**DEPARTMENT OF AGRICULTURE**

**Animal and Plant Health Inspection Service**

**9 CFR Part 93**

**[Docket No. APHIS–2006–0013]**

**RIN 0579–AC00**

## Standards for Permanent, Privately Owned Horse Quarantine Facilities

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the regulations pertaining to the importation of horses to establish standards for the approval of permanent, privately owned quarantine facilities for horses. We are taking this action because regional and seasonal demand for quarantine services for horses often exceeds the space available at existing facilities. Allowing imported horses to be quarantined in permanent, privately owned quarantine facilities that meet the criteria established in this rule will facilitate the importation of horses while continuing to protect against the introduction of communicable diseases of horses.

**DATES:** *Effective Date:* August 3, 2009.

**FOR FURTHER INFORMATION CONTACT:** Dr. Ellen Buck, Staff Veterinary Medical Officer, Equine Imports, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

**SUPPLEMENTARY INFORMATION:**

### Background

The regulations in 9 CFR part 93 govern the importation of specified animals and animal products in order to prevent the introduction of various animal diseases into the United States. The regulations in part 93 require that some of these animals be quarantined upon arrival in the United States as a condition of entry. The Animal and Plant Health Inspection Service (APHIS) operates animal quarantine facilities and authorizes the use of privately owned quarantine facilities for certain animal importations. The regulations in subpart C of part 93 (9 CFR 93.300 through 93.326) pertain to the importation of horses and include requirements for privately owned quarantine facilities for horses. Prior to this final rule, these requirements applied solely to the approval and establishment of temporary quarantine facilities for the purpose of quarantining imported horses for a specific event. However, APHIS did authorize the operation of one permanent, privately owned quarantine facility for horses, located in Los Angeles County, CA.

On December 13, 2006, we published in the **Federal Register** (71 FR 74827–74847; Docket No. APHIS–2006–0013) a proposal[1] to amend the regulations by establishing standards for the approval of permanent, privately owned horse quarantine facilities. We stated that such facilities, if constructed and operated using the proper safeguards, would provide an effective and efficient means of bringing horses into the United States without compromising our ability to protect against the introduction of communicable diseases of horses. In that proposal, we also withdrew an earlier proposal, published in the **Federal Register** on July 1, 2002 (67 FR 44097–44111, Docket No. 99–012–1), which would have established differing requirements in the regulations for the approval and operation of such permanent facilities.

We solicited comments concerning our proposal for 60 days ending February 12, 2007. We received 15 comments by that date. They were from horse owners, breeders, members of Congress, State agricultural agencies, equine industry groups, the operators of a quarantine facility, and several private citizens. They are discussed in the sections below, by topic.

### General Comments on the 2006 Proposed Rule

One commenter suggested that establishing standards for privately owned horse quarantine facilities was unnecessary. Citing the absence of any diseased horses that have passed through the one currently operating permanent, privately owned quarantine facility into the domestic horse population, the commenter stated that this facility has demonstrated adequate biological security measures to prevent the introduction of communicable diseases of horses into the United States. The commenter suggested that the biosecurity requirements of the proposed rule were disproportionate to the actual disease risk associated with quarantining horses at the facility.

Although the biosecurity measures in place at that particular facility may serve to mitigate the risk of disease spread from that site, we still consider the biosecurity requirements described in our proposal to be necessary. This is because APHIS based the requirements on our experience in mitigating the risk of disease introduction via imported horses. We modeled the proposed risk mitigation measures on those in place at APHIS-operated and -approved facilities, after assessing them for adequacy and general applicability. We determined such an approach to be necessary in order to create national standards for such facilities.

The fact that no equine diseases are known to have passed through the one privately owned facility currently in operation into the domestic horse population does not in itself address the potential disease risks that other quarantine facilities elsewhere in the United States could encounter.

Two commenters suggested that private ownership of permanent horse quarantine facilities presents an unavoidable and irresolvable conflict of interest, inasmuch as we allow a private entity to operate a Federally regulated facility. One of these commenters recommended that APHIS withdraw the proposed rule, and assume management of all horse quarantine facilities. If that is not feasible, the commenter suggested exclusive oversight of the facilities should be delegated to public agencies, including universities, agricultural colleges, and other institutions under contract or cooperative agreement with APHIS.

We do not consider private ownership of an equine quarantine facility to present an irresolvable conflict of interest, provided that the facility operates under adequate Federal oversight. We consider the degree of APHIS oversight of private facilities required by this rule to be sufficient to mitigate this potential conflict of interest.

A more extensive discussion of APHIS oversight of permanent, privately owned equine quarantine facilities is found below, in the section titled ''Changes and Clarifications with Regard to APHIS Oversight.''

Several commenters questioned APHIS' intent in establishing standards for privately owned quarantine facilities. One suggested that APHIS will use the rule to expedite the slaughter of horses, while another stated that the rule constitutes collusion with the parimutuel horseracing industry to facilitate gambling. Accordingly, both commenters suggested we withdraw the rule.

As explained in the proposed rule, our reasons for developing standards for permanent, privately owned equine quarantine facilities were the increased demand for import quarantine facilities that has arisen in the last 20 years, the geographic distribution of the currently operating horse quarantine facilities,

[1] To view the proposal and the comments we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0013.*

which can make it difficult or costly to import horses to some areas, and the inability, because of the nature of their construction and operation, of temporary, privately owned quarantine facilities to fill the continual demand for import quarantine services.

One commenter stated that the proposed rule lacked sufficient safeguards to protect the health of the domestic horse population. The commenter pointed out that the rule does not establish a ''follow-up'' system for horses once they are released from quarantine and does not address diseases of horses endemic to the United States.

The purpose of horse quarantine facilities is to observe imported horses for any sign of communicable equine diseases, in order to prevent the introduction or further dissemination of those diseases within the United States. In this regard, it is worth noting that no permanent equine quarantine facility, whether privately or Federally operated, currently has a ''follow-up'' system such as that suggested by the commenter. Instead, APHIS conducts tracebacks during animal disease events to determine the premises of origin of the outbreak, and also administers various domestic surveillance, control and eradication programs for equine diseases. Among these programs are our surveillance and vaccination efforts to prevent the spread of West Nile equine encephalomyelitis and our surveillance and control program for contagious equine metritis (CEM).

The aim of the proposed rule was to create standards and protocols for permanent, privately owned quarantine facilities in order to prevent such diseases from being transmitted through these facilities and into the domestic horse population. Thus, establishing ongoing surveillance of horses of foreign origin and addressing diseases of horses endemic to the United States both fall outside of the scope of this rulemaking.

One commenter asked whether an approved facility, if vacant, could be used to house and quarantine domestic horses in transit from a disaster area, provided that the horses are subject to the same quarantine operations as horses imported into the United States.

Establishing rules for such an alternate use of permanent horse quarantine facilities falls outside of the scope of this rulemaking. However, in the event of an animal disease outbreak or a natural disaster, APHIS may consult with the operators of a quarantine facility in order to facilitate emergency operations, including emergency housing and quarantines.

Finally, one commenter asked whether we intend to gradually phase out existing APHIS-operated and -approved quarantine facilities as a result of the rule, while another suggested that we build another APHIS-operated facility on the west coast.

We will maintain the APHIS-operated facilities that presently exist. However, we have no current plans to build additional facilities.

**Changes and Clarifications With Regard to APHIS Oversight**

In the proposed rule, we stated that permanent, privately owned horse quarantine facilities would be subject to oversight by APHIS representatives, would operate under continuous APHIS oversight, and would have at least one APHIS representative overseeing the care of all horses in quarantine. We also proposed that quarantine operations, the disposal of wastes, and cleaning and disinfection procedures at the facility would occur under the oversight of APHIS representatives, and further specified that incineration activities, whether onsite or offsite, would occur under direct APHIS oversight. We stated that APHIS would furnish services related to maintenance of the facility and daily care of horses under quarantine if the operator of the facility failed to do so as provided in the proposed rule, but did not provide further criteria by which we would evaluate facilities in this regard. Finally, we proposed that the handling, washing, and disposal of soiled and contaminated clothing at the facility would have to occur in a manner approved by APHIS.

Many commenters expressed concern regarding these proposed provisions. One considered continual oversight unnecessary. Others stated that we should reevaluate the need for ongoing and direct APHIS oversight of cleaning and disinfection procedures and incineration activities.

Several commenters asserted that we failed to adequately define ''oversight.'' As a result, these commenters were uncertain whether APHIS oversight consisted of direct and continual supervision only of quarantine operations, of quarantine operations and other related procedures, or of all operations within the quarantine facility. If we intended APHIS oversight to be only of quarantine operations, the commenters stated, it was unclear whether we intended quarantine operations to take place during normal working hours or continually throughout the day. If we intended oversight to cover other procedures, the commenters were uncertain to what degree APHIS representatives would oversee them and when they would occur. Finally, several commenters asked how much APHIS oversight would cost.

We regard APHIS oversight of the facility to be necessary in order for us to carry out our responsibility under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.,* AHPA) to ensure that imported horses released from a quarantine facility are free of communicable equine diseases.

However, we have revisited the proposed rule in light of the commenters' concerns and appreciate the opportunity to clarify the nature of APHIS oversight. In our proposal, we used the term ''APHIS oversight'' in two different ways. In certain instances, it meant the responsibilities and duties that require APHIS to assume ultimate accountability for the biological security of the facility and the welfare of horses onsite, without usually being physically present at the facility. If we determine that either biosecurity or animal welfare is being jeopardized at the facility, this oversight may require us to be physically present at the facility to provide services to safeguard either biosecurity or welfare of the horses. Additionally, APHIS may withdraw approval of the facility. However, APHIS often exercises this type of oversight by developing care plans and compliance agreements with entities, and by conducting subsequent spot audits in order to ensure that the terms of these plans and agreements are followed.

In other instances within the proposed rule, ''APHIS oversight'' meant those occasions when APHIS representatives must be physically present at the facility to carry out a particular function. Those occasions will vary somewhat from facility to facility, and may even vary within the facility from importation to importation. Nonetheless, we have determined that APHIS representatives must be present at a facility to monitor import quarantine operations whenever they occur, and to provide other technical services related to biological security. Technical services include, but are not limited to, those measures necessary to prevent or limit the spread of disease within the facility if a horse in quarantine has been determined to be affected with an equine disease.

To clarify this distinction, we have modified several paragraphs in § 93.308 from our proposal to make the occasions that will necessitate our physical presence at the facility more explicit:

- In the proposed rule, paragraph (c)(1)(ii)(C) stated that, in order for a

facility to be approved, the Administrator must determine that sufficient APHIS personnel are available to serve as representatives at the facility and to provide continuous oversight over import quarantine operations and other technical services related to biological security of the facility. In this final rule, that paragraph now states that, if a facility is approved, APHIS representatives will be present at all import quarantine operations to monitor them and will be present to provide technical services to ensure the biological security of the facility. It also specifies that these technical services include overseeing the disposition of an infected or exposed horse at the facility, in accordance with paragraph (c)(4)(v)(H). Import quarantine operations include, but are not limited to, visual inspection of the animal on arrival, identification of the animal with its accompanying import certificate, serological testing, and monitoring of routine diagnostic tests.

• In the proposed rule, paragraph (c)(2)(ii)(B) stated that the compliance agreement that the operator of a privately owned facility or the operator's agent and the Administrator must execute must provide that the facility's quarantine operations are subject to the oversight of APHIS representatives. In this final rule, as part of the agreement, the operator now must agree to have APHIS representatives present at all import quarantine operations at the facility in order to monitor the import quarantine operations.

• In the proposed rule, paragraph (c)(4)(i)(A) stated that, as part of the operating procedures at the facility, the quarantine of horses at the facility are subject to the oversight of APHIS representatives authorized to perform the services required by the rule and by the compliance agreement. In this final rule, that paragraph now specifies that APHIS representatives will be physically present at and monitor all import quarantine operations at the facility.

• In the proposed rule, paragraph (c)(4)(v)(H) stated that should a horse be determined to be infected with or exposed to a communicable disease of horses, the final disposition of the horse must occur under the direct oversight of APHIS representatives. In this final rule, that paragraph now states that APHIS representatives must be physically present at and directly monitor the disposition of the horse.

• In the proposed rule, we referred throughout § 93.308 to ''quarantine operations.'' In this final rule, to better delineate those procedures for which APHIS representatives will maintain a physical presence at quarantine facilities, we have changed every such reference to ''import quarantine operations.''

As part of the reevaluation that led to these clarifications, we also examined whether the maintenance of the facility, the daily care of horses under quarantine, the disposal of wastes, cleaning and disinfection procedures, incineration activities, and the handling, washing, and disposal of soiled and contaminated clothing at the facility could be performed without APHIS personnel being physically present on each occasion. We have determined that these activities and procedures need APHIS oversight, but that it is not necessary for APHIS representatives to maintain physical presence at them and direct or continual monitoring of them, unless we have reason to believe that these activities are being neglected or carried out in a manner that compromises either the biological security of the facility or the welfare of horses onsite.

In order for APHIS to allow these practices to be conducted without our physical presence, however, we have determined that we must possess adequate knowledge of the standard practices that the operator of the facility will employ regarding these activities prior to APHIS' initial approval of the facility. We have also determined that we must possess some mechanism whereby we can evaluate the operator's adherence to these practices once the site is operational and, if necessary, take remedial measures to address any failure to comply with these standards.

