



State of Wisconsin

LEGISLATIVE REFERENCE BUREAU

RESEARCH APPENDIX - **PLEASE DO NOT REMOVE FROM DRAFTING FILE**

Date Added To File: 06/02/2003 (Per: ARG)



☞ The drafting file for 2003 LRB -2717/P2

has been copied/added to the drafting file for

2003 LRB 03b0272

☞ The attached 2003 draft was incorporated into the new 2003 draft listed above. For research purposes, this cover sheet and the attached drafting file were copied on yellow paper (darkened - auto centered - reduced to 90%), and added, as a appendix, to the new 2003 drafting file. If introduced this section will be scanned and added, as a separate appendix, to the electronic drafting file folder.

☞ This cover sheet was added to rear of the original 2003 drafting file. The drafting file was then returned, intact, to its folder and filed.

2003 DRAFTING REQUEST

Bill

Received: 05/13/2003

Received By: agary

Wanted: Soon

Identical to LRB:

For: Transportation

By/Representing: Paul Nilsen

This file may be shown to any legislator: NO

Drafter: agary

May Contact:

Addl. Drafters:

Subject: Transportation - driver licenses

Extra Copies: TNF, PJH

Submit via email: YES

Requester's email: carol.buckmaster@dot.state.wi.us

Carbon copy (CC:) to: aaron.gary@legis.state.wi.us
paul.nilsen@dot.state.wi.us

Pre Topic:

No specific pre topic given

Topic:

Federal background investigations for CDL holders with hazardous materials endorsements

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?							
/P1	agary 05/13/2003	kgilfoy 05/13/2003	pgreensl 05/14/2003	_____	sbasford 05/14/2003		
/P2	agary 05/23/2003	kgilfoy 05/23/2003	chaskett 05/27/2003	_____	sbasford 05/27/2003		

Vers. Drafted Reviewed Typed Proofed Submitted Jacketed Required

FE Sent For:

<END>

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Bill

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/?				JF/4			
/P1	agary 05/13/2003	kgilfoy 05/13/2003	pgreensl 05/14/2003	5/27	sbasford 05/14/2003		

FE Sent For: *1P2 - 5/23*
king *1P2 - 5/27*
cpk

2003 DRAFTING REQUEST

Bill

Received: **05/13/2003**

Received By: **agary**

Wanted: **Soon**

Identical to LRB:

For: **Transportation**

By/Representing: **Paul Nilsen**

This file may be shown to any legislator: **NO**

Drafter: **agary**

May Contact:

Addl. Drafters:

Subject: **Transportation - driver licenses**

Extra Copies: **TNF, PJH**

Submit via email: **YES**

Requester's email: **carol.buckmaster@dot.state.wi.us**

Carbon copy (CC:) to: **aaron.gary@legis.state.wi.us**
paul.nilsen@dot.state.wi.us

Pre Topic:

No specific pre topic given

Topic:

Federal background investigations for CDL holders with hazardous materials endorsements

Instructions:

See Attached

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1?	agary	1/11-5/13 Kmg	5/14 PJ	5/14 PJ			

FE Sent For: <END>

Gary, Aaron

From: Nilsen, Paul
Sent: Tuesday, May 13, 2003 1:53 PM
To: Gary, Aaron
Subject: RE: HazMat

Gary Guenther, DMV Field Services Director, says we do. "X" is used as single endorsement for haz-mat tanker trucks.

"Unbundle" the X endorsement by adding an in-text sunset to it. That seems easiest way to leave existing ones in effect, stop issuing new ones. Ignore repealer. We will stop issuing X endorsements, and will issue N and H separately instead.

6. "X" endorsement, which is an optional endorsement that may be used to indicate that the licensee holds both "H" and "N" endorsements. The department may not issue or renew an "X" endorsement after the effective date of this act... [revisor inserts date].

Nice catch!

-----Original Message-----

From: Gary, Aaron
Sent: Tuesday, May 13, 2003 12:57 PM
To: Nilsen, Paul
Subject: RE: HazMat

Can you tell me if DOT issues an "x" endorsement (s. 343.17 (3) (d) 6.)? If so, is it in lieu of an H and N, or to have an "x" do you have to have an "h" already issued? Thanks. Aaron

Aaron R. Gary
Legislative Attorney
Legislative Reference Bureau
608.261.6926 (voice)
608.264.6948 (fax)
aaron.gary@legis.state.wi.us

-----Original Message-----

From: Nilsen, Paul
Sent: Tuesday, May 13, 2003 11:12 AM
To: Gary, Aaron
Subject: RE: HazMat

Please make "H" endorsement 4 years (with no change to existing 8 year CDL).
Nothing new on fees.

That will put us in ballpark. We can refine the proposal from that Pdraft, consistent with May 5 rules.
Thanks!

-----Original Message-----

From: Gary, Aaron
Sent: Tuesday, May 13, 2003 11:05 AM
To: Nilsen, Paul
Subject: HazMat

Paul,

Based upon our conversation, how about if I do a very quick, rough P-draft for DOT, with you as "requested by". That might make it easier to have something to work from.

As I understand it, the main points are:

1. DOT submits info. for CDL "H" endorsement holders every 5 yrs. to TSA for background check.
2. TSA notifies CDL holder and WisDOT if person is disqualified from holding "H" endorsement. DOT does no background check itself; DOT only responds to TSA notice.
3. H endorsement must be renewed every 5 years. Background check done at time of renewal. Need "transition" or "trigger" provision for current "H" holders to get into the 5 year cycle.

4. Need provision for DOT to cancel H endorsement (is it cancel or revoke) upon receiving notice from TSA following background check.

5. Need provision requiring DOT to obtain background check from TSA before issuing new H endorsements and prohibiting issuance if TSA notifies that person's background disqualifies person from holding H endorsement.

6. Do you want any funding provision - new appropriation?

Aaron

Aaron R. Gary
Legislative Attorney
Legislative Reference Bureau
608.261.6926 (voice)
608.264.6948 (fax)
aaron.gary@legis.state.wi.us

needed by
5/14
end of
day

King
D-Note

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

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2

Gen. Cat.
AN ACT *relating to:* federal background investigations of persons authorized
to operate vehicles transporting hazardous materials requiring placarding.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

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SECTION 1. 343.125 of the statutes is created to read:

343.125 Endorsements for transporting hazardous materials requiring placarding. (1) Prior to the initial issuance or renewal of an endorsement specified in s. 343.17 (3) (d) 1m. to a commercial driver license, the department shall require the applicant for the endorsement to submit 2 fingerprint cards, each bearing a complete set of the person's fingerprints, to the department for submittal to the federal transportation security administration of the federal department of homeland security for the purposes of conducting a background

1 investigation of the applicant and verifying the applicant's eligibility under federal
2 law to transport hazardous materials requiring placarding.

3 (2) The department may not issue or renew an endorsement specified in s.
4 343.17 (3) (d) 1m. to a commercial driver license if the department has received notice
5 from the federal transportation security administration that the applicant is not
6 eligible to transport hazardous materials requiring placarding. Notwithstanding
7 sub. (3), the department shall cancel an endorsement issued under s. 343.17 (3) (d)
8 1m. to a commercial driver license at any time ^{that} the department receives notice from
9 the federal transportation security administration that the holder of the commercial
10 driver license is not eligible to transport hazardous materials requiring placarding.

11 (3) An "H" endorsement to a commercial driver license issued under this
12 section expires 4 years after the date of issuance. The department may institute any
13 system of initial issuance or renewal of endorsements under this section that it
14 ~~deems~~ ^{considers} advisable for the purpose of gaining a uniform rate of renewals, including
15 providing for the initial issuance or first renewal after the effective date of this
16 subsection [revisor inserts date] ^{of} ~~of~~ endorsement ^{under} ~~under~~ this section that are valid
17 for any period less than 4 years. If the department issues or renews an endorsement
18 under this section that is valid for less than 4 years as authorized by this subsection,
19 the fees due under s. 343.21 (1) shall be prorated accordingly.

20 SECTION 2. 343.16 (1) (a) of the statutes is amended to read:

21 343.16 (1) (a) *General*. The department shall examine every applicant for an
22 operator's license, including applicants for license renewal as provided in sub. (3),
23 and every applicant for authorization to operate a vehicle class or type for which the
24 applicant does not hold currently valid authorization, other than an instruction
25 permit. Except as provided in sub. (2) (cm) and (e), the examinations of applicants

1 for licenses authorizing operation of "Class A", "Class B", "Class C", "Class D" or
2 "Class M" vehicles shall include both a knowledge test and an actual demonstration
3 in the form of a driving skills test of the applicant's ability to exercise ordinary and
4 reasonable control in the operation of a representative vehicle. The department shall
5 not administer a driving skills test to a person applying for authorization to operate
6 "Class M" vehicles who has failed 2 previous such skills tests unless the person has
7 successfully completed a rider course approved by the department. The department
8 may, by rule, exempt certain persons from the rider course requirement of this
9 paragraph. The driving skills of applicants for endorsements authorizing the
10 operation of commercial motor vehicles equipped with air brakes, the transportation
11 of passengers in commercial motor vehicles or the operation of school buses, as
12 provided in s. 343.04 (2) (b), (d) or (e), shall also be tested by an actual demonstration
13 of driving skills. The department may endorse an applicant's commercial driver
14 license for transporting hazardous materials requiring placarding, subject to s.
15 343.125, or the operation of tank vehicles or vehicles towing double or triple trailers,
16 as described in s. 343.04 (2) (a), (c), or (f), based on successful completion of a
17 knowledge test. In administering the knowledge test, the department shall attempt
18 to accommodate any special needs of the applicant. Except as may be required by
19 the department for an "H" or "S" endorsement, the knowledge test is not intended to
20 be a test for literacy or English language proficiency. This paragraph does not
21 prohibit the department from requiring an applicant to correctly read and
22 understand highway signs.

23 SECTION 3. 343.17 (3) (d) 6. of the statutes is amended to read:

24 343.17 (3) (d) 6. "X" endorsement, which is an optional endorsement that may
25 be used to indicate that the licensee holds both "H" and "N" endorsements. The

1 department may not issue or renew an endorsement under this subdivision after the
2 effective date of this subdivision ... [revisor inserts date].

3 SECTION 4. 343.20 (1) (a) of the statutes is amended to read:

4 343.20 (1) (a) Except as otherwise expressly provided in this chapter,
5 reinstated licenses, probationary licenses issued under s. 343.085 and original
6 licenses other than instruction permits shall expire 2 years from the date of the
7 applicant's next birthday. All Subject to s. 343.125 (3), all other licenses and license
8 endorsements shall expire 8 years after the date of issuance. The department may
9 institute any system of initial license issuance which it deems advisable for the
10 purpose of gaining a uniform rate of renewals. In order to put such a system into
11 operation, the department may issue licenses which are valid for any period less than
12 the ordinary effective period of such license. If the department issues a license that
13 is valid for less than the ordinary effective period as authorized by this paragraph,
14 the fees due under s. 343.21 (1) (a), (b) and (d) shall be prorated accordingly.

15 SECTION 5. Nonstatutory provisions.

16 *auto ref. "KA"*
(1) The department of transportation shall require any person who, on the
17 effective date of this subsection, holds a valid endorsement issued under section
18 343.17 (3) (d) 1m. of the statutes to his or her commercial driver license to, not later
19 than the first day of the 7th month beginning after the effective date of this
20 subsection, submit 2 fingerprint cards, each bearing a complete set of the person's
21 fingerprints, to the department of transportation for submittal to the federal
22 transportation security administration of the ~~USA~~ *Federal* department of homeland security
23 for the purposes of conducting a background investigation of the person and verifying
24 the person's eligibility under federal law to transport hazardous materials requiring
25 placarding.

Nonstat.

of transportation

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(2) Notwithstanding section 343.20 (1) (a) of the statutes, the department shall cancel an endorsement issued under section 343.17 (3) (d) 1m. of the statutes to the commercial driver license of a person specified under subsection (1) if any of the following ~~apply~~: *applies*

auto ref. "KA"

(a) The department of transportation receives notice from the federal transportation security administration that the person is not eligible to transport hazardous materials requiring placarding.

(b) The person fails to timely submit the information specified under subsection (1). *auto ref. "KA"*

nonstat.

(3) Notwithstanding section 343.125 of the statutes, as created by this act, a person who has satisfied the requirements under subsection (1) is not required to submit the information specified under section 343.125 (1) of the statutes, as created by this act, upon application, within one year after the effective date of this subsection, for renewal of an endorsement issued under section 343.17 (3) (d) 1m. of the statutes to a commercial driver license.

auto ref. "KA"

SECTION 6. Effective date.

(1) This act takes effect on November 1, 2003, or on the day after publication, whichever is later.

(END)

D - Note

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-2717/P1dn

ARG: *[Handwritten signature]*

ATTN: Paul Nilsen

As I understand the instructions, these federal background checks are only required for "H" endorsements to CDLs. Accordingly, the draft is prepared to apply only to CDLs and not to regular operator's licenses. Is this okay?

Aaron R. Gary
Legislative Attorney
Phone: (608) 261-6926
E-mail: aaron.gary@legis.state.wi.us

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-2717/P1dn
ARG:kmg:pg

May 14, 2003

ATTN: Paul Nilsen

As I understand the instructions, these federal background checks are only required for "H" endorsements to CDLs. Accordingly, the draft is prepared to apply only to CDLs and not to regular operator's licenses. Is this okay?

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State of Wisconsin
2003 - 2004 LEGISLATURE

LRB-2717/P1
ARG:kmg:pg

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

1 **AN ACT to amend** 343.16 (1) (a), 343.17 (3) (d) 6. and 343.20 (1) (a); and **to create**
2 343.125 of the statutes; **relating to:** federal background investigations of
3 persons authorized to operate vehicles transporting hazardous materials
4 requiring placarding.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

5 **SECTION 1.** 343.125 of the statutes is created to read:
6 **343.125 Endorsements for transporting hazardous materials**
7 **requiring placarding.** (1) Prior to the initial issuance or renewal of an
8 endorsement specified in s. 343.17 (3) (d) 1m. to a commercial driver license, the
9 department shall require the applicant for the endorsement to submit 2 fingerprint
10 cards, each bearing a complete set of the person's fingerprints, to the department for

1 submittal to the federal transportation security administration of the federal
2 department of homeland security for the purposes of conducting a background
3 investigation of the applicant and verifying the applicant's eligibility under federal
4 law to transport hazardous materials requiring placarding.

