design or basic principles of operation and that are made in response to information gathered during the course of an investigation.

(ii) *Changes to clinical protocol.* The requirements in paragraph (a)(1) of this section regarding FDA approval of a supplement do not apply to changes to clinical protocols that do not affect:

(A) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;

(B) The scientific soundness of the investigational plan; or

(C) The rights, safety, or welfare of the human subjects involved in the investigation.

(iii) *Definition of credible information.* (A) Credible information to support developmental changes in the device (including manufacturing changes) includes data generated under the design control procedures of § 820.30, preclinical/animal testing, peer reviewed published literature, or other reliable information such as clinical information gathered during a trial or marketing.

(B) Credible information to support changes to clinical protocols is defined as the sponsor's documentation supporting the conclusion that a change does not have a significant impact on the study design or planned statistical analysis, and that the change does not affect the rights, safety, or welfare of the subjects. Documentation shall include information such as peer reviewed published literature, the recommendation of the clinical investigator(s), and/or the data gathered during the clinical trial or marketing.

(iv) *Notice of IDE change.* Changes meeting the criteria in paragraphs (a)(3)(i) and (a)(3)(ii) of this section that are supported by credible information as defined in paragraph (a)(3)(iii) of this section may be made without prior FDA approval if the sponsor submits a notice of the change to the IDE not later than 5-working days after making the change. Changes to devices are deemed to occur on the date the device, manufactured incorporating the design or manufacturing change, is distributed to the investigator(s). Changes to a clinical protocol are deemed to occur when a clinical investigator is notified by the sponsor that the change should be implemented in the protocol or, for sponsor-investigator studies, when a sponsor-investigator incorporates the change in the protocol. Such notices shall be identified as a ''notice of IDE change.''

(A) For a developmental or manufacturing change to the device, the notice shall include a summary of the relevant information gathered during the course of the investigation upon which the change was based; a description of the change to the device or manufacturing process (cross-referenced to the appropriate sections of the original device description or manufacturing process); and, if design controls were used to assess the change, a statement that no new risks were identified by appropriate risk analysis and that the verification and validation testing, as appropriate, demonstrated that the design outputs met the design input requirements. If another method of assessment was used, the notice shall include a summary of the information which served as the credible information supporting the change.

(B) For a protocol change, the notice shall include a description of the change (cross-referenced to the appropriate sections of the original protocol); an assessment supporting the conclusion that the change does not have a significant impact on the study design or planned statistical analysis; and a summary of the information that served as the credible information supporting the sponsor's determination that the change does not affect the rights, safety, or welfare of the subjects.

(4) *Changes submitted in annual report.* The requirements of paragraph (a)(1) of this section do not apply to minor changes to the purpose of the study, risk analysis, monitoring procedures, labeling, informed consent materials, and IRB information that do not affect:

(i) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;

(ii) The scientific soundness of the investigational plan; or

(iii) The rights, safety, or welfare of the human subjects involved in the investigation. Such changes shall be reported in the annual progress report for the IDE, under § 812.150(b)(5).

* * * * *

Dated: October 27, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31245 Filed 11–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 40

[Public Notice 2910]

Visas: Grounds of Ineligibility

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Final rule.

SUMMARY: This rule finalizes the interim rule published December 29 1997 (62 FR 67564) and implements sections of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA). IIRIRA added new grounds of inadmissibility for: certain aliens who have not been inoculated against infectious diseases designated by statute or by the Advisory Committee for Immunization Practices (ACIP); aliens who have been subject to certain civil penalties; alien student visa abusers; aliens present in the United States without admission or parole; aliens who fail to attend removal proceedings; unlawful alien voters; and former citizens who renounced United States citizenship in order to avoid paying taxes. Some of these sections also provide for waivers of grounds of inadmissibility. The rule also incorporates in the Department's regulations a delegation of authority from the Immigration and Naturalization Service pertaining to waivers of inadmissibility under the Immigration and Nationality Act. Finally, the rule makes a technical correction. Generally, these rules are necessary to ensure that consular officers properly enforce the above-mentioned grounds of ineligibility when adjudicating visa applications.