As a result of this determination, in § 93.308, we have modified proposed paragraph (c)(2)(ii), which sets forth requirements for the compliance agreement that an operator of a facility or his or her agent must execute prior to APHIS approval of the facility, to specify that each compliance agreement must provide that the operator agrees to demonstrate, to the satisfaction of the Administrator, that the routine cleaning and maintenance of the facility, the daily care of animals in quarantine, the disposal of wastes at the facility, the cleaning and disinfection procedures employed by the facility, the handling, washing, and disposal of soiled and contaminated clothing worn within the facility, and the disposal of dead horses, whether onsite or offsite, adhere to the best practices of biological security and animal care; and provide that the operator agrees to random spot audits by APHIS representatives to determine whether employees and other personnel are complying with these practices.[2] These two requirements are found in subparagraphs (E) and (F) of paragraph (c)(2)(ii) in § 93.308 of this final rule.

Accordingly, proposed paragraph (c)(4)(i)(B) of § 93.308, which pertained to the maintenance of the facility and the daily care of animals in quarantine, has been modified to reflect these changes to the compliance agreement. In this final rule, the paragraph provides that, if, as the result of a spot audit, or for any other reason, APHIS determines that the operator has failed to properly care for, feed, or handle quarantined horses as required by this final rule or in accordance with the terms of the compliance agreement, or has failed to maintain and operate the facility as provided in the rule or in accordance with the terms of the compliance agreement, APHIS representatives will furnish such services, will make arrangements for the sale or disposal of quarantined horses at the quarantine facility owner's expense, or will begin the process for withdrawal of approval of the quarantine facility. In the proposed rule, this paragraph did not mention either spot audits or the compliance agreement, and did not state that nonadherence to the provisions of the rule could result in withdrawal of approval.

In this final rule, the following paragraphs have been modified to specify that the procedures detailed in the paragraphs must be carried out in accordance with the term of the compliance agreement, and to state that the procedures are therefore subject to spot audits:

• Paragraph (c)(3)(iii)(F), which pertains to the disposal of wastes at the facility;

• Paragraph (c)(3)(iii)(H), which pertains to incineration activities;

• Proposed (c)(3)(iv)(F), which pertains to the disposal of wastes at the facility;

• Paragraph (c)(4)(iv)(C), which pertains to the handling, washing, and disposal of soiled and contaminated clothing worn within the quarantine facility;

• Paragraph (c)(4)(iv)(D), which pertains to cleaning and disinfection procedures for equipment used in the quarantine area;

• Paragraph (c)(4)(iv)(E), which pertains to cleaning and disinfection

[2] Best practices for biological security and animal care are those employed at our Federally maintained quarantine facilities or otherwise specified within operational memoranda issued by APHIS' Veterinary Services division. APHIS will facilitate the operator's access to these best practices prior to the execution of the compliance agreement.

procedures for vehicles entering and exiting the quarantine area; and

• Paragraph (c)(4)(iv)(G), which pertains to cleaning and disinfection procedures for lot-holding areas.

If, at any time, an APHIS representative discovers that employees or other authorized personnel are not following the terms of the compliance agreement, he or she may issue additional instructions regarding the measures that these individuals must take while import quarantine operations are being conducted at the facility (paragraph (c)(4)(ii)(C) of § 93.308). If employees do not follow these additional instructions, APHIS representatives may require the operator to bar these personnel from the facility (paragraph (c)(2)(ii)(D) of § 93.308). Finally, in this final rule, both paragraphs (c)(1)(iv)(C)(*1*) and (c)(4)(i)(B) of § 93.308 provide that nonadherence to the terms of this rule or the compliance agreement by the operator or his or her employees may result in withdrawal of approval of the quarantine facility.

In response to the commenters' questions regarding when APHIS would exercise oversight of the facility, APHIS representatives will ordinarily render their services during their normal tour of duty as APHIS employees. An APHIS employee's tour of duty may vary, but always excludes Sundays and holidays. If circumstances require an APHIS employee to be present at the facility outside of his or her tour of duty, we will charge an overtime rate for those services. This rate is found in 9 CFR 130.30(b).

Similarly, in response to the commenters' questions regarding the cost associated with APHIS oversight, in the proposed rule, we stated that we will charge for APHIS' inspection of a facility at the hourly rates listed in 9 CFR 130.30. We also stated that the operator of the facility would be charged for the services APHIS representatives provide in accordance with 9 CFR part 130.

In a related matter, as we mentioned above, proposed § 93.308(c)(1)(ii)(C) stated that part of APHIS' initial evaluation of an application for approval of a facility would be a determination of whether sufficient APHIS personnel are available to serve as APHIS representatives at the facility, in order to provide continuous oversight of import quarantine operations and other technical services pertaining to biological security.

Several commenters expressed concern regarding this paragraph. One commenter stated that APHIS does not currently have sufficient personnel at existing APHIS-operated quarantine facilities, and thus cannot assume oversight of privately owned facilities. Another stated that recent outbreaks of equine herpes virus (EHV–1) at an APHIS-operated quarantine facility suggest that the biological security risks associated with horse quarantine facilities have increased and necessitate that more personnel be assigned to the facility than APHIS can provide. A third commenter stated that it is unlikely that APHIS personnel will be available to continually staff the facilities, and we should therefore consider providing funding opportunities through cooperative agreements for State animal health officials to provide health inspection services at the facilities. A fourth commenter suggested that, in the event of a lack of adequate personnel, APHIS should delegate supervision of certain quarantine operations, such as the collection of blood samples, to private practitioners.

Those commenters who stated that APHIS does not have sufficient personnel to serve as representatives at or to provide continual oversight of a quarantine facility appear to have based their evaluation, in large part, on an expansive understanding of ''APHIS oversight.'' We consider the clarifications and amendments we have made to the proposed rule regarding the nature of this oversight to be sufficient to address this aspect of the commenters' concerns.

In addition, by making a determination that APHIS must have sufficient personnel to serve as representatives to a facility one of the conditions for the Administrator's initial approval of the facility, we are afforded the opportunity to evaluate both the extent to which such approval could have a detrimental impact on existing import quarantine operations at APHIS-operated facilities, and the likelihood that a future outbreak of a foreign animal disease would cause us to have insufficient personnel to oversee import quarantine operations and assure biosecurity at any facility, whether privately operated or maintained by APHIS. If the Administrator determines that approval of a privately operated facility would jeopardize import quarantine operations or biosecurity at an existing quarantine facility, he or she will not grant such approval.

We consider APHIS oversight of import quarantine operations and other related services conducted at a facility to be necessary for us to carry out our responsibility under the AHPA to prevent the introduction of a foreign communicable disease of horses into the domestic equine population. We do not consider it appropriate to delegate this responsibility to private practitioners or State animal health officials. However, this rule does not amend or supplant the existing regulations in 9 CFR part 93 that pertain to the various operations that accredited veterinarians and State animal health officials may conduct in order to provide care for imported horses or in order to prevent the spread of communicable equine diseases.

We address the commenter's concerns regarding the biological security of equine quarantine facilities in light of the 2006 outbreak of EHV–1 in the section below titled ''Comments on Construction Requirements.''

**Comment Regarding the Role of State Departments of Agriculture**

One commenter asked whether APHIS oversight involves parallel supervision of the quarantine facility by State departments of agriculture, State veterinarians, and State animal health agencies. If it does not, the commenter suggested the final rule authorize such entities to be consulted and have some authority in the approval of the facility, in any decision regarding the location of the facility, in approval of contingency plans for emergency medical care of quarantined horses and possible disposal of all horses housed at the facility, in the granting of variances from the terms of the rule, and in the decisionmaking process for denying or withdrawing approval of the facility.

As we mentioned above, it is APHIS' responsibility under the AHPA to prevent the introduction of foreign communicable diseases of horses into the domestic equine population. As part of this duty, it is necessary for us to make the ultimate determination in those areas described by the commenter. Therefore, we do not consider it possible to delegate responsibility to or share responsibility with State animal health authorities for these determinations in the manner requested by the commenter.

However, our responsibility does not preclude APHIS from asking State authorities to provide guidance regarding the approval of a proposed facility. Indeed, on many occasions, we may have to solicit such input in order to determine whether a proposed facility meets local and State environmental regulations. Such a determination is required in paragraph (c)(5) of § 93.308.

In addition, APHIS has recently undertaken an initiative to facilitate greater communication with State agricultural agencies, and to establish greater collaboration among Federal and State officials in the development of

effective strategies to respond to animal disease events and emergency situations at the State and local levels. We will implement this rule in a manner that is consistent with that initiative, especially in matters pertaining to the biosecurity of the facility and the health of livestock in the area of the facility.

**Comment Regarding Temporary, Privately Owned Quarantine Facilities**

In our proposal, we proposed to amend paragraphs (b) and (c) of § 93.308 by combining the two paragraphs, which contained requirements for temporary, privately owned horse quarantine facilities, into a single paragraph (b), and by making several nonsubstantive changes to the text of these paragraphs.

One commenter asked whether these changes established new regulations for such temporary facilities. In the commenter's estimation, it would prove impracticable to have temporary facilities adhere to the same standards as permanent facilities.

We are maintaining the existing provisions for temporary, privately owned quarantine facilities. This rule establishes standards solely for permanent facilities.

**Comments Regarding Denial or Withdrawal of APHIS Approval**

In § 93.308, proposed paragraph (c)(1)(iv) set forth a protocol for denying or withdrawing approval of a permanent, privately owned horse quarantine facility, and reasons for APHIS to deny or withdraw such approval. Among other reasons, we stated that, if the operator or a person responsibly connected with the business of the quarantine facility acts as a paid agent (broker) for the importation or subsequent sale of a horse, APHIS could deny or withdraw approval of a privately owned horse quarantine facility.

We deemed a person to be responsibly connected with the business of the quarantine facility if that person has an ownership, mortgage, or lease interest in the facility's physical plant, or if that person is a partner, officer, director, holder, or owner of 10 percent or more of its voting stock, or is an employee in a managerial or executive capacity. We included these provisions in our December 2006 proposal in response to comments that we received regarding our July 2002 proposal. The commenters on the earlier proposal suggested that an operator who also acted as a broker would face conflicts of interest while housing, treating, and caring for horses imported by other brokers.

We received two comments regarding these provisions. Both commenters considered the measure to be overly restrictive, and suggested that a person engaged in both operation of the facility and import brokerage would not necessarily encounter a substantive and irresoluble conflict of interest. One of these commenters asserted that the one permanent, privately owned horse quarantine facility currently in operation has functioned as an import broker almost since its establishment, without incident or complaint. In lieu of these provisions, the commenters suggested that APHIS forbid operators from discriminating against any importer or agent, under penalty of fines or withdrawal of approval.

We are making no changes to the proposed rule in response to these comments. If an operator acts as a broker, this may not necessarily lead to conscious discrimination against the horses of other brokers, or in favor of one's own horses. However, it does predispose the operator to act in a manner that serves, or at least preserves, his or her economic interest in the horses under quarantine, and creates an incentive for the operator to discriminate in favor of his or her own horses, those of a family member, or those belonging to an individual who has a business relationship with the operator. Prohibiting operators from acting as brokers is necessary to prevent these conflicts.

Another commenter suggested that APHIS could largely resolve this conflict of interest and make this provision unnecessary by privatizing all existing Federal horse quarantine facilities. The commenter did not explicitly state why such privatization would attenuate this conflict of interest, but appeared to suggest that this action would provide an opportunity for other brokers to assume ownership of these Federal facilities.

Such privatization would not remove the conflict of interest, since it would still allow operators to act as brokers.

The same commenter suggested that, if we do not pursue privatization, these provisions are insufficient. The commenter pointed out that the one currently operating permanent, privately owned horse quarantine facility not only engages in import brokerage, but also functions as a retailer in the shipping industry. The commenter suggested that operators who act as shippers may encounter similar conflicts to those who act as brokers. Therefore, the commenter asked that, if we do not pursue privatization, we should consider prohibiting operators not only from brokerage, but also from retail shipping.

Operators do not possess as immediate and substantive an economic interest in the horses they ship as they do in those horses for which they act as brokers. If an operator assumes brokerage of a horse, the economic interest that the operator gains in the horse necessarily creates incentives for the individual to use his or her position as an operator in order to preserve and, if possible, increase the value of the horse, or conversely, to use that position to create competitive disadvantages for other brokers utilizing his or her facility. If an operator becomes the shipping agent for a horse, but does not function as the horse's broker, the economic interest that the operator has lies not in the horse itself, but in conveyance of the animal to or from the quarantine facility. This sort of interest creates only tangential or incidental incentives for the individual to use his or her position as an operator to maintain or increase the value of the animal to be shipped. For this reason, we do not consider the potential conflicts associated with retail shipping equivalent to those associated with brokerage, and are therefore not including shipping of horses as a reason to deny or withdraw approval of a permanent, privately owned quarantine facility in this final rule.