5 (2) The department may not issue or renew an endorsement specified in s.
6 343.17 (3) (d) 1m. to a commercial driver license if the department has received notice
7 from the federal transportation security administration that the applicant is not
8 eligible to transport hazardous materials requiring placarding. Notwithstanding
9 sub. (3), the department shall cancel an endorsement issued under s. 343.17 (3) (d)
10 1m. to a commercial driver license at any time that the department receives notice
11 from the federal transportation security administration that the holder of the
12 commercial driver license is not eligible to transport hazardous materials requiring
13 placarding.

14 (3) An "H" endorsement to a commercial driver license issued under this
15 section expires 4 years after the date of issuance. The department may institute any
16 system of initial issuance or renewal of endorsements under this section that it
17 considers advisable for the purpose of gaining a uniform rate of renewals, including
18 providing for the initial issuance or first renewal after the effective date of this
19 subsection [revisor inserts date], of endorsements under this section that are valid
20 for any period less than 4 years. If the department issues or renews an endorsement
21 under this section that is valid for less than 4 years as authorized by this subsection,
22 the fees due under s. 343.21 (1) shall be prorated accordingly.

23 **SECTION 2.** 343.16 (1) (a) of the statutes is amended to read:

24 343.16 (1) (a) *General.* The department shall examine every applicant for an
25 operator's license, including applicants for license renewal as provided in sub. (3),

1 and every applicant for authorization to operate a vehicle class or type for which the
2 applicant does not hold currently valid authorization, other than an instruction
3 permit. Except as provided in sub. (2) (cm) and (e), the examinations of applicants
4 for licenses authorizing operation of "Class A", "Class B", "Class C", "Class D" or
5 "Class M" vehicles shall include both a knowledge test and an actual demonstration
6 in the form of a driving skills test of the applicant's ability to exercise ordinary and
7 reasonable control in the operation of a representative vehicle. The department shall
8 not administer a driving skills test to a person applying for authorization to operate
9 "Class M" vehicles who has failed 2 previous such skills tests unless the person has
10 successfully completed a rider course approved by the department. The department
11 may, by rule, exempt certain persons from the rider course requirement of this
12 paragraph. The driving skills of applicants for endorsements authorizing the
13 operation of commercial motor vehicles equipped with air brakes, the transportation
14 of passengers in commercial motor vehicles or the operation of school buses, as
15 provided in s. 343.04 (2) (b), (d) or (e), shall also be tested by an actual demonstration
16 of driving skills. The department may endorse an applicant's commercial driver
17 license for transporting hazardous materials requiring placarding, subject to s.
18 343.125, or the operation of tank vehicles or vehicles towing double or triple trailers,
19 as described in s. 343.04 (2) (a), (c), or (f), based on successful completion of a
20 knowledge test. In administering the knowledge test, the department shall attempt
21 to accommodate any special needs of the applicant. Except as may be required by
22 the department for an "H" or "S" endorsement, the knowledge test is not intended to
23 be a test for literacy or English language proficiency. This paragraph does not
24 prohibit the department from requiring an applicant to correctly read and
25 understand highway signs.

1 **SECTION 3.** 343.17 (3) (d) 6. of the statutes is amended to read:

2 343.17 (3) (d) 6. "X" endorsement, which is an optional endorsement that may
3 be used to indicate that the licensee holds both "H" and "N" endorsements. The
4 department may not issue or renew an endorsement under this subdivision after the
5 effective date of this subdivision [revisor inserts date].

6 **SECTION 4.** 343.20 (1) (a) of the statutes is amended to read:

7 343.20 (1) (a) Except as otherwise expressly provided in this chapter,
8 reinstated licenses, probationary licenses issued under s. 343.085 and original
9 licenses other than instruction permits shall expire 2 years from the date of the
10 applicant's next birthday. All Subject to s. 343.125 (3), all other licenses and license
11 endorsements shall expire 8 years after the date of issuance. The department may
12 institute any system of initial license issuance which it deems advisable for the
13 purpose of gaining a uniform rate of renewals. In order to put such a system into
14 operation, the department may issue licenses which are valid for any period less than
15 the ordinary effective period of such license. If the department issues a license that
16 is valid for less than the ordinary effective period as authorized by this paragraph,
17 the fees due under s. 343.21 (1) (a), (b) and (d) shall be prorated accordingly.

18 **SECTION 5. Nonstatutory provisions.**

19 (1) The department of transportation shall require any person who, on the
20 effective date of this subsection, holds a valid endorsement issued under section
21 343.17 (3) (d) 1m. of the statutes to his or her commercial driver license to, not later
22 than the first day of the 7th month beginning after the effective date of this
23 subsection, submit 2 fingerprint cards, each bearing a complete set of the person's
24 fingerprints, to the department of transportation for submittal to the federal
25 transportation security administration of the federal department of homeland

1 security for the purposes of conducting a background investigation of the person and
2 verifying the person's eligibility under federal law to transport hazardous materials
3 requiring placarding.

4 (2) Notwithstanding section 343.20 (1) (a) of the statutes, the department of
5 transportation shall cancel an endorsement issued under section 343.17 (3) (d) 1m.
6 of the statutes to the commercial driver license of a person specified under subsection
7 (1) if any of the following applies:

8 (a) The department of transportation receives notice from the federal
9 transportation security administration that the person is not eligible to transport
10 hazardous materials requiring placarding.

11 (b) The person fails to timely submit the information specified under subsection
12 (1).

13 (3) Notwithstanding section 343.125 of the statutes, as created by this act, a
14 person who has satisfied the requirements under subsection (1) is not required to
15 submit the information specified under section 343.125 (1) of the statutes, as created
16 by this act, upon application, within one year after the effective date of this
17 subsection, for renewal of an endorsement issued under section 343.17 (3) (d) 1m. of
18 the statutes to a commercial driver license.

19 **SECTION 6. Effective date.**

20 (1) This act takes effect on November 1, 2003, or on the day after publication,
21 whichever is later.

22 (END)

Gary, Aaron

From: Nilsen, Paul
Sent: Tuesday, May 20, 2003 9:59 AM
To: Dyck, Jon; Gary, Aaron
Cc: Baetsen, Karen; Morehouse, Alice; Nilsen, Paul
Subject: RE: Haz-Mat draft

Errata: The date in nonstatutory sub. (1) should be "May 1, 2004", not May 1, 2003.

Rationale: The 180-day renewal notice requirement takes effect on the draft's effective date of November 1, 2003. We cannot give 180-day renewal notice to people whose licenses expire on or before May 1, 2004. The nonstatutory section requires us to give as much renewal notice as practicable, while recognizing it cannot be 180-days notice.

-----Original Message-----

From: Nilsen, Paul
Sent: Monday, May 19, 2003 4:39 PM
To: Dyck, Jon
Cc: Gary, Aaron; Baetsen, Karen; Morehouse, Alice
Subject: Haz-Mat draft

Jon,

Attached is a draft of statutory changes the Department feels are necessary to meet minimum federal requirements relating to background checks for hazardous materials ("H") endorsements.

Because the newly promulgated federal rules at 49 CFR 383 and 384 are "interim final rules" subject to change pending comments, the draft includes numerous references to those federal citations in order to incorporate any subsequent minor changes (to federal law) needed to maintain compliance with federal law (for example, the list of disqualifying crimes or the list of acceptable proofs of citizenship status may change). The draft also includes explanatory material indicated by "[****Note:...]".

Please let me know if you would like a summary of the proposal (in addition to the justification paper Karen Baetsen previously sent to you).

Thanks!

<< File: Haz-Mat endorsement draft5.19.doc >>

Paul E. Nilsen
Assistant General Counsel
Wisconsin Department of Transportation
Paul.Nilsen@dot.state.wi.us
(608) 261-0126

HAZARDOUS MATERIALS ENDORSEMENT TO COMMERCIAL DRIVER LICENSES;
FEDERAL SECURITY THREAT ASSESSMENT REQUIRED

SECTION #. Cr; 340.01 (8) (e)

340.01 (8) (e) The vehicle is transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73. [****NOTE: conforms with changes to definition of "commercial motor vehicle", per 49 CFR 383.5].

SECTION #. Am; 343.03(1)(a)

343.03(1)(a) The department shall institute a classified driver license system meeting all federal standards under 49 USC 31301 to 31317 and 49 CFR 383 and 384. [****NOTE: recognizes federal regulations requiring "State Compliance with CDL Program".]

SECTION #. Cr; 343.04 (1) (c)3.

343.04(1)(c)3. The vehicle is transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73. [****Note: Includes as "Class C" motor vehicle any vehicle transporting newly defined hazardous materials.]

SECTION #. Am; 343.04(2)(a)

343.04(2)(a) Hazardous materials transporter. Hazardous materials transporter vehicles are vehicles transporting hazardous materials requiring placarding or transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73.

SECTION #. Am; 343.055(3)

343.055(3) Vehicles transporting hazardous materials, carrying passengers or towing double or triple trailers not waived. Nothing in this section authorizes the operation of a combination vehicle with double or triple trailers, a vehicle transporting hazardous materials requiring placarding except as provided in sub. (1) (c), a vehicle transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73, or a vehicle carrying or designed to transport the driver and 15 or more persons, by a person who does not hold a valid operator's license properly endorsed to permit such operation. [****NOTE: makes commercial driver license waivers inapplicable to transport of CDC select agents and toxins.]

SECTION #. Cr; 343.07(1m) (d)

343.07(1m) (d) No person holding an instruction permit issued under this subsection may operate a vehicle transporting hazardous materials requiring placarding or any quantity of a material listed as a select agent or toxin under 42 CFR part 73. [****Note: prohibits CDL instructional permit holder from transporting hazardous materials, per 49 CFR 383.23 (c)(3).]

SECTION #. Cr; 343.125

343.125 Endorsements for transporting hazardous materials requiring placarding.

- (1) In this section, "H" endorsement" means an "H" endorsement specified in s. 343.17(3)(d)1m.
- (2) The department may not issue or renew an "H" endorsement to a commercial driver license unless all of the following apply:
 - (a) The applicant has submitted to the department one of the following proofs of United States citizenship, or immigration status:
 1. United States passport.
 2. Certificate of birth that bears an official seal and was issued by a state, county, municipal authority, or outlying possession of the United States.
 3. Certification of Birth Abroad issued by the United States Department of State.
 4. Certificate of Naturalization.
 5. Certificate of United States citizenship.
 6. Permanent Resident Card or Alien Registration Receipt Card.
 7. Other proof specified in 49 CFR 383.71 (a) (9).
 - (b) If the applicant submits proof described under par. (a) 6. or 7., the applicant submits his or her Bureau of Citizenship and Immigration Services alien registration number.
 - (c) The applicant has passed such knowledge test as the department may require.
 - (d) The department has received notice from the federal transportation security administration that the applicant does not pose a security threat warranting denial of an "H" endorsement, or that the applicant has received a waiver under 49 CFR 1572.143.
- (1) (a) An "H" endorsement shall expire on the licensee's birthday 4 years after the date of issuance or renewal.
- (b) Notwithstanding par. (a), the initial period for which an "H" endorsement is valid is the earlier of the following:
 1. The date the licensee's commercial driver license expires. If the initial period determined under this subdivision is less than 12 months duration, the initial period shall be the period determined under subd. 2., if the licensee renews his or her commercial driver license at the same time the "H" endorsement is issued.
 2. The date 4 years before the date the licensee's commercial driver license expires. If the initial period determined under this subd. 1.b. is less than 12 months duration, the initial period for which an "H" endorsement is valid is the period determined under subd. 1.

[****Note: This section creates 4-year "H" endorsement lifecycle. The initial period is between 1 and 5 years long, as necessary to make 4-year renewal period coterminous with CDL expiration. If the initial period is less than 12 months, the period is extended

until the expiration of the CDL or--if the CDL is renewed at the time the "H" endorsement is issued--until the midlife of that renewed CDL.]

- (1) Within 15 days after receiving notice from the federal transportation security administration, the department shall do all of the following:
 - (a) Update the department's records to reflect the notice, the issuance, denial or cancellation of an "H" endorsement and the endorsement's expiration date.
 - (b) Notify the commercial drivers license information system of the notice or action.
 - (c) Issue the "H" endorsement, if the department received notice described in sub. (2) (d) and the applicant is otherwise eligible for the "H" endorsement.
 - (d) Cancel or deny the "H" endorsement, if the notice is of a final administrative determination that the applicant or licensee poses a security threat warranting denial of an "H" endorsement.

[****Note: Actions and timing required under 49 CFR 1572.5 (g) (5).]

- (1) Notwithstanding s. 227.42, there is no right to a hearing on any cancellation or denial of an "H" endorsement under this section. [****Note: Federal law assigns all hearings to TSA, per 49 CFR 1572.141 (i).]
- (2) Notwithstanding s. 343.20 (1) (a) and sub. (3), the department may require any person who holds a valid "H" endorsement on November 1, 2003, to apply for renewal of that endorsement, if that endorsement expires after November 1, 2008. The department shall provide the notice required under s. 343.20 (2) (b). The department may cancel the "H" endorsement of any person who fails to renew within the period specified by the department under this subsection. This subsection does not apply to "H" endorsements that are issued or renewed after November 1, 2003.

SECTION #. CR; 343.14 (2g)

343.14 (2g) (a) In addition to the information required under sub. (2), the application form for an "H" endorsement specified in s. 343.17 (3) (d) 1m. shall include all of the information and statements required under 49 CFR 1572.5(e), including the following:

1. The list of disqualifying felony criminal offenses specified in 49 CFR 1572.103 (b).
2. A statement that the individual signing the application is all of the following:
 - a. Has not been convicted, or found not guilty by reason of insanity, of any disqualifying felony criminal offense described in subd. 1. in any jurisdiction during the 7-year period preceding the date of the application.
 - b. Has not been released from incarceration in any jurisdiction for committing any disqualifying felony criminal offense described in subd. 1. within the 5-year period preceding the date of the application.
 - c. Is not wanted or under indictment for any disqualifying felony criminal offense described in subd. 1.

