodities. Because of the new trading rules, this relies more than ever on excellent disease diagnosis, surveillance, and disease-free certification. New emerging and re-emerging diseases are a serious present concern for animal agriculture and for human health. Higher standards for biocontainment, animal care, operator safety, environmental protection and quality assurance are now also expected and are being implemented around the world. Since many ARS facilities are aged, they do not provide an adequate platform for seriously addressing these future needs, and they might now seriously compromise U.S. livestock agriculture.

Livestock producer groups expressed concern to the Task Force regarding the current status of these containment facilities. The National Pork Producers Council presented a report ... advocated the construction of totally new biocontainment facilities. And, the Task Force staff visited the recently constructed Canadian biocontainment unit ... that houses both Agriculture Canada and Health Canada research facilities. This unit and new or relatively new animal isolation facilities in Australia, Spain, and Switzerland may be models for new federal structures. Recently, Germany initiated planning for a major, new, consolidated national biocontainment facility for animal disease research. This is expected to be completed within 5 years. Several universities have recently constructed Level 2 and Level 3 animal isolation facilities that incorporate new design concepts.

Concerns regarding bio-terrorism targeted to human health and animal and plant production is a national priority, and research is needed to identify mitigation strategies.

Recommendations:

- The ARS, in cooperation with APHIS, must immediately develop and implement plans for state of the art animal health research veterinary services and biocontainment...
Task Force on Research
from page 22

- The ARS must consider upgrading current Level 2 and Level 3 bio-containment for animals and constructing a Level 4 unit.

Specific Laboratory Recommendations:

Ames, Iowa - National Animal Disease Laboratory (NADC), ARS

This laboratory is a critical component of the ARS animal health research program and one of the bio-containment units in the agency. Both the self assessment and the administrative review scores were low because of the extremely high deferred maintenance cost, which has accumulated. The Task Force recommends that this facility be given priority in renovation plans. In addition, the NADC-ARS, APHIS-NVSL and APHIS-CVB are encouraged to continue collaborative planning for renovation or construction of integrated facilities at Ames, Iowa.

Inventory of U.S.-Funded Agricultural Research Facilities.

- ARS - There are 244 laboratories in 107 locations in the ARS research system. ARS owns 400,478 acres of land for research purposes.

ARS has 1,972 scientists working on 1,001 projects and its facilities include 6,524,245 sq. ft. of office/laboratory space, 1,031,147 sq. ft. of greenhouse space and 4,935,538 sq. ft. of other buildings.

A 10-year projected cost for repair and maintenance of these facilities was estimated at $874 million. Deferred maintenance was estimated at $122 million.

The report stated the NADC-ARS has 48 scientists working on 26 projects. There are 260,730 sq. ft. of office/laboratory space and 228,506 sq. ft. of other buildings on 409 acres. The 10-year repair and maintenance cost was estimated at $188 million.

- Forest Service - The Forest Service has 77 laboratories in 67 locations across the country. Of the 191 million acres of forest and range lands managed by the Forest Service, 408,598 acres are officially designated as Experimental Forests.

Deferred maintenance on Forest Service facilities was estimated at $20,779.

- Land Grant Universities - There are 78 land grant universities located in all 50 states, the Caribbean, Pacific territories, and Washington, D.C. (that have USDA funded research facilities).

The land grant institutions have extensive research programs, much of which is conducted through the agriculture experiment station. The research infrastructure is extensive, including 25,236,498 assignable square feet (NASF) of office and laboratory space and 885,863 acres of land. Deferred maintenance was estimated at $656 million.

The ARS operates four biocontainment facilities, as follows:

- NADC, Ames, Iowa.
- Plum Island Animal Disease Center, Orient Point, New York.
- Southeast Poultry Research Laboratory, Athens, Georgia.
- Arthropod-Borne Animal Disease Research Laboratory, Laramie, Wyoming.

BSE & FMD Chaos
from page 1

The effect of BSE diagnosed in our country would cause public fear in eating beef causing economic collapse of cattle producers, feedlots, packing houses and ancillary groups resulting in an economic recession of a magnitude neither Federal Reserve Chairman Greenspan nor President Bush have ever contemplated. Likewise, foot-and-mouth disease would disrupt the U.S. meat production, processing and meat distribution industries and cause the loss of $5 billion in export sales. Yet in the face of this dual threat, both USDA-APHIS and most official state animal health agencies are less prepared with dollars and people than we were 25 years ago. (See Table 2 “Warning Signs,” page 24.)

Foot-and-mouth disease confirmation is done only at Plum Island. BSE diagnosis would be done at Ames or one of the laboratories the USDA has approved. The BSE surveillance of bovine brains that is conducted at Ames is a necessary line of defense. However, the facilities and the number of people are inadequate, and the strain on their capabilities with a U.S. outbreak of either of these diseases is unknown.

