

4.3 To the extent possible, INS and State Department Consular officials will consult, support, and assist the Carrier's efforts to screen passengers prior to boarding.

4.4 The INS shall determine each Carrier's Performance Level (PL) based on statistical analysis of the Carrier's performance, as a means of evaluating whether the Carrier has successfully screened all of its passengers in accordance with 8 CFR 273.3 and this MOU. The PL is determined by taking the number of each Carrier's violations of section 273 of the Act for a fiscal year¹ and dividing this by the number of documented nonimmigrants (i.e., those nonimmigrants that submit an Arrival/Departure Record, Form I-94, I-94T, or I-94W) transported by the Carrier and multiplying the result by 1000.

4.5 The INS shall establish an Acceptable Performance Level (APL), based on statistical analysis of the performance of all carriers, as a means of evaluating whether the Carrier has successfully screened all of its passengers in accordance with 8 CFR 273.3 and this MOU. The APL shall be determined by taking the total number of all carrier violations of section 273 of the Act for a fiscal year¹ and dividing this by the total number of documented nonimmigrants (i.e., those nonimmigrants that submit an Arrival/Departure Record, Form I-94, I-94T, or I-94W) transported by all carriers for a fiscal year and multiplying the result by 1000.

4.6 The INS shall establish a Second Acceptable Performance Level (APL2), based on statistical analysis of the performance of all carriers at or better than the APL, as a means of further evaluating carrier success in screening its passengers in accordance with 8 CFR 273.3 and this MOU. Using carrier statistics for only those carriers which are at or better than the APL, the APL2 shall be determined by taking the total number of these carrier violations of section 273 of the Act for a fiscal year¹ and dividing by the total number of documented nonimmigrants (i.e., those nonimmigrants that submit an Arrival/Departure Record, Form I-94, I-94T, or I-94W) transported by these carriers and multiplying the result by 1000.

4.7 The PL, APL, and APL2 may be recalculated periodically as deemed necessary, based on Carrier performance during the previous period(s).

4.8 Carriers whose PL is at or better than the APL are eligible to receive an automatic 25 percent reduction, if signatory to and in compliance with this MOU, on fines imposed under section 273 of the Act for periods determined by the INS.

4.9 Carriers whose PL is at or better than the APL2 are eligible to receive an automatic 50 percent reduction, if signatory to and in compliance with this MOU, on fines imposed under section 273 of the Act for periods determined by the INS.

¹ The total number of carrier violations of section 273 of the Act for a fiscal year is determined by taking the total number of violations minus violations for the transportation of improperly documented lawful permanent residents and rejected cases. Rejected cases include those cases where the INS has determined that either: (1) No fine occurred; or, (2) sufficient evidence was not submitted to support the imposition of a fine.

4.10 If the Carrier's PL is not at or better than the APL, the Carrier may receive an automatic 25 percent reduction in fines, if it meets certain conditions, including being signatory to and in compliance with the MOU and the carrier submits evidence that it has taken extensive measures to prevent the transport of improperly documented passengers to the United States. This evidence shall be submitted to the Assistant Commissioner for Inspections for consideration. Evidence may include, but is not limited to, the following: (1) Information regarding the Carrier's training program, including participation of the Carrier's personnel in any INS, DOS, or other training programs and the number of employees trained; (2) information regarding the date and number of improperly documented aliens intercepted by the Carrier at the port(s) of embarkation, including, but not limited to, the aliens' name, date of birth, passport nationality, passport number or other travel document information, and reason boarding was refused; and (3) other evidence, including screening procedure enhancements, technological or otherwise, to demonstrate the Carrier's good faith efforts to properly screen passengers destined to the United States.

4.11 The Carrier may defend against imposition or seek further reduction of an administrative fine if the case is timely defended pursuant to 8 CFR part 280, in response to the Form I-79, Notice of Intent to Fine. The Carrier must establish that extenuating circumstances existed at the time of the violation in order to receive any further reduction in fine penalties.