**Comments Regarding the Compliance Agreement for Permanent Facilities**

In § 93.308, proposed paragraph (c)(2) stated that the operator of the facility or his or her agent would have to execute a compliance agreement with the Administrator. In the proposal, we specified that the compliance agreement would have to provide that the facility would have to meet all applicable requirements of proposed § 93.308 and that the facility's quarantine operations would be subject to the oversight of APHIS representatives. The compliance agreement also stated that the operator of the facility would be responsible for:

- The cost of the facility;
- All costs associated with the facility's maintenance and operation;
- All costs associated with the hiring of employees and other personnel to attend to the horses as well as to maintain and operate the facility;
- All costs associated with the care of quarantined horses, such as feed, bedding, medicines, inspections, testing, laboratory procedures, and necropsy examinations; and
- All APHIS charges for the services of APHIS representatives in accordance with § 93.308 and 9 CFR part 130.

The compliance agreement would further provide that the operator would

agree to bar from the facility any employee or other personnel at the facility who fails to comply with the standards governing permanent, privately owned quarantine facilities, found in paragraph (c) of § 93.308, with other provisions of 9 CFR part 93, with any terms of the compliance agreement, or with any related instructions from APHIS representatives.

Two commenters expressed concern regarding the section of the compliance agreement in which the operator agrees to pay all charges for services rendered by APHIS representatives assigned to the facility. One of the commenters stated that this stipulation is at odds with the procedures in place at the one permanent, privately owned quarantine facility currently in operation, and is inconsistent with the practices of APHIS-operated quarantine facilities. The commenter stated that at such facilities the importer of record or the shipping agent is responsible for all fees for APHIS services.

The fees that APHIS assesses on importers and shipping agents at the quarantine facilities that we operate are for services rendered directly on behalf of the importer or shipping agent, such as meeting the importer or agent at the port of entry in order to facilitate transportation of the animal to the quarantine facility, or drawing blood for routine serological tests once import quarantine operations have been completed.

In contrast, the services that APHIS employees will provide at privately owned equine quarantine facilities will be directly related to conducting import quarantine operations and maintaining biosecurity for all horses at the facility, and are thus properly rendered on behalf of the operator of the facility, rather than on behalf of a specific importer or agent. Therefore, it is reasonable that the operator of the facility should agree to pay all charges for such services. This provision is consistent with the standards currently in place for temporary, privately owned quarantine facilities, which require the operator of the facility to bear all maintenance and operation costs.

Finally, it is important to note that this rule does not prohibit the operator of a privately owned equine quarantine facility from passing on the costs of APHIS' services to the importer of record or the shipping agent.

Another commenter asked if pricing structures for the services rendered at the privately owned facilities will correspond to those already in place for APHIS-operated quarantine facilities.

As we mentioned in the proposed rule, APHIS will charge for its services according to 9 CFR part 130. We will not regulate the amount that the operators of a facility may charge for services that they themselves provide.

**Comments Regarding Location Requirements**

In § 93.308, proposed paragraph (c)(3)(i) set forth location requirements for permanent, privately owned quarantine facilities. These required that the quarantine facility must be located in proximity to a port authorized under paragraph (e) of § 93.303 of the regulations, and that the site and the specific routes for the movement of horses from the port to the site must be approved by the Administrator based on consideration of whether the site or routes would put the horses in a position that could result in the transmission of communicable diseases to domestic horses. In both our December 2006 proposal and our July 2002 proposal, we decided not to specify a maximum distance that a facility could be located from a port of entry. In each proposal, we cited the diversity of locations of possible ports of entry as a reason for not setting such a distance: Some may be located in large metropolitan areas, with the nearest concentration of livestock many miles away, while others may be in towns with rural areas and high concentrations of livestock within a very short distance of the port.

Two commenters asked that APHIS add provisions to specify a maximum distance that a quarantine facility can be from a port of entry. One of these commenters stated that, if a quarantine facility were located many miles from a port of entry, a horse refused entry at one of the quarantine facilities would have to be transported a great distance before being exported from the United States. In the commenter's estimation, transporting a diseased horse for such a period of time, even under the most stringent biological security measures, would pose a substantial risk of disease spread through third-party vectors, such as flies and gnats.

We do not consider it possible to set a maximum distance that a quarantine facility can be located from a port of entry. In light of the diversity of places in which persons may consider locating a permanent facility, and the possibly substantive variations among different ports of entry, setting specific distances may result in regulations that are too stringent for some facilities, and too lax for others.

In a similar matter, in our July 2002 proposal, we proposed to require that the facility be located at least one-half mile from premises holding livestock or horses. In response to a commenter who suggested that other requirements in our proposal established adequate biosecurity to render such a requirement unnecessary, we reevaluated the need for this requirement, and removed it from our December 2006 proposal. Instead, we specified that the site would have to be approved by the Administrator as described above. The Administrator will take into consideration the proximity of the quarantine facility to the nearest port of entry, and the disease risks posed by transit of an infected horse from the port to the facility, in making his or her determination whether to approve the construction of the facility.

A commenter on the December 2006 proposal suggested that mandating a minimum distance that a facility can be constructed from the surrounding horse population greatly reduces the likelihood of disease spread to that population and the possibility of a subsequent equine disease outbreak in the vicinity of the facility, and such a requirement ought to be included in the final rule.

We have evaluated the biosecurity requirements we described in the proposed rule, and determined that they are adequate to mitigate the possibility of disease spread. Therefore, if all other procedures described in this rule are followed at a private, permanently owned quarantine facility, a distance requirement is unnecessary.

We note, however, that we are requiring that each application for approval of a quarantine facility must specify the location and street address of the facility. This requirement affords the Administrator the opportunity to assess the specific risks posed by that location, in accordance with paragraph (c)(3)(i) of § 93.308, and to specify additional biological security measures, beyond those specified in the rule, that the facility must adopt in order to address these risks and prevent disease spread. As specified in paragraph (c)(1)(ii)(B) of § 93.308, the Administrator may impose such additional requirements within the terms of the compliance agreement.

If the Administrator decides that the disease risks associated with a particular location are insurmountable, even with the imposition of such additional biosecurity requirements, he or she will not approve the location of the facility.

**Comments Regarding Construction Requirements**

In § 93.308, proposed paragraph (c)(3)(ii) set forth construction requirements for permanent, privately

owned horse quarantine facilities. The proposed basic standards for the facility addressed perimeter fencing, entrances and exits, windows, lighting, loading docks, surfaces, horse stalls, aisleways, isolation stalls, showers, APHIS space, necropsy areas, storage space, restrooms, ventilation, climate control, fire alarms, and communications systems.

Our July 2002 proposed rule included several specific construction requirements for lot-holding areas. These areas, which we defined as ''areas within a permanent, privately owned quarantine facility in which lots of horses are held,'' would have had separate drainage and heating, ventilation, air conditioning systems, and physical barriers. Our December 2006 proposed rule retained the provisions regarding lot-holding areas, but provided more options for operators to provide biological security within these areas, such as cleaning and disinfection after each use of an area.

One commenter suggested that APHIS remove those additional options for lot-holding areas and return to the more stringent requirements presented in the July 2002 proposed rule. The commenter cited the 2006 outbreak of a neurotropic EHV–1 mutation in a lot of horses at a permanent, APHIS-operated quarantine facility as evidence of the significant disease risks that may arise at a quarantine facility, and suggested that the revisions to lot-holding areas set forth in our December 2006 proposal did not take these risks into adequate account. The commenter therefore suggested that APHIS reevaluate the construction standards proposed for these areas in light of the outbreak.

We are making no change in response to this comment. The construction standards in the December 2006 proposal called for physical barriers to be erected to separate different lots of horses at the facility, so that horses in one lot cannot have physical contact with horses in another lot, their excrement, or their discharges. In addition, the sanitary standards in the 2006 proposal stated that each lot-holding area of the facility would have to be thoroughly cleaned with a disinfectant upon release of a lot of horses before a new lot of horses can enter the lot-holding area. APHIS has determined that these safeguards, which are comparable to those at APHIS-operated facilities, effectively limit the spread of communicable diseases of horses between lots of horses at a facility. We note, in this regard, that the biological security measures in place at the quarantine facility that was the site of the EHV–1 outbreak limited the spread of the disease to one lot of horses—neither lots in adjacent holding areas nor subsequent lots at the quarantine facility tested positive for the virus.

Finally, if a disease of horses, whether foreign or endemic to the United States, spreads within a particular lot of horses, the horses in that lot are subject to the provisions of paragraph (c)(4)(v)(H) of § 93.308, which sets forth requirements regarding the final disposition of horses infected with or exposed to a communicable disease of horses.

Another commenter stated that the construction requirements presented in the December 2006 proposed rule were not sufficiently delineated. The commenter asserted that, instead of creating objective and unilaterally binding specifications, APHIS had made standards primarily dependent on the judgment of APHIS representatives who inspect and approve the facility. In the commenter's opinion, this could result in wide deviations regarding the biological security of various facilities, and would necessarily make it difficult for a third party to determine the criteria by which the representative has evaluated a facility. The commenter suggested that, at a minimum, the final rule provide more detailed criteria for the construction of drainage and heating systems, ventilation, air conditioning systems, physical barriers, and material used in the construction of floors and walls within the quarantined area.

We are making no change in response to this comment. Our June 2002 proposed rule contained more specific construction criteria for lot-holding areas, floor drains, physical barriers, showering areas, areas for breaks and meals, and heating and ventilation units within the facility. In response to those proposed requirements, several commenters pointed out that some of these requirements were more restrictive than the design of various APHIS-operated facilities. Other commenters suggested that we generally amend the construction requirements to allow operators as many design variations as possible. Accordingly, in drafting our December 2006 proposal, we reevaluated the construction requirements that we proposed in 2002 and determined that, on certain occasions, the requirements of our 2002 proposal were indeed inconsistent with those at APHIS-approved facilities. On other occasions, we determined that the requirements could be adjusted to allow operators more options to provide adequate biological security at the facility. This led us to modify the construction requirements mentioned by the commenter.

The APHIS approval process will ensure that all permanent, privately owned facilities are constructed in a manner adequate to prevent the transmission of disease between lot-holding areas, thus preventing any wide deviations with regard to biosecurity. In addition, we note that, under paragraph (c)(1)(ii)(B) of § 93.308, the Administrator may impose additional construction requirements within the terms of the compliance agreement, beyond those specified in the rule, if he or she determines these requirements to be necessary to prevent the transmission of diseases into, within, or from the facility.

Several commenters suggested that the construction standards be modified to allow or require exercise equipment or ''turn-out'' pens for horses in quarantine. Such accommodations, the commenters stated, would allow horses under quarantine to maintain muscle tone and general overall health.

Allowing a horse under quarantine to be separated from its lot and released for exercise to an area of the facility outside the lot-holding area, whether indoor or outdoor, presents an unacceptable risk of disease spread. We note, in this regard, that horses that are required under the regulations to be quarantined for extended periods of time after their importation often have been imported from regions where a communicable equine disease is known to exist, or from regions that engage in trade with such regions and do not require testing or vaccination for that disease.

We recognize, however, that it may be possible to place exercise equipment in the stalls or in other parts of the lot-holding areas, depending on the size or construction of such areas. Therefore, we have modified proposed paragraph (c)(3)(i)(G) of § 93.308, which stated that the stalls in which horses are kept would have to be large enough to allow each animal to make normal postural and social adjustments with adequate freedom of movement, to further state that exercise equipment for horses may be kept in the stalls, provided that there will still be sufficient space within the stall for the horses to move freely once the equipment is installed.

Moreover, the regulations in this final rule allow exercise equipment to be kept in the lot-holding areas themselves. Any such equipment would, however, be subject to the cleaning and disinfection procedures required for lot-holding areas. To clarify this provision, we have modified proposed paragraph (c)(4)(iv)(D), which contained cleaning and disinfection requirements for equipment used within the quarantine area of the facility, to specify that these

requirements also pertain to exercise equipment located within the quarantine area.

**Comment Regarding Requirements for Isolation Stalls**

In § 93.308, proposed paragraph (c)(3)(ii)(I) addressed requirements for the means of isolation within permanent, privately owned facilities. We stated that the facility must have physical barriers to separate different lots of horses at the facility, so that horses in one lot cannot have physical contact with horses in another lot, or their excrement or discharges. We also stated that the facility must have stalls capable of isolating any horses exhibiting signs of illness.

One commenter pointed out that we did not specify a location for these stalls. As a result, the commenter was uncertain whether APHIS intended stalls to be constructed in a separate building or merely in such a manner that the horse does not have direct contact with other horses in its lot.

An isolation stall may be constructed in a separate building or within the quarantine area, provided that, in the estimation of the Administrator, the stall is able to physically isolate the horse from other horses at the facility.

**Comment Regarding Requirements for Necropsy Areas and Carcass Removal**

In § 93.308, proposed paragraph (c)(3)(ii)(L) set forth construction requirements for necropsy areas used by permanent, privately owned quarantine facilities. These required that all facilities must either have an area for conducting necropsies onsite, or must have designated an alternate facility, approved by the Administrator, at which a suitable necropsy area is available. In proposed paragraph (c)(3)(iii)(G) of § 93.308, which set forth sanitation requirements for permanent, privately owned quarantine facilities, we stated that each facility must have the capability to dispose of horse carcasses in a manner approved by the Administrator and under conditions that minimize the risk of disease spread.

One commenter stated that the carcass disposal requirements appear to be based on the quarantine facility's use of an onsite necropsy area. If the quarantine facility utilizes an alternate facility for necropsies, however, the commenter suggested that these disposal requirements no longer apply, since the sanitary disposal of the carcass after necropsy would become the responsibility of this other facility.