To upgrade the Ames facilities, a meager $9 million was appropriated last year for architectural design and engineering for which $37 million is required. We lobbied unsuccessfully for the full amount. But even with the $9 million, Congress foolishly restricted that only $2 million be spent before March 1st when the Secretary of Agriculture must justify the other $7 million. This is classic “a day late and a dollar short.” Despite the urgency and despite what we felt was a consistent job to inform the House and Senate appropriators, we obviously failed to connect. The new Secretary of Agriculture, Ann Veneman, has not responded to the appropriation committees on the question of the remaining $7 million the committees will supposedly release for Ames.

It may be that Secretary Veneman is being held up by the new Bush Office of Management and Budget (OMB) or somebody in the White House is telling her to go slow, but the delay is dangerous.

American Veterinary Medical Association (AVMA) President Jim Nave and President-elect Jim Brant, have asked for a meeting with Secretary Veneman to talk about coordination between USDA and veterinarians on BSE and FMD, and also to discuss the under-funded facilities at Ames that is central to BSE surveillance and diagnosis.

From the food provider side dependent upon consumer confidence, I sought out McDonald’s head of food safety, Dr. Skip Seward. Based on what they have learned in Europe, I asked him what steps they believe the United States should take to minimize the threat and to protect us from BSE.

Dr. Seward tells me that not all slaughter cattle are stunned safely.
BSE & FMD Chaos from page 23

In some instances brain hemorrhage occurs and that could disseminate the prion associated with the disease.

That is just one of their concerns about what we are doing to minimize the chance of BSE devastating the U.S. beef industry. Dr. Seward also says that it is essential to be able to trace an infected animal to the originating feedlot and herd. Dr. Gary Weber believes that the National Cattlemen’s Beef Association is ready to consider a method of traceback.

What do we do now? We should let Secretary Veneman and the White House know that the funds for the Ames Master Plan rather, than being delayed, should be accelerated. Know anyone in the White House? I have called Vice President Cheney’s office and they are checking into it. New Health and Human Services Secretary Thompson has let it be known that he has a great concern about BSE and is making it a high priority. That is good because Thompson and Veneman together can have much more impact in the Bush White House than would be the case if it were just the Secretary of Agriculture arguing that BSE or FMD are grave threats that need emergency funding.

The AVMA is working with Senator Allard to draft an emergency foreign animal diseases bill. Research on transmissible spongiform encephalopathies will be an important part. It is also essential to give the Secretary of Agriculture authority in emergencies to be able to use Commodity Credit Corporation funds immediately to hire veterinarians to assist APHIS, and to assure sufficient funding for both Ames and Plum Island.

Legislation is necessary and Senator Allard is drafting this emergency bill to be introduced soon. Dr. Finnegem and all of us in the Government Relations Division of the AVMA are consulting closely with Dr. Torres and others in USDA as well as Senators Allard, Harkin, and Grassley and the key House members.

We would appreciate any ideas or suggestions you have.

Note: Dr. Melcher serves as a consultant to the American Veterinary Medical Association.

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### Table 2 Warning Signs: Some Recent Occurrences of Disruptive Animal Diseases*