4.12 Nothing in this MOU precludes a carrier from seeking reduction under 8 CFR 273.4.

(Representative's Signature)

(Title)

(Carrier Name)

Dated: _____

Assistant Commissioner, Office of
Inspections, United States Immigration and
Naturalization Service

Dated: _____

[FR Doc. 96-14470 Filed 6-7-96; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 161

RIN 1076-AC81

Navajo Partitioned Land Grazing Regulations

AGENCY: Bureau of Indian Affairs, Department of the Interior.

ACTION: Proposed Rule; reopening of comment period and additional request for comments.

SUMMARY: The comment period on the Department's proposed rule to 25 C.F.R. to govern the grazing of livestock on the Navajo Partitioned Land (NPL) of the Navajo-Hopi Former Joint Use Area (FJUA) of the 1882 Executive Order reservation is reopened to provide additional opportunity for public comment. Comments on this issue will be considered along with comments on the proposed rule published in the Federal Register on November 1, 1995.

DATES: Comments on these proposed rules must be submitted September 9, 1996.

ADDRESSES: Send comments to Bureau of Indian Affairs, Division of Water and Land Resources, Mail Stop: 4559-MIB, 1849 C Street, NW., Washington, DC 20240, or telephone number (202) 208-4004.

FOR FURTHER INFORMATION CONTACT: Robert Curley, (602) 871-5151, Ext. 5105, at the Navajo Area Office in Window Rock, Arizona.

SUPPLEMENTARY INFORMATION: The proposed rule was originally published in the Federal Register November 1, 1995 (60 FR 55507). The original comment period ended on January 2, 1996. Since the opening of the comment period considerable input has been received from the Navajo and Hopi Tribes. Due to the remoteness of the location and the inclement weather a large number of Tribal members have not been able to include their written comments. The reopening of this comment period for a period of 90 days will allow for maximum input from the public.

Dated: April 8, 1996.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 96-14549 Filed 6-7-96; 8:45 am]

BILLING CODE 4310-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 72

RIN 0905-AE70

Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service (PHS), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is being promulgated in accordance with Section

511 of Public Law 104-132, "The Antiterrorism and Effective Death Penalty Act of 1996," (enacted April 24, 1996) which requires such a proposal be issued within 60 days of enactment and a final rule not later than 120 days of enactment. CDC proposes this rule to place additional shipping and handling requirements on laboratory facilities that transfer or receive select infectious agents capable of causing substantial harm to human health. CDC is concerned about the possibility that the interstate transportation of certain infectious agents could have adverse health consequences for human health and safety. These requirements apply to laboratory facilities such as those operated by government agencies, universities, research institutions, and commercial entities. Those facilities requesting select infectious agents listed in the regulation must register with the Secretary of HHS, or with registering entities authorized by the Secretary, as capable and equipped to handle the select infectious agents in accordance with requirements developed by CDC, the National Institutes for Health (NIH), and the Department of Defense.

DATES: Written comments must be received on or before July 10, 1996. Written comments on the proposed information collection requirements should also be submitted on or before July 10, 1996.

ADDRESSES: Mail written comments to the following address: Lynn Myers, Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333; telephone (404) 639-2453 or 639-3235. Mail written comments on the proposed information collection requirements to: Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th Street, NW, rm. 10235, Washington, DC 20503, Attn: Desk Officer for CDC.

Copies: To order copies of the Federal Register containing this document, send your request to: New orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose a Visa or MasterCard number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost of each copy is \$8.00. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and private libraries throughout

the country that receive the Federal Register.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen Morse, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333; telephone (404) 639-3222.