- d. A United States citizen who has not renounced that citizenship, or is lawfully admitted for permanent residence to the United States. If the applicant is lawfully admitted for permanent residence to the United States, the applicant shall provide his or her alien registration number issued by the federal department of homeland security.
 1. A statement that the individual signing the application has been informed that s. 343.245(2)(a)1. and federal regulations under 49 CFR 1572.5 impose an ongoing obligation to disclose to the department within 24 hours if he or she is convicted, or found not guilty by reason of insanity, of any disqualifying felony criminal offense described in subd. 1., or adjudicated as a mental defective or committed to a mental institution, while he or she holds and "H" endorsement specified in s. 343.17(3)(d)1m.
 2. Space for the applicant's social security number. The exceptions under sub. (2) (br) or provided for in a memorandum of understanding entered into under s. 49.857 (2) do not apply to applications under this paragraph. [****Note: There are no religious exceptions or Workforce Development exceptions to the social security requirement for "H" endorsements.]
- (b) Upon receiving a completed application form for an "H" endorsement specified in s. 343.17(3)(d)1m., the department shall immediately forward the application to the federal transportation security administration. The department shall also inform the applicant that he or she has a right to obtain a copy of his or her criminal history record by submitting a written request for that record to the federal transportation security administration. [****Note: actions required per 49 CFR 1572.5(e)(2) and (3)]

SECTION #. Am; 343.16 (1) (a)

343.16(1)(a) General. The department shall examine every applicant for an operator's license, including applicants for license renewal as provided in sub. (3), and every applicant for authorization to operate a vehicle class or type for which the applicant does not hold currently valid authorization, other than an instruction permit. Except as provided in sub. (2) (cm) and (e), the examinations of applicants for licenses authorizing operation of "Class A", "Class B", "Class C", "Class D" or "Class M" vehicles shall include both a knowledge test and an actual demonstration in the form of a driving skills test of the applicant's ability to exercise ordinary and reasonable control in the operation of a representative vehicle. The department shall not administer a driving skills test to a person applying for authorization to operate "Class M" vehicles who has failed 2 previous such skills tests unless the person has successfully completed a rider course approved by the department. The department may, by rule, exempt certain persons from the rider course requirement of this paragraph. The driving skills of applicants for endorsements authorizing the operation of commercial motor vehicles equipped with air brakes, the transportation of passengers in commercial motor vehicles or the operation of school buses, as provided in s. 343.04 (2) (b), (d) or (e), shall also be tested by an actual demonstration of driving skills. The department may endorse an applicant's commercial driver license for transporting hazardous materials requiring placarding, subject to s. 343.125, or the operation of tank vehicles or vehicles towing double or triple trailers, as described in s. 343.04 (2) (a), (c) or (f), based on successful completion of a knowledge test. In administering the knowledge test, the department shall attempt to accommodate any special needs of the applicant. Except as may be required by the department for an "H" or "S" endorsement, the knowledge test is not intended to be a test for literacy or English language proficiency. This paragraph does not prohibit the department from requiring an applicant to correctly read and understand highway signs.

SECTION #. Am; 343.17(3)(d)1m.

343.17(3)(d)1m. "H" endorsement, which authorizes the driver to operate vehicles transporting hazardous materials requiring placarding or any quantity of a material listed as a select agent or toxin under 42 CFR part 73. [****NOTE: expands "H" endorsement to recognize addition of CDC select agents to federal definition of "hazardous materials"]

SECTION #. AM; 343.17(3)(d)6.

343.17(3)(d)6. "X" endorsement, which is an optional endorsement that may be used to indicate that the licensee holds both "H" and "N" endorsements. The department may not issue or renew an endorsement under this subdivision after the effective date of this subdivision [revisor inserts date].

SECTION #. Am; 343.20(1)(a)

343.20(1)(a) Except as otherwise expressly provided in this chapter, reinstated licenses, probationary licenses issued under s. 343.085 and original licenses other than instruction permits shall expire 2 years from the date of the applicant's next birthday. ~~All~~ Subject to s. 343.125 (3), all other licenses and license endorsements shall expire 8 years after the date of issuance. The department may institute any system of initial license issuance which it deems advisable for the purpose of gaining a uniform rate of renewals. In order to put such a system into operation, the department may issue licenses which are valid for any period less than the ordinary effective period of such license. If the department issues a license that is valid for less than the ordinary effective period as authorized by this paragraph, the fees due under s. 343.21 (1) (a), (b) and (d) shall be prorated accordingly. [****Note: recognizes "H" endorsement is not valid for 8-year period.]

SECTION #. Ra; 343.20 (2); 343.20 (2) (a)

343.20(2) (a) The department shall mail to the last-known address of a licensee at least 30 days prior to the expiration of the license a notice of the date upon which such license must be renewed.

(c) Failure to receive notice to renew ~~such a~~ license or endorsement shall not be a defense to a charge of operating a motor vehicle without a valid operator's license. [****Note: this makes room for 343.20 (2) (b), to keep all renewal notices together, and to ensure that anatomical donation notices are sent under s. 343.20 (2m) to "H" holders.]

SECTION #. Cr; 343.20 (2)(b)

343.20(2) (b) Notwithstanding par. (a), at least 180 days prior to the expiration of an "H" endorsement specified in s.343.17(3)(d)1m. the department shall mail a notice to the last-known address of the licensee that the licensee must pass a security threat assessment screening by the federal transportation security administration of the federal department of homeland security as part of the application to renew the endorsement. The notice shall inform the licensee that he or she may commence the federal security threat assessment screening at any time, but no later than 90 days before the expiration of the endorsement. [****Note: requires 180 day renewal notice, per 49 CFR 383.141 (c).]

SECTION #. Am; 343.23(2)(a)

343.23(2)(a) The department shall maintain a file for each licensee or other person containing the application for license, permit or endorsement, a record of reports or abstract of convictions, any notice

received from the federal transportation security administration concerning the person's eligibility for an "H" endorsement specified under s. 343.17(3)(d)1m., the status of the person's authorization to operate different vehicle groups, a record of any out-of-service orders issued under s. 343.305 (7) (b) or (9) (am) and a record of any reportable accident in which the person has been involved, including specification of any type of license and endorsements issued under this chapter under which the person was operating at the time of the accident and an indication whether or not the accident occurred in the course of any of the following: [****Note: requires department to keep TSA notices of threat assessment screening results.]

SECTION 343.245 (2) (a) 1.

343.245(2)(a)1. 'To state.' A person, after applying for or receiving a commercial driver license issued by this state, who is convicted of violating in a motor vehicle any law of this state or local ordinance adopted in conformity therewith or a law enacted by a federally recognized American Indian tribe or band in this state which is in conformity with any law of this state, or the law of another jurisdiction, relating to motor vehicle traffic control, other than parking violations, shall notify the department of the conviction in the manner specified by the department within 30 days after the date of conviction. A person who holds an "H" endorsement specified in s. 343.17(3)(d)1m. shall notify the department within 24 hours if he or she is convicted, or found not guilty by reason of insanity, of any disqualifying felony criminal offense described in s. 343.14 (2g) (a) 1., or adjudicated as a mental defective or committed to a mental institution.

SECTION #. Cr; 343.265 (1r)

343.265 (1r) Notwithstanding sub. (1), the department shall accept the voluntary surrender of an "H" endorsement specified in s. 343.17(3)(d)1m. Upon accepting the surrender, the department shall immediately cancel the endorsement if the licensee is not eligible for the endorsement. Following cancellation under this subsection, the department shall take the actions required in s. 343.125 (4) (a) and (b). Upon accepting the surrender from a person to whom the department would not be prohibited from issuing an "H" endorsement, the department may remove that endorsement from the licensee's commercial driver license as a temporary surrender. The department may not issue an "H" endorsement to any person whose "H" endorsement is removed as a temporary surrender under this subsection unless the person applies for initial issuance of an "H" endorsement. [****Note: For cancellations, this section requires department to update driver records and notify CDLIS, per 49 CFR 1572.5 (g) (5). This section also authorizes 'voluntary temporary surrenders' by otherwise-eligible licensees, under which the licensee may relinquish the "H" endorsement without having that endorsement 'cancelled' (because cancellations may have negative insurance and employment consequences).]

SECTION #. AM; 343.28(1)

343.28 (1) Whenever a person is convicted of a moving traffic violation under chs. 341 to 349 or under a local ordinance enacted under ch. 349, the clerk of the court in which the conviction occurred, or the justice, judge or magistrate of a court not having a clerk, shall, as provided in s. 345.48, forward to the department the record of such conviction. The record of conviction forwarded to the department shall state whether the offender was involved in an accident at the time of the offense, whether the offender was operating a commercial motor vehicle at the time of the offense and, if so, whether the offender was transporting hazardous materials requiring placarding, transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73, or operating a vehicle designed to carry, or actually carrying, 16 or more passengers, including the driver. Whenever a person is convicted of exceeding a posted

speed limit, the record of conviction forwarded to the department shall include the number of miles per hour in excess of the posted speed limit. [****Note: recognizes newly defined "hazardous materials".]

SECTION #. Am; 343.28 (2)

343.28(2) Whenever a person is convicted of any offense for which s. 343.31 makes mandatory the revocation by the secretary of such person's operating privilege, the court in which the conviction occurred shall require the surrender to it of any license then held by such person. The clerk of the court, or the justice, judge or magistrate if the court has no clerk, shall, as provided in s. 345.48, forward to the department the record of conviction and any surrendered licenses. The record of conviction forwarded to the department shall state whether the offender was involved in an accident at the time of the offense, whether the offender was operating a commercial motor vehicle at the time of the offense and, if so, whether the offender was transporting hazardous materials requiring placarding, transporting any quantity of a material listed as a select agent or toxin under 42 CFR part 73, or operating a vehicle designed to carry, or actually carrying, 16 or more passengers, including the driver. [****Note: recognizes newly defined "hazardous materials".]

SECTION #. Am; 343.315(2)(i)

343.315(2)(i) If the violation listed in par. (h) occurred in the course of transporting hazardous materials requiring placarding or any quantity of a material listed as a select agent or toxin under 42 CFR part 73, or while operating a vehicle designed to carry, or actually carrying, 16 or more passengers, including the driver, the person shall be disqualified from operating a commercial motor vehicle for 180 days upon a first conviction, or for a 3-year period for a 2nd or subsequent conviction, arising from separate occurrences committed within a 10-year period while driving or operating a commercial motor vehicle. A disqualification under this paragraph shall be in addition to any penalty imposed under s. 343.44. [****NOTE: provides disqualification for transporting CDC select agents consistent with disqualification for unlawful transport of hazardous materials.]

SECTION #. Am; 345.11 (2m) (b)

345.11(2m)(b) Whether the vehicle was transporting hazardous materials requiring placarding or any quantity of a material listed as a select agent or toxin under 42 CFR part 73. [****NOTE: amends uniform traffic citation contents to include newly defined "hazardous materials" that do not require placarding].

SECTION #. Nonstatutory provisions.

- (1) Notwithstanding section 343.20 (2) (b) of the statutes, as created by this act, the department of transportation shall provide the holder of an "H" endorsement specified in section 343.17(3)(d)1m. of the statutes that expires before May 1, 2003, with as much advance written notice as practicable of the renewal requirements for the endorsement. [****NOTE: this gives as much renewal notice as practicable to holders whose endorsements expire before the 180 day notice period required under 343.20 (2) (b), consistent with 49 CFR 383.141 (c).]
- (2) Notwithstanding section 343.125 (2) and (3) of the statutes, as created by this act, the department of transportation may renew a commercial driver license with an "H" endorsement until such

time as the department receives from the federal transportation security administration a final notice of threat assessment or a notice of no security threat concerning the applicant, or until April 29, 2004, whichever is earlier. [****Note: this allows renewals to occur while TSA completes the threat assessment screening of existing H" endorsement holders, consistent with 49 CFR1572.5(c)(3).]

SECTION #. Effective date.

(1) This act takes effect on November 1, 2003, or on the day after publication, whichever is later.

either accidental or intentional release of a select agent or toxin. The cost of such an event in human life could be very high. A release caused by one of the select agents or toxins would require a complicated and expensive emergency response effort. This effort could include extensive public health measures, such as quarantine, preventative treatment and health testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs could be incurred by hospitals and other medical facilities and institutions of government at all levels. A release, or widespread fear of one, also would create significant secondary effects. It could disrupt business, transportation, and many other aspects of normal behavior, on both a short-term and potentially a long-term basis.

The impacts resulting from the October 2001 anthrax attacks provide an example of the costs that a limited release could incur. The anthrax attacks caused five fatalities and 17 illnesses, disrupted business and government activities, closed substantial parts of the postal service, and caused widespread apprehension and changes in behavior. Costs included more than \$23 million to decontaminate one Senate office building; approximately \$2 billion in revenues lost to the postal service, and as much as \$3 billion in additional costs to the postal service for cleanup of contamination and procurement of mail-sanitizing equipment. Substantial costs due to lost productivity throughout the economy and from ongoing costs of the investigations into the incident are additional impacts.

Implementation of the interim final rule will provide a means of determining where select agents and toxins are located; ensure that their transfer, storage, and use can be tracked; provide for the screening of personnel with access to such agents or toxins; and require that entities in possession of such agents or toxins develop and implement effective means of biosafety and physical security. The benefit of these provisions is a reduced likelihood of either an accidental or intentional release of select agents and toxins and the consequent avoidance of costs associated with such a release.

In large part, the rule establishes common sense rules that already should be followed by entities conducting activities under the rule. Moreover, any costs of compliance should not be significant. The annualized cost on small entities would not exceed one percent of sales or revenue stream and the initial cost would not exceed three percent of sales or revenue stream. A

copy of the economic analysis, "Regulatory Impact Analysis, 42 CFR part 73, Select Biological Agents and Toxins, Interim Final Rule," is available from the CDC Web site at <http://www.cdc.gov>.

Therefore, the HHS Secretary hereby certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532 that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

List of Subjects in 42 CFR Part 73

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

List of Subjects in 42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs-health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties, Social security.

Dated: December 4, 2002.

Tommy G. Thompson,
Secretary.