EFFECTIVE DATES: The effective dates are as follows: for §§ 40.11, 40.52, 40.66, 40.104, and 40.105 the effective date is September 30, 1996; for § 40.67 the effective date is November 30, 1996; for §§ 40.61, 40.62, 40.91, 40.92, 40.93, the effective date is April 1, 1997; and for § 40.22, the effective date is September 30, 1997.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Room L603–C, SA–1, Washington, DC 20520–0106 (odomhe@sa1wpoa.us-state.gov).

SUPPLEMENTARY INFORMATION: The Department published an interim rule, Public Notice 2666 at 62 FR 67564, December 29, 1997, with a request for comments, for numerous sections of Title 22, Part 40 of the Code of the Federal Regulations. The rules were primarily proposed to implement provisions of the Illegal Immigration

Reform and Immigrant Responsibility Act of 1996, Pub. L. 104–208 (IIRIRA), though they also make a technical correction. The rules were discussed in detail in Public Notice 2666, as were the Department's reasons for the regulations. The rules incorporate changes to those sections of Part 40 shown in the table below. A minor wording change now will be made to § 40.91(a).

22 CFR part affected	Heading	IIRIRA section No.
§ 40.11	Medical Grounds of Ineligibility	§ 341
§ 40.22	Suspended Sentences	§ 322
§ 40.52	Unqualified Physicians	N/A (typographic correction)
§ 40.61	Aliens Present Without Admission or Parole	§ 301
§ 40.62	Failure to Attend Removal Proceedings	§ 301
§ 40.66	Aliens Subject of Civil Penalty	§ 345
§ 40.67	Student Visa Abusers	§ 346
§ 40.91	Certain Aliens Previously Removed	§ 301
§ 40.92	Aliens Unlawfully Present	§ 301
§ 40.93	Aliens Unlawfully Present After Previous Immigration Violations	§ 301
§ 40.104	Unlawful voters	§ 347
§ 40.105	Former Citizens Who Renounced Citizenship to Avoid Taxation	§ 352

Analysis of Comments

The interim rules were published for comment at 62 FR 67564. The commenting period was closed on February 27, 1998. The Department received three timely comments in response to the interim rule. As the interim rule contained numerous regulations, each commentator made a variety of comments. Many of the comments received proposed clarifications of terminology used in the published rules. Others asked for specific changes in the regulations to meet perceived inadequacies.

The Department received two comments regarding the waiver clause of 22 CFR 40.92(c). The commentators were concerned that the waiver standards, as provided for in INA section 212(a)(9)(B)(v) lack specificity and are therefore inadequate to assure proper visa application adjudication. The Attorney General is responsible for the approval of such waivers, and the INS has issued guidance as to situations where visa applicants may qualify for a waiver (see 8 CFR 207.3(b)). The Department, and Consular Officers more specifically, are not participants in the Attorney General's decision to consent to an alien's application for a waiver. Clarification of the waiver standards in the Department's regulations, therefore, while ostensibly desirable, would not be appropriate. The Department must defer to the Attorney General for such standards.

Similarly, two commentators remarked that the term 'unlawfully present' as used in 22 CFR 40.92 was inadequately defined. As above, the Department must defer to the Attorney General, and more specifically to the INS, to promulgate the regulations surrounding that term. While awaiting such regulations, however, the Department, with INS approval, issued interim guidance on April 4, 1998, to aid posts in making determinations of unlawful presence. At such time as regulations are put forward by INS, the Department will provide further guidance as appropriate.