SUPPLEMENTARY INFORMATION: The current rules found at 42 C.F.R. Part 72 were last updated in 1980 and contain specific requirements for the packaging, labeling, and transport of infectious agents shipped in interstate commerce. That regulation does not currently contain provisions restricting parties who may transfer these agents. This proposed rule is designed to ensure that select infectious agents are not shipped to parties who are not equipped to handle them appropriately, or who otherwise lack proper authorization for their requests, and to implement a system whereby scientists in research institutions may continue transferring and receiving these agents without undue burdens.

I. Background

In recent years, the threat of illegitimate use of infectious agents has attracted increasing interest from the perspective of public health. CDC is concerned about the possibility that the interstate transportation of certain infectious agents could have adverse consequences for human health and safety. CDC has already requested that all those entities that ship dangerous human infectious agents exercise increased vigilance prior to shipment to minimize the risk of illicit access to infectious agents. Of special concern are pathogens and toxins causing anthrax, botulism, brucellosis, plague, Q fever, tularemia, and all agents classified for work at Biosafety level 4.

In particular, CDC has already requested that potential providers of these agents carefully and thoroughly review all requests before transferring these agents. This March, 1996, CDC request for voluntary safeguards has been a first step in strengthening regulatory and statutory protections in this area.

II. Proposed Rule

In accordance with Section 511 of Public Law 104-132, "The Antiterrorism and Effective Death Penalty Act of 1996," CDC is proposing new regulations regarding acquisition and transfer of select infectious agents. These proposed regulations have been developed with input from professional associations, the research community, law enforcement authorities, and

concerned members of the public. It is anticipated that most facilities transferring these agents are engaged in activities consisting of interstate commerce, thus subjecting both intrastate and interstate transfers made by such facilities to this regulation. In addition, because these agents have the potential for causing mass destruction or widespread disease in humans, CDC has determined intrastate transfers of these agents from one geographical site to another also pose a risk of potential interstate transmission of disease; therefore, intrastate transfers of these agents are also subject to the regulation. Transfers within a single facility at a single geographical site, however, are not subject to this regulation provided, that the intended use of the agent remains consistent with that specified in the most current transfer form. Facilities that receive select infectious agents are responsible for implementing their own tracking mechanisms of intra-facility transfers of agents within a single geographical site.

The proposed rule is based upon the key principles of ensuring that the public safety is protected without encumbering legitimate scientific and medical research. In addition, the proposed rule focuses on strengthening public-private sector accountability through involvement with professional associations and close coordination with the research community actually handling these agents. Such relationships, combined with expanded federal criminal sanctions, minimize the need for an additional, expansive federal regulatory structure.

Specifically, the rule is designed to:

- collect and provide information concerning the location where certain potentially-hazardous infectious agents are transferred;
- track the acquisition and transfer of these specific infectious agents; and
- establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents.

The proposed rule is premised upon the following fundamental components: (1) A comprehensive list of select infectious agents; (2) a registration of facilities transferring these agents; (3) transfer requirements; (4) verification procedures including audit, quality control, and accountability mechanisms; (5) agent disposal requirements; and (6) research and clinical exemptions.

III. Select Infectious Agents List

The proposed list of select infectious agents (Appendix A) was originally developed from agents placed on the "Australia list" (15 C.F.R. Part 799.1,

Supplement No. 1, Export Control Classification Number 1C61B) of selected infectious agents whose export from the U.S. is controlled due to their capacity for causing substantial harm to human health. After consultation with experts representing affected professional groups, the proposed list now includes those agents provided in Appendix A. CDC will continue consultation with these groups and update the list as necessary. Future updates will be published in the Federal Register for public review and comment. Comments are specifically solicited regarding those agents included or not included on this proposed list.