<table>
<thead>
<tr>
<th>Disease</th>
<th>Last outbreak</th>
<th>Recent outbreak</th>
<th>Country</th>
<th>Species affected</th>
<th>Impact of outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot &amp; Mouth Disease</td>
<td>1981</td>
<td>2001</td>
<td>United Kingdom</td>
<td>Cattle, sheep, swine</td>
<td>In addition to the loss of animals, farmers could lose $73 million each week that the ban on transport and marketing continues.</td>
</tr>
<tr>
<td>Foot &amp; Mouth Disease</td>
<td>1994</td>
<td>2000</td>
<td>Argentina</td>
<td>Cattle</td>
<td>Planned $5 billion expansion of exports disrupted.</td>
</tr>
<tr>
<td>Foot &amp; Mouth Disease</td>
<td>2000</td>
<td>Brazil</td>
<td>Cattle</td>
<td>Increased vaccination; loss of export from disease-free regions</td>
<td></td>
</tr>
<tr>
<td>Foot &amp; Mouth Disease</td>
<td>1994</td>
<td>Paraguay</td>
<td>Cattle</td>
<td>To be determined</td>
<td></td>
</tr>
<tr>
<td>Foot &amp; Mouth Disease</td>
<td>1973</td>
<td>Mongolia</td>
<td>Cattle, sheep, goats, calves</td>
<td>Disease spreading; vaccination program initiated</td>
<td></td>
</tr>
<tr>
<td>Bovine Spongiform</td>
<td>Never before</td>
<td>1986</td>
<td>United Kingdom</td>
<td>Cattle</td>
<td>Major disruption of cattle industry</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bovine Spongiform</td>
<td>Never before</td>
<td>2000</td>
<td>Germany, Portugal, Italy, Spain</td>
<td>Cattle</td>
<td>European Union’s Executive Office estimated that dealing with BSE in Europe would cost about $1 billion per 6 months.</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>reported</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hog Cholera</td>
<td>1987</td>
<td>2000</td>
<td>United Kingdom</td>
<td>Swine</td>
<td>16 confirmed cases; 75,000 pigs slaughtered and 190,000 pigs removed from entry into food chain; pig meat production down 10%; impact expected to hurt hog industry for two years because of impact on breeding program</td>
</tr>
<tr>
<td>Hog Cholera</td>
<td>1997</td>
<td>Dominican Republic</td>
<td>Swine</td>
<td>Spread from Haiti to Dominican Republic; between 1997 and 1999, slaughter of 17,000 pigs and vaccination of 1.3 million pigs; concern of potential spread to U. S.</td>
<td></td>
</tr>
<tr>
<td>Hog Cholera</td>
<td>1984</td>
<td>Netherlands</td>
<td>Swine</td>
<td>Slaughter of 8 million pigs; costs estimated at $2.3 billion</td>
<td></td>
</tr>
<tr>
<td>Nipah Virus</td>
<td>Never before</td>
<td>1998</td>
<td>Malaysia</td>
<td>Swine, humans, cats, dogs</td>
<td>One million pigs eradicated; 200 people infected with 100 fatalities</td>
</tr>
<tr>
<td>West Nile Virus</td>
<td>Never before</td>
<td>1999</td>
<td>United States</td>
<td>Birds, horses, humans</td>
<td>First identified in New York City; carried by birds and mosquitoes; spread to four states in 1999 and to 12 states and the District of Columbia in 2000; causes severe neurologic infections in humans, horses, and/or other mammal species</td>
</tr>
</tbody>
</table>

*We thank the Institute for International Cooperation in Animal Biologics (IICAB), Iowa State University for developing this table utilizing ProMed and OIE sources.

USAHA’s resolution supporting Page 25, Col. 1
Representing the United States Animal Health Association, First Vice President Bob Frost (third from right) meets with leaders of the National Animal Disease Center, National Veterinary Services Laboratories and Center for Veterinary Biologics in Ames, Iowa, to discuss the proposed USDA, ARS-APHIS Master Plan for Facility Consolidation & Modernization - July, 2000

**USAHA Resolution* Supports Master Plan**  
*Passed unanimously at the 103rd Annual USAHA Meeting, October, 2000, Birmingham, Alabama.

**Background Information**

The United States Department of Agriculture (USDA) has identified the need to establish, fund and maintain a new facility in Ames, Iowa, to meet urgent national needs for research, diagnosis, and product testing related to animal health. The proposed facility will replace outdated and inefficient facilities currently used by the Animal Plant Health Inspection Service (APHIS) National Veterinary Services Laboratories (NVSL), the APHIS Center for Veterinary Biologics (CVB), and the Agriculture Research Service (ARS), National Animal Disease Center (NADC).

USDA’s ARS-APHIS Master Plan for facility consolidation and modernization is of vital concern to the USAHA. The United States presently cannot meet the standards we require of our trading partners, nor will we be able to continue to meet the requirements established by the Office of International Epizootics (OIE). The deplorable condition of these laboratories jeopardizes the health of the nation’s vast animal populations, including its animal industries, and places our country in a position of reliance on foreign laboratories and foreign diagnostic procedures.

The 100 billion dollar animal industry is second to none in the world and it contributes greatly to the positive side of our trade balance. This nation’s livestock stakeholders and citizens must have modern, updated diagnostic, research and reference laboratory facilities if they are to compete in the international marketplace. These updated facilities are critical to detect and prevent the incursion of devastating and deadly foreign animal or emerging diseases into the United States.

The USAHA and other national stakeholders must inform their memberships and their government representatives of the urgency to implement the USDA’s Master Plan. Such action is necessary to safeguard this nation’s animal health and trade, and to protect the citizens of the United States of America from food-borne diseases, bioterrorism, and emerging and foreign animal disease.

**Resolution**

The United States Animal Health Association strongly supports the United States Department of Agriculture’s Agriculture Research Service (ARS)-Animal and Plant Health Inspection Service (APHIS) Master Plan for Facility Consolidation and Modernization of the ARS National Animal Disease Center, the APHIS National Veterinary Services Laboratories, and the APHIS Center for Veterinary Biologics and recommends the construction, equipping, operation and maintenance of the Ames, Iowa National Animal Health facilities depicted in the United States Department of Agriculture Master Plan. These facilities are essential to protect and ensure our nation’s food safety and supply and its 100 billion dollar animal industries.