We are making no change in response to this comment. When a horse dies at a permanent, privately owned facility, the operator assumes ultimate responsibility for the disposal of its carcass in a manner acceptable to the Administrator, and under direct oversight of APHIS, whether the necropsy is conducted onsite or at another facility. The location of the necropsy, then, has no bearing on the disposal requirements.

**Comment Regarding Security Requirements**

In proposed paragraph (c)(3)(iv) of § 93.308, we set forth security requirements for permanent, privately owned facilities. We proposed that the facility and premises be kept locked and secure at all times. We also proposed to require that the facility and premises must have signs indicating that the facility is a quarantine area and no visitors are allowed.

Further, we proposed to require that the facility and premises either be guarded at all times by representatives of a bonded security company or, alternatively, have an electronic security system that indicates the entry of unauthorized persons into the facility.

Finally, we proposed to require that the operator of the facility notify the designated APHIS representative whenever a breach of security occurs or is suspected of having occurred. Further, if a disease is diagnosed in quarantined horses, we stated that the Administrator may require the operator to have the facility guarded by a bonded security company in a manner that the Administrator deems necessary to ensure the biological security of the facility.

One commenter stated that these provisions appear to prohibit any individual, including authorized personnel, from entering the facility, except in the presence of an APHIS representative. During all other times, it appeared to the commenter as if the facility would have to be locked and the entrances to it guarded, protected by alarm, barred, or sealed.

Paragraph (c)(4)(iii) grants authorized employees and other personnel assigned to work at the facility access to the facility premises as well as the quarantine area, even in the absence of an APHIS representative. This provision addresses the commenter's concerns.

**Comment Regarding Personnel Requirements**

In proposed paragraph (c)(4)(ii) of § 93.308, we set forth personnel requirements for permanent, privately owned quarantine facilities. Among other provisions, these proposed that:

- The operator of the facility would have to provide APHIS with a continually updated list of all personnel who have access to the facility; and
- The operator of the facility would have to provide APHIS with signed statements from every employee and any other personnel hired by the operator and working at the facility in which the person agrees to comply with all regulations governing permanent, privately owned horse quarantine facilities, other applicable provisions of 9 CFR part 93, all terms of the compliance agreement, and any related instructions from APHIS representatives pertaining to quarantine operations.

One commenter stated that both the list of personnel and the signed compliance statements appear to be unnecessary, if APHIS representatives will be physically present at all times to oversee the facility.

As discussed earlier, APHIS will ordinarily only maintain a physical presence at and direct supervision of import quarantine operations and certain technical services related to the biological security of the facility. Therefore, in order to ensure the general biological security of the facility, it is important that APHIS representatives have a continually updated list of all personnel with access to the facility, one that takes into consideration employee turnover at the facility itself and at any company with access to the facility. It is also important that all personnel agree to adhere to the biological security measures set forth within the rule and the compliance agreement.

That said, we do recognize that the proposed rule could be construed to suggest that, although APHIS personnel will be physically present at the facility, compliance agreements and signed statements from personnel must be submitted to APHIS employees at an off-site location, rather than to the personnel assigned to the facility, for review. This is not the case. The operator may submit such records to APHIS personnel assigned to the facility. The records will then be forwarded to the appropriate area veterinarian-in-charge office.

**Comments Regarding Showering Requirements**

In § 93.308, proposed paragraph (c)(4)(iv) set forth sanitation requirements for permanent, privately owned facilities. Proposed (c)(4)(iv)(A)(*1*) and (*2*) included provisions requiring that all persons granted access to the quarantine area shower when entering and leaving that area, and that all persons shower when leaving the necropsy area if a necropsy is in the process of being performed or

has just been completed, and portions of the animal remain exposed.

One commenter stated that these provisions were not the practice of the one permanent, privately owned horse quarantine facility currently in operation. The commenter suggested that the facility's standards, which require personnel to wash their overalls and shower before leaving work, would provide a less burdensome alternative to the provisions of our proposal.

''Shower in/shower out'' is considered a cornerstone of biosecurity, and is recognized and recommended by government, academia, and industry to prevent the spread of disease agents into or from live animal facilities. Accordingly, APHIS has determined that showering reduces the risk of disease spread from quarantine or necropsy areas, and may, in certain instances, remove a pathway for the transmission of a communicable disease of horses. Therefore, these provisions represent the practices of APHIS-operated facilities. They have thus been evaluated for efficacy and general applicability. Conversely, the commenter provided no data suggesting that the practices of the one permanent, privately owned horse quarantine facility currently in operation are equally effective risk-mitigation measures.

The same commenter stated that showering requirements, in themselves, do not adequately address the risk of the spread of communicable diseases of horses, since they do not preclude the movement of waste material from a quarantined area.

The rule provides multiple safeguards to prevent the movement of waste material from the quarantine area. In § 93.308, paragraphs (c)(4)(iv)(A)(*3*) through (*5*) require that personnel at the facility who enter or leave the quarantine area must wear protective work clothing and footwear upon entering the area and must change this clothing if it becomes soiled or contaminated. Paragraph (c)(4)(iv)(C) stipulates that the operator of the facility must handle, wash, or dispose of this soiled and contaminated clothing in accordance with the terms of the compliance agreement, and thus in a manner approved by the Administrator as consistent with the best practices of biological security. Paragraphs (c)(4)(iv)(D), (E), (F), and (G) establish cleaning and disinfection protocols for equipment and vehicles used within the facility, loading docks, and lot-holding areas. Thus, our proposed showering requirements were simply one of several sanitary practices that the facility would have to employ to address, among other things, the risk associated with the movement of waste material from the quarantine area.

Finally, the commenter asserted that the sanitary requirements of the proposed rule do not prevent grooms, owners, and other personnel who have traveled with a diseased horse from its country of origin from moving freely throughout the United States once they have disembarked. The commenter suggested that, if such individuals became exposed to a communicable equine disease, they could spread the disease throughout the United States.

APHIS personnel and employees of the Department of Homeland Security's Bureau of Customs and Border Protection may inspect individuals, their clothing, and their articles at ports of entry in order to prevent the introduction of a communicable equine disease into the domestic equine population.

**Comments Regarding Requirements for the Handling of Horses Under Quarantine**

In § 93.308, proposed paragraph (c)(4)(v) set forth requirements for the handling of horses in quarantine at a permanent, privately operated facility. Proposed paragraph (c)(4)(v)(B) stated that each lot of horses to be quarantined must be placed in the facility on an ''all in, all out'' basis, so that no horse may be taken out of the lot while it is in quarantine, except for diagnostic purposes or as provided in paragraph (a)(4) of § 93.308, and no horse may be added to the lot while the lot is in quarantine.

One commenter objected to the ''all in, all out'' requirement. The commenter stated that this requirement is not the practice of the one permanent, privately owned horse quarantine facility currently in operation, and is not consistent with the practices employed at APHIS-operated quarantine facilities. At the privately operated facility, the commenter stated, a horse under quarantine may be removed from its lot if the importer provides evidence that the horse has originated from a separate premise of origin than other horses in the lot.

It presents a grave risk to the biological security of a facility to allow horses onsite to be separated from their lot before import quarantine operations are conducted or while they are still ongoing for any reason other than diagnostic purposes or disposition of a diseased horse. For this reason, we only allow horses to be separated from their lot at an APHIS-operated facility for the purposes of diagnosis or disposition. Therefore, the provisions of the proposed rule were indeed modeled on APHIS' practices at our facilities.

However, in reviewing our proposal, we have determined that, once import quarantine operations are completed, these risks are attenuated, and horses still at the facility may be separated from their lot without a significant risk of disease spread. Accordingly, we have modified proposed paragraph (c)(4)(v)(B) to specify that, once import quarantine operations have been completed on a lot, but while the lot is still at the facility, a horse may be removed from that lot.

Proposed paragraph (c)(4)(v)(C) stated that the facility must provide sufficient feed and bedding for horses in quarantine, and that the feed and bedding must be free of vermin and not spoiled, and cannot originate from an area that we have designated as an area quarantined for splenetic or tick fever.

One commenter agreed that feed and bedding should not originate from an area quarantined for splenetic or tick fever, but suggested that we should also prohibit facilities from being constructed in those areas.

We are making no change in response to this comment. The initial application for approval of a facility must provide the location of the proposed facility. This is necessary, in part, for the Administrator to adequately evaluate the disease risks endemic to the area in which the facility would be located, and the biological security measures that the facility would need to adhere to in order to adequately respond to these disease risks. Approval of the facility is contingent on such evaluations.

Proposed paragraph (c)(4)(v)(D) would have prohibited the breeding of horses or collection of germplasm from horses during the quarantine period, and stated that horses in quarantine would be subject to tests and procedures as directed by an APHIS representative to determine whether they are free from communicable diseases of horses.

Two commenters suggested that we remove our prohibition on the collection of germplasm during the quarantine period. One stated that such collection is often necessary during quarantine operations to aid in the differential diagnosis and proper treatment of a horse under quarantine. Another pointed out that the July 2002 proposed rule had provided for the collection of germplasm during quarantine operations, if it was necessary for a required import testing procedure. This commenter suggested that our reason for removing this exception from the December 2006 proposed rule, that no such testing procedures are currently required, does

not take into account mandatory testing requirements for CEM.

The first commenter provided no examples of diseases for which germplasm collection is necessary for differential diagnosis or treatment, nor did the commenter explain under what circumstances the efficacy of quarantine operations depends on germplasm collection.

We note that germplasm collection is not part of APHIS' required import testing procedures for CEM. In § 93.301(e)(3) of the regulations, as part of these testing procedures, APHIS does require the collecting of specimens from the surface of the prepuce, urethral sinus, and fossa glandis of stallions while the horses are in full erection. However, the specimens collected are not germplasm, but a bacterial culture from the areas.

There are, therefore, no foreign communicable diseases of horses for which APHIS considers germplasm collection necessary for differential diagnosis or proper treatment.

Proposed paragraph (c)(4)(v)(I) of § 93.308 would have prohibited the vaccination of horses in quarantine.

Several commenters suggested that APHIS remove this prohibition. They agreed with APHIS that vaccinating a horse before serological exams are conducted may alter a horse's immune system, affect diagnostic serology, and potentially produce inaccurate results. However, they suggested that after the results of these serological exams have been obtained and confirmed, but before horses have been released from the facility, we should allow the animals to be vaccinated, especially for equine diseases endemic to the area of the United States in which the facility is located.

We agree with these commenters, and have therefore modified in this rule proposed paragraph (c)(4)(v)(I) to provide that, once import quarantine operations have been completed on a lot at the facility, but while the lot is still held at the facility, horses in that lot may be vaccinated.

**Miscellaneous**

In our proposal, we proposed to define a ''temporary, privately owned quarantine facility'' as ''a facility that offers quarantine services for a special event and that is owned and operated by an entity other than the Federal government (also temporary facility).'' In reviewing our proposal, we have decided that it may be difficult, in some instances, to determine what constitutes a special event, and that our intent in proposing such a definition was to differentiate such temporary facilities from permanent facilities by stating that the services offered by such facilities are not continuous. We have therefore changed ''special'' to ''specific.''

In proposed paragraph (c)(4)(ii)(C), we stated that, as part of APHIS' oversight of a privately owned equine quarantine facility, the operator of the facility must provide APHIS with signed statements from each employee and any other personnel hired by the operator and working at the facility in which the person agrees to comply with related instructions from APHIS representatives pertaining to quarantine operations, including contact with animals both inside or outside the facility, that are issued while the facility is operational. Moreover, in proposed paragraph (c)(2)(ii)(D), we stated that, in each compliance agreement executed by the operator of a quarantine facility or his or her agent and the Administrator, there must be a provision that the operator agrees to bar from the facility any employee or other personnel who fails to comply with these related instructions. Finally, in proposed paragraph (c)(2)(ii), we stated that the compliance agreement would be renewed yearly.

In reviewing our proposal, we have determined that these provisions could result in a scenario where the compliance agreement did not reflect related additional instructions issued by APHIS representatives while the facility is operational, or where these related instructions had provided an amendment to, interpretation of, or redaction of the compliance agreement. Moreover, depending on the date of issuance of these instructions, it could be several months before the compliance agreement was updated during the renewal process to reflect these changes. In such a scenario, the operator of the facility could be compelled to bar employees or personnel from the facility for non-compliance with instructions issued by APHIS representatives while the facility was operational without knowledge of the exact provisions of these instructions.

Therefore, we have added an additional provision to the requirements for each compliance agreement: The operator of the facility will allow APHIS to amend the compliance agreement at any time after approval of the facility in order to incorporate related instructions issued by APHIS representatives while the facility is operational. This provision is paragraph (c)(2)(ii)(G) § 93.308 in this final rule. APHIS will contact the operator or his or her agent each time the compliance agreement needs to be so amended.

In proposed paragraph (c)(4)(v)(H) of § 93.308, we stated that, if a horse were determined to be infected with or exposed to a communicable disease of horses, arrangements for the final disposition of the horse would have to be accomplished within 10 days of the date the importer is notified by an APHIS representative that the horse has been refused entry into the United States.