IV. Registration of Facilities Transferring Select Infectious Agents

Commercial suppliers of these select infectious agents, as well as government agencies, universities, research institutions, individuals and private companies that transfer or obtain these agents, or that wish to work with these agents, must register with the Secretary of HHS or with an organization authorized by the Secretary. Registration requires that a responsible facility official certify that the facility and its laboratory operations meet the biosafety level 2, 3, and/or 4 requirements for working with infectious agents as described in the Third Edition of "CDC/NIH Biosafety in Microbiological and Biomedical Laboratories." Inspection of the facility seeking registration may be required by the Secretary or an organization authorized by the Secretary to determine whether the applicant facility meets the appropriate biosafety level requirements. In return for the certification and a site registration fee, facilities will be issued a unique registration number by the Secretary or the registering entity indicating that the facility is registered to work with these select infectious agents at the prescribed biosafety level. The registration number will then be used to help validate all requests for transfer of these agents.

Registration requests may be denied if the Secretary or the registering entity determines that the applicant facility is not able to comply with any provision of the regulation. Registrations may be withdrawn by the Secretary or registering entity for failure to comply with the regulation or if it is determined that a registered facility can no longer handle agents at the appropriate biosafety level or handles agents in a manner that appears intended to harm the health of humans. Withdrawals and denials will be based upon sufficient evidence in the discretion the Secretary

or registering entity. Any withdrawal or denial may be appealed to the Secretary.

V. Transfer Requirements

Prior to transferring one of these select infectious agents, the proposed rule requires both the shipping (transferor) and receiving (requestor) parties to initiate completion of an approved transfer form. Completion of the form is finalized when the requestor acknowledges receipt of the requested agent. The form includes the list of these restricted agents and requires information about the requestor, transferor, the requesting and transferring facilities, their registration numbers, the restricted agent requested, and the proposed use of the agent. The form must accompany the request or purchase order for obtaining these restricted agents, a copy must be maintained by both the requesting and transferring facility, and a copy must be sent to a designated central repository which would be available to Federal and authorized local law enforcement authorities and other officials authorized by the Secretary. The form could later be used for tracking purposes in case of illegitimate access to these agents. Falsification of this form is a Federal criminal offense.

VI. Verification Procedures

To facilitate the shipment of these select infectious agents, each facility shipping or receiving a covered agent must have a "responsible facility official." This person should be either a biosafety officer, a senior management official of the facility, or both. The responsible facility official should not be the same person as those individuals actually transferring and receiving the agents at the facilities.

The requestor's responsible facility official must sign each request, certifying that the individual researcher requesting the agent is officially affiliated with the facility and that the laboratory meets current CDC/NIH Guidelines for working with the requested agent. The responsible facility official sending the restricted agent is required to verify that the receiving facility holds a currently valid registration number, indicating that the recipient has the required biosafety level capability. Inability to validate the necessary information may result in immediate notification of the appropriate authorities.

After transfer of the agent, receipt must be acknowledged by the recipient to the transferor electronically or telephonically within 24 hours, followed by a paper copy of receipt within 3 business days of receiving the

agent. Copies of the completed transfer form must be retained by both the requestor's and transferor's facilities for a period of five (5) years after the date of shipment or for one (1) year after the agents are properly disposed, whichever is longer, and one copy must be sent to the transferor's authorized registering entity for placement in a centralized repository.

VII. Agent Disposal Requirements

The form requires a signed statement that the agents will be stored in accordance with prudent laboratory practices, destroyed after completion of the work, or transferred to an approved repository. Facilities must have in place procedures for the appropriate disposal of agents.

VIII. Research and Clinical Exemptions

In order to provide strains for reference diagnostic and research studies at Biosafety Level 2 facilities, less pathogenic strains of restricted viral agents as described in the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" manual or those specifically mentioned on the new CDC Form EA-101 are exempt from the list of select infectious agents. Toxins for medical use, inactivated for use as vaccines, or preparations for biomedical research use at an LD₅₀ for vertebrates of more than 100 nanograms per kilogram of body weight, are exempt. Transfer of clinical specimens for diagnostic and verification purposes is also exempt. However, isolates of these agents from clinical specimens must be destroyed after confirmation or sent to an approved repository after diagnostic procedures are complete. Other than for these purposes, such isolates may not be transferred to another site without using the transfer form and approval by the responsible facility officials.