A copy of this resolution shall be delivered to the Secretary of Agriculture, Congress, and the President of the United States of America.

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**U.S. Animals at Risk**  
from page 24

the proposed Master Plan is a continuation of its long-standing alarm over the progressive deterioration of the capabilities of these vital national labs and the associated increased risk to the the health of the nation’s vast animal populations. (See “USAHA Resolution,” next column.)

In 1998, the “USAHA” newsletter began reporting on the condition of these facilities and programs with front-page, banner-headline stories: “Renovation Needed At NADC” (April 1998), “NVSL & CVB Facility Needs Acute” (September 1998), and “Foreign Animal Disease Training at Plum Island” (February 1999).

Many animal owners and organizations concerned with animal health issues have expressed similar alarm and are actively supporting the Master Plan including:

- American Veterinary Medical Association
- American Association of Veterinary Laboratory Diagnosticians
- National Association of State Departments of Agriculture
- American Farm Bureau Federation
- National Institute for Animal Agriculture
- National Cattlemen’s Beef Association
- National Bison Association
- Animal Agriculture Coalition
- National Chicken Council
- National Pork Producers
- National Poultry Improvement Plan
- And many, many more

**Purpose of Special Edition**

The purpose of this special edition of the newsletter is to provide readers with information about the NVSL, CVB and the NADC, the critically important role they play in the protection of animal and public health in the United States, their facility needs and how the Master Plan proposes to address these needs.
Delivering Health Care to the Nation's 1.7 Billion Plus Animals
(Selected Resources and Activities)

U.S. Animals at Risk from page 25

Providing health care to the nation’s animal populations

The data in Table 1 (front page) estimates there are 1.7 billion animals of selected types living daily in the United States. Other animal populations, including laboratory animals, aquaculture, the complete spectrum of wildlife, and exotic animals are not included. The actual size of the animal population living daily in the country is larger.

Since the founding of our country, animals have and continue to play an important role in our lives in terms of food, companionship, recreation, work and stewardship of nature. Maintaining the health these vast populations is important to our way of life, economy and to public health.

Over the decades, we have developed an effective animal health care delivery system in the United States, which is graphically depicted by Figure 1 above.

The successful delivery of quality health care to animals is dependent on a myriad of cooperative programs and the flow of information and services between and among independent local, regional and national resources.

Local animal health resources are largely private-sector enterprises, whereas regional and national resources are largely public-sector institutions and agencies at the state and national levels.

Generally speaking, local resources deliver health care to privately owned animals, whereas regional and national resources provide health care for publicly owned animals and wildlife. All use the resources of the allied animal health industry.

Regional and national resources provide additional capabilities vital to delivery of effective health care for all animals, including:

- Animal disease research and diagnostic support services.
- Regulation of animal biologics, drugs, and safety of foods of animal origin.
- Leadership, resources and legal authorities for cooperative regulatory disease control and care programs that protect our animal populations and facilitate interstate and international shipment of animals and animal products.

Paramount in this leadership responsibility is the development and implementation of our nation’s plan for prevention of, preparedness for, response to and recovery from outbreaks of foreign animal diseases. (See “6th Edition of Foreign Animal Disease.” page 30.)

National forum for animal health

Developing a national consensus among local, regional and national resources on uniform methods to solve certain animal health problems is critically important to the effectiveness of our animal health-care delivery system. This can only be accomplished by providing a permanent, dynamic, science-based forum for interested parties at all levels in the private and public sector to discuss and develop solutions to animal health problems.

The United States Animal

Page 27, Col. 1
Health Association has served as the nation’s science-based, animal health forum for this very purpose since 1897. (See “What is the USAHA?” page 32.)

Other national organizations, such as the National Institute of Animal Agriculture, have provided a similar, though somewhat different, forum for many years.

**Benefits**

Benefits of an effective animal health care system include:

- **Economic** - Maintaining the nation’s diverse animal populations to meet domestic and international need is a large enterprise in the United States and contributes significantly to the nation’s economy. Good health of our animals is central to the productivity and economic viability of this enterprise.

- **Food, nutrition and personal freedom** - Foods of animal origin are a major part of Americans’ diet and nutrition. Maintaining good animal health is central to providing plentiful, high quality foods at low cost to the consumer.

Americans enjoy the lowest expenditure for food consumed at home as a percent of total personal consumption expenditures in compared countries, thus freeing up individual financial resources and priceless time for many citizens to pursue personal interests.