For the reasons stated in the preamble, 42 CFR Chapters I and V are amended as follows:

1. Part 73 is added to 42 CFR chapter I to read as follows:

PART 73—SELECT AGENTS AND TOXINS

- 73.0 Applicability and related requirements.
- 73.1 Definitions.
- 73.2 Purpose and scope.
- 73.3 General prohibition.
- 73.4 HHS select agents and toxins.
- 73.5 Overlap select agents and toxins.
- 73.6 Exemptions from requirements under this part.
- 73.7 Registration.
- 73.8 Security risk assessments.
- 73.9 Responsible Official.
- 73.10 Safety.
- 73.11 Security.
- 73.12 Emergency response.
- 73.13 Training.
- 73.14 Transfers.
- 73.15 Records.
- 73.16 Inspections.
- 73.17 Notification for theft, loss, or release.
- 73.18 Administrative review.
- 73.19 Civil money penalties.

73.20 Criminal penalties.

73.21 Submissions and forms.

Authority: 42 U.S.C. 262a; sections 201-204, 221 and 231 of Title II of Public Law 107-188, 116 Stat. 637 (42 U.S.C. 262a)

§ 73.0 Applicability and related requirements.

(a) For those entities that on February 7, 2003, were conducting activities under a certificate of registration issued under § 72.6 of this chapter, or were lawfully possessing select agents and toxins, the provisions of part 73 and § 72.6 of this chapter are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable: §§ 73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); § 73.9 (Responsible Official); § 73.10 (Safety); § 73.12 (emergency response); and §§ 73.15 through 73.21 (records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms).

(2) On and after February 7, 2003, the provisions of § 73.13 concerning training related to safety and emergency response are applicable; and on and after September 12, 2003, the remaining provisions of § 73.13, including those concerning training related to security, are applicable.

(3) On and after March 12, 2003, the provisions of § 73.14 (transfers) are applicable.

(4) On and after April 12, 2003, the provisions of § 73.8 regarding security risk assessments for the entity, the Responsible Official, and any individual who owns or controls the entity are applicable; and on and after June 12, 2003, the remainder of § 73.8 (including the provisions regarding individual risk assessments for other than the Responsible Official or any individual who owns or controls the entity) is applicable.

(5) On and after June 12, 2003, the provisions of § 73.11 regarding the development of a security plan are applicable, and on and after September 12, 2003, the remainder of the provisions of § 73.11, including the provisions regarding the implementation of a security plan, is applicable.

(6) On and after November 12, 2003, the provisions of § 73.7 (registration) are applicable.

(b) The following also applies to those entities that on February 7, 2003, already were conducting activities under a certificate of registration issued

under § 72.6 of this chapter or already were lawfully possessing select agents and toxins:

(1) During the period from March 12, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under § 73.7 certifying compliance with the provisions referred to in paragraph (a)(1) of this section and the provisions in § 73.13 concerning training related to safety and emergency response.

(2) During the period from March 12, 2003, through April 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessment) to the Attorney General for the entity, the Responsible Official, and any individual who owns or controls the entity.

(3) During the period from April 12, 2003, through June 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted applications for approval under § 73.8 (security risk assessments) to the Attorney General for all individuals (other than the Responsible Official and any individual who owns or controls the entity) with access to select agents and toxins.

(4) Such an entity remains:

(i) Subject to the registration provisions of § 72.6 of this chapter until November 12, 2003, when superseded by § 73.7;

(ii) Subject to the security provisions of § 72.6 of this chapter regarding development of a security plan until June 12, 2003, when superseded by the requirement to develop a security plan under § 73.11;

(iii) Subject to the security provisions of § 72.6 of this chapter regarding implementation of a security plan until September 12, 2003, when superseded by the requirement to fully comply with § 73.11;

(iv) Subject to the training provisions of § 72.6 of this chapter related to security until September 12, 2003, when superseded by the training provisions of § 73.13 relating to security; and

(v) Subject to the transfer provisions of § 72.6 of this chapter until March 12, 2003, when superseded by § 73.14.

(c) For those entities that on February 7, 2003, were not already were conducting activities under a certificate of registration issued under § 72.6 of this chapter and were not already lawfully possessing select agents and toxins, the provisions of part 73 are applicable as follows:

(1) On and after February 7, 2003, the following sections are applicable:

§§ 73.1 through 73.6 (definitions, purpose and scope, general prohibition, HHS select agents and toxins, overlap select agents and toxins, exemptions from requirements under this part); §§ 73.8 through 73.10 (Security risk assessments, Responsible Official, Safety); §§ 73.12 through 73.21 (emergency response, training, transfers, records; inspections; notification for theft, loss, or release; administrative review; civil money penalties; criminal penalties; and submissions and forms) and must hold a valid permit under 9 CFR part 122 and/or 42 CFR part 71.54.

(2) The provisions of § 73.11 are applicable on and after September 12, 2003.

(3) On and after November 12, 2003, the provisions of § 73.7 (registration) are applicable.

(4) During the period from February 7, 2003, through November 11, 2003, such an entity may not conduct activities regulated under this part unless the entity has submitted to HHS or USDA an application package under § 73.7 certifying compliance with the provisions referred to in paragraph (b)(2) of this section.

§ 73.1 Definitions.

For purposes of this part:

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent or toxin provided that such analysis is directly related to protecting the public health or safety.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Department of Health and Human Services or his or

her designee, unless otherwise specified.

HHS select agent or toxin means a biological agent or toxin included in § 73.4.

Overlap select agent or toxin means a biological agent or toxin included in § 73.5.

Proficiency testing means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Select agent or toxin or select agent and toxin without identification as HHS or overlap means all of those biological agents or toxins included in §§ 73.4 and 73.5 of this part.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means the United States of America, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

USDA means the United States Department of Agriculture.

USDA Secretary means the Department of Agriculture or his or her designee, unless otherwise specified.

Verification means the processes required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

§ 73.2 Purpose and scope.

(a) This part sets forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Act was

designed to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The agents and toxins subject to requirements under this part are those that have the potential to pose a severe threat to public health and safety. They are further identified as either HHS select agents and toxins or overlap select agents and toxins. The term HHS select agents and toxins refers to those select agents and toxins subject to these regulations but not subject to USDA requirements at 9 CFR part 121. The overlap group consists of those select agents and toxins subject to requirements promulgated by the HHS Secretary under this part and also subject to corresponding requirements promulgated by USDA at 9 CFR part 121.

(b) This part does not set requirements for the exportation of select agents or toxins. The Department of Commerce has primary responsibility for regulating the exportation of microorganisms and toxins in Title 15 of the Code of Federal Regulations.

(c) This part does not set requirements for the transportation in commerce of select agents or toxins. The Department of Transportation has primary responsibility for regulating the transportation of such select agents and toxins as hazardous materials under 49 CFR parts 171 through 180.

§ 73.3 General prohibition.

An entity or individual may not possess or use in the United States, receive from outside the United States, or transfer within the United States, a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of this part. Registration, exclusions, and exemptions are automatically revoked when any event occurs that results in an entity or individual no longer being eligible.

§ 73.4 HHS select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are HHS select agents and toxins.

- (a) Viruses:
- (1) Crimean-Congo haemorrhagic fever virus.
 - (2) Ebola viruses.
 - (3) Cercopithecine herpesvirus 1 (Herpes B virus).
 - (4) Lassa fever virus.
 - (5) Marburg virus.

(6) Monkeypox virus.

(7) South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito).

(8) Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]).

(9) Variola major virus (Smallpox virus) and Variola minor virus (Alastrim).

(b) Bacteria:

- (1) *Rickettsia prowazekii*.
- (2) *Rickettsia rickettsii*.
- (3) *Yersinia pestis*.

(c) Fungi: *Coccidioides posadasii*.

(d) Toxins:

- (1) Abrin.
- (2) Conotoxins.
- (3) Diacetoxyscirpenol.
- (4) Ricin.
- (5) Saxitoxin.
- (6) Tetrodotoxin.
- (7) Shiga-like ribosome inactivating proteins.

(e) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

- (i) Are in a vector or host chromosome;
- (ii) Can be expressed *in vivo* or *in vitro*; or
- (iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include non-viable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) of this section does not include the vaccine strain of Junin virus (Candid #1).

(4) Paragraph (d) of this section does not include the following toxins (in the

purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(5) The HHS Secretary may exclude from this section attenuated strains of HHS select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety. To apply for an exclusion an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing that the attenuated strain or toxin is eligible for exclusion. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the Federal Register and will be listed on the CDC Web site at <http://www.cdc.gov>. Exclusions also will be referenced in this section when changes are made based on periodic reviews.

§ 73.5 Overlap select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are overlap select agents and toxins.

(a) Viruses:

- (1) Eastern Equine Encephalitis virus.
- (2) Nipah and Hendra Complex viruses.
- (3) Rift Valley fever virus.
- (4) Venezuelan Equine Encephalitis virus.

(b) Bacteria:

- (1) *Bacillus anthracis*.
- (2) *Brucella abortus*.
- (3) *Brucella melitensis*.
- (4) *Brucella suis*.
- (5) *Burkholderia mallei* (formerly *Pseudomonas mallei*).

(6) *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*).

(7) Botulinum neurotoxin producing species of *Clostridium*.

(8) *Coxiella burnetii*.

(9) *Francisella tularensis*.

(c) Fungi: *Coccidioides immitis*.

(d) Toxins:

- (1) Botulinum neurotoxins.
- (2) *Clostridium perfringens* epsilon toxin.
- (3) Shigatoxin.
- (4) Staphylococcal enterotoxins.
- (5) T-2 toxin.

(e) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.

(3) Viruses, bacteria, fungi, and toxins listed in paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include non-viable select agent organisms or nonfunctional toxins.

(3) Paragraph (a) does not include the vaccine strain of Rift Valley fever virus (MP-12) or Venezuelan Equine encephalitis virus vaccine strain TC-83.

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 0.5 mg of Botulinum neurotoxins; 5 mg of Staphylococcal enterotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; or 1,000 mg of T-2 toxin.

(5) The HHS Secretary, after consultation with the USDA Secretary, may exclude from this section attenuated strains of overlap select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety and do not meet the criteria in 9 CFR part 121 for inclusion. To apply for an exclusion, an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary or the USDA Secretary in accordance with 9 CFR part 121, establishing that the attenuated strain is eligible for exclusion. In response to an application submitted to

the HHS Secretary, the HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the Federal Register and will be listed on the CDC Web site at <http://www.cdc.gov>. Also, they will be referenced in this section when changes are made based on periodic reviews.

§ 73.6 Exemptions from requirements under this part.

(a) An entity is exempt from the provisions of this part, other than § 73.14 (transfer), provided that all of the following apply:

(1) The only activities conducted by the entity that are subject to this part concern select agents or toxins that are contained in specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing;

(2) Upon identification of a select agent or toxin as the result of diagnosis or verification, the entity immediately reports to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21 any of the following: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito);

(3) The entity reports as required under Federal, State, or local law, to appropriate authorities;

(4) After the diagnosis, verification, or proficiency testing, the entity either transfers the specimens or isolates containing a select agent or toxin from the specimens to a facility eligible for receiving them under this part, or destroys them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;

(5) The entity transfers or destroys those select agents or toxins used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after consultation with the HHS Secretary; and

(6) The entity transfers or destroys those select agents or toxins used for proficiency testing within 90 days after receipt; and

(7) The entity prepares a record of the identification and transfer or destruction on CDC Form 0.1318, submits the completed form to the HHS

Secretary in accordance with § 73.21 within seven days after identification, and maintains a copy of the record for a period of three years.

(b) Unless the HHS Secretary issues an order to an entity making specific provisions of this part applicable to protect the public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use is only for the approved purpose and meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(c) The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section and additional regulation under this part is not necessary to protect public health and safety. To apply for an exemption an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section, and that additional regulation under this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. The applicant must notify the HHS Secretary when an authorization for an investigation no longer exists. This exemption automatically ceases when such authorization is no longer in effect.

(d) The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in

response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days. To apply for an exemption or an extension of an exemption, an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

(e) Upon request of the USDA Secretary, after the USDA Secretary has granted an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 based on a finding that there is an agricultural emergency, the HHS Secretary may temporarily exempt an entity from the applicability of the requirements of this part, in whole or in part, to provide for the timely participation of the entity in response to the agricultural emergency. With respect to the emergency, the exemption under this part may not exceed 30 days, except that upon the request of the USDA Secretary, the HHS Secretary may grant one extension of an additional 30 days.

§ 73.7 Registration.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has been granted a certificate of registration by the HHS Secretary or the USDA Secretary.

(b) To apply for a certificate of registration an entity must:

(1) Obtain a registration application number from the HHS Secretary and then apply for approval under § 73.8 for the entity, the Responsible Official, and any individual who owns or controls the entity; and

(2) In accordance with § 73.21, submit the information requested to the HHS Secretary or the USDA Secretary as specified in the registration application package [CDC Form 0.1319]. Information submitted will be used to determine whether the applicant would be eligible to conduct activities under this part. Minimum information required includes:

(i) Identification information (e.g., name, address, contact numbers, identification number assigned by the Attorney General for compliance with § 73.8);

(ii) The name, source, and characterization information on select agents and toxins included in the registration, and quantities held at the time of the application;

(iii) The location, including building and room and floor plans for each building and room, where each select agent or toxin will be stored or used;

(iv) Information addressing safety, security, emergency response plans, and training, including descriptions of any equivalent measures adopted pursuant to § 73.11(d);

(v) The name, position, and identification information regarding the Responsible Official, including the identification number assigned by the Attorney General for compliance with § 73.8;

(vi) A list of individuals who will need access to select agents and toxins;

(vii) A certification statement signed by the Responsible Official attesting to the accuracy of the information submitted; and

(viii) Any other information necessary for the determination.

(c) An application that covers any HHS select agents or toxins (regardless of whether it also covers overlap select agents or toxins) must be submitted to the HHS Secretary in accordance with § 73.21. An application that covers only overlap select agents or toxins may be submitted to either the HHS Secretary or the USDA Secretary.