In reviewing our proposal, we have determined that this paragraph could be interpreted as stating that infection with or exposure to any communicable disease of horses will result in a horse in quarantine being euthanized or refused entry to the United States. This is not the case. Only infection with or exposure to a Federally regulated disease of horses will result in such disposition. We have therefore amended the paragraph by removing the word ''communicable'' and adding ''Federally regulated'' in its place.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

**Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this final rule, which is set out below. It includes a final regulatory flexibility analysis, in accordance with 5 U.S.C. 604, regarding the probable economic impact of this rule on small entities and a cost-benefit analysis, in accordance with Executive Order 12866.

Under the AHPA, specifically 7 U.S.C. 8303, the Secretary of Agriculture is authorized to promulgate regulations requiring that any animal imported or entered into the United States be raised or handled under post-importation quarantine conditions by or under the supervision of the Secretary for the purpose of determining whether the animal is or may be affected by any pest or disease of livestock.

This rule establishes standards for the approval of permanent, privately owned quarantine facilities for horses. We are taking this action because regional and seasonal demand for quarantine services for horses often exceeds the space available at existing facilities. Such privately owned facilities, if constructed and operated using the proper safeguards, will provide an effective and efficient means of bringing horses into

the United States without compromising our ability to protect against the introduction of communicable diseases of horses.

**Costs and Benefits Associated With This Rule**

The horse industry in the United States contributes $39 billion annually to the U.S. gross domestic product via direct spending, and it supports 1.4 million full-time equivalent jobs. The horse industry pays approximately $1.9 billion in taxes annually to all levels of government. Approximately 1.96 million people own the estimated 9.2 million horses in the United States.[3]

In the last 20 years, as the level of trade between the equine industry in the United States and that in other countries has risen, the number of horses imported into the United States and subject to quarantine has likewise increased. This, in turn, has led to an increased demand for the resources provided by import quarantine facilities. In some cases, the demand for quarantine services for horses has exceeded the space available at existing Federal facilities.

From 2003 through 2007, the annual average number of equines imported into the United States originating in countries for which quarantine is required at the port of entry was about 7,500 (see table 1).[4] This represents an increase of more than 225 percent over the annual average for 1990 through 1994, which was about 2,300 horses per year.

TABLE 1—U.S. EQUINE IMPORTS FROM COUNTRIES FOR WHICH QUARANTINE IS REQUIRED, 2003–2007, NUMBER OF HEAD

| Country | 2003 | 2004 | 2005 | 2006 | 2007 |
|---|---|---|---|---|---|
| The Netherlands | 2,176 | 2,810 | 3,035 | 2,920 | 2,600 |
| Germany | 1,424 | 1,285 | 1,345 | 1,630 | 1,517 |
| Argentina | 683 | 771 | 869 | 741 | 786 |
| United Kingdom | 587 | 630 | 640 | 614 | 529 |
| Other countries | 2,270 | 2,036 | 1,956 | 1,746 | 1,691 |

The establishment of standards for the approval and operation of permanent, privately owned quarantine facilities for horses has the potential to make the import process easier and timelier while simultaneously protecting against the introduction of communicable diseases of horses. This will provide a clear benefit to importers when demand for quarantine services surpasses the number of spaces available at APHIS' Federal facilities. In addition, the geographic distribution of the currently operating horse quarantine facilities can make it difficult or costly to import horses to some areas; in some geographically isolated locations, such as Hawaii and Puerto Rico, no facilities for quarantining imported horses exist, reducing the ability of importers to profitably bring horses into those areas. Because of their nature and size, temporary facilities are not always able to meet these demands. The construction of additional permanent, privately owned equine quarantine facilities could remove or attenuate some of those difficulties and thus facilitate imports to those areas.

The implementation of this rule will likely require upgrades at the one permanent, privately owned equine quarantine facility in operation. In addition, when a facility is approved for operation under these regulations, it will incur the cost of any needed renovations to the facility as well as the costs associated with being in compliance with the regulations. We expect one or two such facilities to be approved and open in the years immediately following implementation of this rule.

The rule sets forth requirements for the physical structure of permanent, privately owned horse quarantine facilities. These include basic standards for the facility for perimeter fencing, entrances and exits, windows, lighting, loading docks, surfaces, horse stalls, aisleways, isolation stalls, showers, APHIS space, necropsy areas, storage space, restrooms, ventilation, climate control, fire alarms, and communication systems. The rule also sets forth the type of services that APHIS employees will provide at a privately owned equine quarantine facility. These services include overseeing the conduct of import quarantine operations and maintaining biosecurity at the facility. Necessary upgrades to the physical structure of the permanent, privately owned horse quarantine facility currently in operation, as well as additional APHIS supervision of operations at that facility, will likely result in an increase in costs for the facility. Similar costs are likely to be borne by future privately owned equine quarantine facilities. The fees that APHIS assesses related to import quarantine operations and maintaining biosecurity at a private facility will be charged to the operator of the facility. Fees for services rendered directly on behalf of the importer or shipping agent, such as meeting the importer or agent at the port of entry in order to facilitate transportation of the animal to the quarantine facility, or drawing blood for routine serological tests once import quarantine operations have been completed, are charged directly to the importer or agent. These distinctions in fee assessments will continue.

It has been estimated that, on average, this rule will add 2 to 3 hours per workday for additional APHIS supervision at the one current permanent, privately owned quarantine facility. Based on this estimate, the facility could expect to be billed for between 520 and 780 additional hours of APHIS supervision annually as a result of the rule. At the normal rate of $84/hour, this will be an annual cost of between $43,680 and $65,520.[5] We expect that some additional onsite supervision will be needed during an initial evaluation phase for other aspects of import quarantine operations, which will be reduced to spot checks over time. As such, the cost associated with APHIS onsite supervision will be higher initially, and then decline.

The new requirements may also alter the type of horses that move through the one current permanent, privately owned horse quarantine facility. The importation of horses intended for resale at low margins may decline if the

[3] *Source:* The American Horse Council. Found at *http://www.horsecouncil.org/statistics.*

[4] This does not include horses from Mexico. Under the regulations in 9 CFR part 93, these horses are subject to quarantine but may be quarantined either at one of the permanent equine quarantine facilities in the United States or at a facility located at a border port in Mexico.

[5] In accordance with 9 CFR part 130, services performed outside an APHIS employee's normal tour of duty, Monday through Saturday, cost $100/hour, and, on Sunday and holidays, $112/hour.

cost of quarantine at the facility increases. These horses constitute a large portion of the current imports at this quarantine facility. Any reduction of this type of import through the facility as a result of increased quarantine fees will negatively affect revenues at the facility to the extent they are not replaced by other classes of imported horses.

However, a significant portion of the horses imported annually into the United States must go through quarantine, and this rule will not alter those requirements. Imports of horses from countries requiring quarantine have increased more than 225 percent since 1990, but there are still only three permanent quarantine facilities operating in the United States: Two Federal facilities, and one private one. Moreover, as we mentioned above, demand for quarantine services for horses often exceeds the space available at the existing Federal facilities. The cost of providing quarantine services at the private facility should be similar to providing the same services at a Federal facility. In addition, this facility is the only permanent horse quarantine facility located on the west coast, making it an appealing alternative to quarantine in a Federal facility for horse imports arriving in the Western United States.

Additional costs incurred at the private facility because of this rule can most likely be passed on to importers who elect to use the facility to quarantine imported horses, at least in the short run, given the limited space at Federal horse quarantine facilities and the fact that there are no other permanent, privately owned quarantine facilities operating at this time. Over the long term, the impact of the rule on the facility is less certain, given the possibility of additional—and potentially competing—quarantine facilities opening in the future. The effect of implementation of this rule on the facility's business volume and revenue is uncertain. However, the fact that only one or two additional permanent, privately owned quarantine facilities are expected to open in the next several years suggests that these effects will be limited, even in the long run.

It is not possible to predict the number of additional horses that might be imported into the United States as a result of this rule. Nevertheless, any increase in horse imports that the rule may facilitate should yield net benefits. This is because trade of a commodity generally increases social welfare. To the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline, gains in consumer surplus will outweigh losses in domestic producer surplus.[6] Although the rule's impact on domestic producers is uncertain, it is expected to provide benefits to consumers (domestic importers, brokers) that will exceed any potential losses to domestic producers. The net welfare effect for the United States of increased horse imports will be positive. However, because the rule is expected to result in only one or two additional permanent, privately owned quarantine facilities over the next several years, the expected benefits are likely to be small.

**Final Regulatory Flexibility Analysis**

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small business, small organizations, and small governmental jurisdictions. Section 604 of the Act requires agencies to prepare and make available to the public a final regulatory flexibility analysis (FRFA) describing any changes made to the rule as a result of comments received and the steps the agency has taken to minimize any significant economic impacts on small entities. Section 604(a) of the Act specifies the content of a FRFA. In this section, we address these FRFA requirements.

**Objectives and Need for the Rule**

Demand for quarantine services for horses often exceeds the space available at existing Federal facilities. In addition, the geographic distribution of the currently operating horse quarantine facilities can make it difficult or costly to import horses to some areas; in some geographically isolated locations, such as Hawaii and Puerto Rico, no facilities for quarantining imported horses exist, reducing the ability of importers to profitably bring horses into those States. Finally, temporary, privately owned quarantine facilities cannot always meet the demand for quarantine services, because such facilities are established, approved, and operated by importers on a temporary basis to handle horses imported for a unique importation, race, or show.

This final rule will establish standards for the approval of permanent, privately owned horse quarantine facilities. Such facilities, if constructed and operated using the proper safeguards, will provide an effective and efficient means of bringing horses into the United States without compromising our ability to protect against the introduction of communicable diseases of horses.

**Summary of Significant Issues Raised by Commenters**

In our proposal, we invited comments about expected impacts of the rule on small entities. We particularly asked for estimates of compliance costs and impacts on revenue for the one permanent, privately owned equine quarantine facility currently in operation.

One commenter suggested that APHIS' basis for rulemaking, that nationwide demand for such permanent quarantine facilities currently outpaces supply, is erroneous. The commenter cited the decreasing number of horses quarantined between 2004 and 2006 at the one permanent, privately owned horse quarantine facility currently in operation: In 2004, this facility quarantined approximately 2,500 horses, whereas in 2006 the facility quarantined 2,238 horses.

Since we issued the proposed rule, the number of horses imported yearly into the United States and subject to quarantine has decreased slightly. However, from 2003 through 2007, the annual average number of equines imported into the United States that originated from countries for which post-importation quarantine is required was nearly 7,500. This represents an increase of more than 225 percent from the annual average for 1990 through 1994, which was about 2,300 horses per year. Moreover, in our proposal, we did not cite yearly importation trends as our sole basis for proposing standards for privately owned equine quarantine facilities. Rather, we also cited the limited space at our existing Federal facilities, a demand for quarantine services that often exceeds the spaces available, and the inability of temporary, privately owned equine quarantine facilities to fill the continual demand for quarantine services.

As several commenters on our proposal pointed out, even with the recent decrease in the number of horses imported yearly into the United States, seasonal and regional demand for quarantine services still often surpasses the number of spaces available at our Federal facilities. Moreover, because of their nature and size, temporary facilities are not always able to meet this demand. Therefore, we have determined that the need for permanent, privately owned equine quarantine facilities still remains.

Several commenters suggested that the proposed rule could be construed to

[6] Consumer surplus is the difference between the amount a consumer is willing to pay for a good and the amount actually paid. Producer surplus is the amount a seller is paid for the good less the seller's cost.

mean that APHIS representatives must be present to supervise and staff the facility at all hours, or that the facility can only operate while APHIS representatives are physically present to supervise its operations. Either interpretation, these commenters stated, would have a direct, substantive, and detrimental economic impact on all permanent, privately owned equine quarantine facilities, in general, and the one such facility currently in operation, in particular. One of the commenters stated that APHIS oversight would cost this facility approximately $360,000 annually.

The amount submitted by the commenter could be construed to suggest that the facility does not currently pay for APHIS' services. This is not the case; in fact, the facility has always paid for APHIS' oversight of import quarantine operations.

It is true that this rule will add an additional annual cost to the facility, beyond those costs already assumed for our services. However, as we mentioned earlier, we expect the additional annual cost to be no greater than $65,520.

Finally, we have clarified the nature of APHIS oversight to make more explicit those occasions when we will be present at the facility and charge for our monitoring of certain activities. In light of these clarifications, we find the estimate submitted by the commenter, irrespective of current costs, to be high.

One commenter suggested that meeting certain of the proposed construction requirements would reduce the overall capacity of the one currently operating permanent, privately owned facility, would reduce its flexibility in providing quarantine services, and could eliminate the facility's ability to quarantine ruminants.

We received no information from the commenter regarding the potential cost of the upgrades necessary to bring this facility into compliance with the construction requirements of the proposed rule, or the amount of revenue the facility would stand to lose because of adherence to these requirements. In the absence of itemized expenditures, an estimate of lost yearly revenue, or an estimated total cost, it is difficult to assess the impact of these requirements on the facility.

Moreover, we consider the construction requirements that we are finalizing in this rule to be necessary in order to promote the biological security of any permanent, privately owned equine quarantine facility. In addition, as we mentioned above in the section titled ''Comments Regarding Construction Requirements,'' we have made most of these requirements performance-based in order to provide facilities with a degree of flexibility in meeting them.