- **Public health** - The prevention and control of zoonotic diseases (diseases of animals that are transmissible to man) in animals, such as rabies, tuberculosis, brucellosis, West Nile virus, bovine spongiform encephalopathy, E. coli, and salmonella is important to the health of Americans.

- **Environmental health** - Assuring the safety of foods of animal origin contributes to a safer environment for humans, similar to efforts to assure safe water supplies and sanitary sewage disposal. Animals can serve as important sentinels of the environment and monitoring animals and animal products for microbial and chemical agents provides valuable medical intelligence.

- **Mental health and humane needs** - Animals play an important role in the life of many citizens. The humane treatment and responsible stewardship of our vast animal populations, including the provision of good health care, is important to the nation.

### Cost of disease and other warning signs

Estimates of annual U.S. costs of selected diseases being addressed by programs of the NVSL, CVB and NADC are shown in Table 3 below. Three types of costs are considered: value of lost productivity, monitoring costs, and the cost of a potential outbreak.

As a nation, we are receiving a cascade of warning signs that our country’s animal populations are at risk, not only from domestic diseases, but also from disruptive foreign

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Annual U.S. costs of selected diseases being addressed by NADC, NVSL and CVB programs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Value of lost productivity</td>
</tr>
<tr>
<td>Cattle</td>
<td>(millions)</td>
</tr>
<tr>
<td>Mastitis (dairy)</td>
<td>$1,700</td>
</tr>
<tr>
<td>Johne’s Disease (dairy)</td>
<td>$200-250</td>
</tr>
<tr>
<td>Bovine leukosis virus (BLV) (dairy)</td>
<td>$700</td>
</tr>
<tr>
<td>Brucellosis</td>
<td></td>
</tr>
<tr>
<td>Bovine tuberculosis</td>
<td></td>
</tr>
<tr>
<td>Swine</td>
<td></td>
</tr>
<tr>
<td>Porcine Reproductive &amp; Respiratory Syndrome (PRRS)</td>
<td>$284-706</td>
</tr>
<tr>
<td>Respiratory diseases</td>
<td>$92-126</td>
</tr>
<tr>
<td>Pseudorabies virus (PRV)</td>
<td>$21-33</td>
</tr>
<tr>
<td>Poultry</td>
<td></td>
</tr>
<tr>
<td>Avian influenza (AI)</td>
<td></td>
</tr>
<tr>
<td>Equine</td>
<td></td>
</tr>
<tr>
<td>Equine infectious anemia (EIA)</td>
<td></td>
</tr>
<tr>
<td>Contagious equine metritis (CEM)</td>
<td></td>
</tr>
<tr>
<td>Transmissible spongiform encephalopathies (TSE)</td>
<td></td>
</tr>
<tr>
<td>Scapie</td>
<td></td>
</tr>
<tr>
<td>Bovine spongiform encephalopathy (BSE)</td>
<td></td>
</tr>
<tr>
<td>Chronic Wasting Disease (CWD)</td>
<td></td>
</tr>
<tr>
<td>Food-borne diseases</td>
<td></td>
</tr>
</tbody>
</table>

* estimated cost without eradication program; ** value of ‘98 equine exports; *** value of beef & cattle exports; **** About one-fourth of estimated $6.4 million cumulative cost to states and elk producers for control of CWD in captive elk, 1997-2000. (Table was prepared using excerpts from a summary of publications provided by the NADC, NVSL & the Center for Epidemiology and Animal Health. The years the cost estimates were based on varied from 1992 to 2001.)

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animal diseases now active in many areas of the world. Such diseases have grave economic and public health consequences. (See Table 2, “Warning Signs,” page 24.)

These costs and warnings emphasize the importance and value of maintaining and improving animal health in the United States.

Where do the NVSL, CVB and NADC fit in all of this?

The NVSL, CVB and NADC are critical and indispensable national resources for our animal health care delivery system. The programs of these three USDA laboratories, based in Ames, Iowa, touch the lives of the estimated 1.7 billion animals living daily in our country in a variety of ways.

The NVSL is the foundation for the nation’s multitude of veterinary diagnostic laboratories located throughout the 50 states. It is the premier national reference resource for all diagnostic laboratories. (See “What is the NVSL?,” page 8.)

NVSL is an active support partner for APHIS-Veterinary Services animal health programs, including the diagnosis of foreign animal diseases. The latter is carried out by NVSL’s Foreign Animal Disease Diagnostic Laboratory, which is co-located with the Plum Island Animal Disease Center on Plum Island, New York.