(d) A certificate of registration will be valid only for the specific select agents and toxins, and the specified activities and locations that are consistent with the information provided by the entity upon which the certificate of registration or amendment was granted. The Responsible Official must promptly notify the HHS Secretary in writing in accordance with § 73.21, if a change occurs in any information submitted to the HHS Secretary in the application for the certificate of registration or amendments. This includes modifications to the list of individuals approved under § 73.8, changes in area of work, or changes in protocols or objectives of studies. To apply for an amendment to a certificate of registration to add select agents or toxins or to change specified activities or locations, an entity must obtain the relevant portion of the registration application package and submit the information requested in the package to the agency that issued the certificate of registration. The package must be submitted to the appropriate address specified in the package.

(e) In response to an application to the HHS Secretary for a certificate of registration or amendment for select

agents and toxins, the HHS Secretary will issue a certificate of registration or amendment if it is determined that the stated activities would be lawful (based on information submitted by the applicant or otherwise obtained by the HHS Secretary) and meet the requirements of this part. Otherwise, the application for a certificate of registration or amendment will be denied. The HHS Secretary will issue a certificate of registration or amendment for an overlap select agent or toxin only if the USDA Secretary concurs that the requirements for obtaining a certificate of registration or amendment under 9 CFR part 121 have been met. The determination of whether a certificate of registration or amendment will be granted may be contingent upon inspection or submission of additional information.

(f) A certificate of registration will cover activities at only one general physical location (a building or a complex of buildings at a single mailing address).

(g) Unless terminated sooner in accordance with this paragraph, a certificate of registration will be valid for up to three years. To obtain a new certificate of registration an entity must submit a new application. (Note: To help ensure timely processing of an application for a certificate of registration or amendment, the applicant should submit the application at least eight weeks prior to the expiration date.)

(1) The HHS Secretary will terminate a certificate of registration based on a determination that the recipient no longer conducts activities covered by the certificate.

(2) Also, the HHS Secretary may terminate a certificate of registration based on a security risk assessment under § 73.8 or failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health or safety. Upon such termination, any select agent or toxin in the possession of the entity must be destroyed or transferred as directed by the HHS Secretary.

(h) An entity must provide notice in writing to the HHS Secretary in accordance with § 73.21 at least five business days before destroying a select agent or toxin, if the destruction would be for the purpose of discontinuing activities with a select agent or toxin covered by a certificate of registration. This will allow the HHS Secretary to observe the destruction or take other action as appropriate.

§ 73.8 Security risk assessment.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless approved by the HHS Secretary or the USDA Secretary based on a security risk assessment by the Attorney General. This paragraph does not apply to Federal, State, or local governmental agencies, but does apply to the Responsible Official and others working for or otherwise acting on behalf of such agencies.

(b) An entity may not provide an individual access to a select agent or toxin and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or the USDA Secretary, based on a security risk assessment by the Attorney General.

(c) To obtain a security risk assessment under this section, an entity must submit to the Attorney General the information requested for the entity, the Responsible Official, any individual who owns or controls the entity, and any other individuals required to obtain approval under this section. The determinations regarding approval will be made by the agency that is responsible for making determinations regarding the corresponding certificate of registration. An entity will receive prompt notice of action taken in response to a request for approval for the entity, the Responsible Official, and individuals. An individual will receive prompt notice of a denial of approval.

(d) The Attorney General will conduct a security risk assessment on entities and individuals whose identifying information is properly submitted. Based on the security risk assessment, the Attorney General will notify the HHS Secretary if the Attorney General identifies any entity, individual who owns or controls the entity, or any other individual who is:

(1) A restricted person under 18 U.S.C. 175b; or

(2) Reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5);

(ii) Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(e) The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as a

restricted person under paragraph (d)(1). The HHS Secretary will deny or revoke access to any select agent or toxin to an entity or individual identified by the Attorney General as meeting the criteria of paragraph (d)(2) unless determined by the HHS Secretary to be warranted in the interest of the public health and safety or national security. For individuals meeting the criteria of paragraph (d)(2) the HHS Secretary may provide a limited approval for a specified time based upon the finding that circumstances warrant such action in the interest of the public health and safety or national security.

(f) Unless a shorter period is granted under paragraph (e) of this section, an approval for an entity or individual under this section will be valid for five years unless terminated sooner. The HHS Secretary may terminate an approval for an entity or an individual based on a request from the entity or individual, a security risk assessment under this section, or a failure to comply with the provisions of this part, and may take such action immediately if necessary to protect the public health and safety, or national security.

(g) The HHS Secretary will request the Attorney General to expedite the review process for an individual and will take action to expedite the HHS Secretary's review process for an individual upon a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher). To apply for an expedited review, an entity must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing the need for such action. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

§ 73.9 Responsible Official.

(a) As a condition of conducting activities regulated under this part, an entity must identify and authorize an individual as the Responsible Official. The Responsible Official may identify one or more individuals, any of whom may serve as the Alternate Responsible Official when the Responsible Official is unavailable. The Responsible Official and all individuals identified to serve as the Alternate Responsible Official must meet all of the qualifications for a Responsible Official. The Responsible Official and all Alternate Responsible Officials must:

(1) Be approved under § 73.8;

(2) Be familiar with the requirements of this part; and

(3) Have authority and responsibility to ensure that the requirements of this part are met, on behalf of the entity.

(b) For purposes of this part, the Alternate Responsible Official acting in the absence of the Responsible Official may conduct all of those activities required under this part to be performed by the Responsible Official.

(c) The Responsible Official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing safety, security and emergency response plans in accordance with § 73.10—§ 73.12;

(2) Allowing only approved individuals to have access to select agents or toxins in accordance with § 73.8 and § 73.11;

(3) Providing appropriate training for safety, security and emergency response in accordance with § 73.13;

(4) Transferring select agents or toxins in accordance with § 73.14;

(5) Providing timely notice of any theft, loss, or release of a select agent or toxin in accordance with § 73.13;

(6) Maintaining detailed records of information necessary to give a complete accounting of all activities related to select agents or toxins in accordance with § 73.15.

(7) The reporting of the identification of a select agent or toxin as a result of diagnosis, verification or proficiency testing in accordance with § 73.6.

§ 73.10 Safety.

(a) An entity subject to the provisions of this part, must develop and implement a safety plan. In developing a safety plan, an entity should consider:

(1) The biosafety standards and requirements for BSL 2, 3, or 4 operations, as they pertain to the respective select agents, that are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," including all appendices except Appendix F. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250-7954 or call in the Washington, DC metropolitan area 202-512-1800 or outside that area call toll free 1-866-512-1800. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia. This publication is also available on the CDC Web site at <http://www.cdc.gov>.

(2) The specific requirements for handling toxins found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories" and/or 29 CFR 1910.1200, "Hazard

Communication," whichever applies and specific provisions for handling toxins found in Appendix I in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories,"

(3) For provisions of the safety plan relating to genetic elements, recombinant nucleic acids and recombinant organisms, the "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). This includes, among other things, provisions regarding risk assessment, physical containment, biological containment, and local review and applies to all recombinant DNA research, regardless of funding. Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia. The "NIH Guidelines for Research Involving Recombinant DNA Molecules," is also available on the CDC Web site at <http://www.cdc.gov>.

(b) The Responsible Official or his or her designee must conduct regular inspections (at least annually) of the laboratory where select agents and toxins are stored or used to ensure compliance with all of the procedures and protocols of the safety plan. The results of these inspections must be documented, and any deficiencies identified during inspections must be corrected.

(c) An entity may not conduct the following experiments unless approved by the HHS Secretary after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

(d) [Reserved]

§ 73.11 Security.

(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks

associated with those vulnerabilities are mitigated with a security systems approach.

(b) The plan must:

(1) Describe inventory control procedures, minimal education and experience criteria for those individuals with access to select agents or toxins, physical security, and cyber security;

(2) Contain provisions for routine cleaning, maintenance, and repairs; provisions for training personnel in security procedures; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes;

(3) Describe procedures for loss or compromise of keys, passwords, combinations, etc.;

(4) Contain procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records;

(5) Contain provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons;

(6) Contain provisions for ensuring that all individuals with access, including workers and visitors, understand security requirements and are trained and equipped to follow established procedures;

(7) Establish procedures for reporting and removing unauthorized persons; and

(8) Establish procedures for securing the area when individuals approved under § 73.8 are not present (e.g., card access system, key pads, locks), including protocols for changing access numbers or locks following staff changes.

(c) The security plan must be reviewed by the RO at least annually and after any incident.

(d) With respect to areas containing select agents and toxins, the entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(1) Allow unescorted access only to individuals who have been approved under § 73.8 and who are performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce);

(2) Allow individuals not approved under § 73.8 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually

monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under § 73.8 does not share with any other person, his or her unique means (e.g., keycards or passwords) of accessing the area or select agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

(i) Any loss or compromise of their keys, passwords, combinations, etc.;

(ii) Any suspicious persons or activities;

(iii) Any loss or theft of select agents or toxins;

(iv) Any release of select agents or toxins; and

(v) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.

(e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.

(f) Upon termination of the use, a select agent or toxin must be

(1) Securely stored in accordance with the requirements of this section;

(2) Transferred to another registered facility in accordance with § 73.14; or

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

§ 73.12 Emergency response.

(a) An entity required to register under this part must develop and implement an emergency response plan that meets the requirements of OSHA Hazardous waste operations and emergency response standard at 29 CFR 1910.120. Nothing in this section is to supersede or preempt the enforcement of the emergency response requirements

imposed by the other statute or regulation.

(b) The emergency response plan must be coordinated with any entity-wide plans. The plan must address such events as bomb threats, severe weather (hurricanes, floods), earthquakes, power outages, and other natural disasters or emergencies.

(c) The emergency response plan must address the following:

- (1) The hazards associated with the use of the select agents and toxins;
- (2) Any hazards associated with response actions that could lead to a spread of a select agent or toxin;
- (3) Planning and coordination with outside parties;
- (4) Personnel roles, lines of authority, training, and communication;
- (5) Emergency recognition and prevention;
- (6) Safe distances and places of refuge;
- (7) Site security and control;
- (8) Evacuation routes and procedures;
- (9) Decontamination;
- (10) Emergency medical treatment and first aid;
- (11) Emergency alerting and response procedures;
- (12) Critique of response and follow-up;
- (13) Personal protective and emergency equipment; and
- (14) Special procedures needed to address the hazards of specific agents.

§ 73.13 Training.

(a) An entity required to register under this part and falls outside of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030(a) must provide information and training on safety and security for working with select agents and toxins to each individual approved for access under § 73.8 and each unapproved individual working in, or visiting, areas where select agents and toxins are handled or stored. The information and training must meet the requirements of this section and must ensure that all individuals who work in, or visit, the areas understand the hazards of select agents and toxins present in the area.

(b) The entity must provide information and training at the time of an individual's initial assignment to a work area where select agents or toxins are present and prior to assignments involving new exposure situations. The entity must provide refresher training annually.

(c) The Responsible Official must provide appropriate training in safety, containment, and security to all individuals with access to areas where select agents and toxins are handled or stored.

(d) In lieu of initial training for those individuals already involved in handling select agents or toxins, the Responsible Official may certify in writing that the individual has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities.

(e) The entity must ensure that each individual with access to areas where select agents or toxins are handled or stored received and understood the training required by this section unless certified under paragraph (d) of this section. The entity must record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training.

§ 73.14 Transfers.

A select agent or toxin may not be transferred from one entity to another entity within the United States (regardless of whether the transfer is interstate or intrastate), or received by an entity in the United States from an entity outside the United States, unless:

- (a) The sender:
 - (1) Has a certificate of registration that covers the transfer of the particular select agent or toxin to be transferred,
 - (2) Meets the exemption requirements under § 73.6 (a) for the particular select agent or toxin to be transferred, or
 - (3) Is transferring the select agent or toxin from outside the United States (and all import requirements are met);
- (b) The recipient has a certificate of registration that includes the particular select agent or toxin to be transferred;
- (c) Prior to the transfer, the recipient and sender completes CDC Form EA-101, and the recipient submits to the HHS Secretary in accordance with § 73.21 a completed CDC Form EA-101.
- (d) CDC has authorized the transfer based on the finding that the recipient has a certificate of registration covering the transfer of the select agent or toxin;
- (e) The sender complies with all applicable laws concerning packaging and shipping;
- (f) The Responsible Official of the recipient provides a completed paper copy or facsimile transmission of CDC Form EA-101 to the sender and to the HHS Secretary within 2 business days of receipt of the select agent or toxin; and
- (g) The recipient immediately reports to the HHS Secretary if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package received containing select agents or toxins has been leaking or was otherwise damaged.
- (h) When the select agents or toxins are consumed or destroyed after a transfer, the recipient must within five

business days report such fact to the HHS Secretary in accordance with § 73.21 on a CDC Form EA-101.

Note to § 73.14: This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

§ 73.15 Records.

The Responsible Official must maintain complete records relating to the activities covered by this Part. Such records include:

(a) An entity required to register under this part must maintain an up-to-date, accurate list of the individuals approved under § 73.8 for access to select agents and toxins.

(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

- (1) The name, characteristics, and source data;
 - (2) The quantity held on the date of the first inventory (toxins only);
 - (3) The quantity acquired, the source, and date of acquisition;
 - (4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;
 - (5) The quantity used and date(s) of the use (toxins only);
 - (6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);
 - (7) The current quantity held (toxins only);
 - (8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and
 - (9) A written explanation of any discrepancies.
- (c) The entity must maintain the following records:
- (1) For access to the select agents or toxins:
 - (i) The name of each individual who has accessed any select agent or toxin;
 - (ii) The select agent or toxin used;
 - (iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;
 - (iv) The quantity removed (toxins only);
 - (v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and
 - (vi) The quantity returned (toxins only);
 - (2) For access to the area where select agents are used or stored:

- (i) The name of each individual who has accessed the area;
- (ii) The date and time the individual entered the area;
- (iii) The date and time the individual left the area; and
- (iv) For individuals not approved under § 73.8, the individual approved under § 73.8 who accompanied the unapproved individual into the area.
- (d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.
- (e) The entity must create a record concerning inspections conducted under § 73.10(b).
- (f) Safety, security, and emergency response plans.
- (g) Training records.
- (h) Transfer documents (CDC Form EA-101) and permits.
- (i) Safety and security incident reports.
- (j) The entity must maintain all records created under this part for three years.

§ 73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

§ 73.17 Notification for theft, loss, or release.