The same commenter stated that the operator of the one permanent, privately owned quarantine facility currently in operation also acts as a broker. The commenter pointed out that, under the provisions of the rule, the operator would no longer be able to act as a broker, and cited this among the reasons why the rule, if finalized, would have an adverse economic impact on that operator.

We received no information from the commenter regarding the revenue that the operator currently generates as a broker, or estimated losses that the operator expected to incur by no longer acting as a broker. Without such information, we cannot assess the economic impact that these provisions will have on the operator.

We proposed to require that each facility would have to have a supply of potable water adequate to meet all watering and cleaning needs.

A commenter stated that, in order to comply with this standard, the one permanent, privately owned equine quarantine facility in operation would have to install automatic water bowls for all horses in quarantine.

The commenter suggests one means by which that facility could meet this requirement. There are, however, other means by which the facility could secure a supply of potable water that would not require the installation of such bowls or any other modifications to existing structures at the facility.

**Description and Estimate of Small Entities**

We have identified two types of small entities that could be affected by the implementation of this rule: The existing permanent, privately owned quarantine facility and horse importers and owners.

According to the Small Business Administration (SBA) criteria, a horse quarantine facility is considered a small entity if it has annual revenues of $6 million or less. The existing permanent, privately owned quarantine facility that operates in Los Angeles is believed to be a small entity. According to SBA criteria, a farm that keeps horses for breeding and has annual revenues of $750,000 or less is considered a small entity. According to the most recent Census of Agriculture data, average per-farm revenue for all U.S. equine farms in 2002 was $7,158, an indication that these farms are by and large small entities.

The establishment of standards for the approval and operation of permanent, privately owned quarantine facilities for horses has the potential to make the import process easier and timelier while simultaneously protecting against the introduction of communicable diseases of horses. This will provide a clear benefit to importers when seasonal or regional demand for quarantine facilities surpasses the number of spaces available at our Federal facilities. In addition, the geographic distribution of equine quarantine facilities, which currently makes it difficult or costly to import horses to some areas, may change with the construction of more quarantine facilities throughout the United States.

On the other hand, importers may be subject to higher fees and charges at the current permanent, privately owned equine quarantine facility. This is because the implementation of this rule will likely require upgrades at that facility. Moreover, if another quarantine facility is approved for operation under these regulations (*e.g.,* if a ruminant quarantine facility seeks approval to begin to quarantine imported horses), it will incur the cost of any renovations needed to establish adherence to the construction requirements, as well as the costs associated with maintaining compliance with the regulations.

This rule sets forth requirements for the physical structure of permanent, privately owned equine quarantine facilities. The rule also sets forth the type of services that APHIS employees will provide at a privately owned equine quarantine facility: Overseeing the conduct of import quarantine operations and maintaining biosecurity at the facility. Necessary upgrades to the physical structure of the currently operating privately owned horse quarantine facility and additional APHIS supervision of operations at that facility will likely result in an increase in costs at the facility. The fees that APHIS assesses related to import quarantine operations and maintaining biosecurity at a private facility will be charged to the operator of the facility. Similar costs are likely to be borne by any other privately owned horse quarantine facilities that begin operations in the future.

Additional costs incurred at the private facility will most likely be passed on to importers of horses who elect to use the facility to quarantine imported horses, at least in the short run, given the limited space at APHIS-operated horse quarantine facilities, the fact that there are no other permanent, privately owned quarantine facilities operating at this time, and the fact that

quarantines are mandatory for significant classes of imported horses. If the low-margin horse imports that pass through the permanent, privately owned quarantine facility decline because of increased quarantine fees, and those imports are not replaced by other classes of imported horses, however, revenues at the facility could be negatively affected. Over the long term, the possibility of additional—and, potentially, competing—quarantine facilities opening in the future creates more uncertainty regarding the effects of this rule on the facility. The effect of the rule on the facility's business volume and revenue is uncertain. However, it is likely that, following implementation of this rule, only one or two additional permanent, privately owned quarantine facilities will open in the next several years. This suggests that these effects will be limited, even in the long run.

It is not possible to predict the number of additional horses that might be imported into the United States as a result of this rule. Nevertheless, any increase in horse imports that the rule may facilitate should yield net benefits. This is because trade of a commodity generally increases social welfare. To the extent that consumer choice is broadened and the increased supply of the imported commodity leads to a price decline, gains in consumer surplus will outweigh losses in domestic producer surplus. Although the rule's impact on domestic producers is uncertain, it is expected to provide benefits to consumers (domestic importers, brokers) that will exceed any potential losses to domestic producers. The net welfare effect for the United States of increased horse imports will be positive. However, because the rule will likely result in only one or two additional permanent, privately owned quarantine facilities over the next several years, the expected benefits are likely to be small.

**Description and Estimate of Compliance Requirements**

This rule establishes various information collection and recordkeeping requirements for the operators of permanent, privately owned equine quarantine facilities. A description of the requirements associated with the rule was presented in the proposal under the heading ''Paperwork Reduction Act.''

**Alternatives Considered**

This rule establishes standards for the approval of permanent, privately owned quarantine facilities for horses. Alternatives to the rule would have been to either leave the regulations unchanged, or to require a different set of standards than those being implemented in this rule. Leaving the regulations unchanged would be unsatisfactory, because it would perpetuate the current situation, *i.e.,* one which does not facilitate the importation of horses or address the disease risks associated with such importation in as timely and quick a manner as possible.

APHIS considers the set of standards implemented by this rule to be the minimum necessary to accomplish the rule's objectives. In this regard, we have made substantive changes to several of the provisions of our proposal that we expect to reduce the compliance costs associated with this rulemaking. In particular, we have decided that several of a permanent, privately owned equine quarantine facility's operating procedures—the routine cleaning and maintenance of the facility, the daily care of animals in quarantine, the disposal of wastes at the facility, the cleaning and disinfection procedures employed by the facility, the handling, washing, and disposal of soiled and contaminated clothing worn within the facility, and the incineration of dead horses, whether onsite or offsite—will not ordinarily need APHIS' direct supervision or physical presence.

**Description of Steps Taken To Minimize Significant Economic Impacts on Small Entities**

In our proposal, we solicited comments regarding how the rule could be modified to reduce expected impacts on small entities. While no commenters cited this request in providing their responses, as we mentioned above, several commenters asked us to clarify the nature of APHIS oversight required by the proposal, and to reevaluate the need for ongoing and direct APHIS oversight of several operations at the facility: Cleaning and disinfection procedures and incineration activities. In response to these comments, we have decided that these operations, as well as maintenance of the facility, the daily care of horses under quarantine, the disposal of wastes at the facility, and the handling, washing, and disposal of soiled and contaminated clothing at the facility, will not ordinarily require our direct presence and/or continual oversight. We expect that this change from the terms of the proposal will lessen the economic impact of this rule on small entities.

**Executive Order 12988**

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

**Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 301 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0313.

E-Government Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

**List of Subjects in 9 CFR Part 93**

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 93 as follows:

## PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

**Authority:** 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 93.300 is amended by revising the definition for *Operator* and by adding, in alphabetical order, new definitions of *Lot, Lot-holding area, Nonquarantine area, Permanent, privately owned quarantine facility, Quarantine area,* and *Temporary, privately owned quarantine facility* to read as follows:

**§ 93.300 Definitions.**

* * * * *

*Lot.* A group of horses that, while held on a premises or conveyance, have had opportunity for physical contact with other horses in the group or with their excrement or discharges at any time

during their shipment to the United States.

*Lot-holding area.* That area in a permanent, privately owned quarantine facility in which a single lot of horses is held at one time.

*Nonquarantine area.* That area in a permanent, privately owned quarantine facility that includes offices, storage areas, and other areas outside the quarantine area, and that is off limits to horses, samples taken from horses, and any other objects or substances that have been in the quarantine area during the quarantine of horses.

*Operator.* A person other than the Federal Government who owns or manages and has responsibility for the services provided by a temporary, privately owned quarantine facility or a permanent, privately owned quarantine facility.

*Permanent, privately owned quarantine facility.* A facility that offers quarantine services for horses to the general public on a continuing basis and that is owned and operated by an entity other than the Federal Government (also permanent facility).

* * * * *

*Quarantine area.* That area in a permanent, privately owned quarantine facility that comprises all of the lot-holding areas in the facility, and any other areas in the facility that horses have access to, including loading docks for receiving and releasing horses, and any areas used to conduct examinations of horses and take samples and where samples are processed or examined.

* * * * *

*Temporary, privately owned quarantine facility.* A facility that offers quarantine services for horses imported for a specific event and that is owned and operated by an entity other than the Federal Government (also temporary facility).

* * * * *

■ 3. Section 93.303 is amended as follows:

■ a. By revising the heading of paragraph (e) to read as set forth below.

■ b. In paragraph (e), by removing the words ''provided by the importer'' and by adding the words ''privately owned'' before the word ''quarantine''.

**§ 93.303 Ports designated for the importation of horses.**

* * * * *

(e) *Ports for horses to be quarantined at privately owned quarantine facilities.*

* * *

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**§ 93.304 [Amended]**

■ 4. Section 93.304 is amended as follows:

■ a. In paragraph (a)(1)(i), first sentence, by removing the words ''quarantine facility provided by the importer'' and adding the words ''privately owned quarantine facility'' in their place.

■ b. In paragraph (a)(2), by removing the words ''of the regulations, horses intended for quarantine at a quarantine facility provided by the importer'', and by adding the words ''or horses intended for quarantine at a privately owned quarantine facility'' in their place.

■ 5. Section 93.308 is amended as follows:

■ a. In paragraph (a)(3), by redesignating footnote 14 as footnote 13.

■ b. By revising paragraphs (b) and (c) to read as set forth below.

■ c. By adding an OMB citation at the end of the section to read as set forth below.

**§ 93.308 Quarantine requirements.**

* * * * *

(b) *Temporary, privately owned quarantine facilities.* Horses presented for entry into the United States as provided in § 93.303(e) may be quarantined in temporary, privately owned quarantine facilities that meet the requirements of paragraphs (b)(1) and (b)(2) of this section and that have been approved by the Administrator for a specific importation.

(1) *Approval.* Requests for approval and plans for proposed temporary facilities must be submitted no less than 15 days before the proposed date of entry of horses into the facility to APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737–1231. Before facility approval can be granted, a veterinary medical officer of APHIS must inspect the facility to determine whether it complies with the standards set forth in this section: *Provided, however,* that approval of any temporary facility and use of such facility will be contingent upon a determination made by the Administrator that adequate personnel are available to provide required services at the facility. Approval of any facility may be refused and approval of any quarantine facility may be withdrawn at any time by the Administrator, upon his or her determination that any requirements of this section are not being met. Before such action is taken, the operator of the facility will be informed of the reasons for the proposed action by the Administrator and afforded an opportunity to present his or her views. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The cost of the facility and all maintenance and operational costs of the facility will be borne by the operator.

(2) *Standards and handling procedures.* The facility must be maintained and operated in accordance with the following standards:

(i) *Inspection.* Inspection and quarantine services must be arranged by the operator or his or her agent with the APHIS Veterinarian in Charge for the State in which the approved facility is located [14] no less than 7 days before the proposed date of entry of the horses into the quarantine facility.

(ii) *Physical plant requirements.*

(A) The facility must be located and constructed to prevent horses from having physical contact with animals outside the facility.

(B) The facility must be constructed only with materials that can withstand repeated cleaning and disinfection. Disinfectants authorized in 9 CFR part 71 must be used. All walls, floors, and ceilings must be constructed of solid material that is impervious to moisture. Doors, windows, and other openings of the facility must be provided with double screens that will prevent insects from entering the facility.

(iii) *Sanitation and security.*

(A) The operator of the facility must arrange for a supply of water adequate to clean and disinfect the facility.

(B) All feed and bedding must originate from an area not under quarantine because of splenetic or tick fever (*see* part 72 of this chapter) and must be stored within the facility.

(C) Upon the death of any horse, the operator must arrange for the disposal of the horse's carcass by incineration. Disposal of all other waste removed from the facility during the time the horses are in quarantine or from horses that are refused entry into the United States must be either by incineration or in a public sewer system that meets all applicable environmental quality control standards. Following completion of the quarantine period and the release of the horses into the United States, all waste may be removed from the quarantine facility without further restriction.

(D) The facility must be maintained and operated in accordance with any additional requirements the Administrator deems appropriate to prevent the dissemination of any communicable disease.

[14] The name and the address of the Veterinarian in Charge in any State is available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737–1231.

(E) The facility must comply with all applicable local, State, and Federal requirements for environmental quality.

(iv) *Personnel.*

(A) Access to the facility will be granted only to persons working at the facility or to persons specifically granted such access by an APHIS representative.

(B) The operator must provide attendants for the care and feeding of horses while in the quarantine facility.

(C) Persons working in the quarantine facility may not come in contact with any horses outside the quarantine facility during the quarantine period for any horses in the facility.

(v) *Handling of horses in quarantine.* Horses offered for importation into the United States that are quarantined in an approved temporary facility must be handled in accordance with paragraph (a) of this section while in quarantine.

(c) *Permanent, privately owned quarantine facilities.* Horses presented for entry into the United States as provided in § 93.303(e) may be quarantined in permanent, privately owned quarantine facilities approved by the Administrator as meeting the requirements of paragraphs (c)(1) through (c)(6) of this section.