The CVB’s influence on animal health is enormous through its responsibility for the safety, efficacy and licensing of all commercial vaccines and biologics used in animals. Whereas responsibility for human vaccine licensing is with the Food and Drug Administration, for animal vaccines it is the responsibility of the USDA. (See “What is the CVB?,” page 8.)

The NADC is the nation’s largest animal disease research laboratory and is a critical national resource for the development of new information and technology for the control of animal diseases and safety of foods of animal origin. (See “What is the NADC?,” page 9.)

The importance and impact of these three Ames, Iowa, national resources on the delivery of health care in the United States cannot be overemphasized. (See Figure 1, page 26.)

Food expenditure in the U.S.

Putman and Allhouse’s study of food consumption from 1970-97 found that Americans spent $715 billion for food in 1997 and of this individuals paid 84 percent, governments and businesses spent 15 percent and 1 percent was produced and consumed at home with little cash outlay.

Away-from-home meals (restaurants, etc.) and snacks captured 45 percent of the food dollar in 1997, up from 34 percent in 1970.

In real terms (adjusted for inflation) per capita income increased 48 percent between 1970 and 1997 and during the same period, real food expenditures per capita increased 23 percent. As a result, the percentage of income spent for food has declined.

Food expenditures by families and individuals were 13.8 percent of disposable income in 1970 and 10.7 percent in 1997.

In 1994, Americans spent only 7.4 percent of their personal consumption expenditures for food to be eaten at home. This compares with 10.3 percent for Canada and 11.2 percent for the United Kingdom. In less developed countries, such as as India and the Philippines, at-home food expenditures often account for more than 50 percent of a household’s budget.

In relation to total per capita personal consumption, Americans spend the least on food.

American agriculture’s unprecedented productivity over the decades has been a key factor in the lowest-cost-of-food advantage we, as citizens, enjoy every day.

Food of animal origin in the American diet

Foods of animal origin (red meat, poultry meat, dairy products, eggs and fish) are a major choice for Americans and provide us with a wide variety of nutrients, including 28 percent of the calories, 62 percent of the protein, 48 percent of the fat, 77 percent of the calcium, 60 percent of the phosphorous and 99.4 percent of the vitamin B-12 in our diet. (See Figure 2, adjacent column.)

The trend in the United States for consumption of
foods of animal origin remains strong. In 1998, per capita consumption of poultry meat was 123 percent of that consumed in 1989, table eggs 104 percent, dairy products 103 percent, red meat 100 percent, and fish 95 percent. (See Figure 3, opposite page and Table 4, above.)

Maintaining a plentiful and efficient supply of foods of animal origin, then, is a vital national goal. And protecting the health of our livestock and poultry populations is a strategy of highest national priority in the attainment of this goal.

Livestock and poultry production in the United States

Of the estimated 1.7 billion animals of selected types living daily in the United States, livestock and poultry populations number approximately 1.6 billion. These include: 99 million cattle, 60 million pigs, 7 million sheep, 600 thousand Angora goats, 1.3 billion chickens, and 82 million turkeys.

In 1999, the nation’s livestock and poultry populations generated $96 billion in cash receipts. This represented about half of the cash receipts from plant and animal commodity sales. (See Table 5, column 3.) Preliminary receipts in 2000 are estimated at $99 million.

The nation’s agricultural crop producers also benefit from and are dependent on our stewardship of our animal populations. Approximately $20 billion of the cash receipts generated by plant agriculture in 1999 was from the production of crops used for animal feed. (See Table 5 below.)

**World trade & international laboratory standards**

The United States is an active participant in foreign agricultural trade markets and in 1999 exported some $50 billion of agricultural products, and imported $38 billion for a net positive trade balance of $12 billion. (See Table 6 below.)

Exports of products of animal origin were $10 billion, imports $7 billion for a net positive trade balance of $3 billion.

In order to maintain access to foreign markets, our livestock and poultry populations must remain healthy and free from disruptive domestic and foreign animal diseases and we, as a nation, must be able to certify their health status according to accepted standards.

Besides the ever present threat of disruptive disease, the emergence of the necessity for accreditation of laboratories according to accepted international standards may present future roadblocks to trade. There is concern that USDA laboratory facilities in Ames, Iowa, may not meet international standards and that these laboratories may not pass the assessment required for accreditation. (See “Update on Laboratory Accreditation, page 21.”)

If our laboratories do not meet international accreditation standards, other countries can deny the importation of our animals and animal products because of our inability to prove freedom from disease.

**U.S. ranking in the world**

In terms of the size of livestock populations, the United States ranks fourth in the world in number of cattle and buffalo (after India, Brazil and China), second in hogs (after China) and fourth in milk cows (after India, Brazil and Russia). (See Figure 3, page 30)

In terms of production, the United
U.S. Animals at Risk from page 29

States ranks second in the world in the production of red meat (after China), first in poultry meat, first in milk, and second in eggs (after China). (See Figure 4, next column.)