IX. Criminal and Civil Penalties

Violations of proposed 42 C.F.R. Part 72 are subject to criminal penalties as prescribed in 42 U.S.C. 271 and 18 U.S.C. 3559 and 3571. Specifically, individuals in violation of this rule are subject to a fine of no more than \$250,000 or one more year in jail, or both. Violations by organizations are currently subject to a fine no greater than \$500,000 per event. A false, fictitious, fraudulent statement or representation on the forms required in the regulation for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both, for an individual; and a fine for an organization. 18 U.S.C. 1001, 3517.

X. Public Comment

Public comment is solicited on all aspects of this proposed amendment to the CDC regulation, "Interstate Shipment of Etiologic Agents," 42 C.F.R. Part 72. In addition, CDC solicits comments on the following items:

(1) The list of select infectious agents covered by this proposed rule (see Appendix A);

(2) The names of organizations that would be candidates to be authorized by the Secretary as a "registering entity" to determine those facilities that are capable of handling the agents covered by this regulation;

(3) The names and addresses of all facilities with biosafety level capacity that may handle these agents; and

(4) The utility of conducting mandatory preregistration inspections of all applicant facilities versus random or for cause preregistration inspections conducted in the discretion of the registering entity or the Secretary.

(5) The advantages or disadvantages of the Secretary or registering entity sending copies of transfer forms to the applicable state health departments.

We are not able to acknowledge or respond to comments individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to the document. In addition, all commenters are advised that, pursuant to the Administrative Procedure Act, all information provided to CDC in response to this request for comment will be publicly available.

XI. Analysis of Impacts

A. Review Under Executive Order 12866, Sections 202 and 205 of the Unfunded Mandate Reform Act of 1995 (P.L. 104-4), and by the Regulatory Flexibility Act (5 USC 603-605)

The Department has examined the potential impact of this proposed rule as directed by Executive Order 12866, by sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4, and by the Regulatory Flexibility Act (5 U.S.C. 603-605).

Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives, and, when regulation is necessary, to select regulatory approaches that maximize net benefits. This proposed rule is designed to ensure that select infectious agents are not shipped to parties who are not equipped to handle them appropriately or who otherwise lack proper authorization for their requests.

The approach selected decentralizes the oversight process for this purpose, imposes minimal administrative costs, and prevents possible serious, harmful effects to public safety and health. (The proposal has been reviewed by the Office of Management and Budget under the terms of the Executive Order.)

The Unfunded Mandates Reform Act of 1995, in sections 202 and 205, requires that agencies prepare several analytic statements before proposing a rule that may result in annual expenditures by State, local and tribal governments, or by the private sector, of \$100 million. As any final rule resulting from this proposal would not result in expenditures of this magnitude, such statements are not necessary.

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis, describing the impact of the proposed rules on small entities, but also permits agency heads to certify that a proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The Secretary hereby has determined that this proposed rule would not have such impact, as it would primarily affect large research institutions.

B. Review under the Paperwork Reduction Act of 1995

The proposed rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The title, description and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. With respect to the following collection of information, CDC invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of CDC's functions, including whether the information shall have practical utility; (b) the accuracy of CDC's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automatic collection techniques for other forms of information technology.

Title: Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents.

Description: The Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132) authorizes the Secretary of Health and Human Services (HHS) to regulate the transfer of certain infectious agents harmful to humans. The Centers for Disease Control and Prevention (CDC) is the agency within the Department responsible for promulgating this regulation. CDC is proposing a rule designed to ensure that select infectious agents are not shipped to parties who are not equipped to handle them appropriately, or who otherwise lack proper authorization for their requests, and to implement a system whereby scientists in research institutions may continue transferring and receiving these agents without undue burdens. Respondents include laboratory facilities such as those operated by government agencies, universities, research institutions, and commercial entities.