(1) *APHIS approval.*

(i) *Approval procedures.* Persons seeking APHIS approval of a permanent, privately owned quarantine facility must write to the Administrator, c/o National Center for Import and Export, Veterinary Services, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231. The application letter must include the full name and mailing address of the applicant; the location and street address of the facility for which approval is sought; blueprints of the facility; a description of the financial resources available for construction, operation, and maintenance of the facility; the anticipated source or origin of horses to be quarantined, as well as the expected size and frequency of shipments; a contingency plan for horses needing emergency veterinary care; and a contingency plan for the disposal of all the horses capable of being housed in the facility.

(A) If APHIS determines that an application is complete and merits further consideration, the person applying for facility approval must enter into a service agreement with APHIS wherein the applicant agrees to pay the cost of all APHIS services associated with APHIS' evaluation of the application and facility. APHIS charges for the evaluation of the application and facility at hourly rates listed in § 130.30 of this chapter. This service agreement applies only to fees accrued during the application process. If the facility is approved by APHIS, facility owners must enter into a compliance agreement in accordance with paragraph (c)(2) of this section.

(B) Requests for approval must be submitted to APHIS at least 120 days prior to the date of application for local building permits. Requests for approval will be evaluated on a first-come, first-served basis.

(ii) *Criteria for approval.* Before a facility may operate as a permanent, privately owned quarantine facility for horses, it must be approved by APHIS. To be approved:

(A) The facility must meet all of the requirements of this section;

(B) The facility must meet any additional requirements that may be imposed by the Administrator in each specific case, as specified in the compliance agreement required under paragraph (c)(2) of this section, to ensure that the quarantine of horses in the facility will be adequate to determine their health status, as well as to prevent the transmission of diseases into, within, and from the facility; and

(C) The Administrator must determine that sufficient personnel, including one or more APHIS veterinarians and other professional, technical, and support personnel, are available to serve as APHIS representatives at the facility. If the facility is approved, APHIS representatives will be present at all import quarantine operations in order to monitor them and will be present in order to provide other technical services to ensure the biological security of the facility, including, but not limited to, those specified in paragraph (c)(4)(v)(H) of § 93.308. The Administrator's determination will be based on the expected size and frequency of shipments to the facility, as described in the application for approval of a permanent facility, as well as any other pertinent information in the application. APHIS will assign personnel to facilities requesting approval in the order that the facilities are approved. The Administrator has sole discretion on the number of APHIS personnel to be assigned to the facility.

(iii) *Maintaining approval.* To maintain APHIS approval, the operator must continue to comply with all the requirements of paragraph (c) of this section and the terms of the compliance agreement executed in accordance with paragraph (c)(2) of this section.

(iv) *Denial or withdrawal of approval.* Approval for a proposed permanent, privately owned quarantine facility may be denied or approval for a facility already in operation may be withdrawn at any time by the Administrator for any of the reasons provided in paragraph (c)(1)(iv)(C) of this section.

(A) Before facility approval is denied or withdrawn, the operator of the facility will be informed of the reasons for the proposed action by the Administrator and afforded an opportunity to present his or her views. If there is a conflict as to any material fact, APHIS will afford the operator, upon request, the opportunity for a hearing with respect to the merits or validity of such action.

(B) The Administrator may withdraw approval of an existing facility prior to a final determination in the hearing if the Administrator determines that such action is necessary to protect animal health or the public health, interest, or safety. Such withdrawal will be effective upon oral or written notification, whichever is earlier, to the operator of the facility. In the event of oral notification, APHIS will promptly give written confirmation to the operator of the facility. This withdrawal will continue in effect pending the completion of the hearing and any judicial review, unless otherwise ordered by the Administrator. In addition to withdrawal of approval for the reasons provided in paragraph (c)(1)(iv)(C) of this section, the Administrator will also automatically withdraw approval when the operator of any approved facility notifies the APHIS Veterinarian in Charge for the State in which the facility is located, in writing, that the facility is no longer in operation.[15]

(C) The Administrator may deny or withdraw approval of a permanent, privately owned facility if:

(*1*) Any requirement of this section or the compliance agreement is not complied with; or

(*2*) The operator fails to remit any charges for APHIS services rendered; or

(*3*) The operator or a person responsibly connected with the business of the quarantine facility acts as a paid agent (broker) for the importation or subsequent sale of horses; or

(*4*) The operator or a person responsibly connected with the business of the quarantine facility is or has been found by a court of competent jurisdiction to have violated any law or regulation pertaining to the importation or quarantine of any animal; or

(*5*) The operator or a person responsibly connected with the business of the quarantine facility is or has been

[15] The name and address of the Veterinarian in Charge in any State is available from APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 39, Riverdale, MD 20737–1231.

convicted of any crime involving fraud, bribery, or extortion or any other crime involving a lack of the integrity needed for the conduct of operations affecting the importation of animals; or

(*6*) The approved quarantine facility has not been in use to quarantine horses for a period of at least 1 year.

(D) For the purposes of this section, a person is deemed to be responsibly connected with the business of the quarantine facility if such person has an ownership, mortgage, or lease interest in the facility's physical plant, or if such person is a partner, officer, director, holder, or owner of 10 percent or more of its voting stock, or is an employee in a managerial or executive capacity.

(v) *Approval for existing facilities.* Any permanent, privately owned quarantine facility operating under APHIS authorization on August 3, 2009 must be approved by APHIS to continue quarantine operations by August 3, 2010 or else must cease horse quarantine operations.

(2) *Compliance agreement.*

(i) All permanent, privately owned quarantine facilities for horses must operate in accordance with a compliance agreement executed by the operator or his or her agent and the Administrator, which must be renewed on an annual basis.

(ii) The compliance agreement must provide that:

(A) The facility must meet all applicable requirements of this section;

(B) The operator agrees to have APHIS representatives present at all import quarantine operations at the facility in order to monitor the import quarantine operations;

(C) The operator agrees to be responsible for the cost of the facility; all costs associated with its maintenance and operation; all costs associated with the hiring of employees and other personnel to attend to the horses as well as to maintain and operate the facility; all costs associated with the care of quarantined horses, such as feed, bedding, medicines, inspections, testing, laboratory procedures, and necropsy examinations; and all APHIS charges for the services of APHIS representatives in accordance with this section and part 130 of this chapter;

(D) The operator agrees to bar from the facility any employee or other personnel at the facility who fails to comply with paragraph (c) of this section or other provisions of this part, any terms of the compliance agreement, or related instructions from APHIS representatives;

(E) The operator agrees to demonstrate, to the satisfaction of the Administrator, that the routine cleaning and maintenance of the facility, the daily care of animals in quarantine, the disposal of wastes at the facility, the cleaning and disinfection procedures employed by the facility, the handling, washing, and disposal of soiled and contaminated clothing worn within the facility, and the disposal of dead horses, whether onsite or offsite, adhere to the best practices of biological security and animal care;

(F) The operator agrees to random spot audits by APHIS representatives to determine whether employees and other personnel are complying with these practices; and

(G) The operator of the facility allows the Administrator to amend the compliance agreement at any time after approval of the facility in order to incorporate related instructions issued by APHIS representatives while the facility is operational

(3) *Physical plant requirements.* The facility must meet the following requirements as determined by an APHIS inspection prior to admitting horses into the facility:

(i) *Location.* The quarantine facility must be located in proximity to a port authorized under § 93.303(e). The site and the specific routes for the movement of horses from the port to the site must be approved by the Administrator based on consideration of whether the site or routes would put the horses in a position that could result in the transmission of communicable diseases to domestic horses.

(ii) *Construction.* The facility must be of sound construction, in good repair, and properly designed to prevent the escape of quarantined horses. It must have adequate capacity to receive and house shipments of horses as lots on an ''all in, all out'' basis, whereby separate lots of horses can be received and housed without contact with any other lots being quarantined at the facility. The facility must include the following:

(A) *Perimeter fencing.* The facility must be surrounded by a security fence of sufficient height and design to prevent the entry of unauthorized people and animals from outside the facility and to prevent the escape of the horses in quarantine.

(B) *Entrances and exits.* All entryways into the nonquarantine area of the facility must be equipped with a secure and lockable door. While horses are in quarantine, all access to the quarantine area for horses must be from within the building, and each such entryway to the quarantine area must be equipped with a series of solid self-closing double doors. Emergency exits to the outside are permitted in the quarantine area. Such emergency exits must be constructed so as to permit their being opened from the inside of the facility only.

(C) *Windows and other openings.* The facility must be constructed so that any windows or other openings in the quarantine area are double-screened with screening of sufficient gauge and mesh to prevent the entry or exit of insects and other vectors of diseases of horses and to provide ventilation sufficient to ensure the comfort and safety of all horses in the facility. The interior and exterior screens must be separated by at least 3 inches (7.62 cm). All screening of windows or other openings must be easily removable for cleaning, but must otherwise remain locked and secure at all times in a manner satisfactory to APHIS representatives in order to ensure the biological security of the facility.

(D) *Lighting.* The entire facility, including its stalls and hallways, must have adequate lighting.

(E) *Loading docks.* The facility must have separate docks for animal receiving and releasing and for general receiving and pickup, unless a single dock used for both purposes is cleaned and disinfected after each use in accordance with paragraph (c)(4)(iv)(F) of this section.

(F) *Surfaces.* The facility must be constructed so that the floor surfaces with which horses have contact are nonslip and wear-resistant. All floor surfaces with which the horses, their excrement, or discharges have contact must provide for adequate drainage. All floor and wall surfaces with which the horses, their excrement, or discharges have contact must be impervious to moisture and be able to withstand frequent cleaning and disinfection without deterioration. Ceilings and wall surfaces with which the horses, their excrement, or discharges do not have contact must be able to withstand cleaning and disinfection between shipments of horses. All floor and wall surfaces must be free of sharp edges that could cause injury to horses.

(G) *Horse stalls.* The stalls in which horses are kept must be large enough to allow each animal to make normal postural and social adjustments with adequate freedom of movement. Exercise equipment for horses may be kept in the stalls, provided that there will still be sufficient space within the stalls for the horses to move freely once the equipment is installed.

(H) *Aisleways.* The aisleways through which horses are moved to and from stalls must be wide enough to provide for safe movement of horses, including allowing horses to turn around in the aisleway, preventing horses in facing

stalls from coming into contact with horses in the aisleway, and adequately ventilating the stalls.

(I) *Means of isolation.* Physical barriers must separate different lots of horses in the facility so that horses in one lot cannot have physical contact with horses in another lot or with their excrement or discharges. Stalls must be available that are capable of isolating any horses exhibiting signs of illness.

(J) *Showers.* A shower must be located at each entrance to the quarantine area. If the facility has a necropsy area, a shower must be located at the entrance to the necropsy area. A clothes-storage and clothes-changing area must be provided with each shower area. There must also be one or more receptacles near each shower so that clothing that has been worn into the quarantine area can be deposited in a receptacle prior to entering the shower.

(K) *APHIS space.* The facility must have adequate space for APHIS representatives to conduct examinations and testing of the horses in quarantine, prepare and package samples for mailing, and store the necessary equipment and supplies for duplicate samples. The space provided to conduct examinations and testing must include a refrigerator-freezer in which to store samples. The examination space must include equipment to provide for the safe inspection of horses. The facility must also include a secure, lockable office for APHIS use with enough room for a desk, chair, and filing cabinet.

(L) *Necropsy area.* The facility must either include an area for conducting necropsies onsite or must have designated an alternate facility at which a suitable necropsy area is available. If the facility has a necropsy area, it must be of sufficient size to perform necropsies on horses and be equipped with adequate lighting, hot and cold running water, a drain, a cabinet for storing instruments, a refrigerator-freezer for storing specimens, and an autoclave to sterilize veterinary equipment. If the facility does not have such an area, it must specify an alternate facility at which a suitable necropsy area is available, a route from the quarantine facility to the alternate facility's necropsy area, and the safeguards that will be in place to ensure that communicable diseases of horses are not spread during transit. This alternate facility and transport methodology must be approved by the Administrator under the procedures for requesting variances outlined in paragraph (c)(6) of this section.

(M) *Storage.* The facility must have sufficient storage space for equipment and supplies used in import quarantine operations. Storage space must include separate, secure storage for pesticides and for medical and other biological supplies, as well as a separate vermin-proof storage area for feed and bedding, if feed and bedding are stored at the facility. If the facility has multiple lot-holding areas, then separate storage space for any reusable supplies and equipment that are not disinfected after each use in accordance with part 71 of this chapter must be provided for each lot-holding area.

(N) *Additional space needs.* The facility must have an area for washing and drying clothes, linens, and towels and an area for cleaning and disinfecting equipment used in the facility. The facility must also include a work area for the repair of equipment.

(O) *Restrooms.* The facility must have permanent restrooms in both the quarantine and nonquarantine areas of the facility.

(P) *Ventilation and climate control.* The facility must be constructed with an air handling system capable of controlling and maintaining the ambient temperature, air quality, humidity, and odor at levels that are not injurious or harmful to the health of horses in quarantine. Air supplied to the quarantine area must not be recirculated or reused for other ventilation needs. Air handling systems for lot-holding areas must be separate from air handling systems for other operational and administrative areas of the facility. In addition, if the facility is equipped to handle more than one lot of horses at a time, the air handling system must be adequate to ensure that there is no cross-contamination of air between separate lot-holding areas.