- (a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with § 73.21.
- (b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.
- (c) When reporting a theft or loss, the entity must provide the following information:
 - (1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);
 - (2) An estimate of the quantity lost or stolen;
 - (3) An estimate of the time during which the theft or loss occurred; and
 - (4) The location (building, room) from which the theft or loss occurred.
- (d) The entity shall immediately notify the HHS Secretary and State and

local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers. The report must be made to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21.

(e) When reporting a release, the entity must provide the following information:

- (1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);
- (2) An estimate of the quantity released;
- (3) The time and duration of the release;
- (4) The environment into which the release occurred (e.g., in building or outside of building, waste system);
- (5) The location (building, room) from which the release occurred;
- (6) The number of individuals potentially exposed at the facility.
- (7) Actions taken to respond to the release; and
- (8) Hazards posed by the release.
- (f) Within seven calendar days of theft, loss, or release, the entity must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316 in accordance with § 73.21.

§ 73.18 Administrative review.

An entity may obtain review of a decision denying or revoking a certificate of registration under § 73.7 and the affected entity or individual may obtain review of a decision denying or revoking approval under § 73.8 by requesting such review in writing within 30 calendar days after the adverse decision. The request for review must state the factual basis for the review, which will be carried out in accordance with 42 U.S.C. 262a(e)(7). Where the adverse decision is in whole or in part based upon notification by the Attorney General under 42 U.S.C. 262a(e)(3), the request for review will be forwarded to the Attorney General for the Attorney General's review and final notification to the HHS Secretary.

§ 73.19 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The delegation of authority includes all powers contained in section

6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board (DAB) have been delegated authority to conduct hearings and to render decisions with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The DAB of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

§ 73.20 Criminal Penalties.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) provides specific criminal penalties for violation of provisions of this part. This is in addition to any other criminal penalties that would apply for violation of provisions of this part.

§ 73.21 Submissions and forms.

(a) CDC forms referred to in this part, including registration application packages, may be obtained on the Select Agent Program Web site at <http://www.cdc.gov>, or by requesting them in writing from the Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333. Forms (including any required attachments) must be submitted in accordance with the instructions on the form.

(b) Applications, requests, notifications, and other information required to be submitted to the HHS Secretary in writing, but not required to be on a form, unless otherwise specified, must be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at lrsat@cdc.gov.

(c) Information not required to be submitted to the HHS Secretary on a form may be submitted to the Select Agent Program, Center for Disease Control and Prevention, 1600 Clifton

Road, NE., Mail Stop E 79, Atlanta, Georgia 30333, or by e-mail at lrsat@cdc.gov.

(d) If an application or request submitted to the HHS Secretary is incomplete or additional information is needed to allow the decision maker to make a determination, the HHS Secretary will notify the applicant or requester in writing of the deficiency and request additional information. If the applicant or requester fails to respond within 30 calendar days (or within such time period agreed upon by the applicant or requester and the HHS Secretary) the application or request will be deemed abandoned.

(e) You may request forms or other information from the USDA at the following address: APHIS, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 40, Riverdale, MD 20737-1231.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

1. The authority citation for part 1003 is revised to read as follows:

Authority: 42 U.S.C. 262a, 1302, 1320-7, 1320a-7a, 1320b-10, 1395u(j), 1395u(k), 1395cc(j), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

2. Section 1003.100 is amended by revising paragraph (a), republishing the introductory text for paragraphs (b) and (b)(1), revising paragraphs (b)(1)(xiv) and (b)(1)(xv), and by adding a new paragraph (b)(1)(xvi) to read as follows:

§ 1003.100 Basis and purpose.

(a) *Basis.* This part implements sections 1128(c), 1128A, 1140, 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act;

sections 421(c) and 427(b)(2) of Pub. L. 99-860; and section 201(f) of Pub. L. 107-188 (42 U.S.C. 1320-7(c), 1320a-7a, 1320b-10, 1395mm, 1395ss(d), 1396b(m), 11131(c), 11137(b)(2) and 262).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(xiv) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

(xv) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act; or

(xvi) Violate the provisions of part 73 of this chapter, implementing section 351A(b) and (c) of the Public Health Service Act, with respect to the possession and use within the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins in use, or transfer of listed biological agents and toxins.

3. Section 1003.101 is amended by republishing the introductory text and by adding, in alphabetical order, a definition for the term "Select agents and toxins" to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

Select agents and toxins means agents and toxins that are listed by the HHS Secretary as having the potential to pose a severe threat to public health and safety, in accordance with section

351A(a)(1) of the Public Health Service Act.

4. Section 1003.102 is amended by republishing the introductory text for paragraph (b), and by adding a new paragraph (b)(16) to read as follows:

§ 1003.102 Basis for civil money penalties and assessments.

(b) The OIG may impose a penalty and, where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(16) Is involved in the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins in violation of part 73 of this chapter as determined by the HHS Secretary, in accordance with sections 351A(b) and (c) of the Public Health Service Act.

5. Section 1003.103 is amended by adding a new paragraph (l) to read as follows:

§ 1003.103 Amount of penalty.

(l) For violations of section 351A(b) or (c) of the Public Health Service Act and 42 CFR part 73, the OIG may impose a penalty of not more than \$250,000 in the case of an individual, and not more than \$500,000 in the case of any other person.

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[Code of Federal Regulations]
[Title 49, Volume 4]
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TITLE 49--TRANSPORTATION

CHAPTER III--FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION,
DEPARTMENT OF TRANSPORTATION

PART 383--COMMERCIAL DRIVER'S LICENSE STANDARDS; REQUIREMENTS AND PENALTIES--Table o

Subpart E--Testing and Licensing Procedures

Sec. 383.71 Driver application procedures.

Source: 53 FR 27649, July 21, 1988, unless otherwise noted.

(a) Initial Commercial Driver's License. Prior to obtaining a CDL, a person must meet the following requirements:

(1) A person who operates or expects to operate in interstate or foreign commerce, or is otherwise subject to part 391 of this title, shall certify that he/she meets the qualification requirements contained in part 391 of this title. A person who operates or expects to operate entirely in intrastate commerce and is not subject to part 391, is subject to State driver qualification requirements and must certify that he/she is not subject to part 391;

(2) Pass a knowledge test in accordance with the standards contained in subparts G and H of this part for the type of motor vehicle the person operates or expects to operate;

(3) Pass a driving or skills test in accordance with the standards contained in subparts G and H of this part taken in a motor vehicle which is representative of the type of motor vehicle the person operates or expects to operate; or provide evidence that he/she has successfully passed a driving test administered by an authorized third party;

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(4) Certify that the motor vehicle in which the person takes the driving skills test is representative of the type of motor vehicle that person operates or expects to operate;

(5) Provide to the State of issuance the information required to be included on the CDL as specified in subpart J of this part;

(6) Certify that he/she is not subject to any disqualification under Sec. 383.51, or any license suspension, revocation, or cancellation under State law, and that he/she does not have a driver's license from more than one State or jurisdiction;

(7) Surrender the applicant's non-CDL driver's licenses to the State; and

(8) Provide the names of all States where the applicant has previously been licensed to drive any type of motor vehicle during the previous 10 years.

(b) License transfer. When applying to transfer a CDL from one State of domicile to a new State domicile, an applicant shall apply for a CDL from the new State of domicile within no more than 30 days after establishing his/her new domicile. The applicant shall:

(1) Provide to the new State of domicile the certifications contained in Sec. 383.71(a) (1) and (6):

(2) Provide to the new State of domicile updated information as specified in subpart J of this part;

(3) If the applicant wishes to retain a hazardous materials endorsement, comply with State requirements as specified in Sec. 383.73(b) (4);

(4) Surrender the CDL from the old State of domicile to the new State of domicile; and

(5) Provide the names of all States where the applicant has previously been licensed to drive any type of motor vehicle during the previous 10 years.

(c) License renewal. When applying for a renewal of a CDL, all applicants shall:

(1) Provide certification contained in Sec. 383.71(a) (1);

(2) Provide update information as specified in subpart J of this part; and

(3) If a person wishes to retain a hazardous materials endorsement, pass the test for such endorsement as specified in Sec. 383.121; and

(4) Provide the names of all States where the applicant has previously been licensed to drive any type of motor vehicle during the previous 10 years.

(d) License upgrades. When applying to operate a commercial motor vehicle in a different group or endorsement from the group or endorsement in which the applicant already has a CDL, all persons shall:

(1) Provide the necessary certifications as specified in Sec. 383.71(a) (1) and (4); and

(2) Pass all tests specified in Sec. 383.71(a) (2) and (3) for the new vehicle group and/or different endorsements.

(e) Nonresident CDL. When an applicant is domiciled in a foreign jurisdiction, as defined in Sec. 383.5, where the commercial motor vehicle operator testing and licensing standards do not meet the standards contained in subparts G and H of this part, as determined by the Administrator, such applicant shall obtain a Nonresident CDL from a State which meets such standards. Such applicant shall:

(1) Complete the requirements to obtain a CDL contained in Sec. 383.71(a); and

(2) After receipt of the CDL, and for as long as it is valid, notify the State which issued the CDL of any adverse action taken by any jurisdiction or governmental agency, foreign or domestic, against his/her driving privileges. Such adverse actions would include but not be limited to license suspension or revocation, or disqualification from operating a commercial motor vehicle for the convictions described in Sec. 383.51. Notifications shall be made within the time periods specified in Sec. 383.33.

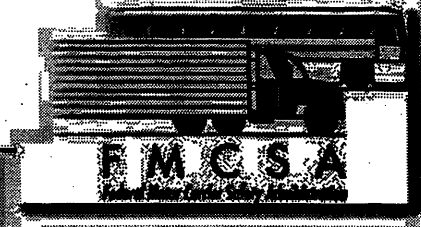
(f) If a State uses the alternative method described in Sec. 383.73(i) to achieve the objectives of the certifications in Sec. 383.71(a), then the driver applicant shall satisfy such alternative methods as are applicable to him/her with respect to initial licensing, license transfer, license renewal, and license upgrades.

[53 FR 27649, July 21, 1988, as amended at 67 FR 49759, July 31, 2002]

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Regulations

§ 383.71 Driver application procedures.

(a) *Initial Commercial Driver's License.* Prior to obtaining a CDL, a person must meet requirements:

(a)(1) A person who operates or expects to operate in interstate or foreign commerce otherwise subject to part 391 of this title, shall certify that he/she meets the qualification requirements contained in part 391 of this title. A person who operates or expects to in intrastate commerce and is not subject to part 391, is subject to State driver qualification requirements and must certify that he/she is not subject to part 391;

(a)(2) Pass a knowledge test in accordance with the standards contained in subpart part for the type of motor vehicle the person operates or expects to operate;

(a)(3) Pass a driving or skills test in accordance with the standards contained in subpart this part taken in a motor vehicle which is representative of the type of motor vehicle operates or expects to operate; or provide evidence that he/she has successfully pass test administered by an authorized third party;

(a)(4) Certify that the motor vehicle in which the person takes the driving skills test is of the type of motor vehicle that person operates or expects to operate;

(a)(5) Provide to the State of issuance the information required to be included on the specified in subpart J of this part;

(a)(6) Certify that he/she is not subject to any disqualification under § 383.51, or any suspension, revocation, or cancellation under State law, and that he/she does not have license from more than one State or jurisdiction;

(a)(7) Surrender the applicant's non-CDL driver's licenses to the State; and

(a)(8) Provide the names of all States where the applicant has previously been licensed type of motor vehicle during the previous 10 years.

(a)(9) If applying for a hazardous materials endorsement, comply with Transportation

Administration requirements codified in 49 CFR Part 1572, and provide proof of citizen immigration status as specified in Table 1 to this section. A lawful permanent resident States requesting a hazardous materials endorsement must additionally provide his or her Citizenship and Immigration Services (BCIS) Alien registration number.

Table 1 to § 383.71 List of Acceptable Proofs of Citizenship
Immigration

Status	Proof of status
U.S. Citizen.....	<ul style="list-style-type: none"> [bull] U.S. Passport [bull] Certificate of Naturalization that bears an official seal and was issued by a Federal, State, county, municipal or outlying possession of the United States [bull] Certification of Citizenship Abroad issued by the Department of State (Forms DS-545 or DS-1350) [bull] Certificate of Naturalization (Form N-570) [bull] Certificate of Citizenship (Form N-561)
Lawful Permanent Resident.....	<ul style="list-style-type: none"> [bull] Permanent Resident Card, Alien Registration Receipt Card (Form I-551) [bull] Temporary I-94

in foreign passport
[sbull] Temporary I-94
on Form I-94, Arrival
Departure Record, with
photograph of the bearer
[sbull] Reentry Permit
327)

(b) *License transfer.* When applying to transfer a CDL from one State of domicile to a new State of domicile, an applicant shall apply for a CDL from the new State of domicile within 30 days after establishing his/her new domicile. The applicant shall:

(b)(1) Provide to the new State of domicile the certifications contained in § 383.71(a);

(b)(2) Provide to the new State of domicile updated information as specified in subpart J of this part;

(b)(3) If the applicant wishes to retain a hazardous materials endorsement, he/she must meet the requirements for such endorsement specified in § 383.71(a)(9) and State requirements specified in § 383.73(b)(4);

(b)(4) Surrender the CDL from the old State of domicile to the new State of domicile;

(b)(5) Provide the names of all States where the applicant has previously been licensed and the type of motor vehicle during the previous 10 years.

(c) *License renewal.* When applying for a renewal of a CDL, all applicants shall:

(c)(1) Provide certification contained in § 383.71(a)(1);

(c)(2) Provide updated information as specified in subpart J of this part; and

(c)(3) If a person wishes to retain a hazardous materials endorsement, he/she must meet the requirements specified in § 383.71(a)(9) and pass the test specified in § 383.121 for such endorsement.

(c)(4) Provide the names of all States where the applicant has previously been licensed and the type of motor vehicle during the previous 10 years.

(d) *License upgrades.* When applying to operate a commercial motor vehicle in a different vehicle group or endorsement from the group or endorsement in which the applicant already has a CDL, the applicant shall:

(d)(1) Provide the necessary certifications as specified in § 383.71(a)(1) and (a)(4);

(d)(2) Pass all tests specified in § 383.71(a)(2) and (a)(3) for the new vehicle group or endorsement.

endorsements; and

(d)(3) To obtain a hazardous materials endorsement, comply with the requirements for endorsement specified in § 383.71(a)(9).