Those facilities requesting select infectious agents listed in the regulation must register with the Secretary of HHS, or with registering entities authorized by the Secretary, as capable and equipped to handle the select infectious agents in accordance with requirements developed by CDC, the National Institutes for Health (NIH) and the Department of Defense.

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Those facilities requesting select infectious agents listed in the regulation must register with the Secretary of HHS, or with registering entities authorized by the Secretary, as capable and

equipped to handle the select infectious agents in accordance with requirements developed by CDC, the National Institutes for Health (NIH) and the Department of Defense.

Once registered, facilities must complete a federally-developed form, CDC Form EA-101, for each transfer of an agent covered by this proposed rule. Information on this form will include

the name of the requestor and requesting facility, the name of the transferor and transferring facility, the name of the responsible facility official for the transferor and requestor, the requesting facility's registration number, the transferring facility's registration number, the name of the agent(s) being shipped, and the proposed use of the agent. The package is being revised to

include the burden for laboratories to register with the Secretary.

Description of Respondents: Commercial suppliers of these select infectious agents, as well as government agencies, universities, research institutions, and private companies that transfer or obtain these agents, or that wish to work with these agents.

ESTIMATED ANNUAL REPORTING BURDEN

CFR section	No. of respondents	Frequency of responses	Total annual responses	Hour per response	Total hours
72.6(a)	1,000	1	1,000	.25	250
72.6(d)	1,000	3	3,000	1.05	3,150
72.6(e)	120	21	2,520	.17	428
72.6(f)	1,000	3	3,000	.11	330
Total					4,158

Reporting or Disclosures: These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on past experience of respondents reporting such information to CDC. There are no capital costs or operating and maintenance costs for the respondents associated with this information collection.

The agency has submitted a copy of this proposed rule to OMB for its review of these information collection. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing the burden, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th Street, NW., rm 10235, Washington, DC 20503, Attn: Desk Officer for CDC. Submit written comments on the information collection by July 10, 1996.

List of Subjects in 42 CFR Part 72

Biologics, Packaging and containers, Transportation.

Dated: May 16, 1996.

David Satcher,

Director, Centers for Disease Control and Prevention.

Dated: May 28, 1996.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

For the reasons set out in the preamble, it is proposed to amend 42 CFR Chapter 1 as follows:

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS

1. The authority citation for Part 72 is revised to read as follows:

Authority: 42 U.S.C. 264, 271; 31 U.S.C. 9701; 18 U.S.C. 3559, 3571; Public Law 104-132.

2. Sections 72.6 and 72.7 are added to read as follows:

§ 72.6 Additional requirements for facilities transferring or receiving select infectious agents.

(a) Registration of facilities. (1) Prior to transferring or receiving a select infectious agent listed in Appendix A of this part, a laboratory facility shall register with a registering entity authorized by the Secretary (paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BSL) 2, 3, or 4, depending on the agent.

(2) Registration will include:
 (i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BSL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents;

(ii) Inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;

(iii) Issuance by the registering entity of a registration number unique to each facility;

(iv) Collection of a periodic site registration fee by the registering entity or the Secretary. A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be

published in the Federal Register and updated annually.

(v) Follow-up inspections of the facility by the registering entity or the Secretary, as appropriate, to ensure the facility continues to meet approved standards and recordkeeping requirements.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:

(i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;

(ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;

(iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;

(iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or

(v) Failure to pay any required registration fee.

(5) The requirements for BSL-2, 3, and 4 operations pertaining to this section are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition, May 1993 which is hereby incorporated by reference. To the extent the document and this part are inconsistent, the part shall control.

(6) Additional specific requirements for handling toxins subject to this part must be met and are found in 32 CFR 627.17 and in The Biological Defense

Safety Program, Technical Safety Requirements (DA Pamphlet 385-69), Subpart C—Operational Requirements.