America, then, maintains huge livestock and poultry populations of unparalleled productivity in relation to the rest of the world. Protecting the health of these animals is in our national interest and it is a big job.

The ARS-APHIS Master Plan is a key factor in assuring future protection of these and other animal populations in our country. The roles the NVSL, CVB and NADC play in the delivery of animal health care in the United States is vital. Their need for new laboratories and facilities is urgent. The USAHA urges funding of the Master Plan as rapidly as possible.

1 The $447 million cost and nine-year phasing are preliminary Shive-Hattery estimates for the Master Plan. We anticipate these estimates will change. Final official estimates were not available to us when this newsletter went to press.


The 6th edition of “Foreign Animal Diseases” is 460 pages of text plus 128 color photographs. The following are excerpts from Dr. Lonnie King’s review of the 6th and latest edition (1998) of Foreign Animal Diseases. Dr. King is Dean of the College of Veterinary Medicine, Michigan State University, and former Administrator of USDA’s, Animal and Plant Health Inspection Service.

“The United States Animal Health Association has published a new edition of Foreign Animal Diseases. This 6th edition has a revised format, a new glossary and an excellent set of colored photographs of lesions, vectors, and clinical signatures of foreign animal diseases (FAD).”

“The text is especially well done and successfully blends together essential scientific components of FAD with a practical guide that describes the diagnosis, transmission, prevention, control and eradication features of 40 potentially devastating FAD.”

“The new edition clearly and succinctly discusses and describes: etiology, host range, transmission, pathogenesis, vaccination policies, clinical findings and pathognomonic lesions, potential outcomes, public health consequences, and control and eradication strategies. The book’s format is user-friendly and with the colored photographs, Foreign Animal Diseases is an easily accessible and immensely useful reference.”

“... Because FAD may involve companion animals, horses, wildlife, zoo animals, humans since some are zoonotic, in addition to our livestock and poultry populations, I strongly believe this text should be part of every veterinarian’s library next to our medical and surgery books.”

“It is not if we will have another FAD outbreak, but rather when; it is our professional responsibility to be prepared and understand our roles and obligations. Foreign Animal Diseases is an essential reference for all private and public practitioners and should be fundamental to our intellectual and diagnostic armamentarium and ingrained in our veterinary conscience.”

“The USAHA and the many contributors that put the 1998 edition of Foreign Animal Diseases together are to be congratulated. I am impressed with this unique, concise and easily useable book and sincerely believe that it is a "must" for all veterinarians and food-animal producers.”

TO PURCHASE - The 6th edition of “Foreign Animal Diseases” is 460 pages of text plus 128 color photographs. To order, please send a check to USAHA, PO Box 47277, Richmond, VA 23286. Cost is $15 per copy including shipping and handling in the U.S. For more information, contact USAHA at: telephone (804) 285-3210; fax (804) 285-3367; email usaha@usaha.org; webpage www.usaha.org

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The West Nile Story
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provided from one flamingo was tested for antibodies to avian influenza, Newcastle disease, eastern and western equine encephalitis viruses.

On September 14, a virus was isolated from the eggs and in cell culture. Tests of the isolate demonstrated that it was not eastern, western, or Venezuelan equine encephalitis, avian influenza or Newcastle virus. On September 15, DVL's most experienced electron microscopist, Gary Gustafson, interrupted his vacation to come into the laboratory to examine the morphologic features of the virus isolate. He saw a virus that had the spherical shape and size (40 nm in diameter) of a flavivirus, tentatively placing it in the large family of arboviruses that are often transmitted by mosquitoes and can cause encephalitis in birds, mammals and humans (see photo inset).

At this point, a decision was made to send the unknown, putative flavivirus to the Centers for Disease Control Division of Vector-borne Infectious Diseases laboratory in Fort Collins, Colorado, for further studies. On September 25, CDC announced that they had identified the unknown virus as West Nile-like, a previously unrecognized virus in the Western hemisphere. Affected people from NYC that had been diagnosed with St. Louis encephalitis were subsequently re-diagnosed as having suffered from West Nile virus infection.

On October 5, NVSL received tissues from horses showing encephalitic signs in Suffolk County, Long Island, NY. Once again, a virus was isolated by the staff in DVL and identified as West Nile virus based on tests of the viral nucleic acid.

The diagnosis of West Nile virus in horses led the European Union to shut down the importation of horses through John F. Kennedy International Airport in NYC. There were initial concerns that horses might be a source of virus for mosquito transmission to humans.