Regarding 22 CFR 40.104, Unlawful Voters, one comment suggested that a ''good faith error exception'' for an alien who votes illegally should be added. This comment stemmed from the sometimes confusing circumstances surrounding who is eligible to vote in certain elections. For example, noncitizens may be eligible to vote in some local school board elections. As the laws of the several states address this problem differently, however, it would be impractical to attempt to cover all situations in the Department's regulations. Instead, the Department's guidance on the subject will reflect that, to the extent that the constitutional provision, statute, regulation, or ordinance in question provides that violations occur only as the result of knowing acts, an alien will not be held ineligible if the alien establishes to the satisfaction of the Consular Officer that the alien did not knowingly violate the provision, statute, regulation or ordinance.

With respect to 22 CFR 40.62, Failure to Attend Removal Proceedings, one commentator expressed a concern with the lack of specificity surrounding the term ''reasonable cause.'' Owing to the gravity of the sanctions for a failure to attend removal proceedings, the commentator argued, a more illuminating definition of ''reasonable cause'' should be put forward. While the commentator's concern is well founded, the term ''reasonable cause'' is not without interpretation. The Board of Immigration Appeals (BIA) has decided many cases giving guidance to the meaning of this term (*see, e.g., Matter of Rivera,* 19 I&N Dec. 688, *Matter of Patel,* 19 I&N Dec. 260N (*aff'd Patel* v. *I.N.S.,* 803 F.2d 804 (5th Cir. 1986)); *Matter of Marallag,* 13 I&N Dec. 775; *Matter of Haim* 19 I&N Dec. 641N; *Matter of Ruiz* 20 I&N Dec. 91). With such a foundation, in those instances where a Consular Officer will have to make a ''reasonable cause'' determination, his/her decision will be informed to the extent possible by BIA decisions. Further, the Consular Officer will rely on interpretive material provided to him or her both in the Foreign Affairs Manual and other sources. With this guidance, therefore, the Consular Officer will be well informed and will be in the best position to exercise discretion to make such a determination. Any further explication of the term in the CFR may interfere with and confuse those efforts.

Several comments focused on the interim regulations' effect on the Violence Against Women's Act of 1994 (VAWA). Particularly, the commentators noted that the regulation and the preamble thereto were unclear as to the interpretation of IIRIRA 301(c)(2), which exempts any battered spouse or child who otherwise qualifies as a self-petitioner and who first arrived in the United States before April 1, 1997 from having to demonstrate a ''substantial connection'' between the battering or extreme cruelty and the applicant's unlawful entry into the United States. According to IIRIRA, these applicants need only show that they qualify under the VAWA provisions, which is accomplished if the applicant has an approved petition from INS. This is an important distinction that will be brought to consular officers' attention through the interpretive materials of the

Foreign Affairs Manual associated with aliens unlawfully present and also through future changes to the regulations associated with the immediate relative visa categories.

Finally, one commentator expressed a concern that a battered spouse who has to leave the country may face protracted delays in his or her visa processing if the Consular Officer ''readjudicates'' the INS approved petition that is part of the application. While the concern of the commentator is appreciated, such petitions for battered spouses must be treated in accord with other petitions used by applicants. To that end, 22 CFR 42.41 states that a Consular Officer is authorized to grant the status requested upon receipt of an approved petition, but that the applicant still has ''the burden of establishing to the satisfaction of the Consular Officer that the [applicant] is eligible in all respects to receive a visa.'' The Consular Officer will not readjudicate the petition, therefore, but still must consider and report to INS any information which leads the Consular Officer to believe that the petition was approved in error.

Final Rule

This rule is not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. This rule imposes no reporting or recordkeeping action from the public requiring the approval of the Office and Management and Budget under the Paperwork Reduction Act requirements. This rule has been reviewed as required by E.O. 12778 and certified to be in compliance therewith. This rule is exempted from E.O. 12866 but has been coordinated with INS and reviewed to ensure consistency therewith.

List of Subjects in 22 CFR Part 40

Aliens, Immigrants, Immigration, Nonimmigrants, Passports and visas.