(b) Appeals. A decision made by the Secretary or a registering entity to deny or withdraw registration of a particular facility may be appealed to the Secretary. An application for appeal must be received by the Secretary no later than 14 days after the appealing party's application for registration was denied or no later than 14 days after the appealing party's registration was withdrawn. The application must clearly identify the issues presented by the appeal and fully explain the appealing party's position with respect to those issues. The Secretary may allow the filing of opposing briefs, informal conferences, or whatever steps the Secretary considers appropriate to fairly resolve the appeal.

(c) Authorized registering entities. (1) The Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select infectious agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Third Edition.

(2) A registering entity shall maintain: (i) A database of all facilities formerly and currently registered as BSL 2, 3, or 4 capable of working with agents in Appendix A of this part. The database shall include the name and address of the registered facility, the date the facility was registered, the facility's registration number, and the name and phone number of the responsible facility representative. The database shall remain publicly available.

(ii) A copy of each CDC Form EA-101 transmitted by each transferor registered by that registering entity. Such forms shall be made readily accessible to the Secretary and to appropriate federal law enforcement authorities and/or authorized local law enforcement authorities.

(3) In the event the Secretary authorizes more than one registering entity, or if otherwise necessary, the Secretary may require the establishment of a consolidated database to carry out the provisions of paragraph (c)(2) of this section.

(d) Requests for infectious agents. (1) Prior to the transfer of any infectious agent contained in Appendix A, of this part a CDC Form EA-101 must be completed for each transfer sought. As specified in CDC Form EA-101, the information provided must include:

(i) The name of the requestor and requesting facility;

(ii) The name of the transferor and transferring facility;

(iii) The names of the responsible facility officials for both the transferor and requestor;

(iv) The requesting facility's registration number;

(v) The transferring facility's registration number;

(vi) The name of the agent(s) being shipped; and

(vii) The proposed use of the agent(s).

(2) The form must be signed by the transferor and requestor, and the responsible facility officials representing both the transferring and requesting facilities. A copy of the completed CDC Form EA-101 must be retained by both transferring and requesting facilities for a period of five (5) years after the date of shipment or for one (1) year after the agents are properly disposed, whichever is longer. All CDC forms EA-101 must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary, and officials of the registering entity.

(e) Verification of registration. (1) Prior to transferring any agent covered by this part, the transferor's responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:

(i) That the requesting facility retains a valid, current registration;

(ii) That the requestor is officially affiliated with the requesting facility; and

(iii) That the proposed use of the agent by the requestor is correctly indicated on CDC Form EA-101.

(2) In the event that any party is unable to verify the information required in paragraph (e)(1) of this section, or there is suspicion that the agent may not be used for the requested purpose, then the party shall immediately notify CDC and the appropriate law enforcement authorities.

(f) Transfer. (1) Upon completion of the CDC Form EA-101 and verification of registration, the transferring facility must ship the agents in accordance with packaging and shipping requirements in this part or other applicable regulations.

(2) The requesting facility's responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 24 hours of receipt and provide a paper copy of receipt to the transferor within 3 business days of receipt of the agent.

(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed copy of CDC Form EA-101 within 24 hours to the registering entity (holding that facility's registration), in accordance with paragraph (c)(2) of this section for filing in a centralized repository.

(g) Inspections. (1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intra-facility transfers not subject to this part as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with paragraph (c)(3) of this section, to assure compliance with this part.

(h) Exemptions. Select infectious agents otherwise covered by this part are exempt from its provisions if:

(1) The agent(s) are less pathogenic strains which can be used for reference diagnostic or verification procedures and/or research studies at BSL-2, or lower, as described in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition; or

(2) The agent is part of a clinical specimen intended for diagnostic and/or reference verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with paragraph (i) of this section after diagnostic procedures have been completed.

(3) The agent is a toxin having an LD₅₀ for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures.