Subsequent studies by NVSL (at the Foreign Animal Disease Diagnostic Laboratory, Plum Island, NY) and Colorado State University/CDC have shown there are low levels of viremia in horses inoculated with West Nile virus, thereby indicating that horses are most likely dead-end hosts. The NVSL has become the primary laboratory in the U.S. for diagnosis of WNV in horses, confirming 25 cases in 1999 and 59 cases in 2000.

Chicken inoculation studies by NVSL have demonstrated levels of viremia that could foster a transmission by mosquitoes, but there was no clinical disease or contact transmission between birds. It appears West Nile virus is not a concern as a pathogen in chickens, but that chickens can be a source of virus.

The result of this outstanding work by NVSL personnel was the discovery of a new, emerging virus in this hemisphere. The discovery was a direct result of the expertise and dedication of NVSL personnel to provide excellent diagnostic testing for their customers. Subsequent to identification of this zoonotic pathogen, NVSL expediently developed and implemented diagnostic tests for West Nile suspect cases. Studies were conducted to examine pathogenicity of the virus in chickens and horses. Additional projects were expedited to produce reagents and control sera.

Although NVSL was able to handle the additional testing and other activities that resulted from the high profile West Nile virus discovery, this workload severely stretched the physical limitations of the DVL. On a national scale, the West Nile outbreak was relatively small. In contrast, if the DVL was faced with a widespread outbreak of a disease such as avian influenza, other activities at NVSL would need to be curtailed to create space for emergency testing.

Our facility needs are very real in regards to coping with emerging diseases such as West Nile encephalitis and ongoing disease threats such as highly pathogenic avian influenza. NVSL needs modern, well designed space to do the important work of a national and international reference laboratory. NVSL has the dedicated, experienced and knowledgeable staff able to respond to emerging disease issues, but lags behind the rest of the world in modern, state of the art, laboratory facilities.
The United States Animal Health Association, the nation’s animal health forum for 104 years, is a science-based, voluntary organization of official state and federal animal health agencies, national allied organizations, regional representatives and individual members founded in 1897 to protect animal and public health.

USAHA’s mission is to:
1. Serve as a forum for communication and coordination among state and federal governments, universities, industry and other groups on issues of animal health and disease control, animal welfare, food safety and public health.
2. Serve as a clearing house for new information and methods which may be incorporated into laws, regulations, policy, and programs.
3. Act to develop solutions to animal-health related issues based on science, new information and methods and the ability to develop a consensus for changing laws, regulations, policies, and programs.

The Association’s mission is implemented through deliberations of its 33 science-based committees and the adoption of resolutions and recommendations aimed at solving problems. Committee size varies from 11 to 107 members.

USAHA is administered and its policy determined by the Executive Committee and Board of Directors. The Association maintains an office in Richmond, Virginia (www.usaha.org).

USAHA has met annually for 104 consecutive years and produces a printed proceedings of each meeting. The proceedings represent the most complete history of the nation’s animal health endeavors over the past century.

The 105th Annual Meeting of the USAHA will be held November 1-8, 2001, at the Hershey Lodge and Convention Center, Hershey, Pennsylvania.

USAHA Membership

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President's Corner from page 2

special edition will discuss some of these disease issues.

The sheer number of animal species in the United States that are susceptible to many serious animal diseases clearly shows the seriousness of our need for modern animal health laboratories.

We have been very fortunate in the United States that the serious diseases currently or recently plaguing Europe, Asia, Africa and South America have not been introduced into the United States. However, most animal disease experts are continuously telling us that “it is not a matter of ‘if’ a serious foreign animal disease will be introduced, it is a matter of ‘when’ such a disease will be introduced.”

Do we currently have the capability to address the incursion of a foreign animal disease such as BSE, FMD or classical swine fever? Many of our experts say we do not. What would be the cost of such an incursion, in terms of loss of animal-origin foods, loss of trade, cost of controlling and eliminating the disease and lost production? These costs would be in billions of dollars.

Several laboratory system experts from within and outside the United States have reported that the deplorable condition of our laboratory system constitutes an emergency. Now is the time for all interests to work together to gain political and financial support to immediately begin the process of rebuilding our laboratory system in the United States. To do anything less is unconscionable.

Table #1 footnotes:

1. Agricultural Statistics 2000,” USDA, NASS.
2. Daily hatching and processing assumed. Lifespan for broilers and meat turkeys estimated at 42 and 105 days respectively. Not adjusted for mortality during growing.
3. “U.S. Pet Ownership & Demographic Sourcebook,” 1997; American Veterinary Medical Association. Table 1-1: Number of dogs and cats on 12/31/96.
5. Southeastern Cooperative Wildlife Disease Study (SCWDS), private correspondence, 2/01. WT = white-tail.