(e) *Nonresident CDL*. When an applicant is domiciled in a foreign jurisdiction, as defined where the commercial motor vehicle operator testing and licensing standards do not meet the standards contained in subparts G and H of this part, as determined by the Administrator, an applicant shall obtain a Nonresident CDL from a State which meets such standards. shall:

(e)(1) Complete the requirements to obtain a CDL contained in § 383.71(a); and

(e)(2) After receipt of the CDL, and for as long as it is valid, notify the State which issued the CDL of any adverse action taken by any jurisdiction or governmental agency, foreign or domestic, which suspends, revokes, or disqualifies his/her driving privileges. Such adverse actions would include but not be limited to license suspension or revocation, or disqualification from operating a commercial motor vehicle. Such notifications shall be made within the time period specified in § 383.33.

(f) If a State uses the alternative method described in § 383.73(i) to achieve the objectives of the CDL program, then the driver applicant shall satisfy such alternative method applicable to him/her with respect to initial licensing, license transfer, license renewal, and license upgrades.

[53 FR 27649, July 21, 1988, as amended at 67 FR 49759, July 31, 2002; 68 FR 23620, April 23, 2003]



that achieves the objective of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows TSA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the agency publishes with the final rule an explanation why that alternative was not adopted.

This interim final rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than \$100 million annually. Thus, TSA has not prepared a written assessment under the UMRA.

Environmental Analysis

TSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this final rule will not have any significant impact on the quality of the human environment.

Energy Impact

TSA has assessed the energy impact of this rule in accordance with the Energy Policy and Conservation Act (EPCA), Public Law 94-163, as amended (42 U.S.C. 6362). TSA has determined that this rule is not a major regulatory action under the provisions of the EPCA.

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Trade Impact Assessment

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. TSA will continue to consult with Mexico and Canada under the North American Free Trade Agreement to ensure that any adverse impacts on trade are minimized. This rule applies only to individuals applying for a State-issued hazardous materials endorsement for a commercial drivers license. Thus, TSA has determined that this rule will have no impact on trade.

List of Subjects in 49 CFR Parts 1570 and 1572

Commercial drivers license, Criminal history background checks, Explosives, Hazardous materials, Motor carriers, Motor vehicle carriers, Security measures, Security threat assessment.

The Amendments

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For the reasons set forth in the preamble, the Transportation Security Administration amends 49 CFR Chapter XII, Subchapter D as follows:

SUBCHAPTER D--MARITIME AND LAND TRANSPORTATION SECURITY

0

1. Add a Part 1570 to read as follows:

PART 1570--LAND TRANSPORTATION SECURITY: GENERAL RULES

Sec.

1570.1 Scope.

1570.3 Fraud and intentional falsification of records.

Authority: 49 U.S.C. 114, 40113, 46105.

Sec. 1570.1 Scope.

This part applies to any person involved in land transportation as specified in this part.

Sec. 1570.3 Fraud and intentional falsification of records.

No person may make, or cause to be made, any of the following:

(a) Any fraudulent or intentionally false statement in any record or report that is kept, made, or used to show compliance with this subchapter, or exercise any privileges under this subchapter.

(b) Any reproduction or alteration, for fraudulent purpose, of any record, report, security program, access medium, or identification medium issued under this subchapter or pursuant to standards in this subchapter.

PART 1572--CREDENTIALING AND BACKGROUND CHECKS FOR LAND TRANSPORTATION SECURITY

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2. Revise the authority citation for part 1572 to read as follows:

Authority: 49 U.S.C. 114, 5103a, 40113, 46105.

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3. Sections 1572.1 through 1572.11 are designated as subpart A, with the following heading:

Subpart A--Requirements to Undergo Security Threat Assessments

0

4. Add a new Sec. 1572.3 to read as follows:

Sec. 1572.3 Terms used in this part.

For purposes of this part:

Alien means any person not a citizen of the United States.

Alien registration number means the number issued by the United States Department of Homeland Security to an individual when he or she becomes a lawful permanent resident of the United States.

Commercial drivers license (CDL) is used as defined in 49 CFR 383.5.

Convicted means any plea of guilty or nolo contendere, or any finding of guilt.

Endorsement is used as defined in 49 CFR 383.5.

Final Notification of Threat Assessment means a final administrative determination by TSA that an individual poses a security threat warranting denial of the authorization for which the individual is applying.

Hazardous materials is used as defined in 49 CFR 383.5.

Incarceration means confined or otherwise restricted to a jail-type institution, half-way house, treatment facility, or another institution, on a full or part-time basis pursuant to a sentence imposed as the result of a conviction.

Initial Notification of Threat Assessment means an initial administrative determination by TSA that an individual poses a security threat warranting denial of the authorization for which the individual is applying.

Lawful permanent resident means an individual who has been lawfully admitted for permanent residence to the United States, as defined in 8 U.S.C. 1101.

Mental institution means a mental health facility, mental hospital, sanitarium, psychiatric facility, and any other facility that provides diagnoses by licensed professionals of mental retardation or mental illness, including a psychiatric ward in a general hospital.

Notification of No Security Threat means an administrative determination by TSA that an individual does not pose a security threat warranting denial of the authorization for which the individual is applying.

Severe transportation security incident means a security incident resulting in a significant loss of life, environmental damage, transportation system disruption, or economic disruption in a particular area.

State means a State of the United States and the District of Columbia.

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5. Add a new section 1572.5 to read as follows:

Sec. 1572.5 Security threat assessment for commercial drivers' licenses with a hazardous materials endorsement.

(a) Scope. This section applies to State agencies responsible for issuing hazardous materials endorsements for a commercial drivers license, and individuals who hold or are applying for such endorsements, under 49 CFR part 383.

(b) Individuals. (1) Requirements. Beginning on September 2, 2003:

(i) Prohibitions. No individual may hold a CDL with a hazardous materials endorsement, or exercise the privileges of a hazardous materials endorsement, if:

(A) The individual does not meet the citizenship status requirements in Sec. 1572.105;

(B) The individual has a disqualifying criminal offense, as described in Sec. 1572.103;

(C) The individual has been adjudicated as a mental defective or committed to a mental institution, as described in Sec. 1572.109; or

(D) TSA has notified the individual that he or she poses a security threat warranting denial of the endorsement, as described in Sec. 1572.107.

(ii) Surrender of endorsement. An individual who is prohibited from holding a CDL with a hazardous materials endorsement under this section must surrender the hazardous materials endorsement to the issuing State.

(iii) Continuing responsibilities. Each individual with a hazardous materials endorsement who is convicted of, wanted, or under indictment in any jurisdiction, civilian or military, for, or found not guilty by reason of insanity of, a disqualifying crime listed in Sec. 1572.103; who is adjudicated as a mental defective or committed to a mental institution as specified in Sec. 1572.109; or who renounces his or her

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U.S. citizenship; must report the offense, adjudication, or commitment to the State that issued the endorsement, and surrender the endorsement to the State, within 24 hours of the conviction, finding of not guilty by reason of insanity, adjudication, commitment, or renunciation.

(2) Submission of fingerprints. (i) From May 5, 2003, to November 3, 2003, an individual may submit fingerprints, in a form and manner specified by TSA, when a State revokes the individual's hazardous materials endorsement under paragraph (c)(1) of this section.

(ii) Beginning on November 3, 2003, an individual must submit fingerprints, in a form and manner specified by TSA, when he or she applies to obtain, renew, or transfer a hazardous materials endorsement for a CDL, or when requested by TSA.

(iii) When submitting fingerprints under this section, the individual, or his or her employer, is responsible for the fee charged by the person or other entity collecting the fingerprints and generating the individual's criminal history.

(c) States. (1) From May 5, 2003, to November 3, 2003, each State must revoke an individual's hazardous materials endorsement if TSA informs the State that the individual does not meet the standards for security threat assessment in paragraph (d) of this section.

(2) No later than November 3, 2003:

(i) No State may issue, renew, or transfer a hazardous materials endorsement for a CDL unless the State receives a Notification of No Security Threat from TSA.

(ii) Each State must notify each individual holding a hazardous materials endorsement issued by that State that he or she will be subject to the security threat assessment described in this section as part of any application for renewal of the endorsement, at least 180 days prior to the expiration date of the endorsement. The notice must inform the individual that he or she may initiate the security threat assessment required by this section at any time after receiving the notice, but no later than 90 days before the expiration date of the endorsement.

(3) From November 3, 2003, to April 29, 2004, while TSA is conducting a security threat assessment on an individual--

(i) If the individual holds a CDL with a hazardous materials endorsement, and is applying for renewal or transfer of the endorsement, the State that issued the endorsement may extend the expiration date of the individual's endorsement until the State receives a Final Notification of Threat Assessment or Notification of No Security Threat from TSA.

(ii) If the individual is applying for a hazardous materials endorsement for the first time, the State may not issue the endorsement until the State receives a Notification of No Security Threat from TSA.

(d) Standards for security threat assessment. (1) TSA determines that an individual does not pose a security threat warranting denial of a hazardous materials endorsement for a CDL if:

(i) The individual meets the citizenship status requirements in Sec. 1572.105;

(ii) The individual does not have a disqualifying criminal offense, as described in Sec. 1572.103;

(iii) The individual has not been adjudicated as a mental defective or committed to a mental institution, as described in Sec. 1572.109; and

(iv) TSA conducts the analyses described in Sec. 1572.107 and determines that the individual does not pose a security threat.

(2) In conducting the security threat assessment requirements of

this section, TSA uses one or more of the following:

- (i) An individual's fingerprints.
- (ii) An individual's name.
- (iii) Other identifying information.

(3) When reviewing the individual's criminal history records, TSA will not issue a Notification of No Security Threat, and will alert the State(s) and the Federal Motor Carrier Safety Administration (FMCSA) if the records indicate a disqualifying criminal offense listed in the FMCSA's rules for holders of CDLs at 49 CFR 383.51, until the FMCSA or the State(s) informs TSA that the individual is not disqualified under that section.

(4) If TSA determines during the course of conducting a security threat assessment, that it is necessary to revoke a hazardous materials endorsement immediately, TSA will direct the State to revoke a hazardous materials endorsement immediately. The individual may appeal the revocation following surrender of the endorsement, pursuant to the procedures set forth in Sec. 1572.141(i).

(e) Application form. (1) When an individual applies to a State to issue, renew, or transfer a hazardous materials endorsement for a CDL, the State must have the individual complete an application that includes the following:

- (i) The disqualifying crimes identified in Sec. 1572.103.
- (ii) A statement that the individual signing the application:
 - (A) Was not convicted, or found not guilty by reason of insanity, of any disqualifying crime in any jurisdiction, civilian or military, during the 7 years before the date of the individual's application;
 - (B) Was not released from incarceration in any jurisdiction, civilian or military, for committing any disqualifying crime during the 5 years before the date of the individual's application;
 - (C) Is not wanted or under indictment in any jurisdiction, civilian or military, for a disqualifying crime;
 - (D) Has not been adjudicated as a mental defective or committed to a mental institution involuntarily;
 - (E) Is either a United States citizen who has not renounced his or her United States citizenship, or a lawful permanent resident of the United States;
 - (F) Has or has not served in the military, and if so, the branch in which he or she served, the date of discharge, and the type of discharge; and
 - (G) Has been informed that Federal regulations under 49 CFR 1572.5(b) impose a continuing obligation to disclose to the State within 24 hours if he or she is convicted, or found not guilty by reason of insanity, of any disqualifying crime, or adjudicated as a mental defective or committed to a mental institution, while he or she has a hazardous materials endorsement for a CDL.

- (iii) A statement reading:

Privacy Act Notice: Authority: The authority for collecting this information is 49 U.S.C. 114, 40113, and 49 U.S.C. 5103a. Purpose: This information is needed to verify your identity and to conduct a security threat assessment to evaluate your suitability for a hazardous materials endorsement for a commercial drivers license. Your Social Security Number (SSN) or alien registration number will be used as your identification number in this process and to verify your identity. Furnishing this information, including your SSN or alien registration number, is voluntary; however, failure to provide it will prevent the completion of your security threat assessment, without which you may not be granted a hazardous materials endorsement. Routine Uses: Routine uses of this information include disclosure to the FBI to retrieve your criminal history record; to

TSA contractors or other agents who are providing services relating to the security threat assessments; to appropriate governmental agencies for licensing, law enforcement, or security purposes, or in the interests of national security; and to foreign and international governmental authorities in accordance with law and international agreement.

(iv) A statement reading:

The information I have provided on this application is true, complete, and correct to the best of my knowledge and belief and is provided in good faith. I understand that a knowing and willful false statement, or an

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omission of a material fact, on this application can be punished by fine or imprisonment or both (see section 1001 of Title 18 United States Code), and may be grounds for denial of a hazardous materials endorsement.

(v) Lines for the individual's--

(A) Printed name, including first, middle, and last, and any applicable suffix.

(B) Current residential address, and all other residential addresses for the previous seven years.

(C) Date of birth.

(D) Social security number, if the individual is a citizen of the United States, and date of naturalization, if the individual is a naturalized citizen of the United States.

(E) Gender.

(F) City, State, and country of birth.

(G) Citizenship.

(H) Alien registration number, if the individual is a lawful permanent resident of the United States.

(I) Signature and date of signature.

(2) Each individual must complete and sign the application form. The State must forward it to TSA in a form and manner acceptable to TSA.

(3) The State must inform the individual that a copy of the individual's criminal history record will be provided to the individual by TSA, if the individual makes a written request for the record.

(f) Determination of arrest status. When a criminal history records check on an individual applying for a hazardous endorsement for a CDL discloses an arrest for any disqualifying crime listed in Sec. 1572.103 without indicating a disposition, TSA follows the procedures in Sec. 1572.103.

(g) Notification. (1) Notification of No Security Threat. If, after conducting the security threat assessment, TSA determines that an individual meets the standards described in paragraph (d) of this section, TSA serves a Notification of No Security Threat to the State in which the individual applied for the hazardous material endorsement.