(i) Agent disposal. (1) Upon termination of the use of the agent, all cultures and stocks of it will be

(i) Securely stored in accordance with prudent laboratory practices,

(ii) Transferred to another registered facility in accordance with this part, or

(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.

(2) When an agent, previously transferred to a facility in accordance with this part, is destroyed, the

responsible facility official must formally notify the registering entity. A copy of such formal notification must be kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

(j) Definitions. As used in this section: *Facility* means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographical site that may transfer or receive through any means a select infectious agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary to register facilities as capable of handling select infectious agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

Requestor means any person who receives or seeks to receive through any means a select infectious agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select infectious agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a biosafety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select infectious agent means an agent, virus, bacteria, fungi, rickettsiae or toxin listed in Appendix A of this part. The term also includes genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity from organisms on Appendix A, and genetically modified microorganisms on Appendix A, and genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in Appendix A, or their toxic subunits.

Transfer (a) means the conveyance or movement from a point of origination to a point of destination either

(1) From one state or territory to another or

(2) Entirely within one contiguous state or territory.

(b) The term does not include intra-facility conveyances within a facility located at a single geographical site provided, that the intended use of the agent remains consistent with that

specified in the most current transfer form.

Transferor means any person who transfers or seeks to transfer through any means a select infectious agent subject to this part to any other person.

§72.7 Penalties.

Individuals in violation of this part are subject to a fine of no more than \$250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than \$500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

Appendix A to Part 72—Select Infectious Agents

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Chikungunya virus
3. Ebola virus
4. Hantaviruses
5. Japanese encephalitis virus
6. Lassa fever virus
7. Marburg virus
8. Rift Valley fever virus
9. Tick-borne encephalitis viruses
10. Variola major virus (Smallpox virus)
11. Yellow fever virus
12. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Guanarito, and those yet to be described)
13. Encephalitis viruses (Venezuelan, Western, Eastern)
14. Kyasanur Forest Disease virus

Exemptions: Vaccine strains of these viral agents as described in the third edition of the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" are exempt.

Bacteria*

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Chlamydia psittaci
4. Clostridium botulinum
5. Francisella tularensis
6. Burkholderia (Pseudomonas) mallei
7. Burkholderia (Pseudomonas) pseudomallei
8. Yersinia pestis

Rickettsiae*

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Histoplasma capsulatum (incl. var duboisii)

Toxins

1. Abrin
2. Botulinum toxins
3. Clostridium perfringens toxin
4. Corynebacterium diphtheriae toxin
5. Cyanginosins
6. Staphylococcal enterotoxins
7. Shigella dysenteriae neurotoxin
8. Ricin

9. Saxitoxin
10. Shigatoxin
11. Tetanus toxin
12. Tetrodotoxin
13. Trichothecene mycotoxins
14. Verrucologen

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD₅₀ for vertebrates of more than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and Shigella dysenteriae neurotoxin) are exempt.

Recombinant organisms/molecules

1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity from organisms on restricted list.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on the restricted list, or their toxic subunits.

* The deliberate transfer of a drug resistance trait to microorganisms on this list that are not known to acquire the trait naturally is prohibited by HHS "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[CS Docket No. 95-178; FCC 96-197]

Definition of Markets for Purposes of the Cable Television Must-Carry Rules

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comment on transitional mechanisms to facilitate the switch from a local market definition based on Arbitron's "Areas of Dominant Influence" ("ADIs") to one using Nielsen's "Designated Market Areas" ("DMAs") for purposes of the cable television broadcast signal carriage rules. The Commission amended its rules to continue to use Arbitron 1991-1992 ADIs to define local markets for the triennial must-carry/retransmission consent election that must take place by October 1, 1996, and to switch to Nielsen's DMAs beginning with the 1999 election in a *Report and Order* adopted concurrently with the *Further Notice of Proposed Rulemaking* ("Further NPRM") and summarized elsewhere in this issue of the Federal Register. The Commission previously anticipated that updated market lists