In view of the foregoing, the interim rule amending 22 CFR 40 which was published at 62 FR 67564 on December 29, 1997, is adopted as a final rule with the following change:

PART 40—REGULATIONS PERTAINING TO BOTH NONIMMIGRANTS AND IMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

1. The authority citation for Part 40 continues to read as follows:

Authority: 8 U.S.C. 1104, Pub. L. 104–208, 110 Stat. 3009, 22 U.S.C. 26512.

2. Section 4091(a) is revised as follows:

§ 40.91 Certain aliens previously removed.

(a) *5-year bar.* An alien who has been found inadmissible, whether as a result of a summary determination of inadmissibility at the port of entry under INA 235(b)(1) or of a finding of inadmissibility resulting from proceedings under INA 240 initiated upon the alien's arrival in the United States, shall be ineligible for a visa under INA 212(a)(9)(A)(i) for 5 years following such alien's first removal from the United States.

* * * * *

Dated: October 5, 1998.

Mary A. Ryan,

Assistant Secretary for Consular Affairs.

[FR Doc. 98–30858 Filed 11–20–98; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–98–071]

Drawbridge Operation Regulation; St. Croix River

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation in 33 CFR Part 117.667 governing the operation of the Burlington Northern Railroad Drawbridge across the St. Croix River at Mile 0.2, at Prescott, Wisconsin. This deviation allows the bridge to open upon receipt of 24 hours advance notice from 12:01 a.m. on November 15, 1998, to 11:59 p.m. on December 15, 1998. This action will facilitate maintenance work on the bridge.

DATES: The deviation is effective from 12:01 a.m. on November 15, 1998, to 11:59 p.m. on December 15, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Roger Wiebusch at Director, Western Rivers Operations (ob), Eighth Coast Guard District, 1222 Spruce Street, St. Louis, MO 63103–2832, telephone number (314) 539–3900, ext. 378.

SUPPLEMENTARY INFORMATION: The Burlington Northern Railroad Drawbridge across the St. Croix River at Mile 0.2, at Prescott, Wisconsin provides a vertical clearance of 20.4 feet above normal pool in the closed to navigation position. Navigation on the waterway is a mixture of recreational boats and commercial tows. A temporary deviation has been requested from the normal operation of the bridge in order to accommodate maintenance work. The work is essential for the continued safe operation of the drawbridge. The deviation was coordinated with waterway users and no objections to the deviation have been made.

This deviation allows the Burlington Northern Railroad Drawbridge across the St. Croix River at Mile 0.2, at Prescott, Wisconsin to remain closed to navigation from 12:01 a.m. on November 15, 1998 to 11:59 p.m. on December 15, 1998, with openings provided upon receipt of 24 hours advance notice.

The deviation will be effective from 12:01 a.m. on November 15, 1998 until 11:59 p.m. on December 15, 1998. Presently, the draw is required to open on signal when drawbridge operation regulations are not amended by a deviation.

Dated: November 2, 1998.

A.L. Gerfin, Jr.,

Captain, U.S. Coast Guard, Acting Commander, 8th Coast Guard District.

[FR Doc. 98–31212 Filed 11–20–98; 8:45 am]

BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[IL173–1a; FRL–6191–1]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Illinois; Control of Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Direct final rule.

SUMMARY: The USEPA is approving the Illinois State Plan submittal for implementing the Municipal Solid Waste (MSW) Landfill Emission Guidelines. The State's plan was submitted to USEPA on July 21, 1998, in accordance with the requirements for adoption and submittal of State plans for designated facilities in 40 CFR part 60, subpart B. The state plan establishes performance standards for existing MSW landfills and provides for the implementation and enforcement of those standards. The USEPA finds that Illinois' Plan for existing MSW landfills adequately addresses all of the Federal requirements applicable to such plans. In the proposed rules section of this **Federal Register**, the USEPA is proposing approval of, and soliciting