(Q) *Fire protection.* The facility, including the lot-holding areas, must have a fire alarm voice communication system.

(R) *Communication system.* The facility must have a communication system between the nonquarantine and quarantine areas of the facility.

(iii) *Sanitation.* To ensure that proper animal health and biological security measures are observed, the facility must have the following:

(A) Equipment and supplies necessary to maintain the facility in clean and sanitary condition, including pest control equipment and supplies and cleaning and disinfecting equipment with adequate capacity to disinfect the facility and equipment.

(B) Any reusable equipment and supplies that are not disinfected after each use in accordance with part 71 of this chapter maintained separately for each lot of horses.

(C) Equipment and supplies used in the quarantine area maintained separately from equipment and supplies used in the nonquarantine area.

(D) A supply of potable water adequate to meet all watering and cleaning needs, with water faucets for hoses located throughout the facility. An emergency supply of water for horses in quarantine must also be maintained.

(E) A stock of disinfectant authorized in part 71 of this chapter or otherwise approved by the Administrator that is sufficient to disinfect the entire facility.

(F) The capability to dispose of wastes, including manure, urine, and used bedding, by means of burial, incineration, or public sewer. Other waste material must be handled in such a manner that minimizes spoilage and the attraction of pests and must be disposed of by incineration, public sewer, or other preapproved manner that prevents the spread of disease. Disposal of wastes must be carried out in accordance with the terms of the compliance agreement, and is subject to spot audits by APHIS representatives.

(G) The capability to dispose of horse carcasses in a manner approved by the Administrator and under conditions that minimize the risk of disease spread from carcasses.

(H) For incineration to be carried out at the facility, the facility must have incineration equipment that is detached from other facility structures and is capable of burning animal waste and refuse. The incineration site must also include an area sufficient for solid waste holding. Incineration may also take place at a local site away from the facility premises. All incineration activities, whether onsite or offsite, must be carried out in accordance with the terms of the compliance agreement, and are subject to spot audits by APHIS representatives.

(I) The capability to control surface drainage and effluent into, within, and from the facility in a manner that prevents the spread of disease into, within, or from the facility. If the facility is approved to handle more than one lot of horses at the same time, the drainage system must be adequate to ensure that there is no cross-contamination between lot-holding areas.

(iv) *Security.* Facilities must provide the following security measures:

(A) The facility and premises must be kept locked and secure at all times while horses are in quarantine.

(B) The facility and premises must have signs indicating that the facility is a quarantine area and no visitors are allowed.

(C) The facility and premises must be guarded at all times by one or more representatives of a bonded security company, or, alternatively, the facility must have an electronic security system that indicates the entry of unauthorized persons into the facility. Electronic security systems must be coordinated through or with the local police so that monitoring of the quarantine facility is maintained whenever APHIS representatives are not at the facility. The electronic security system must be of the ''silent type'' and must be triggered to ring at the monitoring site and not at the facility. The electronic security system must be approved by Underwriter's Laboratories. The operator must provide written instructions to the monitoring agency stating that the police and a representative of APHIS designated by APHIS must be notified by the monitoring agency if the alarm is triggered. The operator must also submit a copy of those instructions to the Administrator. The operator must notify the designated APHIS representative whenever a breach of security occurs or is suspected of having occurred. In the event that disease is diagnosed in quarantined horses, the Administrator may require the operator to have the facility guarded by a bonded security company in a manner that the Administrator deems necessary to ensure the biological security of the facility.

(D) The operator must furnish a telephone number or numbers to APHIS at which the operator or his or her agent can be reached at all times.

(E) APHIS is authorized to place APHIS seals on any or all entrances and exits of the facility when determined necessary by APHIS and to take all necessary steps to ensure that such seals are broken only in the presence of an APHIS representative. If someone other than an APHIS representative breaks such seals, APHIS will consider the act a breach in security and APHIS representatives will make an immediate accounting of all horses in the facility. If a breach in security occurs, APHIS may extend the quarantine period as long as necessary to determine that the horses are free of communicable diseases.

(4) *Operating procedures.* The following procedures must be observed at the facility at all times:

(i) *Oversight by APHIS representatives.*

(A) Import quarantine operations at a privately owned quarantine facility may only be conducted with the physical presence of and monitoring by APHIS representatives. APHIS representatives are also authorized to perform the services required by this section and by the compliance agreement.

(B) If, as the result of a spot audit, or for any other reason, APHIS determines that the operator has failed to properly care for, feed, or handle quarantined horses as required in this paragraph (c) or in accordance with the terms of the compliance agreement, or has failed to maintain and operate the facility as provided in this paragraph (c) or in accordance with the terms of the compliance agreement, APHIS representatives will furnish such services, will make arrangements for the sale or disposal of quarantined horses at the quarantine facility owner's expense, or will begin the process for withdrawal of approval of the quarantine facility specified in paragraph (c)(1)(iv) of this section.

(ii) *Personnel.*

(A) The operator must provide adequate personnel to maintain the facility and care for the horses in quarantine, including attendants to care for and feed horses, and other personnel as needed to maintain, operate, and administer the facility.

(B) The operator must provide APHIS with an up-to-date list of all personnel who have access to the facility. The list must include the names, current residential addresses, and employee identification numbers of each person. When the operator wishes to grant access to the facility to persons who have not previously had access to it, the operator must update the list prior to such persons having access to the quarantine facility.

(C) The operator must provide APHIS with signed statements from each employee and any other personnel hired by the operator and working at the facility in which the person agrees to comply with paragraph (c) of this section and applicable provisions of this part, all terms of the compliance agreement, and any related instructions from APHIS representatives pertaining to import quarantine operations, including contact with animals both inside and outside the facility.

(iii) *Authorized access.* Access to the facility premises as well as inside the quarantine area will be granted only to APHIS representatives, authorized employees, and other personnel of the operator assigned to work at the facility. All other persons are prohibited from the premises unless specifically granted access by an APHIS representative. Any visitors granted access must be accompanied at all times by an APHIS representative while on the premises or in the quarantine area of the facility.

(iv) *Sanitary requirements.*

(A) All persons granted access to the quarantine area must:

(*1*) Shower when entering and leaving the quarantine area;

(*2*) Shower when leaving the necropsy area if a necropsy is in the process of being performed or has just been completed, or if all or portions of the examined animal remain exposed;

(*3*) Wear clean protective work clothing and footwear upon entering the quarantine area;

(*4*) Wear disposable gloves when handling sick horses and then wash hands after removing gloves; and

(*5*) Change protective clothing, footwear, and gloves when they become soiled or contaminated.

(B) The operator is responsible for providing a sufficient supply of clothing and footwear to ensure that all persons provided access to the quarantine area at the facility have clean, protective clothing, and footwear when they enter the quarantine area.

(C) The operator is responsible for the handling, washing, and disposal of soiled and contaminated clothing worn within the quarantine facility in accordance with the terms of the compliance agreement. At the end of each workday, work clothing worn into the quarantine area must be collected and kept in a bag until the clothing is washed. Used footwear must either be left in the clothes-changing area or cleaned with hot water (148 °F minimum) and detergent and disinfected in accordance with the terms of the compliance agreement. APHIS representatives may conduct spot audits of all handling, cleaning, and/or disposal of used clothing or used footwear.

(D) All equipment (including tractors) must be cleaned and disinfected prior to being used in the quarantine area of the facility with a disinfectant authorized in part 71 of this chapter or otherwise approved by the Administrator. The equipment must remain dedicated to the facility for the entire quarantine period. Any equipment used with quarantined horses (*e.g.,* halters, floats, feed, water buckets, and exercise equipment) must remain dedicated to that particular lot of quarantined horses for the duration of the quarantine period or be cleaned and disinfected before coming in contact with horses from another lot. Prior to its removal from the quarantine premises, any equipment must be cleaned and disinfected in accordance with the terms of the compliance agreement. APHIS representatives may conduct spot audits of all cleaning and disinfection of equipment.

(E) Any vehicle, before entering or leaving the quarantine area of the

facility, must be cleaned and disinfected in accordance with the terms of the compliance agreement within a time period authorized by the APHIS representative and with a disinfectant authorized in part 71 of this chapter or otherwise approved by the Administrator. APHIS representatives may conduct spot audits of all cleaning and disinfection of vehicles.

(F) If the facility has a single loading dock, the loading dock must be cleaned and disinfected after each use in accordance with the terms of the compliance agreement within a time period authorized by the APHIS representative and with a disinfectant authorized in part 71 of this chapter or otherwise approved by the Administrator. APHIS representatives may conduct spot audits of all cleaning and disinfection of the loading dock.

(G) That area of the facility in which a lot of horses has been held or has had access to must be thoroughly cleaned and disinfected, with a disinfectant authorized in part 71 of this chapter or otherwise approved by the Administrator, in accordance with the terms of the compliance agreement, upon release of the horses before a new lot of horses is placed in that area of the facility. APHIS representatives may conduct spot audits of all cleaning and disinfection of lot-holding areas.

(v) *Handling of the horses in quarantine.*

(A) All horses must be handled in accordance with paragraph (a) of this section.

(B) Each lot of horses to be quarantined must be placed in the facility on an ''all-in, all out'' basis. No horse may be taken out of the lot while it is in quarantine, except for diagnostic purposes or as provided in paragraph (a)(4) of this section, and no horse may be added to the lot while the lot is in quarantine. Once import quarantine operations have been completed on a lot, but while the lot is still at the facility, a horse may be removed from that lot.

(C) The facility must provide sufficient feed and bedding for the horses in quarantine, and it must be free of vermin and not spoiled. Feed and bedding must originate from an area that is not listed in part 72 of this chapter as an area quarantined for splenetic or tick fever.

(D) Breeding of horses or collection of germplasm from horses is prohibited during the quarantine period.

(E) Horses in quarantine will be subjected to such tests and procedures as directed by an APHIS representative to determine whether they are free from communicable diseases of horses.

(F) Any death or suspected illness of horses in quarantine must be reported immediately to APHIS. The affected horses must be disposed of as the Administrator may direct, or depending on the nature of the disease, must be cared for as directed by APHIS to prevent the spread of the disease.

(G) Quarantined horses requiring specialized medical attention or additional postmortem testing may be transported off the quarantine site, if authorized by APHIS. A second quarantine site must be established to house the horses at the facility of destination (*e.g.,* veterinary teaching hospital). In such cases, APHIS may extend the quarantine period for that horse and for its lot until the results of any outstanding tests or postmortem results are received.

(H) Should a horse be determined to be infected with or exposed to a Federally regulated disease of horses, arrangements for the final disposition of the infected or exposed horse must be accomplished within 10 days of the date that the importer is notified by the overseeing APHIS representative that the horse has been refused entry into the United States. APHIS representatives must be physically present at and directly monitor the subsequent disposition of the horse. The operator must have a preapproved contingency plan for the disposal of all horses housed at the facility prior to issuance of the import permit.

(I) Vaccination of horses in quarantine is prohibited. However, once import quarantine operations have been completed on a lot, but while the lot is still at the facility, horses in that lot may be vaccinated.

(vi) *Records.*

(A) The facility operator must maintain a current daily record to record the entry and exit of all persons entering and leaving the quarantine facility.

(B) The operator must maintain the daily record, along with any records kept by APHIS and deposited with the operator, for at least 2 years following the date of release of the horses from quarantine and must make such records available to APHIS representatives upon request.

(5) *Environmental quality.* If APHIS determines that a privately operated quarantine facility does not meet applicable local, State, or Federal environmental regulations, APHIS may deny or suspend approval of the facility until appropriate remedial measures have been applied.

(6) *Variances.* The Administrator may grant variances to existing requirements relating to location, construction, and other design features of the physical facility, as well as to sanitation, security, operating procedures, recordkeeping, and other provisions of paragraph (c) of this section, but only if the Administrator determines that the variance causes no detrimental impact to the overall biological security of the import quarantine operations. The operator must submit a request for a variance from the requirements for the construction of the facility in paragraph (c)(3) of this section to the Administrator in writing prior to the construction of the facility. The operator must submit a request for a variance from the operational requirements in paragraph (c)(4) of this section to the Administrator in writing at least 30 days in advance of the arrival of horses to the facility. Any variance must also be expressly provided for in the compliance agreement.

(Approved by the Office of Management and Budget under control number 0579–0313)

■ 6. In § 93.309, the section heading is revised to read as follows:

**§ 93.309 Horse quarantine facilities; payment information.**

* * * * *

■ 7. Section 93.310 is revised to read as follows:

**§ 93.310 Quarantine stations, visiting restricted; sales prohibited.**

Visitors are not permitted in the quarantine enclosure during any time that the horses are in quarantine unless an APHIS representative specifically grants access under such conditions and restrictions as may be imposed by APHIS. An importer (or his or her agent or accredited veterinarian) may be admitted to the lot-holding area(s) containing his or her quarantined horses at such intervals as may be deemed necessary, and under such conditions and restrictions as may be imposed, by an APHIS representative. On the last day of the quarantine period, owners, officers or registry societies, and others having official business or whose services may be necessary in the removal of the horses may be admitted upon written permission from an APHIS representative. No exhibition or sale shall be allowed within the quarantine grounds.

Done in Washington, DC, this 26th day of June 2009.

**Cindy Smith,**

*Acting Deputy Under Secretary for Marketing and Regulatory Programs.*

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