(2) Initial Notification of Threat Assessment. If, after conducting the security threat assessment, TSA determines that an individual does not meet the standards described in paragraph (d) of this section, TSA serves an Initial Notification of Threat Assessment on the individual and the State in which the individual applied for the hazardous materials endorsement, in accordance with Sec. 1572.141(b). The individual may appeal this determination under the procedures in Sec.

1572.141.

(3) Final Notification of Threat Assessment. If, after completing the process in Sec. 1572.141, TSA determines that an individual does not meet the standards described in paragraph (d) of this section, TSA serves a Final Notification of Threat Assessment on the individual and the State in which the individual applied for the hazardous materials endorsement, in accordance with Sec. 1572.141(e). The individual may not appeal this determination, but may apply for a waiver.

(4) Waivers. If an individual does not meet the standards in paragraph (d) of this section, he or she may apply for a waiver under Sec. 1572.143.

(5) State notification requirements. Within 15 days of the receipt of a Notification of No Security Threat, a Final Notification of Threat Assessment, or a grant of a waiver, the State must:

(i) Update the individual's permanent record to reflect:

(A) The results of the security threat assessment;

(B) The issuance or denial of a hazardous materials endorsement;

and

(C) The hazardous materials endorsement expiration date.

(ii) Notify the Commercial Drivers License Information System operator of the results of the security threat assessment.

(iii) Revoke or deny the individual's hazardous materials endorsement, if TSA serves the State with a Final Notification of Threat Assessment.

(iv) Grant or renew the individual's hazardous materials endorsement, if TSA serves the State with a Notification of No Security Threat, or a written decision from TSA to grant a waiver, and the individual is otherwise qualified.

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6. Add a new Subpart B to Part 1572 to read as follows:

Subpart B--Standards, Appeals, and Waivers for Security Threat Assessments

Sec.

1572.101 Scope and definitions.

1572.103 Disqualifying criminal offenses.

1572.105 Citizenship status.

1572.107 Other analyses.

1572.109 Mental defects.

1572.111-1572.139 [Reserved]

1572.141 Notification of threat assessment and appeal.

1572.143 Waivers.

Sec. 1572.101 Scope and definitions.

(a) This subpart applies to individuals who hold or are applying for a hazardous material endorsement for a CDL.

(b) For purposes of this subpart, the following terms have the following definitions.

Associate Administrator/Chief Operating Officer means the Associate Administrator who is also the Chief Operating Officer of TSA, or his or her designee.

Authorization means any credential or endorsement for which TSA conducts a security threat assessment under this part, including a hazardous materials endorsement for a CDL.

Date of service means--

(1) The date of personal delivery in the case of personal service;

- (2) The mailing date shown on the certificate of service;
 - (3) The date shown on the postmark if there is no certificate of service;
 - (4) Another mailing date shown by other evidence if there is no certificate of service or postmark; or
 - (5) The date in an e-mail showing when it was sent.
- Day means calendar day.

Sec. 1572.103 Disqualifying criminal offenses.

(a) An individual has a disqualifying criminal offense if the individual:

(1) Was convicted, or found not guilty by reason of insanity, of any of the disqualifying crimes listed in paragraph (b) of this section in any jurisdiction, civilian or military, during the 7 years before the date of the individual's application for the authorization, except as provided in paragraph (d) of this section;

(2) Was released from incarceration for committing any of the disqualifying crimes listed in paragraph (b) of this section in any jurisdiction, civilian or military, during the 5 years before the date of the individual's application for the authorization, except as provided in paragraph (d) of this section; or

(3) Is wanted or under indictment in any jurisdiction, civilian or military, for any of the disqualifying crimes listed in paragraph (b) of this section.

(b) The disqualifying crimes are felonies involving:

- (1) Any crime listed in 18 U.S.C. Chapter 113B--Terrorism.
- (2) Murder.
- (3) Assault with intent to murder.
- (4) Espionage.
- (5) Sedition.
- (6) Kidnapping or hostage taking.
- (7) Treason.
- (8) Rape or aggravated sexual abuse.
- (9) Unlawful possession, use, sale, distribution, or manufacture of an explosive, explosive device, firearm, or other weapon.
- (10) Extortion.
- (11) Robbery.
- (12) Arson.
- (13) Distribution of, intent to distribute, possession, or importation of a controlled substance.
- (14) Dishonesty, fraud, or misrepresentation, including identity fraud.

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- (15) A crime involving a severe transportation security incident.
 - (16) Improper transportation of a hazardous material.
 - (17) Bribery.
 - (18) Smuggling.
 - (19) Immigration violations.
 - (20) Violations of the Racketeer Influenced and Corrupt Organizations Act; 18 U.S.C. 1961, et seq.
 - (21) Conspiracy or attempt to commit any of the crimes listed in paragraph (b) of this section.
- (c) Determination of arrest status. (1) When a criminal history records check on an individual discloses an arrest for any disqualifying crime listed in paragraph (b) of this section without indicating a disposition, TSA will notify the individual.

(2) The individual must provide TSA with written proof that the arrest did not result in a disqualifying criminal offense within 30 days after the service date of the notification in paragraph (c)(1) of this section. If TSA does not receive proof in that time, TSA may issue an Initial Notification of Threat Assessment in accordance with Sec. 1572.141.

(d) The time periods specified in paragraphs (a)(1) and (a)(2) of this section do not apply to:

- (1) The crimes listed in paragraphs (b)(1), (b)(4), (b)(5), (b)(7), (b)(12), (b)(15), and (b)(16) of this section;
- (2) The crime in paragraph (b)(9) of this section involving an explosive; and
- (3) Conspiracy or attempt to commit the crimes listed in paragraphs (d)(1) and (d)(2) of this section.

Sec. 1572.105. Citizenship status.

(a) An individual applying for an authorization under this part must be either--

- (1) A citizen of the United States who has not renounced his or her United States' citizenship; or
- (2) A lawful permanent resident of the United States.

(b) To determine an individual's citizenship status, TSA checks relevant Federal databases, and may perform other checks, including verifying the validity of the individual's social security number or alien registration number.

Sec. 1572.107 Other analyses.

(a) TSA checks the following databases and conducts a security threat analysis before determining that an individual does not pose a security threat warranting denial of an authorization under this part:

- (1) Interpol and other international databases;
- (2) TSA watchlists; and
- (3) Any other databases relevant to determining whether an individual poses a security threat or that confirm an individual's identity.

(b) An individual poses a security threat under this section when TSA determines or suspects him--or her of being a threat--

- (1) To national security;
- (2) To transportation security; or
- (3) Of terrorism.

Sec. 1572.109 Mental defects.

(a) An individual has a mental defect if he or she has been--

- (1) Adjudicated as a mental defective; or
- (2) Committed to a mental institution.

(b) An individual is adjudicated as a mental defective if--

(1) A court, board, commission, or other lawful authority has determined that the individual, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease, is a danger to him or herself or others, or lacks the mental capacity to contract or manage his or her own affairs.

(2) This includes a finding of insanity by a court in a criminal case; and a finding of incompetency to stand trial or a finding of not guilty by reason of lack of mental responsibility by any court, or

pursuant to articles 50a and 76b of the Uniform Code of Military Justice (10 U.S.C. 850a and 876b).

(c) An individual is committed to a mental institution if--

(1) He or she is formally committed to a mental institution by a court, board, commission, or other lawful authority, including involuntary commitment and commitment for mental defectiveness, mental illness, and drug use.

(2) This does not include a commitment to a mental institution for observation or voluntary admission to a mental institution.

Sec. 1572.111-1572.139 [Reserved]

Sec. 1572.141 Notification of threat assessment and appeal.

(a) Scope. This section applies to individuals who receive an Initial Notification of Threat Assessment stating that they do not meet the standards for a security threat assessment and who wish to appeal the notification.

(b) Initial Notification of Threat Assessment. (1) If TSA determines that an individual poses a security threat warranting denial of the authorization, TSA serves upon the individual an Initial Notification of Threat Assessment.

(2) The Initial Notification includes--

(i) A statement that TSA has determined that the individual poses a security threat warranting denial of the authorization;

(ii) The basis for the determination; and

(iii) Information about the correction of records and appeals processes.

(c) Grounds for Appeal. (1) An individual may appeal an Initial Notification only if the individual is asserting that he or she meets the standards of the authorization for which he or she is applying.

(2) If the Initial Notification was based on a conviction for a disqualifying crime listed in Sec. 1572.103, the individual may present evidence that the underlying criminal record is incorrect, or that the conviction was pardoned, expunged, or overturned on appeal. An executive pardon, expungement, or overturned conviction may nullify a disqualifying conviction if the pardon, expungement, or overturned conviction does not impose any restrictions on the individual. A correction of the record(s) may nullify the disqualifying conviction.

(d) Appeal. An individual may initiate an appeal of an Initial Notification by submitting a written request for materials or a written reply to TSA. If the individual does not initiate an appeal within the time periods specified in this paragraph, TSA serves a Final Notification of Threat Assessment under paragraph (e) of this section.

(1) Request for materials. Not later than 15 days after the date of service of the Initial Notification, the individual may serve upon TSA a written request for copies of the materials upon which the Initial Notification was based.

(2) TSA response. Not later than 30 days after receiving the individual's request for materials, TSA serves copies upon the individual of the releasable materials upon which the Initial Notification was based. TSA will not include any classified information or other protected information described in paragraph (f) of this section.

(3) Correction of records. If the Initial Notification of Threat Assessment was based on an FBI criminal history record that the individual believes is erroneous, the individual may correct the record, as follows:

(i) The individual may contact the local jurisdiction responsible for the information and the FBI or other agency to complete or correct the information contained in his or her record.

(ii) The individual seeking to correct his or her record must provide TSA with the revised FBI criminal history record, or a certified true copy of the information from the appropriate court, before TSA may determine that the

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individual meets the standards for the security threat assessment.

(4) Reply. (i) The individual may serve upon TSA a written reply to the Initial Notification not later than 15 days after the date of service of the Initial Notification, or 15 days after the date of service of TSA's response to the individual's request for materials under paragraph (d) (2) of this section, if the individual served such a request.

(ii) In an individual's reply, TSA will consider only material that is relevant to whether the individual meets the standards for the security threat assessment in Sec. 1572.5(d).

(5) Final determination. Not later than 30 days after TSA receives the individual's reply, TSA serves a Final Notification of Threat Assessment or a Withdrawal of the Initial Notification in accordance with paragraph (e) of this section.

(e) Final Notification of Threat Assessment. (1) Review. The Associate Administrator/Chief Operating Officer reviews the Initial Notification, the materials upon which the Initial Notification was based, the individual's reply, if any, and any other materials or information available to the agency before making a final decision.

(2) Issuance. If the Associate Administrator/Chief Operating Officer determines that the individual poses a security threat, the Associate Administrator/Chief Operating Officer serves upon the individual, and, in the case of a security threat assessment under Sec. 1572.5, the State in which the individual applied for the authorization, a Final Notification of Threat Assessment.

(i) The Final Notification to the individual includes a statement that the Associate Administrator/Chief Operating Officer has reviewed the Initial Notification, the individual's reply, if any, and any other materials or information available to him or her, and has determined that the individual poses a security threat warranting denial of the authorization.

(ii) The Final Notification to the State contains a statement that TSA has determined that the individual poses a security threat warranting denial of the authorization.

(3) Withdrawal of Initial Notification. If the Associate Administrator/Chief Operating Officer does not conclude that the individual poses a security threat warranting denial of the authorization, TSA serves upon the individual a Withdrawal of the Initial Notification. In the case of a security threat assessment under Sec. 1572.5 of this part, TSA will also serve a Notification of No Security Threat to the State in which the individual applied for the authorization.

(f) Nondisclosure of certain information. In connection with the procedures under this section, TSA does not disclose to the individual classified information, as defined in section 1.1(d) of Executive Order 12968, and reserves the right not to disclose any other information or material not warranting disclosure or protected from disclosure under law.

(g) Extension of time. TSA may grant an individual an extension of time of the limits set forth in this section for good cause shown. An

individual's request for an extension of time must be in writing and be received by TSA at least 2 days before the due date to be extended. TSA may grant itself an extension of time for good cause.

(h) Judicial review. For purposes of judicial review, the Final Notification of Threat Assessment constitutes a final TSA order in accordance with 49 U.S.C. 46110.

(i) Appeal of immediate revocation. (1) If TSA directs a State to revoke the hazardous materials endorsement immediately pursuant to Sec. 1572.5(d)(4), the individual may--

(i) Within 10 days of revocation, submit a written request to TSA to appeal the decision on which the revocation was based.

(ii) The written request must include the basis on which the appeal should be granted, including a correction of records, and all supporting documentation.

(2) Within 10 days of receipt of the written request, TSA will serve on the individual and the State in which the individual applied for a hazardous materials endorsement, its final decision and a statement explaining the basis for the decision.

Sec. 1572.143 Waivers.

(a) Scope. (1) Except as provided in paragraph (a)(2), this section applies to individuals who do not meet the standards for a security threat assessment and who are requesting a waiver from those standards.

(2) Individuals who do not meet the standards for a security threat assessment under Sec. 1572.105 or Sec. 1572.107 are not eligible for a waiver.

(b) Waivers. (1) An individual who does not meet the standards for a security threat assessment in this part may send a written request to TSA for a waiver at any time but not later than 15 days from the date of service of the Final Notification of Threat Assessment.

(2) In determining whether to grant a waiver, TSA will consider the following factors, if the disqualification was based on a disqualifying criminal offense:

(i) The circumstances of any disqualifying act or offense;

(ii) Restitution made by the individual;

(iii) Any Federal or State mitigation remedies; and

(iv) Other factors that indicate the individual does not pose a security threat warranting denial of the authorization for which he or she is applying.

(c) Grant or denial of waivers. TSA will send a written decision to grant or deny a waiver under this section to the individual and, if applicable, the State in which the individual applied for the authorization, within 30 days of the service date of the individual's application for a waiver, or such longer period as TSA may determine for good cause.

(d) Extension of time. TSA may grant an individual an extension of time of the limits set forth in this section for good cause shown. An individual's request for an extension of time must be in writing and be received by TSA at least 2 days before the due date to be extended. TSA may grant itself an extension of time for good cause.

Issued in Arlington, VA on April 25, 2003.

J.M. Loy,
Administrator.

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